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

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

TITLE 10. COMMUNITY DEVELOPMENT

PART 1. TEXAS DEPARTMENT OF HOUSING AND COMMUNITY AFFAIRS

CHAPTER 80. MANUFACTURED HOUSING SUBCHAPTER C. LICENSEES' RESPONSIBILITIES AND REQUIREMENTS

10 TAC §80.31, §80.32

The Manufactured Housing Division of the Texas Department of Housing and Community Affairs (the "Department") proposes to amend 10 Texas Administrative Code, Chapter 80, §80.31 and §80.32 relating to the regulation of the manufactured housing program. The rule revisions are for clarification purposes.

10 Texas Administrative Code §80.31(c) is amended to remove an inaccurate reference to having the data plate on the reverse side of the Manufacturer's Certificate of Origin (MCO).

10 Texas Administrative Code §80.32(n) is amended to provide clarification regarding not accepting any document that is executed in blank or allow any alteration to a completed document without the consumer initialing.

Jim R. Hicks, Executive Director of the Manufactured Housing Division of the Texas Department of Housing and Community Affairs, has determined that for the first five-year period that the proposed rules are in effect there will be no fiscal implications for state or local government as a result of enforcing or administering these sections. There will be no effect on small or micro-businesses because of the proposed amendments. The amendments will not cause the loss of any business opportunities or have an adverse effect on the businesses. There are no additional anticipated economic costs to persons who are required to comply with the proposed rules.

Mr. Hicks also has determined that for each year of the first five years that the proposed rules are in effect the public benefit for enforcing the amendments will be to maintain the necessary resources required to improve the general welfare and safety of purchasers of manufactured housing in this state as per §1201.002 of the Manufactured Housing Standards Act.

Mr. Hicks has also determined that for each year of the first five years the proposed rules are in effect there should be no adverse effect on a local economy, and therefore no local employment impact statement is required under Administrative Procedure Act (APA), Texas Government Code §2001.022.

Mr. Hicks has also determined that for each of the first five years the proposed rules are in effect would not have a large government growth impact. The proposed rules do not create or eliminate a government program. Implementation of the proposed rules does not require the creation of new employee positions or the elimination of existing employee positions. Implementation of the proposed rules do not require the increase or decrease in future legislative appropriations to the agency. The proposed rules do not create a new regulation. The proposed rules do not expand, limit, or repeal an existing regulation. The proposed rules do not increase or decrease the number of individuals subject to the rules applicability. The proposed rules do not positively or adversely affect this states economy. This statement is made pursuant to the Administrative Procedure Act, Texas Government Code, §2001.0221.

If requested, the Department will conduct a public hearing on this rulemaking, pursuant to the Administrative Procedure Act, Texas Government Code §2001.029. The request for a public hearing must be received by the Department within 15 days after publication.

Comments may be submitted to Mr. Jim R. Hicks, Executive Director of the Manufactured Housing Division of the Texas Department of Housing and Community Affairs, P.O. Box 12489, Austin, Texas 78711-2489 or by e-mail at mhproposedrulecomments@tdhca.texas.gov. The deadline for comments is no later than 30 days from the date that these proposed rules are published in the *Texas Register*.

The amendments are proposed under §1201.052 of the Texas Occupations Code, which provides the Director with authority to amend, add, and repeal rules governing the Manufactured Housing Division of the Department and §1201.053 of the Texas Occupations Code, which authorizes the board to adopt rules as necessary and the director to administer and enforce the manufactured housing program through the Manufactured Housing Division.

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

§80.31. Manufacturers' Responsibilities and Requirements.

(a) - (b) (No change.)

(c) A manufacturer shall use the Manufacturer's Certificate of Origin (MCO) prescribed by the Department set forth on the Department's website for homes sold to retailers in Texas[~~, on the reverse side of which shall be the data plate~~].

(d) - (e) (No change.)

§80.32. Retailers' Responsibilities and Requirements.

(a) - (m) (No change.)

(n) Notwithstanding the date of sale, transfer, or ownership change; or the date of installation on the application for a Statement of Ownership, a [~~A~~] retailer may not request or accept any document that is executed in blank or allow any alteration to a completed document

without the consumer's initialing and dating such changes to indicate agreement to them. Where information is not available, a statement of that fact (*e.g.,* TBD - to be determined, not available, N/A, not applicable, or the like) may be entered in the blank. A consumer must be provided with copies of all documents they execute.

(o) - (w) (No change.)

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

Filed with the Office of the Secretary of State on September 19, 2025.

TRD-202503383
Jim R. Hicks
Executive Director
Texas Department of Housing and Community Affairs
Earliest possible date of adoption: November 2, 2025
For further information, please call: (512) 475-2206

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TITLE 13. CULTURAL RESOURCES

PART 2. TEXAS HISTORICAL COMMISSION

CHAPTER 11. ADMINISTRATION DEPARTMENT

SUBCHAPTER C. AFFILIATED NONPROFIT ORGANIZATIONS; FRIENDS OF THE TEXAS HISTORICAL COMMISSION

13 TAC §§11.61 - 11.67

The Texas Historical Commission (THC) proposes new Subchapter C of Chapter 11, including §§11.61 - 11.67, related to Affiliated Nonprofit Organizations and the Friends of the THC, as authorized in Texas Government Code §§ 442.005(q), and 442.043, as enacted in H.B. 4187, 89th Legislature, Regular Session.

Subchapter C, Chapter 11, creates a process for designating affiliated nonprofit organizations who will provide services and other benefits, including financial support, to the Commission or one or more state historic sites defined Texas Government Code § 442.071. These proposed new rules also provide operational guidelines, best practices, and standards for compliance for these affiliated nonprofit organizations.

FISCAL NOTE. Joseph Bell, Executive Director, has determined that for each of the first five years the proposed new rules are in effect, there will not be a fiscal impact on state or local government as a result of enforcing or administering the new rule as proposed. The related policy and procedure are in place for this rule and there is no anticipated additional cost as a result of the rulemaking.

PUBLIC BENEFIT/COST NOTE. Mr. Bell has also determined that for the first five-year period the rule is in effect, the anticipated public benefit will be the ability of THC to designate affiliated nonprofit organizations to provide support and benefits, including financial support, to help the THC achieve its goals and objectives.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT. There are no anticipated economic costs to persons who are required to comply with these new rules, as proposed. There is no effect on local economy for the first five years that the proposed new rules are in effect; therefore, no local employment impact statement is required under Texas Government Code § 2001.022 and § 2001.024(a)(6).

COSTS TO REGULATED PERSONS. The proposed new rules do not impose a cost on regulated persons, including another state agency, a special district, or a local government and, therefore, are not subject to Texas Government Code § 2001.0045.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES, MICROBUSINESSES, AND RURAL COMMUNITIES. The proposed new rules provide an opportunity for the THC to designate affiliated nonprofit organizations to provide services and benefits, including financial support, to help THC achieve its goals and objectives. There is no anticipated economic impact of these new rules. Mr. Bell has also determined that there will be no impact on rural communities, small businesses, or micro-businesses as a result of implementing these new rules; therefore, no regulatory flexibility analysis, as specified in Texas Government Code § 2006.002, is required. The proposed new rules do not affect small businesses, micro-businesses, or rural communities because the new rules only apply to affiliated nonprofit organizations designated by THC to support the commission and one or more state historic sites.

GOVERNMENT GROWTH IMPACT STATEMENT. During the first five years that the new rules would be in effect, the proposed new sections: will not create or eliminate a government program; will not result in the addition or reduction of employees; will not require an increase or decrease in future legislative appropriations; will not lead to an increase or decrease in fees paid to a state agency; will not create a new regulation; will not repeal an existing regulation; and will not result in an increase or decrease in the number of individuals subject to the rule. During the first five years that the new rules would be in effect, the proposed new rules will not positively or adversely affect the Texas economy.

REQUEST FOR PUBLIC COMMENT. Comments on the proposed new rules may be submitted to Joseph Bell, Executive Director, Texas Historical Commission, P.O. Box 12276, Austin, Texas 78711. Comments will be accepted for 30 days after publication in the *Texas Register*.

STATUTORY AUTHORITY AND STATEMENT ON AUTHORITY. These new rules are proposed under the authority of Texas Government Code § 442.005(q), which provides the Commission with the authority to promulgate rules for the effective administration of Chapter 442, Texas Government Code, and Texas Government Code § 442.043, as enacted by the 89th Legislature, R.S., in HB 4187, which provides the Commission with authority to adopt rules establishing guidelines and best practices, as well as accounting standards and safeguards for affiliated nonprofit organizations.

CROSS REFERENCE TO STATUTE. The new rules will implement Texas Government Code § 442.043 enacted by the 89th Legislature, R.S., in H.B.4187.

§11.61. Definitions.

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

(1) Affiliated Nonprofit Organization (ANO)--A nonprofit organization designated in Subchapter A-1, Chapter 442, Texas Government Code, for the purpose of supporting the commission or a specific state historic site or sites by providing services and benefits, including financial support.

(2) Commission--Texas Historical Commission.

(3) Director--Executive director of the commission.

(4) Donor--A person who makes a contribution to the commission for which there is no consideration or expectation of consideration in return.

(5) Friends of the Texas Historical Commission (Friends)--the ANO designated in Subchapter A-1, Chapter 442, Texas Government Code, to provide services and benefits, including financial support, to the commission for the purpose of helping the commission achieve its goals and objectives.

(6) Gift--A donation of money or property other than volunteer time for which there is no consideration or expectation of consideration in return.

(7) Improvement--A permanent addition to real property which is in the nature of a fixture.

(8) In-kind donation--A non-cash donation, such as services, personal property or real property.

(9) Interpretive Master Plan--The collection of interpretive themes and plans approved by the commission for each state historic site under Texas Government Code § 442.114.

(10) IRS 990--United States Internal Revenue Service Form 990, Return of Organization Exempt from Tax.

(11) Local sponsorship--A campaign to raise funds in support of a commission program that is intended to benefit a single state historic site.

(12) Nonprofit entity--An incorporated entity that is exempt from federal taxation under §501(c) of the Internal Revenue Code of 1986 (Title 26, United States Code).

(13) Program--An activity, event or project undertaken by an ANO for the benefit of the commission.

(14) Sponsor--A person, corporation, company, or other organization that provides funds in support of a specific commission project, program or event.

(15) Sponsorship--The payment of money, transfer of property, or performance of services by a person, corporation, company, or other organization with respect to which there is no arrangement or expectation of any substantial return benefit other than recognition or a non-substantial benefit.

(16) Statewide sponsorship--A sponsorship or campaign to raise funds in support of a commission program that is intended to benefit more than a single commission facility or is intended to reach the majority of the population of the state.

§11.62. Criteria and General Requirements.

All ANOs must meet the requirements and criteria of this section.

(1) All ANOs must carry out the fiscal, business, legal, and tax responsibilities of a nonprofit entity as required by state and federal law.

(2) ANOs must have obtained from the Internal Revenue Service a valid determination letter that it is an organization described in §501(c) of the Internal Revenue Code of 1986 (Title 26, United States Code), as amended.

(3) An ANO's work with the commission must be consistent with the commission's mission and goals.

(4) Upon dissolution, an ANO may be required to dispose of funds raised for the benefit of the commission in a way that will benefit the commission, in accordance with applicable law.

(5) An ANO must be incorporated in accordance with the Texas Nonprofit Corporation Act (Chapter 22, Texas Business Organizations Code).

(6) Each ANO must enter into an agreement with the commission detailing the responsibilities and duties of the ANO and the commission. Each ANO must maintain such an agreement with the commission for as long as the entity is an ANO. The agreement may also address the obligations of an ANO upon termination of the relationship between the ANO and the commission, including termination resulting from the dissolution of the ANO.

(7) An ANO must promptly notify the commission of any change in its legal or tax-exempt status.

§11.63. Criteria and General Requirements.

(a) ANOs must comply with the general best practices prescribed in this subsection.

(1) ANOs shall not hold or obligate commission funds unless the ANO has entered into written agreement with the commission regarding the use of such funds.

(2) ANOs shall comply with all applicable rules, regulations, and laws, including all applicable laws regarding discrimination based on race, color, national origin, sex, age, and disability.

(3) ANOs shall not use or authorize the use of commission intellectual property, including trademarks, logos, name, or seal, without the express written agreement of the commission.

(4) ANOs may use equipment, facilities, or services of employees of the commission only in accordance with a written agreement that provides for the payment of adequate compensation and/or identifies the benefit to the commission for such use. Notwithstanding this subsection, an ANO may use commission facilities to the same extent and for the same fee as members of the public.

(5) ANOs shall conduct business in a way that will ensure public access and transparency. As used in this subsection, "transparency" shall mean that an ANO's business practices and internal processes are conducted in a way that is open, clear, measurable, and verifiable.

(6) ANOs shall file with the commission and make available to the public an annual report that includes a list of the primary activities undertaken during the previous year, a summary of significant achievements and challenges over the previous year, and other information requested by the commission.

(7) Regardless of whether an ANO is required to file an IRS 990 with the Internal Revenue Service, each ANO must complete and file an IRS 990 with the commission each year, regardless of income.

(8) ANOs shall file with the commission their articles of incorporation, by-laws, most recent financial statements, and any updates to these documents upon request of the commission.

(9) An ANO shall not engage in activities that would require it or a person acting on its behalf to register as a lobbyist under

Chapter 305, Texas Government Code, or other Texas law. However, this subsection is not intended to restrict an ANO from providing information to the legislature or to other elected or appointed officials.

(10) ANOs shall not donate funds to a political campaign or endorse a political candidate.

(11) ANOs shall notify the commission of all meetings and allow a commission representative to attend all meetings, including, but not limited to, meetings of the ANO's general membership, managing board, and committees. Meeting notices must be provided to the commission sufficiently in advance of the meeting so that the commission representative has ample opportunity to attend. Such notice may be provided by letter, email, or telephone.

(12) ANOs must have an annual audit by an independent accounting firm and shall make the results of that audit available to the commission.

(13) ANOs must maintain an adequate directors and officers liability insurance policy.

§11.64. Best Practices (Officers and Directors).

(a) All officers and directors of each ANO must receive a copy of or a link to the commission's current Strategic Plan and the interpretive themes and plan(s) approved by the commission under Texas Government Code § 442.114 for the state historic site or sites supported by the ANO. The officers and directors of the Friends shall receive a copy of the Interpretive Master Plan approved by the commission.

(b) In addition to subsection (a) of this section, ANOs must comply with these best practices regarding officers and directors:

(1) ANOs must adopt and maintain a conflict of interest policy, which includes safeguards to prevent board members or their families from benefiting financially from any business decision of the ANO.

(2) ANOs shall ensure that any compensation paid to executives or managers is reasonable.

(3) ANOs shall not elect, designate, or otherwise select a commission employee as an officer or director, other than as a nonvoting uncompensated representative of the commission.

(4) ANOs shall hold regular meetings of its Board of Directors.

(5) ANOs shall ensure that each board member and/or director is fully informed of the ANO's activities and shall provide the following information to new board members:

(A) articles of incorporation and by-laws;

(B) most recent financial statements;

(C) commission rules on ANOs and sponsorship; and

(D) current agreements with the commission.

§11.65. Best Practices (Fundraising).

(a) All ANOs must comply with the requirements of this subsection regarding fundraising.

(1) ANOs may conduct fundraising to provide additional funds for commission operations, to enhance commission programs, to provide long-term endowments for commission programs, to facilitate special projects, or otherwise support the commission in carrying out its mission, but only as agreed in writing by the commission in advance.

(2) ANOs may undertake programs for the benefit of the commission, so long as such programs are related to and supportive of the commission's mission and are agreed to in writing by the commission in advance. A single agreement may cover multiple programs.

(3) ANOs shall decline donations that require actions, including recognition, by the commission for which the commission has not given prior written consent.

(4) Funds accepted by an ANO for the benefit of the commission are to be managed as a reasonably prudent person would manage funds if acting on his or her own behalf and such funds are to be accounted for according to Generally Accepted Accounting Principles (GAAP).

(5) All projects undertaken for the commission by an ANO must be related to and supportive of the facility, property, or program with which an ANO is associated or must further the ANO's mission related to the facility, property or program.

(6) All donations to an ANO must benefit the commission or the facility, property, or program with which the ANO is associated or must further the ANO's mission related to the facility, property, or program.

(7) For purposes of this subsection, a donation for the purpose of defraying the ANO's operating costs furthers the ANO's mission related to the facility, property, or program.

(8) ANOs shall adopt procedures that address acceptance and granting of funds raised to benefit projects and/or programs of the commission.

(b) Nothing in this subchapter shall limit the ability of an ANO to make an unrestricted cash donation to the commission. Such a donation may also be made for a specific purpose or program in furtherance of the commission's mission.

(c) ANOs may work together towards a common fundraising goal for the benefit of the commission, consistent with the requirements of this subchapter.

§11.66. Best Practices (Sponsorship).

(a) ANOs may solicit and accept sponsorships for commission programs, so long as the ANO complies with the provisions of this subsection and other written guidance that may be provided by the department.

(1) All sponsorships of commission programs and the level of sponsorship recognition provided by the commission must have prior written approval of the commission.

(2) ANOs shall not solicit or accept a sponsorship in support of a commission program from:

(A) a person or entity that has been determined by the commission to conflict with either the commission's mission or legislative mandates; or

(B) a person or entity that is in litigation with the commission at the time of consideration.

(3) Sponsor recognition shall be limited as prescribed in this paragraph.

(A) Sponsor recognition shall be solely in the context of the commission program that the sponsor has supported with a financial or in-kind contribution.

(B) Sponsor recognition shall be permitted only when the financial or in-kind contribution is greater than the costs associated with providing sponsor recognition.

(C) Sponsor recognition shall not include signage of any kind on state-owned motor vehicles or trailers that were purchased or are maintained with department funds.

(D) Sponsor recognition shall not overshadow the project, the purposes of the project, or the mission of the commission or result in the role of the commission being less prominent than that of the sponsor.

(4) In determining the level of sponsorship recognition to provide, the commission will consider:

(A) the level of contribution as a percentage of the total funding required to execute or produce the program, event, or material;

(B) the level of contribution as a percentage of total sponsorship dollars received;

(C) the scope of exposure (e.g. statewide, regional, local, or a single location); and

(D) the duration of exposure (e.g. one day, one month, or one year).

(5) Sponsorship recognition may not promote the sponsor's products, services, or facilities. This subsection does not prohibit the broadcast or display of the sponsor's logo or name and a reference to the sponsor's location.

(6) No officer or employee of the department shall act as the agent for any ANO or donor in negotiating the terms or conditions of any agreement relating to the provision of funds, services, or property to the commission by the ANO or donor.

(b) Nothing in this subchapter shall limit the ability of an ANO to make an unrestricted cash donation to the commission when no sponsorship recognition is provided. Such a donation may also be made for a specific purpose or program in furtherance of the commission's mission.

§11.67. Commission Procedures.

(a) The commission will not obligate ANO funds or property except by written agreement signed by the ANO.

(b) The Friends may reimburse commission employees for legitimate, documented expenses. Additionally, the Friends may award scholarships to commission employees from private, donor-directed sources, so long as there is a benefit to the commission.

(c) The commission may develop model policies and procedures for adoption by ANOs. Where an ANO is required by these rules to adopt a policy or procedure, adoption of the model policy or procedure shall be deemed to comply with that requirement.

(d) All reimbursements made by the Friends under subsection (b) of this section and all donations to the commission of $500 or more must be approved by the commission, voting in public session.

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 September 18, 2025.

TRD-202503307
Joseph Bell
Executive Director
Texas Historical Commission
Earliest possible date of adoption: November 2, 2025
For further information, please call: (512) 463-6100

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TITLE 16. ECONOMIC REGULATION

PART 2. PUBLIC UTILITY COMMISSION OF TEXAS

CHAPTER 22. PROCEDURAL RULES

The Public Utility Commission of Texas (commission) proposes 16 amendments in the Chapter 22 procedural rules. The scope of this rulemaking proceeding is limited to consideration of the proposed rule amendments, additional modifications to these rules that are reasonably related to the proposed changes, and other minor and nonsubstantive amendments. Substantive amendments to these rules not related to the proposed changes are not within the scope of this proceeding.

The proposed amendments are listed in order as follows (Subchapters K-O): Subchapter K, §22.201, Place and Nature of Hearings, §22.204, relating to Transcript and Record, §22.205, relating to Briefs, §22.207, relating to Referral to State Office of Administrative Hearings; Subchapter L, §22.221, relating to Rules of Evidence in Contested Cases, §22.225, relating to Written Testimony and Accompanying Exhibits, §22.228, relating to Stipulation of Facts; Subchapter M, §22.241, relating to Investigations, §22.244, relating to Review of Municipal Rate Actions, §22.246, relating to Administrative Penalties; Subchapter N, §22.261, relating to Proposals for Decision, §22.262, relating to Commission Action After a Proposal for Decision, §22.263, relating to Final Orders, §22.264, relating to Rehearing Subchapter O, §22.281, relating to Initiation of Rulemaking, and §22.282, relating to Notice and Public Participation in Rulemaking Procedures.

Rule Review Stakeholder Recommendations

On May 3, 2025, commission staff filed a preliminary notice and request for comments which was published in the *Texas Register* on May 17, 2024, at 49 TexReg 3635. Comments were received from the Alliance for Retail Markets (ARM) and the Texas Energy Association for Marketers (TEAM), collectively (REP Coalition); Entergy Texas, Inc. (Entergy); the Lower Colorado River Authority and LCRA Transmission Services Corporation (LCRA); the Office of Public Utility Counsel (OPUC); Oncor Electric Delivery Company, LLC (Oncor); the Steering Committee of Cities Served by Oncor (OCSC); Texas Association of Water Companies, Inc. (TAWC); the Texas Rural Water Association (TRWA); Texas-New Mexico Power Company (TNMP); and Vistra Corporation (Vistra). Based upon filed comments and an internal review by commission staff, the commission proposes the following rule changes.

The proposed changes would amend §22.201, relating to Place and Nature of Hearings, to permit the presiding officer to authorize hearings and prehearing conferences to be conducted virtually and to require hearings held at the State Office of Administrative Hearings to be conducted in accordance with commission rules.

The proposed changes would amend §22.204, relating to Transcript and Record to, following an objection to a change to the record, require any change to the record to only be made as ordered by the presiding officer.

The proposed changes would amend §22.205, relating to Briefs, to require briefs to conform with the formatting requirements of

§22.72, relating to Form Requirements for Documents Filed with the Commission, specify page number limitations with and without attachments, authorize the presiding officer to require parties to address certain issues or address issues in a specific order or format, and provide information regarding legal authorities that are not readily accessible by the commission.

The proposed changes would amend §22.207, relating to Referral to State Office of Administrative Hearings to specify that the utility division of SOAH will conduct prehearing conferences and hearings related to contested cases before the commission, other than a prehearing conference conducted by a commission administrative law judge or a hearing conducted by one or more commissioners.

The proposed changes would amend §22.221, relating to Rules of Evidence in Contested Cases to specify that testimony and responses to requests for information by an opposing party that an intervenor or commission staff plans to introduce as part of its direct case must be filed at the time the intervenor or commission staff files its written direct testimony. The proposed changes eliminate the requirement for the presiding officer to establish a date for filing of deposition testimony and requests for information that an applicant plans to introduce as part of its direct case. The proposed changes remove the requirement for deposition testimony and responses to requests for information that a party plans to introduce in support of its rebuttal case to be filed at the time the party files its written rebuttal testimony. The proposed changes also require utilities that file an application for a CCN or an amendment to a CCN for a new electric transmission facility to file written testimony and exhibits supporting its direct case on the same date that the application is filed with the commission. Additionally, the proposed changes specify that, for any contested case that is not a major rate proceeding nor a CCN or CCN amendment proceeding for an electric transmission facility, the prefiling of written testimony and exhibits at the time the filing is made is not required unless otherwise required by statute or rule. The proposed changes clarify that a witness must submit to cross-examination, clarifying questions, redirect examination, and recross-examination, unless the right to cross-examine the witness is waived by all parties and accepted by the presiding officer. The proposed changes also authorize the presiding officer to allow the substitution of a witness or voir dire examination where appropriate.

The proposed changes would amend §22.225, relating to Written Testimony and Accompanying Exhibits, to clarify that the requirement to file deposition testimony and responses to requests for information by an opposing party that is planned to be introduced as part of a direct case with written direct testimony applies to intervenors or commission staff. The proposed changes also entail clarifications regarding objections to rebuttal testimony, certain requirements for prefiled written testimony and exhibits for direct cases involving certificate of convenience and necessity (CCN) applications or CCN amendments, prefiled testimony requirements for contested cases that are neither major rate proceedings nor CCN or CCN amendment proceedings, and waiver of the right to cross-examine witnesses.

The proposed changes would amend §22.228, relating to Stipulation of Facts, to revise the term "settlement" with the term "stipulation."

The proposed changes would amend §22.241, relating to Investigations to specify that the commission may at any time institute formal investigations on its own motion, or the motion of commission staff, into any matter within the commission's jurisdiction.

The proposed changes would amend §22.244, relating to Review of Municipal Electric Rate Actions, to clarify references to the commission's Office of Policy and Docket Management.

The proposed changes would amend §22.246, relating to Administrative Penalties to authorize a notice of violation or continuing violation to be given by e-mail as an alternative to certified mail and, if such an e-mail does not exist, for the commission executive director or their designee to make reasonable efforts to notify the person who is alleged to have committed the violation. The proposed changes would also revise the calculation of load proportions for the distribution and disgorgement of excess revenue. Additionally, if the commission determines that wholesale electric market participants other than those specified by rule are affected by excess revenues, or a different distribution method of such revenues is appropriate, the revisions authorize the commission to require the independent organization to distribute excess revenues to affected wholesale market participants using a different distribution method in the same or subsequent proceeding.

The proposed changes would amend §22.261, relating to Proposals for Decision to authorize commission counsel, in addition to the presiding officer, to establish a deadline for submitting proposed corrections or clarifications and to direct or authorize parties to draft and submit proposed findings of fact and conclusions of law. The proposed changes would also authorize commission counsel or the presiding officer to specify a time period in which parties may file exceptions to a proposal for decision. The proposed changes would limit replies to be filed in response to filed exceptions. The proposed changes also authorize commission counsel or the presiding officer to require issues be addressed in a specified order or according to a specified format and, for good cause shown, to allow additional time to file exceptions or replies.

The proposed changes would amend §22.262, relating to Commission Action After a Proposal for Decision to extend the deadline to file a request for oral argument with the commission from 3:00 p.m. to 5:00 p.m. seven days before the open meeting at which the commission is scheduled to consider the case.

The proposed changes would amend §22.263, relating to Final Orders, to clarify that final order notification requirements will follow the Texas Administrative Procedure Act and §22.74, relating to Service of Pleadings and Documents, to the extent that §22.74 does not conflict with the APA.

The proposed changes would amend §22.264, relating to Rehearing, to clarify references to the commission's Office of Policy and Docket Management.

The proposed changes would amend §22.281, relating to Initiation of Rulemaking to clarify that suggested new rules or amendments that do not comply with the requirements of §22.281, including any rulemaking suggestion made in a contested case proceeding, would be construed as policy recommendations and would not be processed as a formal rulemaking petition. The proposed changes would require petitions for rulemaking to be submitted to a general project for petitions for rulemaking and provide that commission staff will open such a project each calendar year and post the control number on the commission's website. The proposed changes would further specify that commission staff may file a memo in the project for rulemaking petitions that establishes comment deadlines for responding to a petition for rulemaking and otherwise establishes a 21-day deadline for comments if such a memo is not filed. The proposed changes

would also delete certain requirements related to publication of a rulemaking notice for publication with the *Texas Register* and explicitly authorizes commission staff, in consideration or development of new rules or amendments to existing rules, to host workshops, publish questions for comment, or draft rules language for comment.

The proposed changes would amend §22.282, relating to Notice and Public Participation in Rulemaking Procedures replaces the requirement for the solicitation of comments through the *Texas Register* with a requirement to solicit comments through the commission filing system. The proposed changes would also authorize commission staff to extend comment or public hearing deadlines, request reply comments, and to provide additional comment filing instructions. The proposed changes would authorize commission staff to provide a final recommendation on a proposed rule to be filed in the rulemaking proceeding at least seven days prior to the date on which the commission is scheduled to consider the matter unless another date is specified. Additionally, the revisions would specify that the failure of staff to provide such a final recommendation within seven days prior to the date on which the commission is scheduled to consider the matter does not preclude the commission from considering the recommendation or taking action in the rulemaking project. The proposed changes remove the requirement for commission staff to notify all commenters on a proposed rule of the filing of staff's final recommendation. The proposed changes also authorize commission staff to withdraw a rule on its own motion if necessary to facilitate the expeditious republication of proposed amendments to that rule.

The proposed changes would make minor and conforming changes to the aforementioned rules and to §22.225, relating to Written Testimony and Accompanying Exhibits; §22.244, relating to Review of Municipal Rate Actions; §22.263, relating to Final Orders; and §22.264, relating to Rehearing.

Growth Impact Statement

The agency provides the following governmental growth impact statement for the proposed rule, as required by Texas Government Code §2001.0221. The agency has determined that for each year of the first five years that the proposed rule is in effect, the following statements will apply:

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

(2) implementation of the proposed rules will not require the creation of new employee positions and will not require the elimination of existing employee positions;

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

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

(5) the proposed rules will not create a new regulation;

(6) the proposed rules will expand, limit, or repeal an existing regulation;

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

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

Fiscal Impact on Small and Micro-Businesses and Rural Communities

There is no adverse economic effect anticipated for small businesses, micro-businesses, or rural communities as a result of implementing the proposed rule. Accordingly, no economic impact statement or regulatory flexibility analysis is required under Texas Government Code §2006.002(c).

Takings Impact Analysis

The commission has determined that the proposed rule will not be a taking of private property as defined in chapter 2007 of the Texas Government Code.

Fiscal Impact on State and Local Government

Davida Dwyer, Deputy Director, Office of Policy and Docket Management, has determined that for the first five-year period the proposed rule is in effect, there will be no fiscal implications for the state or for units of local government under Texas Government Code §2001.024(a)(4) as a result of enforcing or administering the sections.

Public Benefits

Ms. Dwyer has determined that for each year of the first five years the proposed section is in effect the public benefit anticipated as a result of enforcing the section will be more efficient and clear rules of practice and procedure for matters before the commission. There will be probable economic costs to persons required to comply with the rule under Texas Government Code §2001.024(a)(5).

Local Employment Impact Statement

For each year of the first five years the proposed section is in effect, there should be no effect on a local economy; therefore, no local employment impact statement is required under Texas Government Code §2001.022.

Costs to Regulated Persons

Texas Government Code §2001.0045(b) does not apply to this rulemaking because the commission is expressly excluded under subsection §2001.0045(c)(7).

Public Hearing

The commission will conduct a public hearing on this rulemaking if requested in accordance with Texas Government Code §2001.029. The request for a public hearing must be received by November 14, 2025. If a request for public hearing is received, commission staff will file in this project a notice of hearing.

Public Comments

Interested persons may file comments electronically through the interchange on the commission's website. Comments must be filed by November 17, 2025. Comments must be organized by rule section in sequential order, and each comment must clearly designate which section is being commented on. The commission invites specific comments regarding the effects of the proposed rule, including the costs associated with, and benefits that will be gained by the proposed amendments. The commission also requests any data, research, or analysis from any person required to comply with the proposed rule or any other interested person. The commission will consider the information submitted by commenters and the costs and benefits of implementation in deciding whether to modify the proposed rules on adoption. All comments should refer to Project Number 58402.

Each set of comments should include a standalone executive summary as the last page of the filing. This executive summary must be clearly labeled with the submitting entity's name and

should include a bulleted list covering each substantive recommendation made in the comments.

SUBCHAPTER K. HEARINGS

16 TAC §§22.201, 22.204, 22.205, 22.207

Statutory Authority

The proposed amendments are proposed for publication under PURA § 14.001, which provides the commission with the general power to regulate and supervise the business of each public utility within its jurisdiction and to do anything specifically designated or implied by this title that is necessary and convenient to the exercise of that power and jurisdiction; PURA §14.002 and PURA §14.052 and Texas Water Code § 13.041(b), which provide the commission with the authority to adopt and enforce rules reasonably required in the exercise of its powers and jurisdiction, including rules governing practice and procedure before the commission and, as applicable, practice and procedure before the State Office of Administrative Hearings.

Amended §§22.201, 22.204, 22.205 and 22.207 are proposed under Texas Government Code Chapter 2001, Subchapter C §§2001.051-2001.062 which establish minimum standards of uniform practice and procedure for contested cases held at agencies of the State of Texas.

Amended §22.207 is also proposed under PURA §15.023 which provides the commission with the authority to assess and impose an administrative penalty against a regulated person that violates PURA, or a rule or order adopted by the commission in accordance with PURA.

Cross Reference to Statute: Public Utility Regulatory Act §§14.001, 14.002, 14.052 and Texas Water Code § 13.041(b); PURA §12.201, §15.051, §17.157; PURA Chapter 15, Subchapter B §15.021-15.033 and Texas Water Code Chapter 13, Subchapter K §§13.411-13.419; PURA Chapter 33, Subchapter C §§33.051-33.055; Texas Government Code Chapter 2001, §§2001.004-007 and Subchapter B §§2001.021-2001.041, Subchapter C §§2001.051-2001.062, Subchapter D § 2001.081-103, Subchapter F §§2001.141-2001.147; and HB 1600 (83R) and SB 567 (83R) and Texas Water Code Chapter 13.

§22.201. Place and Nature of Hearings.

(a) Commission-held hearings. All commission-held hearings will be held in person and in Austin, unless the commission determines that it is in the public interest to hold a hearing elsewhere or virtually. The presiding officer may, by written order, authorize a prehearing conference to be conducted virtually. [~~All evidentiary hearings shall be held in Austin, unless the commission determines that it is in the public interest to hold a hearing elsewhere. The commission may, when it is in the public interest, hold regional hearings to obtain public comment.~~]

(b) Hearings held at SOAH. A hearing held at SOAH will be conducted in accordance with commission rules.

§22.204. Transcript and Record.

(a) Preparation of Transcript. When requested by any party to a proceeding, a stenographic record of all proceedings before a presiding officer in any prehearing conference or hearing, including all evidence and argument, must [~~shall~~] be made by an official reporter appointed by the commission. It is the responsibility of the party desiring the stenographic record to arrange for the official reporter to be present.

(b) Purchase of Copies. A party may purchase a copy of the transcript from the official reporter [~~at rates set by the commission~~].

(c) Corrections to Transcript. Proposed written corrections of purported errors in a transcript must [~~shall~~] be filed and served on each party of record, the official reporter, and the presiding officer within a reasonable time after the discovery of the error. The presiding officer may establish time limits for proposing corrections. If no party objects to the proposed corrections within 12 days after filing, the presiding officer may direct that the official reporter correct the transcript as appropriate. In the event that the presiding officer or a party disagrees on suggested corrections, the presiding officer may hold a post-hearing [~~posthearing~~] conference and take evidence and argument to determine whether, and in what manner, the record must [~~shall~~] be changed. Following an objection to a change to the record, any change to the record may only be made as ordered by the presiding officer.

(d) Filing of Transcript and Exhibits. The court reporter must [~~shall~~] serve the transcript and exhibits in a proceeding on the presiding officer at the time the transcript is provided to the requesting party. The presiding officer will [~~shall~~] maintain the transcript and exhibits until they are filed with Central Records [~~the commission filing clerk~~]. If no court reporter is requested by a party, the presiding officer will [~~shall~~] maintain the official record and exhibits until they are filed with Central Records [~~the commission filing clerk~~]. The original record and exhibits must [~~shall~~] be filed with Central Records [~~the commission filing clerk~~] promptly after issuance of a proposal for decision.

(e) Contents of Record. The record in a contested case comprises those items specified in the APA.

§22.205. Briefs.

(a) Briefs must conform, where practicable, to the requirements established for formatting pleadings in this chapter, including requirements for citations in §22.72 of this title (relating to Form Requirements for Documents Filed with the commission). [~~Briefs shall conform, where practicable, to the requirements set forth for formatting pleadings in this chapter. Briefs in excess of ten pages shall contain a table of contents with page numbers stated. The presiding officer may require parties to address certain issues, or address issues in a specific order or format. If the legal authority cited in the briefs is not contained in the commission library, a copy of the legal authority shall be provided at the time the brief is filed.~~]

(1) Unless the presiding officer or commission counsel provides otherwise, briefs must not exceed 35 pages including citations without attachments.

(A) Briefs may include up to an additional 40 pages of attachments, but may not exceed a total of 75 pages with citations and attachments.

(B) Briefs in excess of ten pages must contain a table of contents with page numbers stated.

(2) The presiding officer may require parties to address certain issues or address issues in a specific order or format.

(b) If a legal authority cited in the briefs is not readily accessible, a copy of the legal authority must be provided upon request. Such legal authorities may include slip opinions, unpublished opinions, memorandum opinions, or documents from other jurisdictions that are not readily accessible to the commission.

§22.207. Referral to State Office of Administrative Hearings.

(a) The utility division of SOAH will conduct prehearing conferences and hearings related to contested cases before the commission, other than a prehearing conference conducted by a commission admin-

istrative law judge or a hearing conducted by one or more commissioners. [~~The utility division of the State of Office of Administrative Hearings shall conduct hearings related to contested cases before the commission, other than a hearing conducted by one or more commissioners. At the time SOAH receives jurisdiction of a proceeding, the commission shall provide to the administrative law judge a list of issues or areas that must be addressed. In addition, the commission may identify and provide to the administrative law judge at any time additional issues or areas that must be addressed. The commission shall send a request for setting or hearing, or request for assignment of administrative law judge to SOAH in sufficient time to allow resolution of the proceeding prior to the expiration of any jurisdictional deadline. In order to give the commission sufficient time to consider a proposal for decision, the commission may specify the length of time prior to the expiration of a jurisdictional deadline by which the administrative law judge shall issue a proposal for decision.~~]

(1) The commission will provide to the SOAH administrative law judge a list of issues or areas that must be addressed.

(2) At any time, the commission may identify and provide to the SOAH administrative law judge additional issues or areas that must be addressed. The commission will send a request for setting or hearing, or request for assignment of SOAH administrative law judge to SOAH in sufficient time to allow resolution of the proceeding prior to the expiration of any jurisdictional deadline.

(b) To give the commission sufficient time to consider a proposal for decision, the commission may specify the length of time prior to the expiration of a jurisdictional deadline by which the SOAH administrative law judge will issue a proposal for decision.

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

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Public Utility Commission of Texas
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SUBCHAPTER L. EVIDENCE AND EXHIBITS IN CONTESTED CASES

16 TAC §§22.221, 22.225, 22.228

Statutory Authority

The proposed amendments are proposed for publication under PURA § 14.001, which provides the commission with the general power to regulate and supervise the business of each public utility within its jurisdiction and to do anything specifically designated or implied by this title that is necessary and convenient to the exercise of that power and jurisdiction; PURA §14.002 and PURA §14.052 and Texas Water Code § 13.041(b), which provide the commission with the authority to adopt and enforce rules reasonably required in the exercise of its powers and jurisdiction, including rules governing practice and procedure before the commission and, as applicable, practice and procedure before the State Office of Administrative Hearings.

Amended §§22.221, 22.225 and 22.228 are proposed under Texas Government Code, Subchapter D § 2001.081-103 which govern the usage of and procedures for evidence, witnesses and discovery for contested cases held at agencies of the State of Texas.

Cross Reference to Statute: Public Utility Regulatory Act §§14.001, 14.002, 14.052 and Texas Water Code § 13.041(b); PURA §12.201, §15.051, §17.157; PURA Chapter 15, Subchapter B §15.021-15.033 and Texas Water Code Chapter 13, Subchapter K §§13.411-13.419; PURA Chapter 33, Subchapter C §§33.051-33.055; Texas Government Code Chapter 2001, §§2001.004-007 and Subchapter B §§2001.021-2001.041, Subchapter C §§2001.051-2001.062, Subchapter D § 2001.081-103, Subchapter F §§2001.141-2001.147; and HB 1600 (83R) and SB 567 (83R) and Texas Water Code Chapter 13.

§22.221. Rules of Evidence in Contested Cases.

(a) Texas rules of evidence apply. [~~Rules of civil evidence apply.~~] The Texas Rules of [~~Civil~~] Evidence as applied in nonjury civil cases in the courts of Texas must [~~shall~~] be followed in contested cases. Irrelevant, immaterial, or unduly repetitious evidence must [~~shall~~] be excluded. When necessary to ascertain facts not reasonably susceptible of proof under the Texas Rules of [~~Civil~~] Evidence, evidence not admissible under those rules may be admitted, except where precluded by statute, if it is of a type commonly relied upon by reasonably prudent persons in the conduct of their affairs.

(b) Rules of privilege and exemption. The rules of privilege and exemption recognized by Texas law [~~shall~~] apply.

(c) Objections. Objections to evidentiary offers may be made, must [~~shall~~] be ruled upon, and must [~~shall~~] be noted in the record. Failure to object to evidence at the time it is offered constitutes a waiver of all objections to the evidence.

(d) Formal exceptions not required. Formal exceptions to rulings made by the presiding officer during a hearing are not required. It is [~~shall be~~] sufficient that the party notified the presiding officer of the grounds for the objection and desired ruling.

(e) Public comment. Public comment is not part of the evidentiary record of a contested case.

§22.225. Written Testimony and Accompanying Exhibits.

(a) Prefiling of testimony, exhibits, and objections.

(1) Unless otherwise ordered by the presiding officer upon a showing of good cause, the written direct and rebuttal testimony and accompanying exhibits of each witness must [~~shall~~] be prefiled. Deposition testimony and responses to requests for information by an opposing party that an intervenor or commission staff [~~a party~~] plans to introduce as part of its direct case must [~~shall~~] be filed at the time the intervenor or commission staff [~~party~~] files its written direct testimony. [~~The presiding officer shall establish a date for filing of deposition testimony and requests for information that an applicant plans to introduce as part of its direct case.~~]

[~~(2) Deposition testimony and responses to requests for information that a party plans to introduce in support of its rebuttal case shall be filed at the time the party files its written rebuttal testimony.~~]

(2) [~~(3)~~] A party is not required to prefile documents it intends to use during cross-examination except that the presiding officer may require parties to identify documents that may be used during cross examination if it is necessary for the orderly conduct of the hearing.

(3) [~~(4)~~] Objections to prefiled direct or rebuttal testimony and exhibits, including deposition testimony and responses to requests

for information, must [~~shall~~] be filed on dates established by the presiding officer and will [~~shall~~] be ruled upon before or at the time the prefiled testimony and accompanying exhibits are offered. [~~Objections to prefiled rebuttal testimony shall be filed according to the schedule ordered by the presiding officer.~~]

(4) [~~(5)~~] Nothing in this section precludes [~~shall preclude~~] a party from using discovery responses in its direct or rebuttal case even if such responses were not received prior to the applicable deadline for prefiling written testimony and exhibits.

(5) [~~(6)~~] The prefiled testimony schedule in a major rate proceeding must [~~shall~~] be established as set out in this subsection.

(A) Any utility filing an application to change its rates in a major rate proceeding must [~~shall~~] file the written testimony and exhibits supporting its direct case on the same date that such statement of intent to change its rates is filed with the commission. As set forth in §22.243(b) of this title (relating to Rate Change Proceedings), the prefiled written testimony and exhibits must [~~shall~~] be included in the rate filing package filed with the application.

(B) Other parties in the proceeding must [~~shall~~] prefile written testimony and exhibits according to the schedule set forth by the presiding officer. Except for good cause shown or upon agreement of the parties, [~~the~~] commission staff representing the public interest may not be required to file earlier than seven days prior to hearing.

(C) The presiding officer will [~~shall~~] establish dates for filing of rebuttal testimony.

(6) Utilities filing an application for a certificate of convenience and necessity (CCN), or an amendment to a CCN, for a new electric transmission facility must file written testimony and exhibits supporting its direct case on the same date that the application is filed with the commission. [~~The prefiled testimony schedule in a major rate proceeding shall be established as set out in this subsection.~~]

[~~(A) Any utility filing an application to change its rates in a major rate proceeding shall file the written testimony and exhibits supporting its direct case on the same date that such statement of intent to change its rates is filed with the commission. As set forth in §22.243(b) of this title (relating to Rate Change Proceedings), the prefiled written testimony and exhibits shall be included in the rate filing package filed with the application.~~]

[~~(B) Other parties in the proceeding shall prefile written testimony and exhibits according to the schedule set forth by the presiding officer. Except for good cause shown or upon agreement of the parties, the commission staff representing the public interest may not be required to file earlier than seven days prior to hearing.~~]

[~~(C) The presiding officer shall establish dates for filing of rebuttal testimony.~~]

(7) For any contested case that is not a major rate proceeding nor a CCN or CCN amendment proceeding for an electric transmission facility, the applicant is not required to prefile written testimony and exhibits at the time the filing is made unless otherwise required by statute or rule. [~~For electric and telecommunication rate proceedings, the presiding officer shall establish a prefiled testimony schedule for PURA chapter 36, subchapter D or chapter 53, subchapter D rate cases and for cases other than major rate proceedings. In proceedings that are not major rate proceedings, notice of intent proceedings, applications for certificates of convenience and necessity for new generating plant, or applications for fuel reconciliations, the applicant is not required to prefile written testimony and exhibits at the time the filing is made unless otherwise required by statute or rule.~~]

(8) The times for prefiling set out in this section may be modified by the presiding officer upon a showing of good cause. [~~For all water and sewer matters filed under TWC chapters 12 or 13, the presiding officer shall establish a prefiled testimony schedule. The applicant is not required to prefile written testimony and exhibits at the time the filing is made unless otherwise required by statute or rule.~~]

(9) Late-filed testimony may be admitted into evidence if the testimony is necessary for a full disclosure of the facts and admission of the testimony into evidence would not be unduly prejudicial to the legal rights of any party. A party that intends to offer late-filed testimony into evidence must, at the earliest opportunity, inform the presiding officer, who will establish reasonable procedures and deadlines regarding such testimony. [~~Utilities filing an application for construction of a transmission facility that has been designated by the Electric Reliability Council of Texas (ERCOT) independent system operator as critical to the reliability of the ERCOT system and to be considered on an expedited basis, shall file written testimony and exhibits supporting its direct case on the same date that the application is filed with the commission. This requirement shall also apply to transmission lines located in other reliability councils or administered by other independent system operators provided such councils have a process for designation of critical transmission lines.~~]

[~~(10) The times for prefiling set out in this section may be modified upon a showing of good cause.~~]

[~~(11) Late-filed testimony may be admitted into evidence if the testimony is necessary for a full disclosure of the facts and admission of the testimony into evidence would not be unduly prejudicial to the legal rights of any party. A party that intends to offer late-filed testimony into evidence shall, at the earliest opportunity, inform the presiding officer, who shall establish reasonable procedures and deadlines regarding such testimony.~~]

(b) Admission of prefiled testimony. Unless otherwise ordered by the presiding officer, direct and rebuttal testimony must [~~shall~~] be received in written form. The written testimony of a witness on direct examination or rebuttal, either in narrative or question and answer form, may be received as an exhibit and incorporated into the record without the written testimony being read into the record. A witness who is offering written testimony must [~~shall~~] be sworn and must [~~shall~~] be asked whether the written testimony is a true and accurate representation of what the testimony would be if the testimony were to be given orally at the time the written testimony is offered into evidence. The witness must [~~shall~~] submit to cross-examination, clarifying questions, redirect examination, and recross-examination, unless the right to cross-examine the witness is waived by all parties and accepted by the presiding officer. The presiding officer may allow substitution of a witness or voir dire examination where appropriate. Written testimony is [~~shall be~~] subject to the same evidentiary objections as oral testimony. Timely prefiling of written testimony and exhibits, if required under this section or by order of the presiding officer, is a prerequisite for admission into evidence.

(c) Supplementation of prefiled testimony and exhibits. Oral or written supplementation of prefiled testimony and exhibits may be allowed prior to or during the hearing provided that the witness is available for cross-examination. The presiding officer may exclude such testimony if there is a showing that the supplemental testimony raises new issues or unreasonably deprives opposing parties of the opportunity to respond to the supplemental testimony. The presiding officer may admit the supplemental testimony and grant the parties time to respond.

(d) Tender and service. On or before the date the prefiled written testimony and exhibits are due, parties must file such testimony and

exhibits in accordance with the requirements of [~~shall file the number of copies required by~~] §22.71 of this title (relating to Commission Filing Requirements and Procedures [~~Filing of Pleadings, Documents and Other Materials~~]), or other commission rule or order, of the testimony and exhibits with Central Records and must [~~the commission filing clerk and shall~~] serve a copy upon each party.

(e) Withdrawal of evidence. Any exhibit offered and admitted in evidence may not be withdrawn except with the agreement of all parties and approval of the presiding officer.

§22.228. Stipulation of Facts.

No stipulation of facts between the parties or their authorized representatives will [~~shall~~] be admitted into evidence unless it has been reduced to writing and signed by the parties or their authorized representatives or, upon leave of the presiding officer, dictated into the record during a prehearing conference or hearing at which all parties to the agreement are present, have waived the right to be present, or have received reasonable notice that the stipulation [~~settlement~~] will be read into the record at that prehearing conference or hearing.

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

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SUBCHAPTER M. PROCEDURES AND FILING REQUIREMENTS IN PARTICULAR COMMISSION PROCEEDINGS

16 TAC §§22.241, 22.244, 22.246

Statutory Authority

The proposed amendments are proposed for publication under PURA § 14.001, which provides the commission with the general power to regulate and supervise the business of each public utility within its jurisdiction and to do anything specifically designated or implied by this title that is necessary and convenient to the exercise of that power and jurisdiction; PURA §14.002 and PURA §14.052 and Texas Water Code § 13.041(b), which provide the commission with the authority to adopt and enforce rules reasonably required in the exercise of its powers and jurisdiction, including rules governing practice and procedure before the commission and, as applicable, practice and procedure before the State Office of Administrative Hearings.

Amended §22.241 is proposed under PURA §12.201 which requires the commission to prepare and publicize information of public interest describing the functions of the commission and the commission's procedures by which a complaint is filed with and resolved by the commission. PURA §12.201 also requires the commission to, by rule, establish methods by which consumers and service recipients are notified of the name, mailing address, and telephone number of the commission for the purpose of directing complaints to the commission. Amended §22.241 is also proposed under PURA § 15.051 which authorizes an affected person to complain to the regulatory in writing by a public utility in violation or claimed violation of a law that the regulatory authority has jurisdiction to administer or of an order, ordinance, or rule of the regulatory authority, and requires the commission to, for a reasonable period preserve information about each complaint filed with the commission that the commission has authority to resolve. Amended §22.241 is also proposed under PURA § 17.157 which authorizes the commission to resolve disputes between a retail customer and a billing utility, service provider, telecommunications utility, retail electric provider, or electric utility, including the investigation of alleged violations.

Amended §22.244 is proposed under PURA Chapter 33, Subchapter C §§33.051-33.055 which governs the appeal of municipal ratemaking orders to the commission.

Amended §22.246 is proposed under PURA Chapter 15, Subchapter B §15.021-15.033 and Texas Water Code Chapter 13, Subchapter K §§13.411-13.419 which collectively establish the commission's enforcement authority to enjoin, investigate, or require compliance from a person or entity in violation or alleged violation of statute or commission rules, including the commission's authority to impose and assess administrative penalties.

Cross Reference to Statute: Public Utility Regulatory Act §§14.001, 14.002, 14.052 and Texas Water Code § 13.041(b); PURA §12.201, §15.051, §17.157; PURA Chapter 15, Subchapter B §15.021-15.033 and Texas Water Code Chapter 13, Subchapter K §§13.411-13.419; PURA Chapter 33, Subchapter C §§33.051-33.055; Texas Government Code Chapter 2001, §§2001.004-007 and Subchapter B §§2001.021-2001.041, Subchapter C §§2001.051-2001.062, Subchapter D § 2001.081-103, Subchapter F §§2001.141-2001.147; and HB 1600 (83R) and SB 567 (83R) and Texas Water Code Chapter 13.

§22.241. Investigations.

(a) Commission investigations.

(1) The commission may at any time institute formal investigations on its own motion, or the motion of commission staff, into any matter within the commission's jurisdiction [~~the commission's staff~~]. Orders and pleadings initiating investigations will [~~shall~~] specify the matters to be investigated, and will [~~shall~~] be served upon the person being investigated.

(2) Notice of commission-instituted investigations of specific persons subject to commission regulation and investigative proceedings affecting such persons as a class will be served upon all affected persons under investigation. The commission will [~~shall~~] post notice with the *Texas Register* of prehearing conferences and hearings. The presiding officer may require additional notice.

(b) Show cause orders in complaint proceeding. The presiding officer, either upon his or her own motion or upon receipt of written complaint, may at any time after appropriate notice has been given, summon any person within the commission's jurisdiction to appear in a public hearing and show cause why such person should not be compelled to comply with any applicable statute, rule, regulation, or general order with which the person is allegedly not in compliance. All hearings in such show cause proceedings will [~~shall~~] be conducted in accordance with the provisions of this chapter.

(c) No limitations. Nothing in this section limits [~~shall be construed to limit~~] the commission's authority to investigate persons subject to the commission's jurisdiction.

§22.244. Review of Municipal Electric Rate Actions.

(a) Contents of petitions. In addition to any information required by statute, petitions for review of municipal rate actions filed under PURA §33.052 or §§33.101 - 33.104 must [~~shall~~] contain the original petition for review with the required signatures and following additional information.

(1) Each signature page of a petition must [~~shall~~] contain in legible form above the signatures the following:

(A) A statement that the petition is an appeal of a specific rate action of the municipality in question;

(B) The date of and a concise description of that rate action;

(C) A statement designating a specific individual, group of individuals, or organization as the signatories' authorized representative; and

(D) A statement that the designated representative is authorized to represent the signatories in all proceedings before the commission and appropriate courts of law and to do all things necessary to represent the signatories in those proceedings.

(2) The printed or typed name, telephone number, street or rural route address, and facsimile transmission number, if available, of each signatory must [~~shall~~] be provided. Post office box numbers are not sufficient. In appeals relating to PURA §§33.101 - 33.104, the petition must [~~shall~~] list the address of the location where service is received if the address differs from the residential address of the signatory.

(b) Signatures. A signature must [~~shall~~] be counted only once, regardless of the number of bills the signatory receives. The signature must [~~shall~~] be of the person in whose name service is provided or such person's spouse. The signature must [~~shall~~] be accompanied by a statement indicating whether the signatory is appealing the municipal rate action as a qualified voter of that municipality under PURA §33.052, or as a customer of the municipality served outside the municipal limits under PURA §§33.101 - 33.104.

(c) Validity of petition and correction of deficiencies. The petition must [~~shall~~] include all of the information required by this section, legibly written, for each signature in order for the signature to be deemed valid. The presiding officer may allow the petitioner a reasonable time of up to 30 days from the date any deficiencies are identified to cure any defects in the petition.

(d) Verification of petition. Unless otherwise provided by order of the presiding officer, the following procedures must [~~shall~~] be followed to verify petitions appealing municipal rate actions filed under PURA §33.052 and §§33.101 - 33.104.

(1) Within 15 days of the filing of an appeal of a municipal rate action, the Office of Policy and Docket Management must [~~Commission Advising and Docket Management Division shall~~] send a copy of the petition to the respondent municipality with a directive that the municipality verify the signatures on the petition.

(2) Within 30 days after receipt of the petition from the Office of Policy and Docket Management [~~Commission Advising and Docket Management Division~~], the municipality must [~~shall~~] file with the commission a statement of review, together with a supporting written affidavit sworn to by a municipal official.

(3) The period for the municipality's review of the signatures on the petition may be extended by the presiding officer for good cause.

(4) Failure of the municipality to timely submit the statement of review must [~~shall~~] result in all signatures being deemed valid, unless any signature is otherwise shown to be invalid or is invalid on its face.

(5) Objections by the municipality to the authenticity of signatures must [~~shall~~] be set out in its statement of review and will [~~shall~~] be resolved by the presiding officer.

(e) Disputes. Any dispute over the sufficiency or legibility of a petition will [~~shall~~] be resolved by the presiding officer by interim order.

§22.246. Administrative Penalties.

(a) Scope. This section addresses enforcement actions related to administrative penalties or disgorgement of excess revenues only and does not apply to any other enforcement actions that may be undertaken by the commission or [~~the~~] commission staff.

(b) - (e) (No change.)

(f) Report of violation or continuing violation. If, based on the investigation undertaken in accordance with subsection (e) of this section, the executive director determines that a violation or a continuing violation has occurred, the executive director may issue a report to the commission.

(1) Contents of the report. The report must state the facts on which the determination is based and a recommendation on the imposition of an administrative penalty, including a recommendation on the amount of the administrative penalty and, if applicable under §25.503 of this title, a recommendation that excess revenue be disgorged.

(2) Notice of report.

(A) Within 14 days after the report is issued, the executive director will give written notice of the report to the person who is alleged to have committed the violation or continuing violation which is the subject of the report. The notice must [~~may~~] be given by regular, [~~or~~] certified mail, or email to the mailing address or email address maintained in the commission's records. If no such addresses exist, the executive director or executive director's designee will make reasonable efforts to notify the person who is alleged to have committed the violation.

(B) - (D) (No change.)

(g) (No change.)

(h) Settlement conference. A settlement conference may be requested by any party to discuss the occurrence of the violation or continuing violation, the amount of the administrative penalty, disgorged excess revenue if applicable, and the possibility of reaching a settlement prior to hearing. A settlement conference is not subject to the Texas Rules of Evidence or the Texas Rules of Civil Procedure; however, the discussions are subject to Texas Rules of Civil Evidence 408, concerning compromise and offers to compromise.

(1) (No change.)

(2) If a settlement is reached after the matter has been referred to SOAH [~~the State Office of Administrative Hearings~~], the matter will be returned to the commission. If the settlement is approved, the commission will issue an order memorializing commission approval and setting forth commission orders associated with the settlement agreement.

(i) - (j) (No change.)

(k) Distribution of Disgorged Excess Revenues. Disgorged excess revenues must be remitted to an independent organization, as de-

fined in PURA §39.151. The independent organization must distribute the excess revenue to affected wholesale electric market participants in proportion to their load during the intervals when the violation occurred to be used to reduce costs or fees incurred by retail electric customers. [~~The load of any market participants that are no longer active at the time of the distribution will be removed prior to calculating the load proportions of the affected wholesale electric market participants that are still active.~~] However, if the commission determines other wholesale electric market participants are affected or a different distribution method is appropriate, the commission may direct require the independent organization to distribute the excess revenue to affected wholesale market participants using a different distribution method in the same or [~~commission staff to open~~] a subsequent proceeding [~~to address those issues~~].

(1) - (3) (No change.)

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

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Andrea Gonzalez
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SUBCHAPTER N. DECISION AND ORDERS

16 TAC §§22.261 - 22.264

Statutory Authority

The proposed amendments and repeal are proposed for publication under PURA § 14.001, which provides the commission with the general power to regulate and supervise the business of each public utility within its jurisdiction and to do anything specifically designated or implied by this title that is necessary and convenient to the exercise of that power and jurisdiction; PURA §14.002 and PURA §14.052 and Texas Water Code § 13.041(b), which provide the commission with the authority to adopt and enforce rules reasonably required in the exercise of its powers and jurisdiction, including rules governing practice and procedure before the commission and, as applicable, practice and procedure before the State Office of Administrative Hearings.

Amended §§22.261 - 22.264 are proposed under Texas Government Code Chapter 2001, Subchapter F §§2001.141-2001.147 which establish the requirements and procedures, including notice obligations, associated with the issuance of final decisions and orders by a state agency in a contested case, including the procedures for prerequisites to appeal and requirements for motions for rehearing.

Cross Reference to Statute: Public Utility Regulatory Act §§14.001, 14.002, 14.052 and Texas Water Code § 13.041(b); PURA §12.201, §15.051, §17.157; PURA Chapter 15, Subchapter B §15.021-15.033 and Texas Water Code Chapter 13, Subchapter K §§13.411-13.419; PURA Chapter 33, Subchapter C §§33.051-33.055; Texas Government Code Chapter 2001, §§2001.004-007 and Subchapter B §§2001.021-2001.041, Subchapter C §§2001.051-2001.062, Subchapter D §§2001.081-103, Subchapter F §§2001.141-2001.147; and HB 1600 (83R) and SB 567 (83R) and Texas Water Code Chapter 13.

§22.261. Proposals for Decision.

(a) Requirement and Contents of Proposal for Decision. In a contested case, if a majority of the commissioners has not heard the case or read the record, the commission may not issue a final order, if adverse to a party other than the Commission, until a proposal for decision is served on all parties. The proposal for decision will [~~shall~~] be prepared by the presiding officer [~~officer(s)~~] who conducted the hearing or who have read the record. The proposal for decision will [~~shall~~] include a proposed final order, a statement of the reasons for the proposed decision, and proposed findings of fact and conclusions of law in support of the proposed final order. Any party may file exceptions to the proposed decision in accordance with subsection (d) of this section. The presiding officer may supplement or amend a proposal for decision in response to the exceptions or replies submitted by the parties or upon the presiding officer's own motion. Making corrections or minor revisions of a proposal for decision is not considered issuance of an amended or supplemental proposal for decision.

(b) Procedures Regarding Proposed Orders. If the presiding officer's recommendation is not adverse to any party, the recommendation may be made through a proposed order containing findings of fact and conclusions of law. The proposed order must [~~shall~~] be served on all parties, and the commission counsel or presiding officer will [~~shall~~] establish a deadline for submitting proposed corrections or clarifications.

(c) Findings and Conclusions. The commission counsel or presiding officer may direct or authorize the parties to draft and submit proposed findings of fact and conclusions of law. The commission is not required to rule on findings of fact and conclusions of law that are not required or authorized.

(d) Exceptions and Replies.

(1) Who may file. Any party may file exceptions to the Proposal for Decision within the time period specified by commission counsel or the presiding officer [~~the presiding officer~~]. If any party files exceptions, the opportunity will [~~shall~~] be afforded to all parties to respond within a time period set by the commission counsel or presiding officer. Replies may only be filed in response to filed exceptions.

(2) Presentation. The presiding officer or commission counsel may require that issues be addressed in a specified order or according to a specified format. Proposed findings and conclusions may be submitted in conjunction with exceptions and replies. The evidence and law relied upon will [~~shall~~] be stated with particularity, and any evidence or arguments relied upon will [~~shall~~] be grouped under the exceptions or replies to which they relate.

(3) Request for Extension. A request for extension of time within which to file exceptions or replies must [~~shall~~] be filed with Central Records [~~the commission filing clerk~~] and served on all parties. The presiding officer or commission counsel may allow additional time for good cause shown. If additional time is allowed for exceptions, reasonable additional time will [~~shall~~] be allowed for replies.

§22.262. Commission Action After a Proposal for Decision.

(a) - (c) (No change.)

(d) Oral Argument Before the Commission.

(1) Any party may request oral argument before the commission before the final disposition of any proceeding.

(2) Oral argument may be allowed at the commission's discretion. The commission may limit the scope and duration of oral ar-

gument. The party bearing the burden of proof has the right to open and close oral argument.

(3) A request for oral argument must be filed as a separate written pleading. The request must be filed no later than 5:00 [~~3:00~~] p.m. seven days before the open meeting at which the commission is scheduled to consider the case.

(4) Upon the filing of a motion for oral argument, the Office of Policy and Docket Management must send a separate ballot to each commissioner to determine whether the commission will hear oral argument at an open meeting. An affirmative vote by one commissioner is required to grant oral argument. Two days before the commission is scheduled to consider the case, the Office of Policy and Docket Management will file a notice to the parties regarding whether a request for oral argument has been granted.

(5) The absence or denial of a request for oral argument does not preclude the commissioners from asking questions of any party present at the open meeting.

(e) (No change.)

§22.263. Final Orders.

(a) Form and Content.

(1) A final order of the commission will [~~shall~~] be in writing and signed by a majority of the commissioners.

(2) A final order will [~~shall~~] include findings of fact and conclusions of law separately stated and may incorporate findings of fact and conclusions of law proposed within a proposal for decision.

(3) Findings of fact, if set forth in statutory language, will [~~shall~~] be accompanied by a concise and explicit statement of the underlying facts supporting the findings.

(4) The final order will [~~shall~~] comply with the requirements of §22.262[~~(b)~~] of this title (relating to Commission Action After a Proposal for Decision).

(b) Notice. Parties will [~~shall~~] be notified of the commission's final order as required by the APA and §22.74 of this title (relating to Service of Pleadings and Documents) to the extent that provision does not conflict with the APA.

(c) Effective Date of Order. Unless otherwise stated, the date a final order is signed is the effective date of that order, and such date will [~~shall~~] be stated therein.

(d) Date That an Order is Signed. An order is signed on the date shown on the order. If a sworn motion filed under APA §2001.142(c) is granted, with or without commission action, then, regardless of the date shown on the order, the date that the commission's order is considered to be signed is [~~shall be~~] the date specified in that sworn motion as the date that the movant received the order or obtained actual knowledge of the order. If more than one sworn motion is granted, then the date that the commission's order is considered to be signed is the latest date specified in any such granted motions.

(e) Reciprocity of Final Orders Between States. After reviewing the facts and the issues presented, a final order may be adopted by the commission even though it is inconsistent with the commission's procedural or substantive rules provided that the final order, or the portion thereof that is inconsistent with commission rules, is a final order, or a part thereof, rendered by a regulatory agency of some state other than the State of Texas and provided further that the number of customers in Texas affected by the final order is no more than the lesser of either 1,000 customers or 10% of the total number of customers of the affected utility.

§22.264. Rehearing.

(a) Motions for rehearing, replies thereto, and commission action on motions for rehearing are [~~shall be~~] governed by the APA. Only a party to a proceeding before the commission may file a motion for rehearing.

(b) All motions for rehearing must [~~shall~~] state the claimed error with specificity. If an ultimate finding of fact stated in statutory language is claimed to be in error, the motion for rehearing must [~~shall~~] state all underlying or basic findings of fact claimed to be in error and must [~~shall~~] cite specific evidence which is relied upon as support for the claim of error.

(c) A motion for rehearing or a reply to a motion for rehearing is untimely if it is not filed by the deadlines specified in APA §2001.146 or, if the commission extends the time to file such motion or reply or approves a time agreed to by the parties, the date specified in the order of the commission extending time or approving the time.

(d) A motion by a party to extend time related to a motion for rehearing must be filed no less than ten days before the end of the time period that the party seeks to extend or it is untimely. Such motion must state with specificity the reasons the extension is justified.

(e) Upon the filing of a timely motion for rehearing or a timely motion to extend time, the Office of Policy and Docket Management must [~~Commission Advising and Docket Management Division shall~~] send separate ballots to each commissioner to determine whether they will consider the motion at an open meeting. Untimely motions will [~~shall~~] not be balloted. An affirmative vote by one commissioner is required for consideration of a motion for rehearing or a motion to extend time at an open meeting. If no commissioner votes to add a timely motion to extend time to an open meeting for consideration, the motion is overruled ten days after the motion is filed.

(f) If the commission extends time to act on a motion for rehearing, the Office of Policy and Docket Management [~~Commission Advising and Docket Management Division shall~~] send separate ballots to each commissioner to determine whether they will consider the motion for rehearing at a subsequent open meeting. An affirmative vote by one commissioner is required to place the motion for rehearing on an open meeting agenda.

(g) A party that files a motion for rehearing or a reply to a motion for rehearing must [~~shall~~] deliver a copy of the motion or reply to every other party in the case.

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

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SUBCHAPTER O. RULEMAKING

16 TAC §22.281, §22.282

Statutory Authority

The proposed amendments are proposed for publication under PURA § 14.001, which provides the commission with the general power to regulate and supervise the business of each public utility within its jurisdiction and to do anything specifically designated or implied by this title that is necessary and convenient to the exercise of that power and jurisdiction; PURA §14.002 and PURA §14.052 and Texas Water Code § 13.041(b), which provide the commission with the authority to adopt and enforce rules reasonably required in the exercise of its powers and jurisdiction, including rules governing practice and procedure before the commission and, as applicable, practice and procedure before the State Office of Administrative Hearings.

Amended §22.281 and §22.282 are proposed under Texas Government Code §§2001.004-007 and Subchapter B §§2001.021-2001.041 which establish general rulemaking requirements and procedures, including notice obligations, for agencies of the State of Texas

Cross Reference to Statute: Public Utility Regulatory Act §§14.001, 14.002, 14.052 and Texas Water Code § 13.041(b); PURA §12.201, §15.051, §17.157; PURA Chapter 15, Subchapter B §15.021-15.033 and Texas Water Code Chapter 13, Subchapter K §§13.411-13.419; PURA Chapter 33, Subchapter C §§33.051-33.055; Texas Government Code Chapter 2001, §§2001.004-007 and Subchapter B §§2001.021-2001.041, Subchapter C §§2001.051-2001.062, Subchapter D § 2001.081-103, Subchapter F §§2001.141-2001.147; and HB 1600 (83R) and SB 567 (83R) and Texas Water Code Chapter 13.

§22.281. Initiation of Rulemaking.

(a) Petition for Rulemaking. Any interested person, as defined by the APA, may petition the commission requesting the adoption of a new rule or the amendment of an existing rule.

(1) The petition must [~~shall~~] be in writing and must [~~shall~~] be submitted to the project opened under paragraph (2) of this subsection. The petition must include a brief explanation of the rule, each reason [~~the reason(s)~~] the new or amended rule should be adopted, the statutory authority for such a rule or amendment, and complete proposed text for the rule. The proposed text for the rule must [~~shall~~] indicate by striking through the words, if any, to be deleted from the current rule and by underlining the words, if any, to be added to the current rule. A suggested new rule or rule amendment that does not comply with each of the requirements of this section, including any rulemaking suggestion made in a contested case proceeding, will be construed as a policy recommendation and will not be processed as a formal rulemaking petition.

(2) Each calendar year, commission staff will open a general project for petitions for rulemaking and post the control number on the commission's website. [~~Upon receipt of a petition for rulemaking, the commission shall submit a notice for publication in the "In Addition" section of the *Texas Register*. The notice shall include a summary of the petition, the name of the individual, organization or entity that submitted the petition, and notification that a copy of the petition will be available for review and copying in the commission's central records. Comments on the petition shall be due 21 days from the date of publication of the notice. Failure to publish a notice of a petition for rulemaking in the *Texas Register* shall not invalidate any commission action on the petition for rulemaking.~~]

(3) Commission staff may file a memo in the general project opened under paragraph (2) of this subsection establishing a deadline for interested persons to file comments in response to the petition for rulemaking or designating a new control number for the submission of comments. Commission staff may relocate any relevant filings from the general control number to the new project. If commission staff does not file a memo under this paragraph, comments on a petition for rulemaking may be filed in the general project and the deadline for submitting comments on the petition is 21 days after the date the petition is filed. [~~Within 60 days after submission of a petition, the commission either shall deny the petition in writing, stating its reasons for the denial, or shall initiate rulemaking proceedings.~~]

(4) Within 60 days after submission of a petition that fully complies with the requirements of paragraph (1) of this subsection, the commission will either deny the petition in writing, stating its reasons for the denial, or initiate a rulemaking proceeding.

(b) Commission Initiated Rulemaking. The commission may initiate rulemaking proceedings on its own motion. Nothing in this section precludes [~~shall preclude the commission general counsel or~~] commission staff from consideration or development of new rules or amendments to existing rules, including hosting workshops or publishing questions or draft rules language for comment, without express direction from the commission.

§22.282. Notice and Public Participation in Rulemaking Procedures.

(a) Initial Comments. Prior to the publication of [~~publishing~~] a proposed rule or initiation of [~~initiating~~] an amendment to an existing rule, the commission or commission staff may solicit comments on the need for a rule and potential scope of the rule by filing a request for comments on the commission filing system [~~publication of a notice of rulemaking project in the "In Addition" section of the Texas Register. A notice filed pursuant to this section shall contain a brief description and statement of the intended objective of the proposed rule and indicate if a draft of the proposed rule is available for review by interested persons~~]. Unless otherwise prescribed by the commission or commission staff, any comments concerning the rulemaking project must [~~shall~~] be submitted within 30 days from the date the request for comments is filed. The commission or commission staff may hold workshops or public hearings on the rulemaking project.

(b) Notice. The commission may initiate a rulemaking project by publishing notice of the proposed rule in accordance with Tex. Gov't Code §§ 2001.021 - 2001.037.

(c) Public Comments. Prior to the adoption of any rule, the commission will [~~shall~~] afford all interested persons a reasonable opportunity to submit data, views, or arguments in writing. Written comments must be filed within 30 days of the date the proposed rule is published in the Texas Register unless the commission establishes a different date for submission of comments. The commission may also establish a schedule for reply comments if it determines that additional comments would be appropriate or helpful in reaching a decision on the proposed rule. Commission staff may provide an extension to the comment deadline, request reply comments, or provide additional comment filing instructions in a rulemaking project.

(d) Public Hearing. The commission or commission staff may schedule workshops or public hearings on the proposed rule. Commission staff will hold a public hearing [~~An opportunity for public hearing shall be granted~~] if requested by at least 25 persons, by a governmental subdivision or agency, or by an association having at least 25 members. The request for public hearing must be made no later than 30 days after the date the proposed rule is published in the Texas Register, unless the commission establishes a different date for requesting a public hearing. Commission staff may provide an extension to the public hearing request deadline.

(e) Staff Recommendation. Staff's final recommendation will, if practicable, [~~shall~~] be filed in the rulemaking proceeding [~~submitted to the commission and filed in central records~~] at least seven days prior

to the date on which the commission is scheduled to consider the matter, unless some other date is specified by the commission. If commission staff does not file its final recommendation at least seven days prior to the date on which the commission is scheduled to consider the matter, the commission may still consider the recommendation or take action in the rulemaking project. [~~Staff will notify all persons who have filed comments concerning the proposed rule of the filing of staff's final recommendation.~~]

(f) Final Adoption. Following consideration of comments, the commission will issue an order adopting, adopting as amended, or withdrawing the rule within six months after the date of publication of the proposed rule or the rule is automatically withdrawn. Commission staff may withdraw a rule on its own motion if necessary to facilitate the expeditious republication of proposed amendments to that 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.

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SUBCHAPTER M. PROCEDURES AND FILING REQUIREMENTS IN PARTICULAR COMMISSION PROCEEDINGS

16 TAC §22.248

The Public Utility Commission of Texas (commission) proposes one repeal in the Chapter 22 procedural rules. The proposed repeal is in Subchapter M, §22.248, relating to Retail Public Utilities.

Rule Review Stakeholder Recommendations

On May 3, 2025, commission staff filed a preliminary notice and request for comments which was published in the *Texas Register* on May 17, 2024, at 49 TexReg 3635. Comments were received from the Alliance for Retail Markets (ARM) and the Texas Energy Association for Marketers (TEAM), collectively (REP Coalition); Entergy Texas, Inc. (Entergy); the Lower Colorado River Authority and LCRA Transmission Services Corporation (LCRA); the Office of Public Utility Counsel (OPUC); Oncor Electric Delivery Company, LLC (Oncor); the Steering Committee of Cities Served by Oncor (OCSC); Texas Association of Water Companies, Inc. (TAWC); the Texas Rural Water Association (TRWA); Texas-New Mexico Power Company (TNMP); and Vistra Corporation (Vistra). Based upon filed comments and an internal review by commission staff, the commission proposes the following rule changes.

Growth Impact Statement

The agency provides the following governmental growth impact statement for the proposed rule, as required by Texas Government Code §2001.0221. The agency has determined that for each year of the first five years that the proposed rule is in effect, the following statements will apply:

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

(2) implementation of the proposed rules will not require the creation of new employee positions and will not require the elimination of existing employee positions;

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

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

(5) the proposed rules will not create a new regulation;

(6) the proposed rules will expand, limit, or repeal an existing regulation;

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

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

Fiscal Impact on Small and Micro-Businesses and Rural Communities

There is no adverse economic effect anticipated for small businesses, micro-businesses, or rural communities as a result of implementing the proposed rule. Accordingly, no economic impact statement or regulatory flexibility analysis is required under Texas Government Code §2006.002(c).

Takings Impact Analysis

The commission has determined that the proposed rule will not be a taking of private property as defined in chapter 2007 of the Texas Government Code.

Fiscal Impact on State and Local Government

Davida Dwyer, Deputy Director, Office of Policy and Docket Management, has determined that for the first five-year period the proposed rule is in effect, there will be no fiscal implications for the state or for units of local government under Texas Government Code §2001.024(a)(4) as a result of enforcing or administering the sections.

Public Benefits

Ms. Dwyer has determined that for each year of the first five years the proposed section is in effect the public benefit anticipated as a result of enforcing the section will be more efficient and clear rules of practice and procedure for matters before the commission. There will be probable economic costs to persons required to comply with the rule under Texas Government Code §2001.024(a)(5).

Local Employment Impact Statement

For each year of the first five years the proposed section is in effect, there should be no effect on a local economy; therefore, no local employment impact statement is required under Texas Government Code §2001.022.

Costs to Regulated Persons

Texas Government Code §2001.0045(b) does not apply to this rulemaking because the commission is expressly excluded under subsection §2001.0045(c)(7).

Public Hearing

The commission will conduct a public hearing on this rulemaking if requested in accordance with Texas Government Code §2001.029. The request for a public hearing must be received by November 14, 2025. If a request for public hearing is received, commission staff will file in this project a notice of hearing.

Public Comments

Interested persons may file comments electronically through the interchange on the commission's website. Comments must be filed by November 17, 2025. Comments must be organized by rule section in sequential order, and each comment must clearly designate which section is being commented on. The commission invites specific comments regarding the effects of the proposed rule, including the costs associated with, and benefits that will be gained by the proposed amendments and repeal. The commission also requests any data, research, or analysis from any person required to comply with the proposed rule or any other interested person. The commission will consider the information submitted by commenters and the costs and benefits of implementation in deciding whether to modify the proposed rules on adoption. All comments should refer to Project Number 58402.

Each set of comments should include a standalone executive summary as the last page of the filing. This executive summary must be clearly labeled with the submitting entity's name and should include a bulleted list covering each substantive recommendation made in the comments.

Statutory Authority

The proposed repeal is proposed for publication under PURA § 14.001, which provides the commission with the general power to regulate and supervise the business of each public utility within its jurisdiction and to do anything specifically designated or implied by this title that is necessary and convenient to the exercise of that power and jurisdiction; PURA §14.002 and PURA §14.052 and Texas Water Code § 13.041(b), which provide the commission with the authority to adopt and enforce rules reasonably required in the exercise of its powers and jurisdiction, including rules governing practice and procedure before the commission and, as applicable, practice and procedure before the State Office of Administrative Hearings.

§22.248, relating to Retail Public Utilities is repealed in accordance with HB 1600 (83R), SB 567 (83R) and Texas Water Code Chapter 13 which transferred regulatory jurisdiction of the rates, operations, and services of retail public utilities from the Texas Commission on Environmental Quality to the commission.

Cross Reference to Statute: Public Utility Regulatory Act §§14.001, 14.002, 14.052 and Texas Water Code § 13.041(b); PURA §12.201, §15.051, §17.157; PURA Chapter 15, Subchapter B §15.021-15.033 and Texas Water Code Chapter 13, Subchapter K §§13.411-13.419; PURA Chapter 33, Subchapter C §§33.051-33.055; Texas Government Code Chapter 2001, §§2001.004-007 and Subchapter B §§2001.021-2001.041, Subchapter C §§2001.051-2001.062, Subchapter D § 2001.081-103, Subchapter F §§2001.141-2001.147; and HB 1600 (83R) and SB 567 (83R) and Texas Water Code Chapter 13.

§22.248. Retail Public Utilities.

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

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CHAPTER 25. SUBSTANTIVE RULES APPLICABLE TO ELECTRIC SERVICE PROVIDERS

SUBCHAPTER I. TRANSMISSION AND DISTRIBUTION

DIVISION 1. OPEN-ACCESS COMPARABLE TRANSMISSION SERVICE FOR ELECTRIC UTILITIES IN THE ELECTRIC RELIABILITY COUNCIL OF TEXAS

16 TAC §25.205

The Public Utility Commission of Texas (commission) proposes new 16 Texas Administrative Code (TAC) §25.205 relating to Net Metering Arrangements Involving a Large Load Customer Co-Located with an Existing Generation Resource. This proposed rule will implement Public Utility Regulatory Act (PURA) §39.169 as enacted by Senate Bill (SB) 6 during the Texas 89th Regular Legislative Session. The new rule will apply to a proposed net metering arrangement involving a large load and an existing generation resource and will establish the criteria for ERCOT's study of a proposed net metering arrangement. The rule will also set forth the procedural steps for ERCOT to complete its study of a proposed net metering arrangement within 120 days and the procedural steps for the commission to approve, with or without conditions, or deny a proposed net metering arrangement within 60 days after ERCOT files its study results and recommendations with the commission.

Growth Impact Statement

The agency provides the following governmental growth impact statement for the proposed rule, as required by Texas Government Code §2001.0221. The agency has determined that for each year of the first five years that the proposed rule is in effect, the following statements will apply:

(1) the proposed rule will not create a government program and will not eliminate a government program;

(2) implementation of the proposed rule will not require the creation of new employee positions and will not require the elimination of existing employee positions;

(3) implementation of the proposed rule will not require an increase and will not require a decrease in future legislative appropriations to the agency;

(4) the proposed rule will not require an increase and will not require a decrease in fees paid to the agency;

(5) the proposed rule will create a new regulation;

(6) the proposed rule will not expand, limit, or repeal an existing regulation;

(7) the proposed rule will not change the number of individuals subject to the rule's applicability; and

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

Fiscal Impact on Small and Micro-Businesses and Rural Communities

There is no adverse economic effect anticipated for small businesses, micro-businesses, or rural communities as a result of implementing the proposed rule. Accordingly, no economic impact statement or regulatory flexibility analysis is required under Texas Government Code §2006.002(c).

Takings Impact Analysis

The commission has determined that the proposed rule will not be a taking of private property as defined in chapter 2007 of the Texas Government Code.

Fiscal Impact on State and Local Government

Jessie Horn, Sr. Counsel, Rules and Projects Division, has determined that for the first five-year period the proposed rule is in effect, there will be no fiscal implications for the state or for units of local government under Texas Government Code §2001.024(a)(4) as a result of enforcing or administering the sections.

Public Benefits

Ms. Horn has determined that for each year of the first five years the proposed section is in effect the public benefit anticipated as a result of enforcing the section will be increased transparency about the process for reviewing a proposed net metering arrangement and increased reliability to the ERCOT power grid. There will be no probable economic cost to persons required to comply with the rule under Texas Government Code §2001.024(a)(5).

Local Employment Impact Statement

For each year of the first five years the proposed section is in effect, there should be no effect on a local economy; therefore, no local employment impact statement is required under Texas Government Code §2001.022.

Costs to Regulated Persons

Texas Government Code §2001.0045(b) does not apply to this rulemaking because the commission is expressly excluded under subsection §2001.0045(c)(7).

Public Hearing

Commission staff will conduct a public hearing on this rulemaking if requested in accordance with Texas Government Code §2001.029. The request for a public hearing must be received by October 17, 2025. If a request for public hearing is received, commission staff will file in this project a notice of hearing.

Public Comments

Interested persons may file comments electronically through the interchange on the commission's website or by submitting a paper copy to Central Records, Public Utility Commission of Texas, 1701 North Congress Avenue, P.O. Box 13326, Austin, Texas 78711-3326. Initial comments must be filed by October 17, 2025. Reply comments must be filed by October 31, 2025. Comments should be organized in a manner consistent with the organization of the proposed rule. The commission invites specific comments regarding the costs associated with, and benefits that will be gained by, implementation of the proposed rule. The commission will consider the costs and benefits in deciding whether to modify the proposed rule on adoption. All comments should refer to Project Number 58479.

In addition to general comments on the text of the proposed rule, the commission invites interested persons to address the following specific questions:

Does the commission have authority to approve a net metering arrangement if retail electric service to the large load customer would not be provided by the municipally owned utility or electric cooperative that is certificated to provide retail electric service to the area in which the large load customer is located?

PURA §39.169(c) authorizes the electric cooperative, transmission and distribution utility, or municipally owned utility that provides electric service at the location of the new net metering arrangement to object to the arrangement for reasonable cause, including a violation of other law.

How should the commission interpret "electric service" in PURA §39.169(c)?

What process should be used for addressing an objection to a net metering arrangement based on a violation of other law?

PURA §39.169(g) limits the parties to a proceeding under PURA §39.169 to the commission, ERCOT, the interconnecting electric cooperative, transmission and distribution utility, or municipally owned utility, and a party in the net metering arrangement. How should the commission interpret "interconnecting" in PURA §39.169(g)?

Is there a scenario where the electric cooperative, transmission and distribution utility, or municipally owned utility that objects to a net metering arrangement under PURA §39.169(c) is not a party to the proceeding under PURA §39.169(g)? If so, how can these two statutory provisions be reconciled?

PURA §39.169(d) states that if the commission imposes conditions on a proposed net metering arrangement, the conditions must require a generation resource that makes dispatchable capacity available to the ERCOT region before the implementation of a net metering arrangement under this section to make at least that amount of dispatchable capacity available to the ERCOT power region after the implementation of the arrangement at the direction of the independent organization in advance of an anticipated emergency condition.

How should the commission interpret "dispatchable capacity"?

How should the commission interpret "make available"?

How far in advance of an anticipated emergency condition should ERCOT be able to direct a generation resource to make dispatchable capacity available to the ERCOT region? Should "advance" be measured based on time, megawatt, or some other metric?

How should the commission interpret an "anticipated emergency condition"?

Each set of comments should include a standalone executive summary as the last page of the filing. This executive summary must be clearly labeled with the submitting entity's name and should include a bulleted list covering each substantive recommendation made in the comments.

Statutory Authority

The new rule is proposed under Public Utility Regulatory Act (PURA) §14.001, which grants the commission the general power to regulate and supervise the business of each public utility within its jurisdiction and to do anything specifically designated or implied by this title that is necessary and convenient to the exercise of that power and jurisdiction; §14.002, which authorizes the commission to adopt and enforce rules reasonably required in the exercise of its powers and jurisdiction; PURA §39.151, which grants the commission authority to oversee ERCOT; and PURA §39.169, which requires the commission to approve, deny, or impose reasonable conditions on a proposed net metering arrangement involving a large load customer and an existing generation resource.

Cross Reference to Statute: Public Utility Regulatory Act §14.001; §14.002; §39.151; and §39.169.

§25.205. Net Metering Arrangements Involving a Large Load Customer Co-Located with an Existing Generation Resource.

(a) Applicability. This section applies to a net metering arrangement involving a large load customer and an existing generation resource. This section does not apply to a generation resource or energy storage resource:

(1) the registration for which included a co-located large load customer at the time of the generation resource or energy storage resource's energization, regardless of whether the large load customer was energized at a later date; or

(2) a majority interest of which is owned indirectly or directly as of January 1, 2025, by a parent company of a customer that participates in the new net metering arrangement.

(b) Definitions. The following words and terms, when used in this section, have the following meanings unless the context indicates otherwise:

(1) Applicants--the parties to a net metering arrangement for which approval is sought under this section.

(2) Energy storage resource--an energy storage system registered with ERCOT as an energy storage resource for the purpose of providing energy or ancillary services to the ERCOT grid and associated facilities that are behind the system's point of interconnection, necessary for the operation of the system, and not part of a manufacturing process that is separate from the generation of electricity.

(3) Existing generation resource--a generation resource registered with ERCOT as a stand-alone generation resource as of September 1, 2025 or an energy storage resource registered with ERCOT as a stand-alone energy storage resource as of September 1, 2025.

(4) Generation resource--a generator registered with ERCOT as a generation resource and capable of providing energy or ancillary services to the ERCOT grid, as well as associated facilities that are behind the generator's point of interconnection, necessary for the operation of the generator, and not part of a manufacturing process that is separate from the generation of electricity.

(5) Large load customer--a customer that requests a new or expanded interconnection where the total load at a single site is equal to or greater than 75 megawatts (MW), and as of September 1, 2025, was not modeled in ERCOT's Network Operations Model as part of a generation resource private use network (PUN) or an energy storage resource PUN.

(6) Large load interconnection study--has the same meaning as defined in ERCOT protocols.

(7) Net metering arrangement--a contractual arrangement in which an existing generation resource and a large load customer agree to net the generation resource's output with the customer's load for settlement purposes based on a metering scheme approved by ERCOT.

(8) Stand-alone energy storage resource--an energy storage resource that, as of September 1, 2025, was included in ERCOT's Network Operations Model and such model of the resource site did not include a PUN load.

(9) Stand-alone generation resource--a generation resource that, as of September 1, 2025, was included in ERCOT's Network Operations Model and such model of the resource site did not include a PUN load.

(10) Stranded transmission asset--a transmission asset that, as a result of a net metering arrangement, is no longer providing service to the public or may otherwise be retired from service without impairing the ability of the transmission system to provide adequate transmission service to customers.

(11) System--the bulk power system in the ERCOT region.

(12) Underutilized transmission asset--a transmission asset that, as a result of a net metering arrangement, is expected to transmit on an average, annual basis at least 25% less power and is not providing significant reliability benefits to the system commensurate with its maximum capacity to transmit power.

(c) Commission approval required. A power generation company, municipally owned utility, or electric cooperative must not implement a net metering arrangement involving a large load customer and an existing generation resource unless the net metering arrangement is approved by the commission.

(d) Initiating the process for approval of a net metering arrangement. Prior to ERCOT commencing its study under subsection (g) of this section, the applicants seeking approval of a net metering arrangement must:

(1) apply to the commission, using a new docket number, for approval of the net metering arrangement by filing an application that meets the requirements of §22.73 of this title (relating to General Requirements for Applications) and includes a copy of the notice submitted to ERCOT; and

(2) upon filing its application with the commission, serve copies of the application, consistent with the requirements in §22.74 of this title (relating to Service of Pleadings and Documents), on:

(A) ERCOT;

(B) the interconnecting electric cooperative, transmission and distribution utility, or municipally owned utility; and

(C) the electric cooperative, transmission and distribution utility, or municipally owned utility that provides electric service at the location of the new net metering arrangement.

(e) Parties to a proceeding under this section.

(1) The parties to a proceeding under this section are limited to:

(A) the applicants;

(B) commission staff;

(C) ERCOT; and

(D) the interconnecting electric cooperative, transmission and distribution utility, or municipally owned utility.

(2) The parties to a proceeding under this section need not file a motion to intervene.

(f) Discovery.

(1) Discovery may commence on or after the date an application under this section is filed with the commission.

(2) ERCOT is not required to follow the discovery process to obtain the necessary information to conduct its study under subsection (g) of this section.

(3) The presiding officer may establish reasonable deadlines relating to discovery to facilitate the processing of the application within the statutory deadlines.

(g) Commencement of ERCOT study.

(1) The parties to a net metering arrangement must provide ERCOT all information that ERCOT deems necessary regarding the net metering arrangement.

(2) The interconnecting electric cooperative, transmission and distribution utility, or municipally owned utility must submit the following to ERCOT:

(A) a large load interconnection study;

(B) the results of power flow modeling or any other information relevant to a determination of whether stranded or underutilized transmission assets may result from the arrangement; and

(C) any other information that ERCOT deems necessary.

(3) Upon receipt of all necessary information, ERCOT must conduct a study of the system impacts of the net metering arrangement, including transmission security and resource adequacy impacts, and stranded or underutilized transmission assets associated with the net metering arrangement. Not later than seven days after commencing its study, ERCOT must file notice in the docket indicating the date that ERCOT commenced its study and the date ERCOT must file its study results and recommendations.

(4) ERCOT must provide to commission staff any access, information, support, or cooperation that commission staff determines is necessary to provide its recommendations under this section.

(h) General requirements of ERCOT study. ERCOT's study of a net metering arrangement must include:

(1) a resource adequacy analysis that is comprised of an evaluation of:

(A) the large load customer's curtailment capability;

(B) on-site back up generation capability to offset the large load customer;

(C) expected net generation available to the ERCOT grid after implementation of the net metering arrangement;

(D) the existing generation resource's availability to ERCOT for dispatch after implementation of the net metering arrangement; and

(E) the impacts of reduced net capability or lower availability on reserve margins or other reliability criteria;

(2) a transmission security analysis that is comprised of a steady state and stability load serving study with and without the generation, under peak scenarios and off-peak scenarios;

(3) an analysis identifying transmission assets that may become stranded or underutilized as a result of the net metering arrangement, including the identity of the transmission service provider (TSP) associated with each such asset and the degree to which any transmission assets are expected to be underutilized from both a delivery and a reliability perspective; and

(4) any other analysis or study that ERCOT determines is necessary.

(i) ERCOT study results. Not later than ten days before ERCOT files its study results and recommendations, ERCOT must file notice in the docket indicating the date that ERCOT expects to file its study results and recommendations. Not later than 120 days after ERCOT's filing indicating ERCOT received all information it deems necessary to conduct its study regarding the net metering arrangement, ERCOT must file its study results and associated recommendations. ERCOT's filing must include:

(1) direct testimony supporting the filing;

(2) an executive summary of the study, including any ERCOT recommendations, that identifies:

(A) the large load customer;

(B) whether the large load customer seeks a new or expanded interconnection;

(C) whether the large load customer or any other customer is already located at the requested interconnection site and if so, that customer's peak demand at the requested interconnection site;

(D) whether ERCOT identified any negative impacts to system reliability, including transmission security and resource adequacy impacts;

(E) ERCOT's recommendation to approve, with or without conditions, or deny the net metering arrangement; and

(F) whether ERCOT recommends conditions to mitigate an impact to transmission security, resource adequacy, or both;

(3) the complete study, detailing:

(A) ERCOT's analysis;

(B) the underlying assumptions used in the study;

(C) the sources of data used in the study;

(D) the capacity made available to the ERCOT region by the existing generation resource at the time of annual peak demand each of the last 10 years and how that existing generation resource can comply with a requirement to make at least that same amount of dispatchable capacity available after implementation of the net metering arrangement, as applicable; and

(E) whether ERCOT identified any negative impacts to resource adequacy that cannot be mitigated with curtailment of the large load customer; and

(F) whether any transmission assets are stranded or underutilized, including the degree to which any underutilized transmission assets are underutilized from a delivery or a reliability perspective, and the identity of the associated TSPs;

(4) a detailed explanation of the basis for any conditions that ERCOT recommends and the extent to which those conditions are expected to mitigate a reliability risk to the system; and

(5) any other information that ERCOT relied on or considered.

(j) Procedural schedule. After ERCOT files its study results and recommendations, the presiding officer must set a procedural schedule that will enable the commission to issue an order in the proceeding within 60 days of ERCOT's filing.

(1) The procedural schedule must be substantially similar to the following:

(A) the deadline for the applicants to file a statement of position or direct testimony is five days after ERCOT files its study results and recommendations;

(B) the deadline for ERCOT and the interconnecting electric cooperative, transmission and distribution utility, or municipally owned utility to file a statement of position, direct testimony, or an objection to the net metering arrangement is ten days after ERCOT files its study results and recommendations;

(C) the deadline to request a hearing on the merits is ten days after ERCOT files its study results and recommendations;

(D) the deadline for ERCOT to file a response to other parties' filings is 15 days after ERCOT files its study results and recommendations;

(E) the deadline for commission staff to file a statement of position or direct testimony, including its recommendations, is 17 days after ERCOT files its study results and recommendations;

(F) if no hearing on the merits is requested, the deadline to file a stipulation or agreement, a joint motion to admit evidence, and a joint proposed order is 24 days after ERCOT files its study results and recommendations;

(G) if a hearing on the merits is requested, the hearing on the merits will commence up to 28 days after ERCOT files its study results and recommendations; and

(H) if a hearing on the merits is requested:

(i) the deadline for initial briefs is 34 days after ERCOT files its study results and recommendations; and

(ii) the deadline for reply briefs and proposed orders is 40 days after ERCOT files its study results and recommendations.

(2) Notwithstanding any provision of this section, the presiding officer may set a different procedural schedule than the one set forth in this subsection or adjust any procedural deadlines to facilitate the commission issuing an order in the proceeding within 60 days after ERCOT files its study results and recommendations.

(k) Commission decision. Not later than 60 days after ERCOT files its study results and recommendations, the commission will approve, with or without conditions, or deny an application for a net metering arrangement as necessary to maintain system reliability, including transmission security and resource adequacy impacts.

(1) If the commission approves a net metering arrangement with conditions, then the conditions imposed on the net metering arrangement must include requiring the existing generation resource to make dispatchable capacity available to the ERCOT region as directed by ERCOT in advance of an anticipated emergency condition. The dispatchable capacity made available to the ERCOT region in such an event must be at least equal to the amount of dispatchable capacity that was made available to the ERCOT region before implementation of the net metering arrangement.

(2) The conditions imposed on a net metering arrangement may include requiring:

(A) the retail customer(s) served behind-the-meter to reduce load during certain events;

(B) the existing generation resource to make capacity available to the ERCOT region during certain events;

(C) initiation of a separate hold harmless proceeding for each net metering arrangement that results in stranded or underutilized transmission assets in order to ensure TSPs and their customers are held harmless;

(D) maximum ramp rates for load curtailment; and

(E) any other requirement that is necessary to maintain system reliability.

(3) If the commission imposes a condition that requires a large load customer served behind the meter to reduce load, ERCOT must include any such load reduction when calculating any price adjustments for reliability deployments.

(4) If the commission imposes a condition requiring a hold harmless proceeding and the TSP associated with the stranded or underutilized transmission assets was not a party to the proceeding in which the commission considered approving, with or without conditions, or denying the proposed net metering arrangement, then commission staff must provide notice to the TSP of the requirement to initiate a hold harmless proceeding under subsection (l) of this section not later than seven days after the commission order imposing the condition. Notice may be served by delivering a copy of the commission order by physical or electronic mail to the TSP's authorized representative or attorney of record in the TSP's last comprehensive base rate case.

(l) Hold harmless proceeding. Within 60 days of a commission order requiring a hold harmless proceeding, each TSP associated with stranded or underutilized transmission assets that result from a net metering arrangement must file an application to quantify the costs associated with such assets and to reflect removal of those costs from the TSP's rates. Such costs must not be included in the TSP's rates in future proceedings absent an explicit commission determination in a comprehensive base rate proceeding that the associated transmission assets are no longer stranded or underutilized, and that the TSP has not otherwise been compensated for those costs. Upon removal from rates, these costs must be collected by the TSP from the existing generation resource owner and the interconnecting large load customer in a proportion determined by the commission or by agreement between the existing generation resource owner and the interconnecting large load customer.

(1) The application must include information sufficient to identify the costs associated with the stranded or underutilized transmission assets.

(2) The parties to a hold harmless proceeding under this subsection are not limited to the parties identified in subsection (e) of this section.

(3) Removal from rates of the costs associated with stranded or underutilized transmission assets, along with all associated depreciation, tax, return, and other cost of service components including an appropriate amount of operations and maintenance expenses, may be implemented in a manner otherwise consistent with the ratemaking treatments associated with an interim update of transmission rates under §25.192 of this title (related to Transmission Service Rates), provided that:

(A) increases in costs must not be included in a hold harmless proceeding;

(B) updated billing units are applied when establishing rates reflecting the removal of the appropriate costs associated with the stranded or underutilized transmission assets;

(C) the timeline for approval included in §25.192 does not apply to a hold harmless proceeding under this subsection; and

(D) a hold harmless proceeding under this subsection is not an interim update to a TSP's rates for purposes of determining the frequency of interim updates authorized under §25.192.

(m) Periodic evaluation of conditions imposed. If the conditions imposed on a net metering arrangement under this section are not limited to a specific period, a party to the net metering arrangement must apply for a commission determination of whether the conditions should be extended, with or without modification, or rescinded at least 36 months and not more than 60 months after the order approving the net metering arrangement with conditions.

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 September 19, 2025.

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Andrea Gonzalez
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Public Utility Commission of Texas
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For further information, please call: (512) 936-7244

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SUBCHAPTER O. UNBUNDLING AND MARKET POWER
DIVISION 2. INDEPENDENT ORGANIZATIONS

16 TAC §25.370

The Public Utility Commission of Texas (commission) proposes new 16 Texas Administrative Code (TAC) §25.370 relating to ERCOT Large Load Forecasting Criteria. This proposed rule will implement Public Utility Regulatory Act (PURA) §37.0561(m) as enacted by Senate Bill (SB) 6 during the Texas 89th Regular Legislative Session. The new rule will identify the criteria that a large load customer must meet for inclusion in the load data that a transmission and/or distribution service provider (TDSP) submits to ERCOT for purposes of developing the load forecasts that ERCOT uses for its transmission planning and resource adequacy models and reports.

Growth Impact Statement

The agency provides the following governmental growth impact statement for the proposed rule, as required by Texas Government Code §2001.0221. The agency has determined that for each year of the first five years that the proposed rule is in effect, the following statements will apply:

(1) the proposed rule will not create a government program and will not eliminate a government program;

(2) implementation of the proposed rule will not require the creation of new employee positions and will not require the elimination of existing employee positions;

(3) implementation of the proposed rule will not require an increase and will not require a decrease in future legislative appropriations to the agency;

(4) the proposed rule will not require an increase and will not require a decrease in fees paid to the agency;

(5) the proposed rule will create a new regulation, but this regulation harmonizes a new statutory provision with the language in an existing rule that serves a similar regulatory function;

(6) the proposed rule will not expand, limit, or repeal an existing regulation;

(7) the proposed rule will not change the number of individuals subject to the rule's applicability; and

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

Fiscal Impact on Small and Micro-Businesses and Rural Communities

There is no adverse economic effect anticipated for small businesses, micro-businesses, or rural communities as a result of implementing the proposed rule. Accordingly, no economic impact statement or regulatory flexibility analysis is required under Texas Government Code §2006.002(c).

Takings Impact Analysis

The commission has determined that the proposed rule will not be a taking of private property as defined in chapter 2007 of the Texas Government Code.

Fiscal Impact on State and Local Government

Jessie Horn, Sr. Counsel, Rules and Projects Division, has determined that for the first five-year period the proposed rule is in effect, there will be no fiscal implications for the state or for units of local government under Texas Government Code §2001.024(a)(4) as a result of enforcing or administering the sections.

Public Benefits

Ms. Horn has determined that for each year of the first five years the proposed section is in effect the public benefit anticipated as a result of enforcing the section will be more accurate load forecast data to inform transmission planning and resource adequacy in ERCOT. There will be no probable economic cost to persons required to comply with the rule under Texas Government Code §2001.024(a)(5).

Local Employment Impact Statement

For each year of the first five years the proposed section is in effect, there should be no effect on a local economy; therefore, no local employment impact statement is required under Texas Government Code §2001.022.

Costs to Regulated Persons

Texas Government Code §2001.0045(b) does not apply to this rulemaking because the commission is expressly excluded under subsection §2001.0045(c)(7).

Public Hearing

Commission staff will conduct a public hearing on this rulemaking if requested in accordance with Texas Government Code §2001.029. The request for a public hearing must be received by October 17, 2025. If a request for public hearing is received, commission staff will file in this project a notice of hearing.

Public Comments

Interested persons may file comments electronically through the interchange on the commission's website or by submitting a paper copy to Central Records, Public Utility Commission of Texas, 1701 North Congress Avenue, P.O. Box 13326, Austin, Texas 78711-3326. Initial comments must be filed by October 17, 2025. Reply comments must be filed by October 31, 2025. Comments should be organized in a manner consistent with the organization of the proposed rule. The commission invites specific comments regarding the costs associated with, and benefits that will be gained by, implementation of the proposed rule. The commission will consider the costs and benefits in deciding whether to modify the proposed rule on adoption. All comments should refer to Project Number 58480.

Each set of comments should include a standalone executive summary as the last page of the filing. This executive summary must be clearly labeled with the submitting entity's name and should include a bulleted list covering each substantive recommendation made in the comments.

The amount of the study fee in proposed subsection (c)(3) and the amount of security or contribution in aid of construction that a large load customer is required to pay to demonstrate financial commitment under proposed subsection (c)(4) will be addressed in Project No. 58481, Rulemaking to Implement Large Load Interconnection Standards Under PURA §37.0561. Questions for comment related to these topics were filed in Project No. 58481 on September 12, 2025. Therefore, the commission invites specific comments on these topics in Project No. 58481.

Statutory Authority

The new rule is proposed under Public Utility Regulatory Act (PURA) §14.001, which grants the commission the general power to regulate and supervise the business of each public utility within its jurisdiction and to do anything specifically designated or implied by this title that is necessary and convenient to the exercise of that power and jurisdiction; §14.002, which authorizes the commission to adopt and enforce rules reasonably required in the exercise of its powers and jurisdiction; §37.056, which requires the commission to consider historical load, forecasted load growth, and additional load currently seeking interconnection, including load for which the electric utility has yet to sign an interconnection agreement, as determined by the electric utility with the responsibility for serving the load, when considering need for additional service; §37.0561, which requires the commission by rule to establish criteria by which ERCOT includes forecasted large load of any peak demand in the organization's transmission planning and resource adequacy models and reports; §39.151, which grants the commission authority to oversee ERCOT; and §39.166, which requires ERCOT to use forecasted electrical load, as reasonably determined by the certificated transmission service provider, to identify each region in which transmission capacity is insufficient to meet the region's existing and forecasted electrical load.

Cross Reference to Statute: Public Utility Regulatory Act §14.001; §14.002; §37.0561; §37.0561; §39.151; and §39.166.

§25.370. ERCOT Large Load Forecasting Criteria.

(a) Purpose. The purpose of this section is to establish criteria for a large load customer to be included in ERCOT's load forecasts for transmission planning and resource adequacy models and reports.

(b) Definitions. The following words and terms, when used in this section, have the following meanings unless the context indicates otherwise:

(1) Large load customer--An entity seeking interconnection of one or more facilities at a single site with an aggregate new load or load addition greater than or equal to 25 megawatts (MW) behind one or more common points of interconnection (POI) or service delivery points.

(2) Load--non-coincident peak demand in MW.

(3) Transmission and/or distribution service provider--the electric utility, municipally owned utility, or electric cooperative that is certificated to provide retail electric service at the site that a large load customer seeks to interconnect or the transmission service provider delegated authority by the electric utility, municipally owned utility, or electric cooperative to act on its behalf for purposes of providing information to ERCOT under this section.

(c) Criteria for inclusion in ERCOT load forecast. A large load customer's forecasted demand must not be included in an ERCOT load forecast used for transmission planning or resource adequacy unless the large load customer executed and securitized an interconnection agreement or meets the following criteria:

(1) disclosed to the TDSP whether it is pursuing a separate request for electric service, the approval of which would result in the customer materially changing, delaying, or withdrawing the interconnection request, and if so, the location, size, and anticipated timing of energization associated with such request;

(2) demonstrated to the TDSP site control for the proposed load location through an ownership interest, lease, or other means accepted in the applicable commission rule for large load interconnection standards;

(3) paid a study fee to the TDSP that is the greater of $100,000 or an amount that is set by the applicable commission rule for large load interconnection standards;

(4) demonstrated financial commitment to the TDSP by means of:

(A) payment of security on a dollar per megawatt basis as set by the applicable commission rule for large load interconnection standards;

(B) payment of contribution in aid of construction; or

(C) payment of security provided under an agreement that requires the large load customer to pay for significant equipment or services in advance of signing an agreement to establish electric delivery service;

(5) provided a load ramping schedule to the TDSP, if applicable;

(6) submitted an attestation to the TDSP that attests significant, verifiable progress toward completion of site-related studies and engineering services required for project development before energization (e.g., water, wastewater, or gas); and

(7) submitted an attestation to the TDSP that attests significant, verifiable progress toward obtaining state and local regulatory approvals required for project development before energization (e.g., water, air, or backup generation permits, or city or county building permits).

(d) Submission of forecasted load data to ERCOT. At the time that a TDSP submits its load data to ERCOT through a mechanism designated by ERCOT, the TDSP must also submit to ERCOT a notarized

attestation sworn to by the TDSP's highest-ranking representative, official, or officer with binding authority over the TDSP, attesting that each large load customer included in the TDSP's load data meets the criteria set forth in subsection (c) of this section for inclusion in ERCOT's load forecast. Not later than ten working days after a TDSP reasonably determines there is a change in its load data submitted to ERCOT, a TDSP must report the change to ERCOT by updating its load data.

(e) ERCOT forecast. Using the load data provided by TDSPs under subsection (d) of this section, ERCOT must develop load forecasts for the ERCOT region.

(1) Validation of load data. ERCOT and commission staff may access information collected by a TDSP to ensure compliance with this section and validate load data submitted by a TDSP. If load data submitted by a TDSP cannot be validated, the data must be excluded from the load forecast developed by ERCOT.

(2) Adjustments to load data. ERCOT, in consultation with commission staff, may make adjustments to the load data provided by a TDSP under this section based on actual historical realization rates or other objective, credible, independent information. ERCOT must provide the TDSP with the data and calculations used to adjust the forecasted load.

(3) Use of load forecasts. ERCOT's load forecasts must use the load data provided by TDSPs under this section in its transmission planning and resource adequacy models and reports. Applicable adjustments to the load forecast may be made to accommodate differences in study scope, time horizons, and modeling details.

(f) Confidential information. Customer-specific or competitively sensitive information obtained under this section is confidential and not subject to disclosure under Chapter 552 of the Texas Government Code.

(g) ERCOT compliance. ERCOT must develop the necessary protocols to ensure its 2026 Regional Transmission Plan complies with this section. If ERCOT cannot timely implement the protocols to ensure the 2026 Regional Transmission Plan complies with this section, then ERCOT, in consultation with commission staff, must submit a compliance plan to the commission, detailing how it will ensure the 2026 Regional Transmission Plan complies with this section.

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

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TITLE 22. EXAMINING BOARDS

PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 291. PHARMACIES

SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES

22 TAC §291.133

The Texas State Board of Pharmacy proposes amendments to §291.133, concerning Pharmacies Compounding Sterile Preparations. The amendments, if adopted, update the personnel, environment, compounding process, cleaning and disinfecting, beyond-use dating, cleansing and garbing, environmental testing, sterility testing, recall procedure, and recordkeeping requirements for pharmacies compounding sterile preparations.

Daniel Carroll, Pharm.D., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Dr. Carroll has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to ensure the safety and efficacy of compounded sterile preparations for patients, improve the health, safety, and welfare of patients by ensuring that Class A, Class B, Class C, and Class E pharmacies engaged in sterile compounding operate in a safe and sanitary environment, and provide clearer regulatory language that is appropriately informed by the recently updated guidance in the United States Pharmacopeia-National Formulary. For each year of the first five-year period the rule will be in effect, the probable economic cost to persons required to comply with the amendments is estimated to be $0-$1,973.50 per employee, $0-$7,300 in fixed costs, and $0-$1,110.04 per batch in variable costs based on number of batches and formulations, in addition to providing the drug products, placebos, vials, and active pharmaceutical ingredients necessary for testing. Additionally, dependent on a pharmacy's current operations and equipment, a pharmacy would potentially incur one-time expenses of $0-$5,000 for cleanroom modifications, $0-$6,000 for an autoclave, $0-$4,000 for a pharmaceutical oven, $0-$500 for temperature logs and monitors, and $0-6,330 per formulation for preliminary testing.

Economic Impact Statement

The Texas State Board of Pharmacy (Board) anticipates a possible adverse economic impact on some small or micro-businesses (pharmacies) or rural communities as a result of the proposed amendments to §291.133. The Board is unable to estimate the number of small or micro-businesses subject to the proposed amendments. As of July 15, 2025, there are 891 Class A, Class B, Class C, and Class E pharmacies that perform sterile compounding, as indicated by the pharmacies on Board licensing forms. The Board estimates that 78 rural communities in Texas have a Class A, Class B, Class C, or Class E pharmacy that performs sterile compounding.

The economic impact of the proposed amendments on a particular pharmacy would be dependent on that pharmacy's current environment and the policies and procedures the pharmacy previously had in place for compounding sterile preparations. The additional costs of training personnel who do not compound nor supervise compounding personnel on a pharmacy's SOPs are estimated to be $0 to $1,200 per employee. The additional costs of the updated media-fill testing procedures depend on the compounding risk-level in which a pharmacy is currently engaged. For a pharmacy that is currently engaged in only low-risk and medium-risk compounding, the additional costs are estimated to be $9.95 to $300 annually per employee who engages in sterile compounding. For a pharmacy that is currently engaged

in high-risk compounding, no additional costs are anticipated. The additional costs of the updated gloved fingertip sampling depend on the compounding risk-level in which a pharmacy is currently engaged. For a pharmacy that is currently engaged in only low-risk and medium-risk compounding, the additional costs are estimated to be $1.40 to $3.50 per contact plate and $90 to $250 per test annually for each employee who engages in sterile compounding. For a pharmacy that is currently engaged in high-risk compounding, no additional costs are anticipated. The additional costs of the updated garbing competency testing depend on the compounding risk-level in which a pharmacy is currently engaged. For a pharmacy that is currently engaged in only low-risk and medium-risk compounding, the additional costs are estimated to be $0 to $220 annually per employee who engages in sterile compounding. For a pharmacy that is currently engaged in high-risk compounding, no additional costs are anticipated. For a pharmacy that chooses to engage in Category 3 compounding under the proposed amendments, additional costs are estimated to be $0 to $7,000 annually for additional viable air sampling. For a pharmacy that engages in Category 1 or Category 2 compounding under the proposed amendments, no additional viable air sampling costs are anticipated. The additional costs of the updated surface sampling requirements are estimated to be $85 to $300 per sample taken. The additional costs of the updated sterilization and depyrogenation requirements, for a pharmacy that does not already possess a pharmaceutical oven or autoclave, are one-time costs of $1,000 to $6,000 for an autoclave, $1,000 to $4,000 for a pharmaceutical oven, and $500 for temperature logs and monitors, annual costs of $300 for calibration and $210 for endotoxin testing, and $40 to $50 per usage for washing and wrapping supplies. Preliminary testing is estimated to cost $510 to $1,800 per formulation for method suitability testing, $150 to $345 per formulation for sterility testing, $500 per formulation for endotoxin validation method, $110 to $210 per formulation for endotoxin testing, $250 to $1,200 per formulation for container closure integrity testing, $1,025-$1,275 per formulation for antimicrobial effectiveness testing, and $1,000 per formulation for a method suitability test for antimicrobial effectiveness testing. The additional costs of the updated air exchange requirements are estimated to be a one-time cost of $0 to $5,000 based on the extent of the modifications, if any, needed for a pharmacy's cleanroom. The additional costs of expanded disinfecting with sterile 70% isopropyl alcohol in place of non-sterile 70% isopropyl alcohol are estimated to be a net increase of $5.04 per 32-ounce bottle. The additional costs of sterile low-lint garments and coverings are estimated to $0 to $45 per set. The additional costs of expanded sterility and bacterial endotoxin testing are estimated to be $300 to $500 per batch. The estimated cost of the new beyond-use date requirements is dependent on the pharmacy's current practices. A shortened beyond-use date may require the compound to be made more frequently or discarded more often. Additional testing costs may be incurred to prove that a specific compounded preparation can exceed a new beyond-use date standard.

The Board established a Compounding Rules Advisory Group, comprised of a Sterile Subcommittee and a Non-Sterile Subcommittee, to review the recently issued revisions to United States Pharmacopeia General Chapter <795> Pharmaceutical Compounding- Nonsterile Preparations and United States Pharmacopeia General Chapter <797> Pharmaceutical Compounding- Sterile Preparations, and the proposed amendments are based on the recommendations of the Sterile Subcommittee. The Subcommittee's recommendations were initially presented at the May 7, 2024, Board meeting and four Subcommittee members made oral public comments concerning the recommendations. The Board reviewed the recommendations and provided direction to Board staff on items for which the Subcommittee could not come to consensus. At the August 6, 2024, Board meeting, the Board voted to published the proposed amendments for public comment. The amendments were published in the September 20, 2024, issue of the *Texas Register* (49 TexReg 7588). The Board received eight written public comments concerning the amendments. At the November 5, 2024, Board meeting, the Board received six oral public comments. After reviewing and considering the written and oral comments, the Board made additional changes and voted to propose the updated amendments to §291.133. The amendments were published in the December 27, 2024, edition of the *Texas Register* (49 TexReg 10463). The Board received five written public comments concerning the amendments. At the June 17, 2025, Board meeting, the Board received six oral public comments. After reviewing and considering the written and oral comments, the Board made additional changes and voted to propose the updated amendments to §291.133. Alternative methods of achieving the purpose of the proposed amendments were considered by the Sterile Subcommittee and the Board and the proposed amendments reflect recommendations for the least restrictive methods of ensuring the safety and efficacy of compounded sterile preparations.

Regulatory Flexibility Analysis

The Texas State Board of Pharmacy (Board) anticipates a possible adverse economic impact on some small or micro-businesses (pharmacies) or rural communities as a result of the proposed amendments to §291.133. The Board established a Compounding Rules Advisory Group, comprised of a Sterile Subcommittee and a Non-Sterile Subcommittee, to review the recently issued revisions to United States Pharmacopeia General Chapter <795> Pharmaceutical Compounding- Nonsterile Preparations and United States Pharmacopeia General Chapter <797> Pharmaceutical Compounding- Sterile Preparations, and the proposed amendments are based on the recommendations of the Sterile Subcommittee. The Sterile Subcommittee reviewed the new provisions of USP <797>, discussed whether any of the provisions should be added to §291.133 to ensure patient safety in Texas, and considered various methods of achieving this purpose.

The Sterile Subcommittee discussed the changes to USP <797> during its meetings held on August 2, 2023, August 23, 2023, October 3, 2023, October 30, 2023, and January 23, 2024 meetings. The Sterile Committee considered different options and levels of personnel training, beyond-use dating, environmental requirements, compounding processes, environmental testing requirements, recall procedures, and recordkeeping requirements in determining recommendations for the least restrictive methods of ensuring the safety and efficacy of compounded sterile preparations. In reviewing the new provisions of USP <797>, the Sterile Subcommittee recommended limiting or not adopting several of the new provisions, including preparation per approved labeling, initial gowning competency, use of isolators, precision and accuracy of pressure differentials, compounding notification on label, packaging of compounded sterile preparations, and compounding allergenic extracts.

The Sterile Subcommittee's recommendations were initially presented at the May 7, 2024, Board meeting and four Subcommittee members made oral public comments concerning the recommendations. The Board reviewed the recommendations

and provided direction to Board staff on items for which the Subcommittee could not come to consensus. At the August 6, 2024, Board meeting, the Board voted to published the proposed amendments for public comment. The amendments were published in the September 20, 2024, issue of the *Texas Register* (49 TexReg 7588). The Board received eight written public comments concerning the amendments. At the November 5, 2024, Board meeting, the Board received six oral public comments. After reviewing and considering the written and oral comments, the Board made additional changes and voted to propose the updated amendments to §291.133. The amendments were published in the December 27, 2024, edition of the *Texas Register* (49 TexReg 10463). The Board received five written public comments concerning the amendments. At the June 17, 2025, Board meeting, the Board received six oral public comments. After reviewing and considering the written and oral comments, the Board made additional changes and voted to propose the updated amendments to §291.133. The Board finds that alternative regulatory methods would not be consistent with the health, safety, and environmental and economic welfare of the state.

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

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

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

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

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

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

(6) The proposed amendments both limit and expand an existing regulation by adding and amending operational standards for Class A, Class B, Class C, and Class E, pharmacies engaged in sterile compounding;

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

(8) The proposed amendments would have a de minimis impact on this state's economy.

Written comments on the amendments may be submitted to Eamon D. Briggs, Deputy General Counsel, Texas State Board of Pharmacy, 1801 Congress Avenue, Suite 13.100, Austin, Texas 78701-1319, FAX (512) 305-8061. Comments must be received by 5:00 p.m., November 3, 2025.

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

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

§291.133. Pharmacies Compounding Sterile Preparations.

(a) Purpose. Pharmacies compounding sterile preparations, prepackaging pharmaceutical products, and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:

(1) compounding of sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A-S, Class B, Class C-S, and Class E-S pharmacies;

(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile preparation in Class A-S, Class B, Class C-S, and Class E-S pharmacies to a practitioner's office for office use by the practitioner;

(3) compounding and distribution of compounded sterile preparations by a Class A-S pharmacy for a Class C-S pharmacy; and

(4) compounding of sterile preparations by a Class C-S pharmacy and the distribution of the compounded preparations to other Class C or Class C-S pharmacies under common ownership.

(b) Definitions. In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) ACPE--Accreditation Council for Pharmacy Education.

(2) Airborne particulate cleanliness class--The level of cleanliness specified by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For example:

(A) ISO Class 5 (formerly Class 100) is an atmospheric environment that contains less than 3,520 particles 0.5 microns and larger in diameter per cubic meter of air (formerly stated as 100 particles 0.5 microns in diameter per cubic foot of air);

(B) ISO Class 7 (formerly Class 10,000) is an atmospheric environment that contains less than 352,000 particles 0.5 microns and larger in diameter per cubic meter of air (formerly stated as 10,000 particles 0.5 microns in diameter per cubic foot of air); and

(C) ISO Class 8 (formerly Class 100,000) is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns and larger in diameter per cubic meter of air (formerly stated as 100,000 particles 0.5 microns in diameter per cubic foot of air).

(3) Ancillary supplies--Supplies necessary for the preparation and administration of compounded sterile preparations.

(4) Anteroom [~~Ante-area~~]--An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the pharmacy and the buffer room. [~~An ISO Class 8 or better area where personnel may perform hand hygiene and garbing procedures, staging of components, order entry, labeling, and other high-particulate generating activities. It is also a transition area that:~~]

[~~(A) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas; and~~]

[~~(B) reduces the need for the heating, ventilating and air conditioning (HVAC) control system to respond to large disturbances.~~]

(5) Aseptic processing [~~Processing~~]--A mode of processing pharmaceutical and medical preparations that involves the separate sterilization of the preparation and of the package (containers-clo-

sures or packaging material for medical devices) and the transfer of the preparation into the container and its closure under at least ISO Class 5 conditions.

(6) Automated compounding device--An automated device that compounds, measures, and/or packages a specified quantity of individual components in a predetermined sequence for a designated sterile preparation.

(7) Batch--A specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation cycle.

(8) Batch preparation compounding--Compounding of multiple sterile preparation units, in a single discrete process, by the same individual(s), carried out during one limited time period. Batch preparation/compounding does not include the preparation of multiple sterile preparation units pursuant to patient specific medication orders.

(9) Beyond-use date--The date, or hour and the date, after which a compounded sterile preparation shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded. [~~The date or time after which the compounded sterile preparation shall not be stored or transported or begin to be administered to a patient. The beyond-use date is determined from the date or time the preparation is compounded.~~]

(10) Biological safety cabinet [~~Safety Cabinet~~], Class II--A ventilated cabinet for personnel, product or preparation, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered exhausted air for environmental protection.

(11) Buffer room [~~Area~~]--An ISO Class 7 or cleaner or, if a Class B pharmacy, an ISO Class 8 or cleaner, room with fixed walls and doors where primary engineering controls that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room. [~~An ISO Class 7 or, if a Class B pharmacy, ISO Class 8 or better, area where the primary engineering control area is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.~~]

(12) Clean room--A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

(13) Cleaning agent--An agent, usually containing a surfactant, used for the removal of substances (e.g., dirt, debris, microbes, residual drugs or chemicals) from surfaces.

(14) Cleanroom suite--A classified area that consists of both an anteroom and buffer room.

(15) [~~(13)~~] Component--Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product [~~intended for use in the compounding of a drug preparation, including those that may not appear in such preparation~~].

(16) [~~(14)~~] Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner's prescription drug or medication order based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.

(17) [~~(15)~~] Compounding aseptic isolator [~~Aseptic Isolator~~]--A form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment shall not occur unless it has first passed through a microbial retentive filter (HEPA minimum).

(18) [~~(16)~~] Compounding aseptic containment isolator [~~Aseptic Containment Isolator~~]--A compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

(19) [~~(17)~~] Compounding personnel [~~Personnel~~]--A pharmacist, pharmacy technician, or pharmacy technician trainee who performs the actual compounding; a pharmacist who supervises pharmacy technicians or pharmacy technician trainees compounding sterile preparations, and a pharmacist who performs an intermediate or final verification of a compounded sterile preparation.

(20) [~~(18)~~] Critical area [~~Area~~]--An ISO Class 5 environment.

(21) [~~(19)~~] Critical sites [~~Sites~~]--A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.

(22) [~~(20)~~] Device--An instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner.

(23) [~~(21)~~] Direct compounding area [~~Compounding Area~~]--A critical area within the ISO Class 5 primary engineering control where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

(24) [~~(22)~~] Disinfectant--An agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.

(25) [~~(23)~~] First air [~~Air~~]--The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(26) [~~(24)~~] Hazardous drugs [~~Drugs~~]--Drugs that, studies in animals or humans indicate exposure to the drugs, have a potential for causing cancer, development or reproductive toxicity, or harm to organs. For the purposes of this chapter, radiopharmaceuticals are not considered hazardous drugs.

(27) [~~(25)~~] Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).

(28) [~~(26)~~] HVAC--Heating, ventilation, and air conditioning.

(29) [~~(27)~~] Immediate use--A sterile preparation that is not prepared according to USP 797 standards (i.e., outside the pharmacy and most likely not by pharmacy personnel) which shall be stored for no longer than four hours following the start of preparing [~~one hour after completion of~~] the preparation.

(30) [~~(28)~~] IPA--Isopropyl alcohol (2-propanol).

(31) [~~(29)~~] Labeling--All labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container.

(32) Master formulation record--A detailed record of procedures that describes how the compounded sterile preparation is to be prepared.

(33) [~~(30)~~] Media-fill test [~~Media-Fill Test~~]--A test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as Soybean-Casein Digest Medium is substituted for the actual drug preparation to simulate admixture compounding. The issues to consider in the development of a media-fill test are the following: media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

(34) [~~(31)~~] Multiple-dose container [~~Multiple-Dose Container~~]--A multiple-unit container for articles or preparations intended for parenteral [~~potential~~] administration only and usually contains antimicrobial preservatives. The beyond-use date for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.

(35) [~~(32)~~] Negative pressure room [~~Pressure Room~~]--A room that is at a lower pressure compared to adjacent spaces and, therefore, the net flow of air is into the room.

(36) [~~(33)~~] Office use--The administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 562 of the Act, or for administration or provision by a veterinarian in accordance with §563.054 of the Act.

(37) [~~(34)~~] Pharmacy bulk package [~~Bulk Package~~]--A container of a sterile preparation for potential use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).

(38) [~~(35)~~] Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original container into unit dose packaging or a multiple-dose [~~multiple dose~~] container for distribution within a pharmacy [~~facility~~] licensed as a Class C pharmacy or to other pharmacies under common ownership for distribution within those pharmacies [~~facilities~~]. The term as defined does not prohibit the prepackaging of drug products for use within other pharmacy classes.

(39) [~~(36)~~] Preparation or compounded sterile preparation [~~Compounded Sterile Preparation~~]--A sterile admixture compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber. The components of the preparation may or may not be sterile products.

(40) [~~(37)~~] Primary engineering control [~~Engineering Control~~]--A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding sterile preparations. Such devices include, but may not be limited to, laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators.

(41) [~~(38)~~] Product--A commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

(42) [~~(39)~~] Positive control [~~Control~~]--A quality assurance sample prepared to test positive for microbial growth.

(43) [~~(40)~~] Quality assurance--The set of activities used to ensure that the process used in the preparation of sterile drug preparations lead to preparations that meet predetermined standards of quality.

(44) [~~(41)~~] Quality control--The set of testing activities used to determine that the ingredients, components (e.g., containers), and final compounded sterile preparations prepared meet predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.

(45) [~~(42)~~] Reasonable quantity--An amount of a compounded drug that:

(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office or facility before the beyond-use [~~beyond use~~] date of the drug;

(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and

(C) for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopeia [~~Pharmacopoeia~~] guidelines and accreditation practices.

(46) Restricted-access barrier system--An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations.

(47) [~~(43)~~] Segregated compounding area [~~Compounding Area~~]--A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The segregated compounding area shall contain a PEC and is suitable for preparation of

Category 1 compounded sterile preparations only. [~~A designated space, either a demarcated area or room, that is restricted to preparing low-risk level compounded sterile preparations with 12-hour or less beyond-use date. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of compounded sterile preparations and shall be void of activities and materials that are extraneous to sterile compounding.~~]

(48) [~~(44)~~] Single-dose container--A single-unit container for articles or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include pre-filled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

(49) [~~(45)~~] SOPs--Standard operating procedures.

(50) [~~(46)~~] Sterilizing grade membranes [~~Grade Membranes~~]--Membranes that are documented to retain 100% of a culture of 10^7 [~~107~~] microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22-micron or 0.2 micron [~~0.22-micrometer or 0.2-micrometer~~] nominal pore size, depending on the manufacturer's practice.

(51) [~~(47)~~] Sterilization by filtration [~~Filtration~~]--Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile filtrate [~~effluent~~].

(52) [~~(48)~~] Terminal sterilization [~~Sterilization~~]--The application of a lethal process, e.g., steam under pressure or autoclaving, to sealed final preparation containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10^-6 [~~10-6~~] or a probability of less than one in one million of a non-sterile unit.

(53) [~~(49)~~] Unidirectional airflow [~~Flow~~]--An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

(54) [~~(50)~~] USP/NF--The current edition of the United States Pharmacopeia/National Formulary.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. The pharmacy shall have a pharmacist-in-charge in compliance with the specific license classification of the pharmacy.

(B) Responsibilities. In addition to the responsibilities for the specific class of pharmacy, the pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning the compounding of sterile preparations:

(i) developing a system to ensure that all pharmacy personnel responsible for compounding and/or supervising the compounding of sterile preparations within the pharmacy receive appropriate education and training and competency evaluation;

(ii) determining that all personnel involved in compounding sterile preparations obtain continuing education appropriate for the type of compounding done by the personnel;

(iii) supervising a system to ensure appropriate procurement of drugs and devices and storage of all pharmaceutical materials including pharmaceuticals, components used in the compounding of sterile preparations, and drug delivery devices;

(iv) ensuring that the equipment used in compounding is properly maintained;

(v) developing a system for the disposal and distribution of drugs from the pharmacy;

(vi) developing a system for bulk compounding or batch preparation of drugs;

(vii) developing a system for the compounding, sterility assurance, quality assurance, and quality control of sterile preparations; and

(viii) if applicable, ensuring that the pharmacy has a system to dispose of hazardous waste in a manner so as not to endanger the public health.

(2) Pharmacists.

(A) General.

(i) A pharmacist is responsible for ensuring that compounded sterile preparations are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.

(ii) A pharmacist shall inspect and approve all components, drug preparation containers, closures, labeling, and any other materials involved in the compounding process.

(iii) A pharmacist shall review all compounding records for accuracy and conduct periodic in-process checks as defined in the pharmacy's policy and procedures.

(iv) A pharmacist shall review all compounding records for accuracy and conduct a final check.

(v) A pharmacist is responsible for ensuring the proper maintenance, cleanliness, and use of all equipment used in the compounding process.

(vi) A pharmacist shall be accessible at all times, 24 hours a day, to respond to patients' and other health professionals' questions and needs.

(B) Initial training and continuing education.

(i) All pharmacists who compound sterile preparations or supervise pharmacy technicians and pharmacy technician trainees compounding sterile preparations shall comply with the following:

(I) complete through a single course, a minimum of 20 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE accredited provider;

(II) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides sufficient hours of instruction and experience in the pharmacy's [~~facility's~~] sterile compounding processes and procedures. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and

(III) possess knowledge about:

(-a-) aseptic processing;

(-b-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;

(-c-) chemical, pharmaceutical, and clinical properties of drugs;

(-d-) container, equipment, and closure system selection; and

(-e-) sterilization techniques.

(ii) The required experiential portion of the training programs specified in this subparagraph shall [~~must~~] be supervised by an individual who is actively engaged in performing sterile compounding and is qualified and has completed training as specified in this paragraph or paragraph (3) of this subsection.

(iii) In order to renew a license to practice pharmacy, during the previous licensure period, a pharmacist engaged in sterile compounding shall complete a minimum of:

(I) two hours of ACPE-accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacist is engaged in compounding Category 1 or Category 2 compounded [~~low and medium risk~~] sterile preparations; or

(II) four hours of ACPE-accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacist is engaged in compounding Category 2 prepared from any non-sterile starting component or Category 3 compounded [~~high risk~~] sterile preparations.

(3) Pharmacy technicians and pharmacy technician trainees.

(A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Initial training and continuing education.

(i) Pharmacy technicians and pharmacy technician trainees may compound sterile preparations provided the pharmacy technicians and/or pharmacy technician trainees are supervised by a pharmacist as specified in paragraph (2) of this subsection.

(ii) All pharmacy technicians and pharmacy technician trainees who compound sterile preparations for administration to patients shall:

(I) have initial training obtained either through completion of:

(-a-) a single course, a minimum of 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a course sponsored by an ACPE accredited provider which provides 40 hours of instruction and experience; or

(-b-) a training program which is accredited by the American Society of Health-System Pharmacists.

(II) and

(-a-) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides sufficient hours of instruction and experience in the pharmacy's [~~facility's~~] sterile compounding processes and procedures. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and

(-b-) possess knowledge about:

(-1-) aseptic processing;

(-2-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;

(-3-) chemical, pharmaceutical, and clinical properties of drugs;

(-4-) container, equipment, and closure system selection; and

(-5-) sterilization techniques.

(iii) Individuals enrolled in training programs accredited by the American Society of Health-System Pharmacists may compound sterile preparations in a licensed pharmacy provided the:

(I) compounding occurs only during times the individual is assigned to a pharmacy as a part of the experiential component of the American Society of Health-System Pharmacists training program;

(II) individual is under the direct supervision of and responsible to a pharmacist who has completed training as specified in paragraph (2) of this subsection;

(III) supervising pharmacist conducts periodic in-process checks as defined in the pharmacy's policy and procedures; and

(IV) supervising pharmacist conducts a final check.

(iv) The required experiential portion of the training programs specified in this subparagraph shall [~~must~~] be supervised by an individual who is actively engaged in performing sterile compounding, is qualified and has completed training as specified in paragraph (2) of this subsection or this paragraph.

(v) In order to renew a registration as a pharmacy technician, during the previous registration period, a pharmacy technician engaged in sterile compounding shall complete a minimum of:

(I) two hours of ACPE accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacy technician is engaged in compounding Category 1 or Category 2 compounded [~~low and medium risk~~] sterile preparations; or

(II) four hours of ACPE accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacy technician is engaged in compounding Category 2 prepared from any non-sterile starting component or Category 3 compounded [~~high risk~~] sterile preparations.

(4) Evaluation and testing requirements.

(A) All persons who perform or oversee compounding or support activities shall be trained in the pharmacy's SOPs. All pharmacy personnel preparing sterile preparations shall be trained conscientiously and skillfully by expert personnel through multimedia instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations, garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures before beginning to prepare compounded sterile preparations.

(B) All pharmacy personnel preparing sterile preparations shall perform didactic review and pass written [~~and media-fill~~] testing of aseptic manipulative skills initially and every 12 months. [~~followed by:~~]

~~*[(i)* every 12 months for low- and medium-risk level compounding; and]~~

~~*[(ii)* every six months for high-risk level compounding.]~~

(C) Pharmacy personnel who fail written tests or whose media-fill tests result in gross microbial colonization shall:

(i) be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies; and

(ii) not be allowed to compound sterile preparations for patient use until passing results are achieved.

(D) The didactic and experiential training shall include instruction, experience, and demonstrated proficiency in the following areas:

(i) aseptic technique;

(ii) critical area contamination factors;

(iii) environmental monitoring;

(iv) structure and engineering controls related to facilities;

(v) equipment and supplies;

(vi) sterile preparation calculations and terminology;

(vii) sterile preparation compounding documentation;

(viii) quality assurance procedures;

(ix) aseptic preparation procedures including proper gowning and gloving technique;

(x) handling of hazardous drugs, if applicable;

(xi) cleaning procedures; and

(xii) general conduct in the clean room.

(E) The aseptic technique of all compounding personnel and personnel who have direct oversight of compounding personnel but do not compound [~~each person compounding or responsible for the direct supervision of personnel compounding sterile preparations~~] shall be observed and evaluated by expert personnel as satisfactory through written and practical tests, and media-fill [~~challenge~~] testing, and such evaluation documented. Compounding personnel shall not evaluate their own aseptic technique or results of their own media-fill [~~challenge~~] testing. The pharmacy's SOPs shall define the aseptic technique evaluation for personnel who do not compound nor have direct oversight of compounding personnel such as personnel who restock or clean and disinfect the sterile compounding area, personnel who perform in-process checks or final verification of compounded sterile preparations, and others (e.g., maintenance personnel, certifiers, contractors, inspectors, surveyors).

(F) Media-fill tests shall [~~must~~] be conducted at each pharmacy where an individual compounds [~~low or medium risk~~] sterile preparations under the most challenging or stressful conditions. If pharmacies are under common ownership and control, the media-fill testing may be conducted at only one of the pharmacies provided each of the pharmacies are operated under equivalent policies and procedures and the testing is conducted under the most challenging or stressful conditions. In addition, each pharmacy shall [~~must~~] maintain documentation of the media-fill test. No preparation intended for patient use shall be compounded by an individual until the on-site media-fill tests indicate that the individual can competently perform aseptic procedures, except that a pharmacist may temporarily compound sterile preparations and supervise pharmacy technicians compounding sterile preparations without media-fill tests provided the pharmacist completes the on-site media-fill tests within seven days of commencing work at the pharmacy.

(G) For media-fill testing of compounds using only sterile starting components, the components shall be manipulated in a manner that simulates sterile-to-sterile compounding activities. The sterile soybean-casein digest media shall be transferred into the same types of container closure systems commonly used at the pharmacy.

[~~(G) Media-fill tests must be conducted at each pharmacy where an individual compounds high risk sterile preparations. No preparation intended for patient use shall be compounded by an individual until the on-site media-fill tests indicate that the individual can competently perform aseptic procedures, except that a pharmacist may temporarily compound sterile preparations and supervise pharmacy technicians compounding sterile preparations without media-fill tests provided the pharmacist completes the on-site media-fill tests within seven days of commencing work at the pharmacy.~~]

(H) For media-fill testing of compounds using any non-sterile starting components, a commercially available non-sterile soybean-casein digest powder shall be dissolved in non-bacteriostatic water to make a 3.0% non-sterile solution. The components shall be manipulated in a manner that simulates non-sterile-to-sterile compounding activities. At least one container shall be prepared as the positive control to demonstrate growth promotion, as indicated by visible turbidity upon incubation.

[~~(H) Media-fill testing procedures for assessing the preparation of specific types of sterile preparations shall be representative of the most challenging or stressful conditions encountered by the pharmacy personnel being evaluated and, if applicable, for sterilizing high-risk level compounded sterile preparations.~~]

(I) Final containers shall be incubated in an incubator at 20 to 25 degrees Celsius and 30 to 35 degrees Celsius for a minimum of 7 days at each temperature band to detect a broad spectrum of microorganisms. The order of the incubation temperatures shall be described in the pharmacy's SOPs. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before the end of the incubation period.

[~~(I) Media-fill challenge tests simulating high-risk level compounding shall be used to verify the capability of the compounding environment and process to produce a sterile preparation.~~]

[~~(J) Commercially available sterile fluid culture media for low and medium risk level compounding or non-sterile fluid culture media for high risk level compounding shall be able to promote exponential colonization of bacteria that are most likely to be transmitted to compounding sterile preparations from the compounding personnel and environment. Media-filled vials are generally incubated at 20 to 25 degrees Celsius or at 30 to 35 degrees Celsius for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature. Failure is indicated by visible turbidity in the medium on or before 14 days.~~]

(J) [~~(K)~~] The pharmacist-in-charge shall ensure continuing competency of pharmacy personnel through in-service education, training, and media-fill tests to supplement initial training. Personnel competency shall be evaluated:

(i) during orientation and training prior to the regular performance of those tasks;

(ii) whenever the quality assurance program yields an unacceptable result;

(iii) whenever unacceptable techniques are observed; and

(iv) at least every 12 months, with the exception of media-fill testing which shall be completed every six months for compounding personnel [~~on an annual basis for low- and medium-risk level compounding, and every six months for high-risk level compounding~~].

(K) [~~(L)~~] The pharmacist-in-charge shall ensure that proper hand hygiene and garbing practices of all compounding personnel and personnel who have direct oversight of compounding personnel but do not compound are evaluated prior to compounding, supervising, or verifying sterile preparations intended for patient use and whenever an aseptic media-fill [~~media fill~~] is performed.

(i) Gloved fingertip sampling shall be performed for all [~~Sampling of~~] compounding personnel and personnel who have direct oversight of compounding personnel but do not compound [~~glove fingertips shall be performed for all risk level compounding~~]. If pharmacies are under common ownership and control, the gloved fingertip and thumb sampling may be conducted at only one of the pharmacies provided each of the pharmacies are operated under equivalent policies and procedures and the testing is conducted under the most challenging or stressful conditions. In addition, each pharmacy shall [~~must~~] maintain documentation of the gloved fingertip and thumb sampling [~~of all compounding personnel~~].

(ii) All compounding personnel and personnel who have direct oversight of compounding personnel but do not compound shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands).

(iii) Sterile sampling media devices [~~contact agar plates~~] shall be used to sample the gloved fingertips of compounding personnel and personnel who have direct oversight of compounding personnel but do not compound after garbing in order to assess garbing competency and after completing the media-fill preparation (without applying sterile 70% IPA).

(iv) The visual observation shall be documented and maintained to provide a permanent record and long-term assessment of personnel competency.

(v) All compounding personnel and personnel who have direct oversight of compounding personnel but do not compound shall successfully complete an initial competency evaluation and gloved fingertip and thumb [~~fingertip/thumb~~] sampling procedure no less than three times before initially being allowed to compound sterile preparations for patient use. Immediately after the [~~compounding~~] personnel completes the hand hygiene and garbing procedure (i.e., after donning of sterile gloves and before any disinfecting with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands of the compounding personnel onto contact plates or swabs by having the individual lightly touching each fingertip onto the testing medium. Samples shall be incubated in an incubator. The media device shall be incubated at 30 to 35 degrees Celsius for no less than 48 hours and then at 20 to 25 degrees Celsius for no less than five additional days. Alternatively, to shorten the overall incubation period, two sampling media devices may be incubated concurrently in separate incubators with one media device incubated at 30 to 35 degrees Celsius for no less than 48 hours and the other media device incubated at 20 to 25 degrees Celsius for no less than five days. Media devices shall be handled and stored so as to avoid contamination and prevent condensate from dropping onto the agar during incubation and affecting the accuracy of the cfu reading (e.g., invert containers). [~~The contact plates or swabs will be incubated for the appropriate incubation period and at the appropriate temperature.~~] Action levels for gloved fingertip and thumb sampling are based on the total cfu count from both hands. Results of the initial gloved fingertip and thumb sampling evaluations after garbing shall indicate not greater than zero colony-forming units (0 cfu) [~~(0 CFU)~~] growth on the contact plates or swabs, or the test shall be considered a failure. Results of the initial gloved fingertip evaluations after media-fill testing shall indicate not greater than three colony-forming units (3 cfus) growth on the contact plates or swabs, or the test shall be considered a failure. In the event of a failed gloved fingertip and thumb test, the evaluation shall be repeated until the individual can successfully don sterile gloves and pass the gloved fingertip and thumb sampling evaluation, defined as zero cfus [~~CFUs~~] growth. Surface sampling of the direct compounding area shall be performed. No preparation intended for patient use shall be compounded by an individual until the results of the initial gloved fingertip and thumb and surface sampling evaluations [~~evaluation~~] indicate that the individual can competently perform aseptic procedures except that a pharmacist may temporarily physically supervise pharmacy technicians compounding sterile preparations before the results of the evaluation have been received for no more than three days from the date of the test.

(vi) Re-evaluation of all compounding personnel shall occur at least every six months [~~annually for compounding personnel who compound low and medium risk level preparations and every six months for compounding personnel who compound high risk level preparations~~]. Re-evaluation of personnel who have direct oversight of compounding personnel but do not compound shall occur at least every 12 months. Results of gloved fingertip and thumb tests conducted immediately after compounding personnel complete a compounding procedure shall indicate no more than 3 cfus [~~CFUs~~] growth, or the test shall be considered a failure, in which case, the evaluation shall be repeated until an acceptable test can be achieved (i.e., the results indicated no more than 3 cfus [~~CFUs~~] growth).

(vii) Personnel who have direct oversight of compounding personnel but do not compound shall complete a garbing competency evaluation every 12 months. The pharmacy's SOPs shall define the garbing competency evaluation for personnel who do not compound nor have direct oversight of compounding personnel such as personnel who restock or clean and disinfect the sterile compounding area, personnel who perform in-process checks or final verification of compounded sterile preparations, and others (e.g., maintenance personnel, certifiers, contractors, inspectors, surveyors).

(L) [~~(M)~~] The pharmacist-in-charge shall ensure surface sampling shall be conducted in all ISO classified areas on a periodic basis. Sampling shall be accomplished using contact plates or swabs at the conclusion of compounding. The sample area shall be gently touched with the agar surface by rolling the plate across the surface to be sampled.

(i) Each classified area, including each room and the interior of each ISO Class 5 primary engineering control (PEC) and pass-through chambers connecting to classified areas (e.g., equipment contained within the PEC, staging or work area(s) near the PEC, frequently touched areas), shall be sampled for microbial contamination using a risk-based approach.

(ii) For pharmacies compounding Category 1 or Category 2 compounded sterile preparations, surface sampling of all classified areas and pass-through chambers connecting to classified areas shall be conducted at least monthly. For pharmacies compounding any Category 3 compounded sterile preparations, surface sampling of all classified areas and pass-through chambers connecting to classified areas shall be completed prior to assigning a beyond-use-date longer than the limits established for Category 2 compounded sterile preparations and at least weekly on a regularly scheduled basis regardless

of the frequency of compounding Category 3 compounded sterile preparations.

(iii) The following action levels for surface sampling apply:

(I) for ISO Class 5, greater than 3 cfus per media device;

(II) for ISO Class 7, greater than 5 cfus per media device; and

(III) for ISO Class 8, greater than 50 cfus per media device.

(iv) If levels measured during surface sampling exceed the levels in clause (iii) of this subparagraph for the ISO classification levels of the area sampled, the cause shall be investigated and corrective action shall be taken. Data collected in response to corrective actions shall be reviewed to confirm that the actions taken have been effective. The corrective action plan shall be dependent on the cfu count and the microorganism recovered. The corrective action plan shall be documented. If levels measured during surface sampling exceed the levels in clause (iii) of this subparagraph, an attempt shall be made to identify any microorganism recovered to the genus level with the assistance of a competent microbiologist.

(M) Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control shall complete ongoing training as required by the pharmacy's SOPs.

(5) Documentation of training [~~Training~~]. The pharmacy shall maintain a record of the training and continuing education on each person who compounds sterile preparations. The record shall contain, at a minimum, a written record of initial and in-service training, education, and the results of written and practical testing and media-fill testing of pharmacy personnel. The record shall be maintained and available for inspection by the board and contain the following information:

(A) name of the person receiving the training or completing the testing or media-fill tests;

(B) date(s) of the training, testing, or media-fill [~~challenge~~] testing;

(C) general description of the topics covered in the training or testing or of the process validated;

(D) name of the person supervising the training, testing, or media-fill [~~challenge~~] testing; and

(E) signature or initials of the person receiving the training or completing the testing or media-fill [~~challenge~~] testing and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or media-fill [~~challenge~~] testing of personnel.

(d) Operational standards [~~Standards~~].

(1) General requirements [~~Requirements~~].

(A) Sterile preparations may be compounded:

(i) upon presentation of a practitioner's prescription drug or medication order based on a valid pharmacist/patient/prescriber relationship;

(ii) in anticipation of future prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.

(B) Sterile compounding in anticipation of future prescription drug or medication orders shall [~~must~~] be based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared is stable for the anticipated shelf time. The maximum batch size for all preparations requiring sterility testing shall be limited to 250 final yield units, except the maximum batch size shall be limited to 1,000 final yield units for preparations fully packaged using an automated compounding device.

(i) The pharmacist's professional judgment shall be based on the criteria used to determine a beyond-use date outlined in paragraph (8)(J) [~~(6)(G)~~] of this subsection.

(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time shall [~~must~~] be maintained and be available for inspection.

(iii) Any preparation compounded in anticipation of future prescription drug or medication orders shall be labeled. Such label shall contain:

(I) name and strength of the compounded preparation or list of the active ingredients and strengths;

(II) facility's lot number;

(III) beyond-use date as determined by the pharmacist using appropriate documented criteria as outlined in paragraph (8)(J) [~~(6)(G)~~] of this subsection;

(IV) quantity or amount in the container;

(V) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(VI) device-specific instructions, where appropriate.

(C) Commercially available products may be compounded for dispensing to individual patients or for office use provided the following conditions are met:

(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet individual patient's needs;

(ii) the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and

(iii) the prescribing practitioner has requested that the drug be compounded as described in subparagraph (D) of this paragraph.

(D) A pharmacy may not compound preparations that are essentially copies of commercially available products (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product) unless the prescribing practitioner specifically orders the strength or dosage form and specifies why the individual patient needs the particular strength or dosage form of the preparation or why the preparation for office use is needed in the particular strength or dosage form of the preparation. The prescribing practitioner shall provide documentation of a patient specific medical need and the preparation produces a clinically significant therapeutic response (e.g., the physician requests an alternate preparation due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form)

or if the drug product is not commercially available. The unavailability of such drug product shall [must] be documented prior to compounding. The methodology for documenting unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered, discontinued, or out-of-stock items. This documentation shall [must] be available in hard-copy or electronic format for inspection by the board.

(E) A pharmacy may enter into an agreement to compound and dispense prescription drug or medication orders for another pharmacy provided the pharmacy complies with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

(F) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide sterile prescription compounding services, which may include specific drug preparations and classes of drugs.

(G) A pharmacy may not compound veterinary preparations for use in food producing animals except in accordance with federal guidelines.

(H) Compounded sterile preparations, including hazardous drugs and radiopharmaceuticals, shall be prepared only under conditions that protect the pharmacy personnel in the preparation and storage areas.

(2) Compounded sterile preparation categories. Category 1, Category 2, and Category 3 are primarily based on the state of environmental control under which they are compounded, the probability for microbial growth during the time they will be stored, and the time period within which they must be used.

(A) A Category 1 compounded sterile preparation is a compounded sterile preparation that is assigned a beyond-use date in accordance with paragraph (8)(J)(ii)(I) of this subsection and all applicable requirements of this section for Category 1 compounded sterile preparations.

(B) A Category 2 compounded sterile preparation is a compounded sterile preparation that is assigned a beyond-use date in accordance with paragraph (8)(J)(ii)(II) of this subsection and all applicable requirements of this section for Category 2 compounded sterile preparations.

(C) A Category 3 compounded sterile preparation is a compounded sterile preparation that is assigned a beyond-use date in accordance with paragraph (8)(J)(ii)(III) of this subsection and all applicable requirements of this section for Category 3 compounded sterile preparations.

[(2) Microbial Contamination Risk Levels. Risk Levels for sterile compounded preparations shall be as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF and as listed in this paragraph.]

[(A) Low-risk level compounded sterile preparations.]

[(i) Low-Risk conditions. Low-risk level compounded sterile preparations are those compounded under all of the following conditions:]

[(I) The compounded sterile preparations are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices;]

[(II) The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the compounded sterile preparation;]

[(III) Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing;]

[(IV) For a low-risk level preparation, in the absence of passing a sterility test the storage periods cannot exceed the following time periods: before administration, the compounded sterile preparation is stored properly and are exposed for not more than 48 hours at controlled room temperature, for not more than 14 days if stored at a cold temperature, and for 45 days if stored in a frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius. For delayed activation device systems, the storage period begins when the device is activated.]

[(ii) Examples of Low-Risk Level Compounding. Examples of low-risk level compounding include the following:]

[(I) Single volume transfers of sterile dosage forms from ampules, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampules shall be passed through a sterile filter to remove any particles;]

[(II) Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluent solution to compound drug admixtures and nutritional solutions.]

[(B) Low-Risk Level compounded sterile preparations with 12-hour or less beyond-use date. Low-risk level compounded sterile preparations are those compounded pursuant to a physician's order for a specific patient under all of the following conditions:]

[(i) The compounded sterile preparations are compounded in compounding aseptic isolator or compounding aseptic containment isolator that does not meet the requirements described in paragraph (7)(C) or (D) of this subsection (relating to Primary Engineering Control Device) or the compounded sterile preparations are compounded in laminar airflow workbench or a biological safety cabinet that cannot be located within the buffer area;]

[(ii) The primary engineering control device shall be certified and maintain ISO Class 5 for exposure of critical sites and shall be located in a segregated compounding area restricted to sterile compounding activities that minimizes the risk of contamination of the compounded sterile preparation;]

[(iii) The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation.]

[(iv) For a low-risk level preparation compounded as described in clauses (i) - (iii) of this subparagraph, administration of such compounded sterile preparations must commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less. However, the administration of sterile radiopharmaceuticals, with documented testing of chemical stability, may be administered beyond 12 hours of preparation.]

[(C) Medium-risk level compounded sterile preparations.]

[(i) Medium-Risk Conditions. Medium-risk level compounded sterile preparations, are those compounded aseptically

under low-risk conditions and one or more of the following conditions exists:]

[(I) Multiple individual or small doses of sterile products are combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions;]

[(II) The compounding process includes complex aseptic manipulations other than the single-volume transfer;]

[(III) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogenous mixing (e.g., reconstitution of intravenous immunoglobulin or other intravenous protein products);]

[(IV) The compounded sterile preparations do not contain broad spectrum bacteriostatic substances and they are administered over several days (e.g., an externally worn infusion device); or]

[(V) For a medium-risk level preparation, in the absence of passing a sterility test the storage periods cannot exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 30 hours at controlled room temperature, for not more than 9 days at a cold temperature, and for 45 days in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius.]

[(ii) Examples of medium-risk compounding. Examples of medium-risk compounding include the following:]

[(I) Compounding of total parenteral nutrition fluids using a manual or automated device during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container;]

[(II) Filling of reservoirs of injection and infusion devices with more than three sterile drug products and evacuations of air from those reservoirs before the filled device is dispensed;]

[(III) Filling of reservoirs of injection and infusion devices with volumes of sterile drug solutions that will be administered over several days at ambient temperatures between 25 and 40 degrees Celsius (77 and 104 degrees Fahrenheit); and]

[(IV) Transfer of volumes from multiple ampules or vials into a single, final sterile container or product.]

[(D) High-risk level compounded sterile preparations.]

[(i) High-risk Conditions. High-risk level compounded sterile preparations are those compounded under any of the following conditions:]

[(I) Non-sterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral) are incorporated or a non-sterile device is employed before terminal sterilization.]

[(II) Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour:]

[(-a-) sterile contents of commercially manufactured products;]

[(-b-) CSPs that lack effective antimicrobial preservatives; and]

[(-c-) sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs;]

[(III) Compounding personnel are improperly garbed and gloved;]

[(IV) Non-sterile water-containing preparations are exposed no more than 6 hours before being sterilized;]

[(V) [It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients;]

[(VI) For a sterilized high-risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 24 hours at controlled room temperature, for not more than 3 days at a cold temperature, and for 45 days in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius; or]

[(VII) All non-sterile measuring, mixing, and purifying devices are rinsed thoroughly with pyrogen-free or depyrogenated sterile water, and then thoroughly drained or dried immediately before use for high-risk compounding. All high-risk compounded sterile solutions subjected to terminal sterilization are prefiltered by passing through a filter with a nominal pore size not larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter. Sterilization of high-risk level compounded sterile preparations by filtration shall be performed with a sterile 0.2 micrometer or 0.22 micrometer nominal pore size filter entirely within an ISO Class 5 or superior air quality environment.]

[(ii) Examples of high-risk compounding. Examples of high-risk compounding include the following.]

[(I) Dissolving non-sterile bulk drug powders to make solutions, which will be terminally sterilized;]

[(II) Exposing the sterile ingredients and components used to prepare and package compounded sterile preparations to room air quality worse than ISO Class 5 for more than one hour;]

[(III) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is performed; and]

[(IV) Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.]

(3) Depyrogenation. Dry heat depyrogenation shall be used to render glassware, metal, and other thermostable containers and components pyrogen free. The duration of the exposure period shall include sufficient time for the items to reach the depyrogenation temperature. The items shall remain at the depyrogenation temperature for the duration of the depyrogenation period. The effectiveness of the dry heat depyrogenation cycle shall be established initially and verified annually using endotoxin challenge vials to demonstrate that the cycle is capable of achieving a greater than or equal to 3-log reduction in endotoxins. The effectiveness of the depyrogenation cycle shall be re-established if there are changes to the depyrogenation cycle described in the pharmacy's SOPs (e.g., changes in load conditions, duration, or temperature). This verification shall be documented.

(4) [(3)] Immediate use compounded sterile preparations [Use Compounded Sterile Preparations]. When all of the following conditions are met, compounding of compounded sterile preparations for direct and immediate administration is not subject to the requirements for Category 1, Category 2, or Category 3 compounded sterile preparations: [For the purpose of emergency or immediate patient care, such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical ther-

apy where the preparation of the compounded sterile preparation under low-risk level conditions would subject the patient to additional risk due to delays in therapy. Compounded sterile preparations are exempted from the requirements described in this paragraph for low-risk level compounded sterile preparations when all of the following criteria are met:]

(A) Only simple aseptic measuring and transfer manipulations are performed with not more than three different sterile [nonhazardous commercial drug and diagnostic radiopharmaceutical] drug products, including an infusion or diluent solution, from the manufacturers' original containers and not more than two entries into any one container or package of sterile infusion solution or administration container/device;

(B) Unless required for the preparation, the compounding procedure occurs continuously without delays or interruptions and does not exceed 1 hour;

(C) During preparation, aseptic technique is followed and, if not immediately administered, the finished compounded sterile preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter of biological fluids, mix-ups with other compounded sterile preparations, and direct contact with outside surfaces;

(D) Administration begins not later than four hours [one hour] following the start [completion] of preparing the compounded sterile preparation;

(E) When the compounded sterile preparation [preparations] is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the compounded sterile preparation shall bear a label listing patient identification information such as name and identification number(s), the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact 4-hour [1-hour] beyond-use time and date;

(F) If administration has not begun within four hours [one hour] following the completion of preparing the compounded sterile preparation, the compounded sterile preparation is promptly and safely discarded. Immediate use compounded sterile preparations shall not be stored for later use; [and]

(G) Hazardous drugs shall not be prepared as immediate use compounded sterile preparations; and[.]

(H) Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the pharmacy's SOPs.

(5) [(4)] Single-dose and multiple-dose [multiple dose] containers.

(A) Opened or needle punctured single-dose containers, such as bags bottles, syringes, and vials of sterile products shall be used within one hour if opened in worse than ISO Class 5 air quality. Any remaining contents shall [must] be discarded.

(B) If a single-dose vial is entered or punctured only in ISO Class 5 or cleaner air, it may be used up to 12 hours after initial entry or puncture as long as the labeled storage requirements during that 12 hour period are maintained [Single-dose containers, including single-dose large volume parenteral solutions and single-dose vials, exposed to ISO Class 5 or cleaner air may be used up to six hours after initial needle puncture].

(C) Open single-dose ampules shall not be stored for any time period [Opened single-dose fusion sealed containers shall not be stored for any time period].

(D) Once initially entering or puncturing a multiple-dose container, the multiple-dose container shall not be used for more than 28 days unless otherwise specified by the manufacturer on the labeling [Multiple-dose containers may be used up to 28 days after initial needle puncture unless otherwise specified by the manufacturer].

(E) Conventionally manufactured pharmacy bulk packages shall be restricted to the sterile preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile containers. The pharmacy bulk package shall be used according to the manufacturer's labeling and entered or punctured only in an ISO Class 5 primary engineering control.

(F) Multiple-dose compounded sterile preparations shall meet the criteria for antimicrobial effectiveness testing and the requirements of subparagraph (G) of this paragraph. Multiple-dose compounded sterile preparations shall be stored under conditions upon which the beyond-use date is based (e.g., refrigerator or controlled room temperature). After a multiple-dose compounded sterile preparation is initially entered or punctured, the multiple-dose compounded sterile preparation shall not be used for longer than the assigned beyond-use date or 28 days, whichever is shorter.

(G) A multiple-dose compounded sterile preparation shall be prepared as a Category 2 or Category 3 compounded sterile preparation. An aqueous multiple-dose compounded sterile preparation shall additionally pass antimicrobial effectiveness testing. In the absence of supporting documentation or data in a USP/NF monograph, manufacturer's data, or previously conducted or contracted for testing, compounding personnel may rely on antimicrobial effectiveness testing conducted or contracted for in the particular container closure system in which it will be packaged.

(H) In the absence of container closure data, the container closure system used to package the multiple-dose compounded sterile preparation shall be evaluated for and conform to container closure integrity. The container closure integrity test shall be conducted only once in the particular container closure system in which the multiple-dose compounded sterile preparation shall be packaged.

(I) Multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic compounded sterile preparations. Antimicrobial effectiveness testing under subparagraph (G) of this paragraph is not required if the preparation is prepared as a Category 2 or Category 3 compounded sterile preparation, for use by a single patient, and labeled to indicate that once opened, it shall be discarded after 24 hours when stored at controlled room temperature, 72 hours when stored under refrigeration, or 90 days when frozen if based on documented published stability and effectiveness data.

(J) When a single-dose compounded sterile preparation or compounded sterile preparation stock solution is used as a component to compound additional compounded sterile preparations, the original single-dose compounded sterile preparation or compounded sterile preparation stock solution shall be entered or punctured in ISO Class 5 or cleaner air and stored under the conditions upon which its beyond-use date is based (e.g., refrigerator or controlled room temperature). The component compounded sterile preparation may be used for sterile compounding for up to 12 hours once accessed or its assigned beyond-use date, whichever is shorter, and any remainder shall be discarded.

(6) Proprietary bag and vial systems. Docking and activation of proprietary bag and vial systems in accordance with the manu-

facturer's labeling for immediate administration to an individual patient is not considered compounding and may be performed outside of an ISO Class 5 environment. Docking of the proprietary bag and vial system for future activation and administration is considered compounding and shall be performed in an ISO Class 5 environment. Beyond-use dates for proprietary bag and vial systems shall not be longer than those specified in the manufacturer's labeling.

(7) [~~(5)~~] Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain current or updated copies in hard-copy or electronic format of each of the following:

(A) a reference text on injectable drug preparations, such as Handbook on Injectable Drug Products;

(B) a specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy, e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs;

(C) the United States Pharmacopeia/National Formulary containing USP Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding--Nonsterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding; and

(D) any additional USP/NF chapters applicable to the practice of the pharmacy (e.g., USP Chapter 800, Hazardous Drugs--Handling in Healthcare Settings, USP Chapter 823, Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses).

(8) [~~(6)~~] Environment. Compounding facilities shall be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.

(A) Air exchange requirements. For cleanroom suites, adequate HEPA-filtered airflow to the buffer room(s) and anteroom(s) is required to maintain appropriate ISO classification during compounding activities. Airflow is measured in terms of the number of air changes per hour (ACPH).

(i) Unclassified sterile compounding area. No requirement for ACPH.

(ii) ISO Class 7 room(s). A minimum of 30 total HEPA-filtered ACPH shall be supplied to ISO Class 7 rooms. At least 15 ACPH of the total air change rate in a room shall come from the HVAC through HEPA filters located in the ceiling. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH shall be documented on the certification report.

(iii) ISO Class 8 room(s). A minimum of 20 total HEPA-filtered ACPH shall be supplied to ISO Class 8 rooms. At least 15 ACPH of the total air change rate in a room shall come from the HVAC through HEPA filters located in the ceiling. The total ACPH shall be documented on the certification report.

(B) Cleanroom suite. Seals and sweeps should not be installed at doors between buffer rooms and anterooms. Access doors should be hands-free. Tacky mats shall not be placed within ISO-classified areas.

(C) [~~(A)~~] Category 1 and Category 2 preparations [~~Low and Medium Risk Preparations~~]. A pharmacy that prepares Category 1 compounded sterile preparations outside of a segregated compounding area or Category 2 compounded sterile [~~low- and medium-risk~~] preparations shall have a clean room for the compounding of sterile preparations that is constructed to minimize the opportunities for particulate and microbial contamination. The clean room shall:

(i) be clean, well lit, and of sufficient size to support sterile compounding activities;

(ii) be maintained at a temperature of 20 degrees Celsius or cooler, except that a clean room for the compounding of sterile radiopharmaceuticals shall be maintained at a temperature of 25 degrees Celsius or cooler, and at a humidity of 60% or below, with excursions in temperature or humidity of no more than 10% and lasting no longer than 30 minutes [~~below 60%~~];

(iii) be used only for the compounding of sterile preparations;

(iv) be designed such that hand sanitizing and gowning occurs outside the buffer room [~~area~~] but allows hands-free access by compounding personnel to the buffer room [~~area~~];

(v) have non-porous and washable floors or floor covering to enable regular disinfection;

(vi) be ventilated in a manner to avoid disruption from the HVAC system and room cross-drafts;

(vii) have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices (e.g., coved), non-shedding and resistant to damage by disinfectant agents;

(viii) have junctures of ceilings to walls coved or caulked to avoid cracks and crevices;

(ix) have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning;

(x) contain only the appropriate compounding supplies and not be used for bulk storage for supplies and materials. Objects that shed particles shall not be brought into the clean room. A Class B pharmacy may use low-linting absorbent materials in the primary engineering control device;

(xi) contain an anteroom [~~ante-area~~] that contains a sink with hot and cold running water that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination. A Class B pharmacy may have a sink with hot and cold running water that enables hands-free use with a closed system of soap dispensing immediately outside the anteroom [~~ante-area~~] if antiseptic hand cleansing is performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations once inside the anteroom [~~ante-area~~]; and

(xii) contain a buffer room [~~area~~]. The buffer room shall not contain sources of water (i.e., sinks) or floor drains other than distilled or sterile water introduced for facilitating the use of heat block wells for radiopharmaceuticals. [~~The following is applicable for the buffer area:~~]

~~(I)~~ ~~There shall be some demarcation designation that delineates the ante-area from the buffer area. The demarcation shall be such that it does not create conditions that could adversely affect the cleanliness of the area;~~]

~~(II)~~ ~~The buffer area shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation should be continuously monitored;~~]

~~(III)~~ ~~A buffer area that is not physically separated from the ante-area shall employ the principle of displacement air-~~

flow as defined in Chapter 797, Pharmaceutical Compounding--Sterile Preparations, of the USP/NF, with limited access to personnel; and]

[(IV) The buffer area shall not contain sources of water (i.e., sinks) or floor drains other than distilled or sterile water introduced for facilitating the use of heat block wells for radiopharmaceuticals.]

(D) [(B)] Category 2 prepared from any non-sterile starting component and Category 3 preparations [High-risk Preparations].

(i) In addition to the requirements in subparagraph (C) [(A)] of this paragraph, when Category 2 prepared from any non-sterile starting component or Category 3 compounded sterile [high-risk] preparations are compounded, the primary engineering control shall be located in a buffer room [area] that provides a physical separation, through the use of walls, doors and pass-throughs and has a minimum differential positive pressure of 0.02 [to 0.05] inches water column.

(ii) Presterilization procedures for Category 2 prepared from any non-sterile starting component or Category 3 [high-risk level] compounded sterile preparations, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment using depyrogenated equipment.

(E) [(C)] Automated compounding device.

(i) General. If automated compounding devices are used, the pharmacy shall have a method to calibrate and verify the accuracy of automated compounding devices used in aseptic processing and document the calibration and verification on a daily basis, based on the manufacturer's recommendations, and review the results at least weekly.

(ii) Loading bulk drugs into automated compounding devices.

(I) Automated compounding 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.

(II) The label of an automated compounding device container 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.

(III) Records of loading bulk drugs into an automated compounding device shall be maintained to show:

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

(-b-) manufacturer or distributor;

(-c-) manufacturer's lot number;

(-d-) manufacturer's expiration date;

(-e-) quantity added to the automated compounding device;

(-f-) date of loading;

(-g-) name, initials, or electronic signature of the person loading the automated compounding device; and

(-h-) name, initials, or electronic signature of the responsible pharmacist.

(IV) The automated compounding device shall not be used until a pharmacist verifies that the system is properly loaded and affixes his or her signature or electronic signature to the record specified in subclause (III) of this clause.

(F) [(D)] Hazardous drugs. If the preparation is hazardous, the following is also applicable:

(i) Hazardous drugs shall be prepared only under conditions that protect personnel during preparation and storage;

(ii) Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure;

(iii) All personnel involved in the compounding of hazardous drugs shall wear appropriate protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and appropriate gloving at all times when handling hazardous drugs, including receiving, distribution, stocking, inventorying, preparation, for administration and disposal;

(iv) Appropriate safety and containment techniques for compounding hazardous drugs shall be used in conjunction with aseptic techniques required for preparing sterile preparations;

(v) Disposal of hazardous waste shall comply with all applicable local, state, and federal requirements;

(vi) Prepared doses of hazardous drugs shall [must] be dispensed, labeled with proper precautions inside and outside, and distributed in a manner to minimize patient contact with hazardous agents.

(G) [(E)] Blood-labeling procedures. When compounding activities require the manipulation of a patient's blood-derived material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be performed in an [a] ISO Class 5 biological safety cabinet located in a buffer room [area] and shall be clearly separated from routine material-handling procedures and equipment used in preparation activities to avoid any cross-contamination. The preparations shall not require sterilization.

(H) [(F)] Cleaning and disinfecting the sterile compounding areas. The following cleaning and disinfecting practices and frequencies apply to direct and contiguous compounding areas, which include ISO Class 5 compounding areas for exposure of critical sites as well as buffer rooms [areas], anterooms [ante-areas], and segregated compounding areas.

(i) The pharmacist-in-charge is responsible for developing written standard operating procedures (SOPs) for cleaning and disinfecting the direct and contiguous compounding areas and assuring the procedures are followed.

(ii) In a PEC, sterile 70% IPA shall be applied after cleaning and disinfecting, or after the application of a one-step disinfectant cleaner or sporicidal disinfectant, to remove any residue. Sterile 70% IPA shall also be applied immediately before initiating compounding. During the compounding process sterile 70% IPA shall be applied to the horizontal work surface, including any removable work trays, of the PEC at least every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding shall not be disrupted and the work surface of the PEC shall be disinfected immediately after compounding. [These procedures shall be conducted at the beginning of each work shift, before each batch preparation is started, when there are spills, and when surface contamination is known or suspected resulting from procedural breaches, and every 30 minutes during continuous compounding of individual compounded sterile preparations, unless a particular compounding procedure requires more than 30 minutes to complete, in which case, the direct compounding area is to be cleaned immediately after the compounding activity is completed.]

(iii) Surfaces shall be cleaned prior to being disinfected unless a one-step disinfectant cleaner is used to accomplish both the cleaning and disinfection in one step. The manufacturer's directions or published data for the minimum contact time shall be followed for each of the cleaning, disinfecting, and sporicidal disinfectants used. When sterile 70% IPA is used, it shall be allowed to dry. [~~Before compounding is performed, all items shall be removed from the direct and contiguous compounding areas and all surfaces are cleaned by removing loose material and residue from spills, followed by an application of a residue-free disinfecting agent (e.g., IPA), which is allowed to dry before compounding begins~~]. In a Class B pharmacy, objects used in preparing sterile radiopharmaceuticals (e.g., dose calibrator) which cannot be reasonably removed from the compounding area shall be sterilized with an application of a residue-free disinfection agent.

(iv) Surfaces in classified areas used to prepare Category 1, Category 2, and Category 3 compounded sterile preparations shall be cleaned, disinfected, and sporicidal disinfectants applied in accordance with the following:

(I) PEC(s) and equipment inside PEC(s).

(-a-) Equipment and all interior surfaces of the PEC shall be cleaned daily on days when compounding occurs and when surface contamination is known or suspected. Equipment and all interior surfaces of the PEC shall be disinfected on days when compounding occurs and when surface contamination is known or suspected. Sporicidal disinfectants shall be applied monthly for pharmacies compounding Category 1 or Category 2 compounded sterile preparations and weekly for pharmacies compounding Category 3 compounded sterile preparations.

(-b-) Cleaning and disinfecting agents, with the exception of sporicidal disinfectants, used within the PEC shall be sterile. When diluting concentrated cleaning and disinfecting agents for use in the PEC, sterile water shall be used.

(II) Removable work tray of the PEC, when applicable. Work surfaces of the tray shall be cleaned daily on days when compounding occurs and all surfaces and the area underneath the work tray shall be cleaned monthly. Work surfaces of the tray shall be disinfected on days when compounding occurs and all surfaces and the area underneath the work tray shall be disinfected monthly. Sporicidal disinfectants shall be applied monthly on work surfaces of the tray, all surfaces, and the area underneath the work tray monthly.

(III) Pass-through chambers. Pass-through chambers shall be cleaned daily on days when compounding occurs and disinfected daily on days when compounding occurs. Sporicidal disinfectants shall be applied monthly for pharmacies compounding Category 1 or Category 2 compounded sterile preparations and weekly for pharmacies compounding Category 3 compounded sterile preparations.

(IV) Work surface(s) outside the PEC. Work surfaces outside the PEC shall be cleaned daily on days when compounding occurs and disinfected daily on days when compounding occurs. Sporicidal disinfectants shall be applied monthly for pharmacies compounding Category 1 or Category 2 compounded sterile preparations and weekly for pharmacies compounding Category 3 compounded sterile preparations.

(V) Floor(s). Floors shall be cleaned daily on days when compounding occurs and disinfected daily on days when compounding occurs. Sporicidal disinfectants shall be applied monthly for pharmacies compounding Category 1 or Category 2 compounded sterile preparations and weekly for pharmacies compounding Category 3 compounded sterile preparations.

(VI) Wall(s), door(s), door frame(s), storage shelving and bin(s), and equipment outside of the PEC(s). Walls, doors, door frames, storage shelving and bins, and equipment outside of the PECs shall be cleaned, disinfected, and sporicidal disinfectants applied on a monthly basis.

(VII) Ceiling(s). Ceilings of the classified areas shall be cleaned, disinfected, and sporicidal disinfectant applied on a monthly basis. Ceilings of the segregated compounding area shall be cleaned, disinfected, and sporicidal disinfectants applied when visibly soiled and when surface contamination is known or suspected.

~~*(iv)* Work surfaces in the buffer areas and ante-areas, as well as segregated compounding areas, shall be cleaned and disinfected at least daily. Dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 air quality.~~]

~~*(v)* Floors in the buffer area, ante-area, and segregated compounding area shall be cleaned by mopping with a cleaning and disinfecting agent at least once daily when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs. It is incumbent on compounding personnel to ensure that such cleaning is performed properly.~~]

~~*(vi)* In the buffer area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly. Cleaning and disinfecting agents shall be used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues.~~]

(v) [~~(vii)~~] All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding, and dedicated to use in the buffer room [~~area~~], anteroom [~~ante-area~~], and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer room [~~area~~] and anteroom [~~ante-area~~], but only in that order. If cleaning materials are reused, procedures shall be developed that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bio-burden of the area being cleaned.

(vi) [~~(viii)~~] Supplies and equipment removed from shipping cartons shall [~~must~~] be wiped with a disinfecting agent, such as sterile IPA. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes. However, if sterile supplies are received in sealed pouches, the pouches may be removed as the supplies are introduced into the ISO Class 5 area without the need to disinfect the individual sterile supply items. No shipping or other external cartons may be taken into the buffer room [~~area~~] or segregated compounding area.

(vii) Before any item is introduced into the clean side of the anteroom(s), placed into pass-through chamber(s), or brought into the segregated compounding area, providing that packaging integrity will not be compromised, the item shall be wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. If an EPA-registered disinfectant or sporicidal disinfectant is used, the agent shall be allowed to dwell the minimum contact time specified by the manufacturer. If sterile 70% IPA is used, it shall be allowed to dry. The wiping procedure should not compromise the packaging integrity or render the product label unreadable.

(viii) Immediately before any item is introduced into the PEC, it shall be wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. When sterile items are received

in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure shall not render the product label unreadable.

(ix) Critical sites (e.g., vial stoppers, ampule necks, and intravenous bag septums) shall be wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA shall be allowed to dry before personnel enter or puncture stoppers and septums or break the necks of ampules.

~~*[(ix)* Storage shelving emptied of all supplies, walls, and ceilings shall be cleaned and disinfected at planned intervals, monthly, if not more frequently.]~~

(x) Cleaning shall [~~must~~] be done by personnel trained in appropriate cleaning techniques.

(xi) Proper documentation and frequency of cleaning shall [~~must~~] be maintained and shall contain the following:

(I) date [~~and time~~] of cleaning;

(II) type of cleaning performed; and

(III) name of individual who performed the cleaning.

(I) [~~(G)~~] Security requirements. The pharmacist-in-charge may authorize personnel to gain access to that area of the pharmacy containing dispensed sterile preparations, in the absence of the pharmacist, for the purpose of retrieving dispensed prescriptions to deliver to patients. If the pharmacy allows such after-hours access, the area containing the dispensed sterile preparations shall be an enclosed and lockable area separate from the area containing undispensed prescription drugs. A list of the authorized personnel having such access shall be in the pharmacy's policy and procedure manual.

(J) [~~(H)~~] Storage requirements and beyond-use dating.

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

(ii) Beyond-use dating. When assigning a beyond-use date, compounding personnel shall consult and apply drug-specific and general stability documentation and literature where available, and they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy. A shorter beyond-use date shall be assigned when the physical and chemical stability of the preparation is less than the beyond-use date limits provided in subclauses (I) - (III) of this clause.

(I) Beyond-use date limits for Category 1 compounded sterile preparations. Category 1 compounded sterile preparations shall be prepared in a segregated compounding area or cleanroom suite and have a beyond-use date of not more than 12 hours when stored at controlled room temperature or 24 hours when stored in a refrigerator.

~~*[(I)* Beyond-use dates for compounded sterile preparations shall be assigned based on professional experience, which shall include careful interpretation of appropriate information sources for the same or similar formulations.]~~

(II) Beyond-use date limits for Category 2 compounded sterile preparations. Category 2 compounded sterile preparations shall be prepared in a cleanroom suite.

(-a-) Aseptically processed compounded sterile preparations without sterility testing performed and passed.

(-1-) If prepared from one or more non-sterile starting component(s), the preparation shall have a beyond-use date of not more than one day when stored at controlled room temperature, four days when stored in a refrigerator, or 45 days when stored in a freezer.

(-2-) If prepared from only sterile starting component(s), the preparation shall have a beyond-use date of not more than four days when stored at controlled room temperature, 10 days when stored in a refrigerator, or 45 days when stored in a freezer.

(-b-) Terminally sterilized compounded sterile preparations without sterility testing performed and passed shall have a beyond-use date of not more than 14 days when stored at controlled room temperature, 28 days when stored in a refrigerator, or 45 days when stored in a freezer.

(-c-) If sterility testing is performed and passed, aseptically processed or terminally sterilized compounded sterile preparations shall have a beyond-use date of not more than 45 days when stored at controlled room temperature, 60 days when stored in a refrigerator, or 90 days when stored in a freezer.

(-d-) A Category 2 compounded sterile preparation in a nonaqueous dosage form (i.e., water activity less than 0.6) may have a beyond-use date of not more than 90 days if based on documented current literature supporting stability and sterility.

~~*[(II)* Beyond-use dates for compounded sterile preparations that are prepared strictly in accordance with manufacturers' product labeling must be those specified in that labeling, or from appropriate literature sources or direct testing.]~~

(III) Beyond-use date limits for Category 3 compounded sterile preparations. Category 3 compounded sterile preparations shall be prepared in a cleanroom suite.

(-a-) Aseptically processed compounded sterile preparations that are sterility tested and passed all applicable tests for Category 3 compounded sterile preparations shall have a beyond-use date of not more than 60 days when stored at controlled room temperature, 90 days when stored in a refrigerator, or 120 days when stored in a freezer.

(-b-) Terminally sterilized compounded sterile preparations that are sterility tested and passed all applicable tests for Category 3 compounded sterile preparations shall have a beyond-use date of not more than 90 days when stored at controlled room temperature, 120 days when stored in a refrigerator, or 180 days when stored in a freezer.

(-c-) In the presence of documented published data supporting stability, aseptically processed or terminally sterilized aqueous compounded sterile preparations in batch sizes less than 24 final yield units without sterility and endotoxin testing shall have a beyond-use date of not more than 60 days when stored at controlled room temperature, 90 days when stored in a refrigerator, or 120 days when stored in a freezer. A pharmacy may only compound one batch of less than 24 final yield units of an aseptically processed or terminally sterilized aqueous compounded sterile preparation per day without sterility and endotoxin testing, with the exception of sterile compounding for a patient specific prescription.

(-d-) A Category 3 compounded sterile preparation in a nonaqueous dosage form (i.e., water activity level less than 0.6) may have a beyond-use date of not more than 180 days if based on documented current literature supporting stability and sterility.

(-e-) Additional requirements to assign Category 3 beyond-use dates to compounded sterile preparations.

(-1-) Increased personnel competency requirements as specified in subsection (c)(4)(K) of this section apply to personnel who participate in or oversee the compounding of Category 3 compounded sterile preparations.

(-2-) Category 3 garbing requirements as specified in paragraph (15)(C)(iv)(II) of this subsection apply to all personnel entering the buffer room where Category 3 compounded sterile preparations are compounded and apply at all times regardless of whether Category 3 compounded sterile preparations are being compounded on a given day.

(-3-) Increased environmental monitoring requirements as specified in subsection (c)(4)(L) of this section and paragraph (16)(C)(vi) of this subsection apply to all classified areas where Category 3 compounded sterile preparations are compounded and apply at all times regardless of whether Category 3 compound sterile preparations are being compounded on a given day.

(-4-) The frequency of application of sporicidal disinfectants as specified in paragraph (8)(H)(iv) of this subsection applies to all classified areas where Category 3 compounded sterile preparations are compounded and applies at all times regardless of whether Category 3 compounded sterile preparations are being compounded on a given day.

[(III) ~~When assigning a beyond-use date, compounding personnel shall consult and apply drug-specific and general stability documentation and literature where available, and they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy.~~]

[(IV) ~~The sterility and storage and stability beyond-use date for attached and activated container pairs of drug products for intravascular administration shall be applied as indicated by the manufacturer.~~]

(9) [~~(7)~~] Primary engineering control device. The pharmacy shall prepare sterile preparations in a primary engineering control device (PEC), such as a laminar air flow hood, biological safety cabinet, compounding aseptic isolator (CAI), or compounding aseptic containment isolator (CACI) which is capable of maintaining at least ISO Class 5 conditions for 0.5 micron and larger [~~micrometer~~] particles while compounding sterile preparations.

(A) Laminar air flow hood. If the pharmacy is using a laminar air flow hood as its PEC, the laminar air flow hood shall:

(i) be located in the buffer room [~~area~~] and placed in the buffer room [~~area~~] in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system;

(ii) be certified for operational efficiency using certification procedures, such as those outlined in the Certification Guide for Sterile Compounding Facilities (CAG-003-2022) [~~(CAG-003-2006)~~], which shall be performed by a qualified independent individual initially and no less than every six months and whenever the device or room is relocated or altered or major service to the pharmacy [~~facility~~] is performed;

(iii) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specification, and the inspection and/or replacement date documented; and

(iv) be located in a buffer room [~~area~~] that has a minimum differential positive pressure of 0.02 [~~to 0.05~~] inches water column. [~~A buffer area that is not physically separated from the ante-area shall employ the principle of displacement airflow as defined in Chapter 797, Pharmaceutical Compounding--Sterile Preparations, of the USP/NF, with limited access to personnel.~~]

(B) Biological safety cabinet.

(i) If the pharmacy is using a biological safety cabinet (BSC) as its PEC for the preparation of hazardous sterile compounded preparations, the biological safety cabinet shall be a Class II or III vertical flow biological safety cabinet located in an ISO Class 7 area that is physically separated from other preparation areas. The area for preparation of sterile chemotherapeutic preparations shall:

(I) have not less than 0.01 inches water column negative pressure to the adjacent positive pressure ISO Class 7 or better anteroom [~~ante-area~~]; and

(II) have a pressure indicator that can be readily monitored for correct room pressurization.

(ii) Pharmacies that prepare a low volume of hazardous drugs, are not required to comply with the provisions of clause (i) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., closed-system vial transfer device within a BSC).

(iii) If the pharmacy is using a biological safety cabinet as its PEC for the preparation of non-hazardous sterile compounded preparations, the biological safety cabinet shall:

(I) be located in the buffer room [~~area~~] and placed in the buffer room [~~area~~] in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system;

(II) be certified for operational efficiency using certification procedures, such as those outlined in the Certification Guide for Sterile Compounding Facilities (CAG-003-2022) [~~(CAG-003-2006)~~], which shall be performed by a qualified independent individual initially and no less than every six months and whenever the device or room is relocated or altered or major service to the pharmacy [~~facility~~] is performed;

(III) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specification, and the inspection and/or replacement date documented; and

(IV) be located in a buffer room [~~area~~] that has a minimum differential positive pressure of 0.02 [~~to 0.05~~] inches water column.

(C) Compounding aseptic isolator.

(i) If the pharmacy is using a compounding aseptic isolator (CAI) as its PEC, the CAI shall provide unidirectional airflow within the main processing and antechambers, and be placed in an ISO Class 7 buffer room [~~area~~] unless the isolator meets all of the following conditions:

(I) The isolator shall [~~must~~] provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations;

(II) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall [~~must~~] maintain ISO Class 5 levels during compounding operations;

(III) The CAI shall [~~must~~] be certified for operational efficiency using certification procedures, such as those outlined in the Certification Guide for Sterile Compounding Facilities (CAG-003-2022) [~~(CAG-003-2006)~~], which shall be performed by a qualified independent individual initially and no less than every six months and whenever the device or room is relocated or altered or major service to the pharmacy [~~facility~~] is performed; and

(IV) The pharmacy shall maintain documentation from the manufacturer that the isolator meets this standard when located in worse than ISO Class 7 environments.

(ii) If the isolator meets the requirements in clause (i) of this subparagraph, the CAI may be placed in a non-ISO classified area of the pharmacy; however, the area shall be segregated from other areas of the pharmacy and shall:

(I) be clean, well lit, and of sufficient size;

(II) be used only for the compounding of Category 1 or Category 2 [~~low- and medium-risk,~~] non-hazardous sterile preparations;

(III) be located in an area of the pharmacy with non-porous and washable floors or floor covering to enable regular disinfection; and

(IV) be an area in which the CAI is placed in a manner as to avoid conditions that could adversely affect its operation.

(iii) In addition to the requirements specified in clauses (i) and (ii) of this subparagraph, if the CAI is used in the compounding of Category 2 prepared from any non-sterile starting component or Category 3 [~~high-risk~~] non-hazardous preparations, the CAI shall be placed in an area or room with at least ISO Class 7 [~~8~~] quality air so that high-risk powders weighed in at least ISO Class 7 [~~ISO-8~~] air quality conditions, compounding utensils for measuring and other compounding equipment are not exposed to lesser air quality prior to the completion of compounding and packaging of the Category 2 prepared from any non-sterile starting component or Category 3 [~~high-risk~~] preparation.

(D) Compounding aseptic containment isolator.

(i) If the pharmacy is using a compounding aseptic containment isolator (CACI) as its PEC for the preparation of Category 1 or Category 2 [~~low- and medium-risk~~] hazardous drugs, the CACI shall be located in a separate room away from other areas of the pharmacy and shall:

(I) provide at least 0.01 inches water column negative pressure compared to the other areas of the pharmacy;

(II) provide unidirectional airflow within the main processing and antechambers, and be placed in an ISO Class 7 room [~~area~~], unless the CACI meets all of the following conditions;

(-a-) The isolator shall [~~must~~] provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations;

(-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall [~~must~~] maintain ISO Class 5 levels during compounding operations;

(-c-) The CACI shall [~~must~~] be certified for operational efficiency using certification procedures, such as those outlined in the Certification Guide for Sterile Compounding Facilities (CAG-003-2022) [~~(CAG-003-2006)~~], which shall be performed by a qualified independent individual initially and no less than every six months and whenever the device or room is relocated or altered or major service to the pharmacy [~~facility~~] is performed; and

(-d-) The pharmacy shall maintain documentation from the manufacturer that the isolator meets this standard when located in worse than ISO Class 7 environments.

(ii) If the CACI meets all conditions specified in clause (i) of this subparagraph, the CACI shall not be located in the same room as a CAI, but shall be located in a separate room in the pharmacy, that is not required to maintain ISO classified air. The room in which the CACI is located shall provide a minimum of 0.01 inches water column negative pressure compared with the other areas of the pharmacy and shall meet the following requirements:

(I) be clean, well lit, and of sufficient size;

(II) be maintained at a temperature of 20 degrees Celsius or cooler, except that a clean room for the compounding of sterile radiopharmaceuticals shall be maintained at a temperature of 25 degrees Celsius or cooler, and at a humidity of 60% or below, with excursions in temperature or humidity of no more than 10% and lasting no longer than 30 minutes [~~below 60%~~];

(III) be used only for the compounding of Category 1 or Category 2 hazardous sterile preparations;

(IV) be located in an area of the pharmacy with walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices, non-shedding and resistant to damage by disinfectant agents; and

(V) have non-porous and washable floors or floor covering to enable regular disinfection.

(iii) If the CACI is used in the compounding of Category 2 prepared from any non-sterile starting component or Category 3 [~~high-risk~~] hazardous preparations, the CACI shall be placed in an area or room with at least ISO Class 7 [~~8~~] quality air so that high-risk powders, weighed in at least ISO Class 7 [~~ISO-8~~] air quality conditions, are not exposed to lesser air quality prior to the completion of compounding and packaging of the Category 2 prepared from any non-sterile starting component or Category 3 [~~high-risk~~] preparation.

(iv) Pharmacies that prepare a low volume of hazardous drugs, are not required to comply with the provisions of clauses (i) and (iii) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., CACI that is located in a non-negative pressure room).

(10) [~~(8)~~] Additional Equipment and Supplies. Pharmacies compounding sterile preparations shall have the following equipment and supplies:

(A) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure that proper storage requirements are met, if sterile preparations are stored in the refrigerator;

(B) a calibrated system or device to monitor the temperature where bulk chemicals are stored;

(C) a temperature-sensing mechanism suitably placed in the controlled temperature storage space to reflect accurately the true temperature;

(D) if applicable, a Class A prescription balance, or analytical balance and weights. Such balance shall be properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy;

(E) equipment and utensils necessary for the proper compounding of sterile preparations. Such equipment and utensils used in the compounding process shall be:

(i) of appropriate design, appropriate capacity, and be operated within designed operational limits;

(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug preparation beyond the desired result;

(iii) cleaned and sanitized immediately prior to and after each use; and

(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;

(F) appropriate disposal containers for used needles, syringes, etc., and if applicable, hazardous waste from the preparation of hazardous drugs and/or biohazardous waste;

(G) appropriate packaging or delivery containers to maintain proper storage conditions for sterile preparations;

(H) infusion devices, if applicable; and

(I) all necessary supplies, including:

(i) disposable needles, syringes, and other supplies for aseptic mixing;

(ii) disinfectant cleaning solutions;

(iii) sterile 70% isopropyl alcohol;

(iv) sterile gloves, both for hazardous and non-hazardous drug compounding;

(v) sterile alcohol-based or water-less alcohol based surgical scrub;

(vi) hand washing agents with bactericidal action;

(vii) disposable, lint free towels or wipes;

(viii) appropriate filters and filtration equipment;

(ix) hazardous spill kits, if applicable; and

(x) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.

(11) [~~(9)~~] Labeling.

(A) Prescription drug or medication orders. In addition to the labeling requirements for the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following:

(i) the generic name(s) or the official name(s) of the principal active ingredient(s) of the compounded sterile preparation;

(ii) for outpatient prescription orders other than sterile radiopharmaceuticals, a statement that the compounded sterile preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement); and

(iii) a beyond-use date. The beyond-use date shall be determined as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF, and paragraph (8)(J) [~~(7)(G)~~] of this subsection;

(B) Batch. If the sterile preparation is compounded in a batch, the following shall also be included on the batch label:

(i) unique lot number assigned to the batch;

(ii) quantity;

(iii) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(iv) device-specific instructions, where appropriate.

(C) Pharmacy bulk package. The label of a pharmacy bulk package shall:

(i) state prominently "Pharmacy Bulk Package--Not for Direct Infusion;"

(ii) contain or refer to information on proper techniques to help ensure safe use of the preparation; and

(iii) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.

(12) [~~(10)~~] Written drug information for prescription drug orders only. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing a prescription drug order. A statement which indicates that the preparation was compounded by the pharmacy shall [~~must~~] be included in this written information. If there is no written information available, the patient shall be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate, the prescriber, concerning the drug. This paragraph does not apply to the preparation of radiopharmaceuticals.

(13) [~~(11)~~] Pharmaceutical care services [~~Care Services~~]. In addition to the pharmaceutical care requirements for the pharmacy's specific license classification, the following requirements for sterile preparations compounded pursuant to prescription drug orders shall [~~must~~] be met. This paragraph does not apply to the preparation of radiopharmaceuticals.

(A) Primary provider. There shall be a designated physician primarily responsible for the patient's medical care. There shall be a clear understanding between the physician, the patient, and the pharmacy of the responsibilities of each in the areas of the delivery of care, and the monitoring of the patient. This shall be documented in the patient medication record (PMR).

(B) Patient training. The pharmacist-in-charge shall develop policies to ensure that the patient and/or patient's caregiver receives information regarding drugs and their safe and appropriate use, including instruction when applicable, regarding:

(i) appropriate disposition of hazardous solutions and ancillary supplies;

(ii) proper disposition of controlled substances in the home;

(iii) self-administration of drugs, where appropriate;

(iv) emergency procedures, including how to contact an appropriate individual in the event of problems or emergencies related to drug therapy; and

(v) if the patient or patient's caregiver prepares sterile preparations in the home, the following additional information shall be provided:

(I) safeguards against microbial contamination, including aseptic techniques for compounding intravenous admixtures and aseptic techniques for injecting additives to premixed intravenous solutions;

(II) appropriate storage methods, including storage durations for sterile pharmaceuticals and expirations of self-mixed solutions;

(III) handling and disposition of premixed and self-mixed intravenous admixtures; and

(IV) proper disposition of intravenous admixture compounding supplies such as syringes, vials, ampules, and intravenous solution containers.

(C) Pharmacist-patient relationship. It is imperative that a pharmacist-patient relationship be established and maintained throughout the patient's course of therapy. This shall be documented in the patient's medication record (PMR).

(D) Patient monitoring. The pharmacist-in-charge shall develop policies to ensure that:

(i) the patient's response to drug therapy is monitored and conveyed to the appropriate health care provider;

(ii) the first dose of any new drug therapy is administered in the presence of an individual qualified to monitor for and respond to adverse drug reactions; and

(iii) reports of adverse events with a compounded sterile preparation are reviewed promptly and thoroughly to correct and prevent future occurrences.

(14) [~~(12)~~] Drugs, components, and materials used in sterile compounding.

(A) Drugs used in sterile compounding shall be [~~a~~] USP/NF, British Pharmacopoeia (BP), European Pharmacopoeia (EP), or Japanese Pharmacopoeia (JP) grade substances manufactured in an FDA-registered facility.

(B) If USP/NF, BP, EP, and JP grade substances are not available, substances used in sterile compounding shall be of a chemical grade in one of the following categories:

(i) Chemically Pure (CP);

(ii) Analytical Reagent (AR);

(iii) American Chemical Society (ACS); or

(iv) Food Chemical Codex.

(C) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.

(D) All components shall:

(i) be manufactured in an FDA-registered facility; or

(ii) in the professional judgment of the pharmacist, be of high quality and obtained from acceptable and reliable alternative sources; and

(iii) be stored in properly labeled containers in a clean, dry place [~~area~~], under proper temperatures.

(E) Drug preparation containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug preparation beyond the desired result.

(F) Components, drug preparation containers, and closures shall be rotated so that the oldest stock is used first.

(G) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug preparation.

(H) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.

(15) [~~(13)~~] Compounding process.

(A) Standard operating procedures (SOPs). All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed and implemented for:

(i) the pharmacy [~~facility~~];

(ii) equipment;

(iii) personnel;

(iv) preparation evaluation;

(v) quality assurance;

(vi) preparation recall;

(vii) packaging; and

(viii) storage of compounded sterile preparations.

(B) USP/NF. Any compounded formulation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

(C) Personnel cleansing and garbing [~~Cleansing and Garbing~~].

(i) Any person with an apparent illness or open lesion, including rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infection, that may adversely affect the safety or quality of a drug preparation being compounded shall be excluded from working in ISO Class 5, ISO Class 7, and ISO Class 8 compounding areas until the condition is remedied.

(ii) Before entering the buffer room [~~area~~], compounding personnel shall [~~must remove the following~~]:

(I) remove personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests);

(II) remove all cosmetics;[~~, because they shed flakes and particles; and~~]

(III) remove all hand, wrist, and other body jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of personal protective equipment (e.g., fit of gloves and cuffs of sleeves); and[~~.~~]

(IV) wipe eyeglasses, if worn.

(iii) The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed.

(iv) Personnel shall [~~don personal protective equipment and~~] perform hand hygiene and garbing in an order determined by the pharmacy depending on the placement of the sink. The order of garbing shall be documented in the pharmacy's SOPs. Garb shall be donned and doffed in an order that reduces the risk of contamination. Donning and doffing garb shall not occur in the same area at the same

time. [~~that proceeds from the dirtiest to the cleanest activities as follows:~~]

(I) The minimum garbing requirements for preparing Category 1 or Category 2 compounded sterile preparations include the following:

(-a-) low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gown or coverall);

(-b-) low-lint covers for shoes;

(-c-) low-lint cover for head that covers the hair and ears, and if appliable, cover for facial hair;

(-d-) low-lint face mask;

(-e-) sterile powder-free gloves; and

(-f-) if using a restricted-access barrier system (i.e., a compounding aseptic isolator or compounding aseptic containment isolator), disposable gloves should be worn inside the gloves attached to the restricted-access barrier system sleeves. Sterile gloves shall be worn over the gloves attached to the restricted-access barrier system sleeve.

~~*f(I)* Activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye shield. Eye shields are optional unless working with irritants like germicidal disinfecting agents or when preparing hazardous drugs.~~]

(II) The following additional garbing requirements shall be followed in the buffer room where Category 3 compounded sterile preparations are prepared for all personnel regardless of whether Category 3 compounded sterile preparations are compounded on a given day:

(-a-) skin may not be exposed in the buffer room (i.e., face and neck shall be covered);

(-b-) all low-lint outer garb shall be sterile, including the use of sterile sleeves over gauntlet sleeves when a restricted-access barrier system is used;

(-c-) disposable garbing items shall not be reused and any laundered garb shall not be reused without being laundered and resterilized with a validated cycle; and

(-d-) the pharmacy's SOPs shall describe disinfection procedures for reusing goggles, respirators, and other reusable equipment. If compounding a hazardous drug, appropriate personal protective equipment shall be worn.

(III) [~~(II)~~] After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, personnel shall perform a hand hygiene procedure by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Personnel shall begin washing arms at the hands and continue washing to elbows for at least 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in the anteroom [~~ante-area~~]. Disposable soap containers shall not be refilled or topped off. Brushes shall not be used for hand hygiene. Hands and forearms to the elbows shall be completely dried using lint-free disposable towels, an electronic hands-free hand dryer, or a HEPA filtered hand dryer.

(IV) [~~(III)~~] After completion of hand washing, personnel shall don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclosed at the neck.

(V) [~~(IV)~~] Once inside the buffer room [~~area~~] or segregated compounding area, and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using an alcohol-based hand rub [~~a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations~~]. Hands shall be allowed to dry thoroughly before donning sterile gloves.

(VI) [~~(V)~~] Sterile gloves that form a continuous barrier with the gown shall be the last item donned before compounding begins. Sterile gloves shall be donned in a classified area or segregated compounding area using proper technique to ensure the sterility of the glove is not compromised while donning. The cuff of the sterile glove shall cover the cuff of the gown at the wrist. When preparing hazardous preparations, the compounder shall double glove or shall use single gloves ensuring that the gloves are sterile powder-free chemotherapy-rated gloves. Routine application of sterile 70% IPA shall occur throughout the compounding day and whenever non-sterile surfaces are touched.

(v) Garb shall be replaced immediately if it becomes visibly soiled or if its integrity is compromised. Gowns and other garb shall be stored in a manner that minimizes contamination (e.g., away from sinks to avoid splashing). If compounding Category 1 or Category 2 compounded sterile preparations, gowns may be reused within the same shift by the same person if the gown is maintained in a classified area or adjacent to, or within, the segregated compounding area in a manner that prevents contamination. When personnel exit the compounding area, garb, except for gowns, may not be reused and shall be discarded or laundered before use. The pharmacy's SOPs shall describe disinfection procedures for reusing goggle, respirators, and other reusable equipment. [~~When compounding personnel shall temporarily exit the buffer area during a work shift, the exterior gown, if not visibly soiled, may be removed and retained in the ante-area, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face mask/eye shield, and gloves shall be replaced with new ones before re-entering the buffer area along with performing proper hand hygiene.~~]

(vi) During [~~high-risk level~~] compounding activities that precede terminal sterilization, such as weighing and mixing of non-sterile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 environment. Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 shall re-garb personal protective equipment along with washing their hands properly, performing antiseptic hand cleansing with a sterile 70% IPA-based or another suitable sterile alcohol-based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7 buffer room [~~area~~].

(vii) When compounding aseptic isolators or compounding aseptic containment isolators are the source of the ISO Class 5 environment, at the start of each new compounding procedure, a new pair of sterile gloves shall be donned within the CAI or CACI. In addition, the compounding personnel should follow the requirements as specified in this subparagraph, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any components of personal protective equipment or cleansing are not required.

(16) [~~(14)~~] Quality assurance [~~Assurance~~].

(A) Initial formula validation [~~Formula Validation~~]. Prior to routine compounding of a sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a preparation that is sterile and that contains the stated amount of active ingredient(s).

~~*f(i)* Low risk level preparations.~~]

(i) [~~(I)~~] Quality assurance practices include, but are not limited to the following:

(I) [~~(-a-)~~] Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality;

(II) [~~(-b-)~~] Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments and goggles;

(III) Confirmation that media-fill tests indicate that compounding personnel and personnel who have direct oversight of compounding personnel but do not compound can competently perform aseptic procedures;

(IV) [~~(-c-)~~] Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded; and

(V) [~~(-d-)~~] Visual inspection of compounded sterile preparations, except for sterile radiopharmaceuticals, to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

~~*(II)* Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually by each person authorized to compound in a low-risk level under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low-risk level sterile preparations. Once begun, this test is completed without interruption within an ISO Class 5 air quality environment. Three sets of four 5-milliliter aliquots of sterile fluid culture media are transferred with the same sterile 10-milliliter syringe and vented needle combination into separate sealed, empty, sterile 30-milliliter clear vials (i.e., four 5-milliliter aliquots into each of three 30-milliliter vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.]~~

~~*(ii)* Medium risk level preparations.]~~

~~*(I)* Quality assurance procedures for medium-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations, as well as a more challenging media-fill test passed annually, or more frequently.]~~

~~*(II)* Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. This test is completed without interruption within an ISO Class 5 air quality environment. Six 100-milliliter aliquots of sterile Soybean-Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-milliliter syringe and 18-gauge needle combination is used to exchange two 5-milliliter aliquots of medium from one container to the other container in the pair. For example, after a 5-milliliter aliquot from the first container is added to the second container in the pair, the second container is agitated for 10 seconds, then a 5-milliliter aliquot is removed and returned to the first container in the pair. The first container is then agitated for 10 seconds, and the next 5-milliliter aliquot is transferred from it back to the second container in the pair. Following the two 5-milliliter aliquot exchanges in each pair of containers, a 5-milliliter aliquot of medium from each container is aseptically injected into a sealed, empty, sterile 10-milliliter clear vial, using a sterile 10-milliliter syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.]~~

~~*(iii)* High risk level preparations.]~~

~~*(I)* Procedures for high-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations. In addition, a media-fill test that represents high-risk level compounding is performed twice a year by each person authorized to compound high-risk level compounded sterile preparations.]~~

~~*(II)* Example of a Media-Fill Test Procedure for Compounded Sterile Preparations Sterilized by Filtration. This test, or an equivalent test, is performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level compounded sterile preparations. Note: Sterility tests for autoclaved compounded sterile preparations are not required unless they are prepared in batches of more than 25 units. This test is completed without interruption in the following sequence:]~~

~~[(-a-) Dissolve 3 grams of non-sterile commercially available fluid culture media in 100 milliliters of non-bacteriostatic water to make a 3% non-sterile solution.]~~

~~[(-b-) Draw 25 milliliters of the medium into each of three 30-milliliter sterile syringes. Transfer 5 milliliters from each syringe into separate sterile 10-milliliter vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.]~~

~~[(-c-) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron porosity filter unit and a 20-gauge needle to each syringe. Inject the next 10 milliliters from each syringe into three separate 10-milliliter sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20 to 35 degrees Celsius for a minimum of 14 days. Inspect for microbial growth over 14 days as described in Chapter 797 Pharmaceutical Compounding--Sterile Preparations, of the USP/NF.]~~

(ii) [~~(II)~~] Filter integrity testing [~~Integrity Testing~~]. Filters shall [~~need to~~] undergo testing to evaluate the integrity of filters used to sterilize Category 2 prepared from any non-sterile starting component or Category 3 compounded sterile [~~high-risk~~] preparations, such as bubble point testing [~~Bubble Point Testing~~] or comparable filter integrity testing. Such testing is not a replacement for sterility testing and shall not be interpreted as such. Such test shall be performed after a sterilization procedure on all filters used to sterilize each Category 2 prepared from any non-sterile starting component or Category 3 compounded sterile [~~high-risk~~] preparation or batch preparation and the results documented. The results should be compared with the filter manufacturer's specification for the specific filter used. If a filter fails the integrity test, the preparation or batch shall [~~must~~] be sterilized again using new unused filters.

(B) Finished preparation release checks and tests.

(i) Each time a Category 3 compounded sterile preparation is prepared, it shall be tested for sterility and meet the requirements of Chapter 71, Sterility Tests of the USP/NF, or a validated alternative method that is noninferior to Chapter 71 testing. Each time a Category 2 injectable compounded sterile preparation compounded from one or more non-sterile components and assigned a beyond-use date that requires sterility testing is prepared, the preparation shall be tested to ensure that it does not contain excessive bacterial endotoxins. Each time a Category 3 injectable compounded sterile preparation compounded from one or more non-sterile components is prepared, the preparation shall be tested to ensure that it does not contain excessive bacterial endotoxins. [~~All high-risk level compounded sterile prepara-~~

tions that are prepared in groups of more than 25 identical individual single-dose packages (such as ampules, bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than 12 hours at 2 - 8 degrees Celsius and longer than six hours at warmer than 8 degrees Celsius before they are sterilized shall be tested to ensure they are sterile and do not contain excessive bacterial endotoxins as specified in Chapter 71, Sterility Tests of the USP/NF before being dispensed or administered.]

(ii) All compounded sterile preparations, except for sterile radiopharmaceuticals, that are intended to be solutions shall [must] be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed.

(iii) The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded sterile preparations [at all contamination risk levels] shall be inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are dispensed or administered.

(iv) Written procedures for checking compounding accuracy shall be followed for every compounded sterile preparation during preparation, in accordance with pharmacy's policies and procedures, and immediately prior to release, including label accuracy and the accuracy of the addition of all drug products or ingredients used to prepare the finished preparation and their volumes or quantities. A pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(C) Environmental testing [Testing].

(i) Viable and nonviable environmental sampling testing. Environmental sampling shall occur, at a minimum, every six months as part of a comprehensive quality management program and under any of the following conditions:

(I) as part of the commissioning and certification of new facilities and equipment;

(II) following any servicing of facilities and equipment;

(III) as part of the re-certification of facilities and equipment;

(IV) in response to identified problems with end products or staff technique; or

(V) in response to issues with compounded sterile preparations, observed compounding personnel work practices, or patient-related infections (where the compounded sterile preparation is being considered as a potential source of the infection).

(ii) Total particle counts. Certification that each ISO classified area (e.g., ISO Class 5, 7, and 8), is within established guidelines shall be performed no less than every six months and whenever the equipment is relocated or the physical structure of the buffer room [area] or anteroom [ante-area] has been altered. All certification records shall be maintained and reviewed to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and air changes per hour. These certification records shall [must] include acceptance criteria and be made available upon inspection by the Board. Testing shall be performed by qualified operators using current, state-of-the-art equipment, with results of the following:

(I) ISO Class 5 - not more than 3,520 [3520] particles 0.5 microns [micrometer] and larger in diameter [size] per cubic meter of air;

(II) ISO Class 7 - not more than 352,000 particles of 0.5 microns [micrometer] and larger in diameter [size] per cubic meter of air for any buffer room [area]; and

(III) ISO Class 8 - not more than 3,520,000 particles of 0.5 microns [micrometer] and larger in diameter [size] per cubic meter of air for any anteroom [ante-area].

(iii) Pressure differential monitoring. A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer room [area] and the anteroom [ante-area] and between the anteroom [ante-area] and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 or ISO Class 8 and the general pharmacy area shall not be less than 0.02 inch water column.

(iv) Sampling plan. An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas and in the segregated compounding areas at greatest risk of contamination. The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.

(v) Viable air sampling. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments shall be performed by properly trained individuals for all compounded sterile preparations [compounding risk levels]. Volumetric active air sampling of all active classified areas using an impaction air sampler shall be conducted in each classified area (e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)) during dynamic operating conditions. For entities compounding Category 1 or Category 2 compounded sterile preparations, this shall be completed at least every six months. For entities compounding any Category 3 compounded sterile preparations, this shall be completed within 30 days prior to the commencement of any Category 3 compounding and at least every three months thereafter regardless of the frequency of compounding Category 3 compounded sterile preparations. Air sampling sites shall be selected in all classified areas. [For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning. Locations shall include zones of air backwash turbulence within the laminar airflow workbench and other areas where air backwash turbulence may enter the compounding area. For low-risk level compounded sterile preparations within 12-hour or less beyond-use-date prepared in a primary engineering control that maintains an ISO Class 5, air sampling shall be performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class 5 environment during the certification of the primary engineering control.]

(vi) Air sampling [frequency and] process. [Air sampling shall be performed at least every 6 months as a part of the re-certification of facilities and equipment.]

(I) A sufficient volume of air shall be sampled [and the manufacturer's guidelines for use of the electronic air sampling equipment followed]. Follow the manufacturer's instructions for operation of the impaction air sampler, including placement of media

device(s). Using the impaction air sampler, test at least 1 cubic meter or 1,000 liters of air from each location sampled. At the end of each sampling period, retrieve the media device and cover it. Handle and store media devices to avoid contamination and prevent condensate from dropping onto the agar during incubation and affecting the accuracy of the cfu reading (e.g., invert plates). At the end of the designated sampling or exposure period for air sampling activities, the microbial growth media plates are recovered and their covers secured and they are inverted and incubated pursuant to the procedures in subclause (II) of this clause [~~at a temperature and for a time period conducive to multiplication of microorganisms~~]. Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment.

(II) Incubation procedures.

(-a-) Incubate the media device at 30 to 35 degrees Celsius for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each media device as cfu per cubic meter of air on an environmental sampling form based on sample type (i.e., viable air), sample location, and sample date.

(-b-) Then incubate the media at 20 to 25 degrees Celsius for no less than five additional days. Examine for growth. Record the total number of discrete colonies of microorganisms on each media device as cfu per cubic meter of air on an environmental sampling form based on sample type (i.e., viable air), sample location, and sample date.

(-c-) Alternatively, to shorten the overall incubation period, two sampling media devices may be collected for each sample location and incubated concurrently.

(-1-) The media devices shall either both be trypticase soy agar or shall be one trypticase soy agar and the other fungal media (e.g., malt extract agar or Sabouraud dextrose agar).

(-2-) Incubate each media device in a separate incubator. Incubate one media device at 30 to 35 degrees Celsius for no less than 48 hours, and incubate the other media device at 20 to 25 degrees Celsius for no less than five days. If fungal media are used as one of the samples, incubate the fungal media sample at 20 to 25 degrees Celsius for no less than five days.

(-3-) Count the total number of discrete colonies of microorganisms on each media device, and record these results as cfu per cubic meter of air.

(-4-) Record the results of the sampling on an environmental sampling form based on sample type (i.e., viable air), and include the sample location and sample date.

(III) The following action levels for viable air sampling apply: a [~~If an activity consistently shows elevated levels of microbial growth, competent microbiology or infection control personnel shall be consulted. A~~] colony forming unit (cfu) count greater than 1 cfu per cubic meter of air for ISO Class 5, greater than 10 cfus [~~efu~~] per cubic meter of air for ISO Class 7, and greater than 100 cfus [~~efu~~] per cubic meter of air for ISO Class 8. If levels measured during viable air sampling exceed the action levels in this subclause for the ISO classification levels of the area sampled, the cause shall be investigated and corrective action shall be taken. Data collected in response to corrective actions shall be reviewed to confirm that the actions taken have been effective. The corrective action plan shall be dependent on the cfu count and the microorganism recovered. The corrective action plan shall be documented. If levels measured during viable air sampling exceed the action levels in this subclause, an attempt shall be made to identify any microorganism recovered to the genus level with the assistance of a competent microbiologist. [~~or worse should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed. Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time. Regardless of the number of cfu identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler. Highly pathogenic microorganisms (e.g., gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patient receiving compounded sterile preparations and must be immediately remedied, regardless of colony forming unit count, with the assistance, if needed, of a competent microbiologist, infection control professional, or industrial hygienist.~~]

(vii) Compounding accuracy checks. Written procedures for checking compounding accuracy shall be followed for every compounded sterile preparation during preparation and immediately prior to release, including label accuracy and the accuracy of the addition of all drug products or ingredients used to prepare the finished preparation and their volumes or quantities. At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(17) [~~(15)~~] Quality control.

(A) Quality control procedures. The pharmacy shall follow established quality control procedures to monitor the compounding environment and quality of compounded drug preparations for conformity with the quality indicators established for the preparation. When developing these procedures, pharmacy personnel shall consider the provisions of USP Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding-Non-sterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations, USP Chapter 800, Hazardous Drugs--Handling in Healthcare Settings, USP Chapter 823, Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses, USP Chapter 1160, Pharmaceutical Calculations in Prescription Compounding, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding of the current USP/NF. Such procedures shall be documented and be available for inspection.

(B) Verification of compounding accuracy and sterility.

(i) The accuracy of identities, concentrations, amounts, and purities of ingredients in compounded sterile preparations shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.

(ii) If the correct identity, purity, strength, and sterility of ingredients and components of compounded sterile preparations cannot be confirmed such ingredients and components shall be discarded immediately. Any compounded sterile preparation that fails sterility testing following sterilization by one method (e.g., filtration) is to be discarded and not subjected to a second method of sterilization.

(iii) If individual ingredients, such as bulk drug substances, are not labeled with expiration dates, when the drug substances are stable indefinitely in their commercial packages under labeled storage conditions, such ingredients may gain or lose moisture during stor-

age and use and shall require testing to determine the correct amount to weigh for accurate content of active chemical moieties in compounded sterile preparations.

(C) Sterility testing. Sterility testing shall be performed on a number of units equal to 5% of the number of compounded sterile preparations prepared, rounded up to the next whole number. Sterility tests resulting in failure shall prompt an investigation into the possible causes of the failure and shall include identification of the microorganism and an evaluation of the sterility testing procedure, compounding facility, process, and personnel that may have contributed to the failure. The sources of the contamination, if identified, shall be corrected and the pharmacy shall determine whether the conditions causing the sterility failure affect other compounded sterile preparations. The investigation and resulting corrective actions shall be documented.

(e) Records. Any testing, cleaning, procedures, or other activities required in this subsection shall be documented and such documentation shall be maintained by the pharmacy.

(1) Maintenance of records. Every record required under this section shall [~~must~~] be:

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

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

(2) Compounding records.

(A) Compounding pursuant to patient specific prescription drug orders or medication orders not prepared from non-sterile ingredient(s). Compounding records for all compounded preparations shall be maintained by the pharmacy and shall include a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of each; however, if the sterile preparation is compounded according to the manufacturer's labeling instructions, then documentation of the formula is not required.[~~:~~]

~~*[(i)* the date and time of preparation;]~~

~~*[(ii)* a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of each; however, if the sterile preparation is compounded according to the manufacturer's labeling instructions, then documentation of the formula is not required;]~~

~~*[(iii)* written or electronic signature or initials of the pharmacist or pharmacy technician or pharmacy technician trainee performing the compounding;]~~

~~*[(iv)* written or electronic signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting finals checks of compounded pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the compounding function;]~~

~~*[(v)* the container used and the number of units of finished preparation prepared; and]~~

~~*[(vi)* a reference to the location of the following documentation which may be maintained with other records, such as quality control records:]~~

~~*[(I)* the criteria used to determine the beyond-use date; and]~~

~~*[(II)* documentation of performance of quality control procedures.]~~

(B) Compounding records for compounded sterile preparations prepared from non-sterile ingredient(s) or prepared for more than one patient. [~~when batch compounding or compounding in anticipation of future prescription drug or medication orders.~~]

(i) [~~Master work sheet~~]. A master formulation record [~~master work sheet~~] shall be created for compounded sterile preparations prepared from non-sterile ingredient(s) or prepared for more than one patient. Any changes or alterations to the master formulation record shall be approved and documented according to the pharmacy's SOPs. The master formulation record shall include at least the following information: [~~developed and approved by a pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work sheet shall be used as the preparation work sheet from which each batch is prepared and on which all documentation for that batch occurs. The master work sheet shall contain at a minimum:~~]

(I) name, strength or activity, and dosage form of the compounded sterile preparation [~~the formula~~];

(II) identities and amounts of all ingredients and, if applicable, relevant characteristics or components (e.g., particle size, salt form, purity grade, solubility, assay, loss on drying, water content) [~~the components~~];

(III) type and size of container closure system(s) [~~the compounding directions~~];

(IV) complete instructions for preparing the compounded sterile preparation, including equipment, supplies, a description of the compounding steps, and any special precautions [~~a sample label~~];

(V) physical description of the final compounded sterile preparation, including desired pH of aqueous preparations for buffered eye drops and non-sterile to sterile compounding [~~evaluation and testing requirements~~];

(VI) beyond-use date and storage requirements; [~~specific equipment used during preparation; and~~]

(VII) reference source to support the stability of the compounded sterile preparation; [~~storage requirements.~~]

(VIII) quality control procedures (e.g., pH testing, filter integrity testing); and

(IX) other information as needed to describe the compounding process and ensure repeatability (e.g., adjusting pH and tonicity; sterilization method, such as steam, dry heat, irradiation, or filter).

(ii) A compounding record that documents the compounding process shall be created for all compounded sterile preparations. The compounding record shall include at least the following information:

(I) name, strength or activity, and dosage form of the compounded sterile preparation;

(II) date and time of preparation of the compounded sterile preparation;

(III) assigned internal identification number (e.g., prescription, order, or lot number);

(IV) written or electronic signature or initials of the pharmacist or pharmacy technician or pharmacy technician trainee performing the compounding;

(V) written or electronic signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting final checks of compounded preparations if pharmacy technicians or pharmacy technician trainees perform the compounding function;

(VI) name of each component;

(VII) vendor, lot number, and expiration date for each component for compounded sterile preparations prepared for more than one patient or prepared from non-sterile ingredient(s);

(VIII) weight or volume of each component;

(IX) strength or activity of each component;

(X) total quantity compounded;

(XI) final yield (e.g., quantity, containers, number of units);

(XII) assigned beyond-use date and storage requirements;

(XIII) results of quality control procedures (e.g., visual inspection, filter integrity testing, pH testing);

(XIV) if applicable, master formulation record for the compounded sterile preparation; and

(XV) if applicable, calculations made to determine and verify quantities or concentrations of components.

~~*[(ii)* Preparation work sheet. The preparation work sheet for each batch of preparations shall document the following:]~~

~~*[(I)* identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;]~~

~~*[(II)* lot number for each component;]~~

~~*[(III)* component manufacturer/distributor or suitable identifying number;]~~

~~*[(IV)* container specifications (e.g., syringe, pump cassette);]~~

~~*[(V)* unique lot or control number assigned to batch;]~~

~~*[(VI)* expiration date of batch-prepared preparations;]~~

~~*[(VII)* date of preparation;]~~

~~*[(VIII)* name, initials, or electronic signature of the person(s) involved in the preparation;]~~

~~*[(IX)* name, initials, or electronic signature of the responsible pharmacist;]~~

~~*[(X)* finished preparation evaluation and testing specifications, if applicable; and]~~

~~*[(XI)* comparison of actual yield to anticipated or theoretical yield, when appropriate.]~~

(f) Office use compounding and distribution of sterile compounded preparations. [~~Use Compounding and Distribution of Sterile Compounded Preparations~~]

(1) General.

(A) A pharmacy may compound, dispense, deliver, and distribute a compounded sterile preparation as specified in Subchapter D, Texas Pharmacy Act Chapter 562.

(B) A Class A-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations to a Class C or Class C-S pharmacy.

(C) A Class C-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations that the Class C-S pharmacy has compounded for other Class C or Class C-S pharmacies under common ownership.

(D) To compound and deliver a compounded preparation under this subsection, a pharmacy shall [~~must~~]:

(i) verify the source of the raw materials to be used in a compounded drug;

(ii) comply with applicable United States Pharmacopeia [~~Pharmacopoeia~~] guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);

(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;

(iv) comply with all applicable competency and accrediting standards as determined by the board; and

(v) comply with the provisions of this subsection.

(E) This subsection does not apply to Class B pharmacies compounding sterile radiopharmaceuticals that are furnished for departmental or physicians' use if such authorized users maintain a Texas radioactive materials license.

(2) Written Agreement. A pharmacy that provides sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:

(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded drugs may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except to a veterinarian as authorized by §563.054 of the Act;

(B) require the practitioner or receiving pharmacy to include on a patient's chart, medication order or medication administration record the lot number and beyond-use date of a compounded preparation administered to a patient; and

(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:

(i) a patient to report an adverse reaction or submit a complaint; and

(ii) the pharmacy to recall batches of compounded preparations.

(3) Recordkeeping.

(A) Maintenance of Records.

(i) Records of orders and distribution of sterile compounded preparations to a practitioner for office use or to an institutional pharmacy for administration to a patient shall:

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

(II) be maintained separately from the records of preparations dispensed pursuant to a prescription or medication order; and

(III) be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records shall [~~must~~] be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(B) Orders. The pharmacy shall maintain a record of all sterile compounded preparations ordered by a practitioner for office use or by an institutional pharmacy for administration to a patient. The record shall include the following information:

(i) date of the order;

(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the institutional pharmacy ordering the preparation; and

(iii) name, strength, and quantity of the preparation ordered.

(C) Distributions. The pharmacy shall maintain a record of all sterile compounded preparations distributed pursuant to an order to a practitioner for office use or by an institutional pharmacy for administration to a patient. The record shall include the following information:

(i) date the preparation was compounded;

(ii) date the preparation was distributed;

(iii) name, strength and quantity in each container of the preparation;

(iv) pharmacy's lot number;

(v) quantity of containers shipped; and

(vi) name, address, and phone number of the practitioner or institutional pharmacy to whom the preparation is distributed.

(D) Audit trail [~~Trail~~].

(i) The pharmacy shall store the order and distribution records of preparations for all sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a pharmacy licensed to compound sterile preparations for administration to a patient in such a manner as to be able to provide an audit trail for all orders and distributions of any of the following during a specified time period:

(I) any strength and dosage form of a preparation (by either brand or generic name or both);

(II) any ingredient;

(III) any lot number;

(IV) any practitioner;

(V) any facility; and

(VI) any pharmacy, if applicable.

(ii) The audit trail shall contain the following information:

(I) date of order and date of the distribution;

(II) practitioner's name, address, and name of the institutional pharmacy, if applicable;

(III) name, strength and quantity of the preparation in each container of the preparation;

(IV) name and quantity of each active ingredient;

(V) quantity of containers distributed; and

(VI) pharmacy's lot number.

(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:

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

(B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";

(C) name and strength of the preparation or list of the active ingredients and strengths;

(D) pharmacy's lot number;

(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;

(F) quantity or amount in the container;

(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(H) device-specific instructions, where appropriate.

(g) Recall procedures [~~Procedures~~].

(1) The pharmacy shall have SOPs [~~written procedures~~] for the recall of any compounded sterile preparation provided to a patient, to a practitioner for office use, or a pharmacy for administration. The SOPs [~~Written procedures~~] shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.

(2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.

(3) In the event of a recall, the pharmacist-in-charge shall ensure that:

(A) the distribution of any affected compounded sterile preparation is determined, including the date and quantity of distribution;

(B) [~~(A)~~] each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;

(C) [~~(B)~~] each patient to whom the preparation was dispensed is notified, in writing, of the recall;

(D) [~~(C)~~] the board is notified of the recall, in writing, not later than 24 hours after the recall is issued;

(E) [~~(D)~~] if the preparation is distributed for office use, the Texas Department of State Health Services, Drugs and Medical Devices Group, is notified of the recall, in writing;

(F) [~~(E)~~] any unused dispensed compounded sterile preparations are recalled and any stock remaining in the pharmacy is quarantined [~~the preparation is quarantined~~]; and

(G) [~~(F)~~] the pharmacy keeps a written record of the recall including all actions taken to notify all parties and steps taken to ensure corrective measures.

(4) Recall of out-of-specification dispensed compounded sterile preparations.

(A) If a compounded sterile preparation is dispensed or administered before the results of testing are known, the pharmacy shall have SOPs in place to:

(i) immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., sterility, strength, purity, bacterial endotoxin, or other quality attributes); and

(ii) investigate if other lots are affected and recall if necessary.

(B) SOPs for recall of out-of-specification dispensed compounded sterile preparations shall contain procedures to:

(i) determine the severity of the problem and the urgency for implementation and completion of the recall;

(ii) determine the disposal and documentation of the recalled compounded sterile preparation; and

(iii) investigate and document the reason for failure.

(5) [~~(4)~~] If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if there is potential for or confirmed harm to a patient.

(6) [~~(5)~~] A pharmacy that compounds sterile preparations shall notify the board immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy.

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 September 19, 2025.

TRD-202503315
Daniel Carroll, Pharm.D.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: November 2, 2025
For further information, please call: (512) 305-8084

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PART 22. TEXAS STATE BOARD OF PUBLIC ACCOUNTANCY

CHAPTER 516. MILITARY SERVICE MEMBERS, SPOUSES AND VETERANS

22 TAC §516.1

The Texas State Board of Public Accountancy (Board) proposes an amendment to §516.1 concerning Definitions.

Background, Justification and Summary

HB 5629 established new licensing accommodations for military members, their spouses and military veterans. The proposed revision in this section eliminates no longer needed language and defines that these rules apply to Certified Public Accountants.

Fiscal Note

William Treacy, Executive Director of the Board, has determined that for the first five-year period the proposed amendment is in effect, there will be no additional estimated cost to the state, no estimated reduction in costs to the state and to local governments, and no estimated loss or increase in revenue to the state, as a result of enforcing or administering the amendment.

Public Benefit

The adoption of the proposed rule amendment will incorporate the provision of the new legislation into the board's rule providing greater notice to the public of the accommodations.

Probable Economic Cost and Local Employment Impact

Mr. Treacy, Executive Director, has determined that there will be no probable economic cost to persons required to comply with the amendment and a Local Employment Impact Statement is not required because the proposed amendment will not affect a local economy.

Small Business, Rural Community and Micro-Business Impact Analysis

William Treacy, Executive Director, has determined that the proposed amendment will not have an adverse economic effect on small businesses, rural communities or micro-businesses because the amendment does not impose any duties or obligations upon small businesses, rural communities or micro-businesses; therefore, an Economic Impact Statement and a Regulatory Flexibility Analysis are not required.

Government Growth Impact Statement

William Treacy, Executive Director, has determined that for the first five-year period the amendment is in effect, the proposed rule: does not create or eliminate a government program; does not create or eliminate employee positions; does not increase or decrease future legislative appropriations to the Board; does not increase or decrease fees paid to the Board; does not create a new regulation; limits the existing regulation; does not increase or decrease the number of individuals subject to the proposed rule's applicability; and does not positively or adversely affect the state's economy.

Takings Impact Assessment

No takings impact assessment is necessary because there is no proposed use of private real property as a result of the proposed rule revision.

The requirement related to a rule increasing costs to regulated persons does not apply to the Texas State Board of Public Accountancy because the rule is being proposed by a self-directed semi-independent agency. (§2001.0045(c)(8))

Public Comment

Written comments may be submitted to J. Randel (Jerry) Hill, General Counsel, Texas State Board of Public Accountancy, 505 E. Huntland Dr., Suite 380, Austin, Texas 78752 or faxed to his attention at (512) 305-7854, no later than noon on November 3, 2025.

The Board specifically invites comments from the public on the issues of whether or not the proposed amendment will have an adverse economic effect on small businesses. If the proposed rule is believed to have an adverse effect on small businesses, estimate the number of small businesses believed to be impacted by the rule, describe and estimate the economic impact of the rule on small businesses, offer alternative methods of achieving the purpose of the rule; then explain how the Board may legally and feasibly reduce that adverse effect on small businesses considering the purpose of the statute under which the proposed rule is to be adopted; and finally, describe how the health, safety, environmental, and economic welfare of the state will be impacted by the various proposed methods. See Texas Government Code, §2006.002(c).

Statutory Authority

The amendment is proposed under the Public Accountancy Act ("Act"), Texas Occupations Code §901.151, which authorizes the Board to adopt rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by this proposed amendment.

§516.1. Definitions.

The following words and terms, when used in Title 22, Part 22 of the Texas Administrative Code relating to the Texas State Board of Public Accountancy, shall have the following meanings:

(1) "Active duty" means current full-time military service in the armed forces of the United States or active duty military service as a member of the Texas military forces, as defined by §437.001 of the Texas Government Code (relating to Definitions), or similar military service of another state.

(2) "Armed forces of the United States" means the army, navy, air force, space force, coast guard, or marine corps of the United States or a reserve unit of one of those branches of the armed forces.

(3) "Military service member" means a person who is on active duty.

(4) "Military spouse" means a person who is married to a military service member.

(5) "Military veteran" means a person who has served on active duty and who was discharged or released from active duty.

(6) "Scope of practice" means a licensed Certified Public Accountant.

~~[(6) "Restrictive license" includes the following or its equivalent:]~~

~~[(A) an individual license that does not permit the attest service practice;]~~

~~[(B) an individual's retired or disabled license that limits an individual's authority to practice public accountancy;]~~

~~[(C) an individual's non-public industry license or authorization to practice; or]~~

~~[(D) a license that limits the scope of the individual's right to practice public accountancy.]~~

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 September 18, 2025.

TRD-202503299
J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Earliest possible date of adoption: November 2, 2025
For further information, please call: (512) 305-7842

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22 TAC §516.2

The Texas State Board of Public Accountancy (Board) proposes an amendment to §516.2 concerning Licensing for Military Service Members and Spouses.

Background, Justification and Summary

The proposed rule revision bundles the persons affected into one rule, requires the issuance of a license within 10 days of a complete application, directs the issuance of a license to a licensee of another state in good standing licensed as a CPA and defines good standing.

Fiscal Note

William Treacy, Executive Director of the Board, has determined that for the first five-year period the proposed amendment is in effect, there will be no additional estimated cost to the state, no estimated reduction in costs to the state and to local governments, and no estimated loss or increase in revenue to the state, as a result of enforcing or administering the amendment.

Public Benefit

The adoption of the proposed rule amendment will incorporate the provisions of the new legislation into the board's rule providing greater notice to the public of the accommodations.

Probable Economic Cost and Local Employment Impact

Mr. Treacy, Executive Director, has determined that there will be no probable economic cost to persons required to comply with the amendment and a Local Employment Impact Statement is not required because the proposed amendment will not affect a local economy.

Small Business, Rural Community and Micro-Business Impact Analysis

William Treacy, Executive Director, has determined that the proposed amendment will not have an adverse economic effect on small businesses, rural communities or micro-businesses because the amendment does not impose any duties or obligations upon small businesses, rural communities or micro-businesses; therefore, an Economic Impact Statement and a Regulatory Flexibility Analysis are not required.

Government Growth Impact Statement

William Treacy, Executive Director, has determined that for the first five-year period the amendment is in effect, the proposed rule: does not create or eliminate a government program; does

not create or eliminate employee positions; does not increase or decrease future legislative appropriations to the Board; does not increase or decrease fees paid to the Board; does not create a new regulation; limits the existing regulation; does not increase or decrease the number of individuals subject to the proposed rule's applicability; and does not positively or adversely affect the state's economy.

Takings Impact Assessment

No takings impact assessment is necessary because there is no proposed use of private real property as a result of the proposed rule revision.

The requirement related to a rule increasing costs to regulated persons does not apply to the Texas State Board of Public Accountancy because the rule is being proposed by a self-directed semi-independent agency. (§2001.0045(c)(8))

Public Comment

Written comments may be submitted to J. Randel (Jerry) Hill, General Counsel, Texas State Board of Public Accountancy, 505 E. Huntland Dr., Suite 380, Austin, Texas 78752 or faxed to his attention at (512) 305-7854, no later than noon on November 3, 2025.

The Board specifically invites comments from the public on the issues of whether or not the proposed amendment will have an adverse economic effect on small businesses. If the proposed rule is believed to have an adverse effect on small businesses, estimate the number of small businesses believed to be impacted by the rule, describe and estimate the economic impact of the rule on small businesses, offer alternative methods of achieving the purpose of the rule; then explain how the Board may legally and feasibly reduce that adverse effect on small businesses considering the purpose of the statute under which the proposed rule is to be adopted; and finally, describe how the health, safety, environmental, and economic welfare of the state will be impacted by the various proposed methods. See Texas Government Code, §2006.002(c).

Statutory Authority

The amendment is proposed under the Public Accountancy Act ("Act"), Texas Occupations Code §901.151, which authorizes the Board to adopt rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by this proposed amendment.

§516.2. Licensing for Military Service Members, Military Veteran and Military Spouses.

(a) The board will issue a license to a [~~A~~] military service member, military veteran or military spouse who: [~~may obtain a license if the applicant for licensure:~~]

[~~(1) through the fingerprinting process, has been deemed to have an acceptable criminal history according to Chapter 53 of the Texas Occupations Code (relating to Consequences of Criminal Conviction); and~~]

(1) [~~(2)~~] holds a current license as a Certified Public Accountant [~~with no restrictions~~] issued by a licensing authority of another state and is in good standing in that state and any other state the applicant may hold a license as a Certified Public Accountant [~~another jurisdiction that has licensing requirements that are substantially equivalent to the licensing requirements in this state~~]; or

(2) [~~(3)~~] held a license in this state within the five years preceding the application date [~~held a license in this state~~].

(b) The executive director may:

(1) waive any prerequisite to obtaining a license for an applicant described in subsection (a) of this section after reviewing the applicant's credentials; or

(2) consider, other methods that demonstrate the applicant is qualified to be licensed.

(c) The board will:

(1) process a military service member, military veteran or military spouse's license application, as soon as practical but no more than 10 [~~30~~] days from the date of receipt of the application, and [~~issue a non-provisional license when the board determines the applicant is qualified in accordance with board rules~~];

(A) issue a license;

(B) notify the applicant that the application is incomplete; or

(C) notify the applicant that the board does not recognize the out-of-state license because the board does not issue a license similar in scope of practice to the applicant's license.

(2) consider [~~waive the license application and examination for~~] a military service member, military veteran or military spouse applicant to be in good standing if the person:

(A) holds a license as a certified public accountant that is current, has not been suspended or revoked, and has not been voluntarily surrendered during an investigation for unprofessional conduct by the licensing authority of another state;

[~~(A) whose military service, training or education substantially meets all the requirements for a license; or~~]

(B) has not been disciplined by the licensing authority of another state with respect to the license or person's practice as a certified public accountant for which the license was issued; and

[~~(B) who holds a current license issued by another jurisdiction that has licensing requirements that are substantially equivalent to this agency's requirements; and~~]

(C) is not currently under investigation by the licensing authority of another state for unprofessional conduct related to the person's license as a certified public accountant.

(3) notify the license holder of the requirements for renewing the license in writing or by electronic means and the term of the license.

(d) A member of the military, a military veteran and a spouse of a military member who receive a license under this chapter are exempt from any increased fee or other penalty imposed by the board for failing to renew the license in a timely manner if the licensee establishes to the satisfaction of the board that the licensee failed to renew the license in a timely manner because the licensee was serving as a military service member.

(e) A military service member who holds a license is entitled to two years of additional time to complete:

(1) any continuing education requirements; and

(2) any other requirement related to the renewal of the military service member's license.

(f) The board will credit verified military service, training, or education toward the licensing requirements, other than an examination requirement, for a license issued by the board.

(g) Credit may not be awarded to an applicant who:

(1) holds a license not in good standing with another Certified Public Accountant state licensing agency; or

(2) has an unacceptable criminal history according to the law applicable to the state agency.

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 September 18, 2025.

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J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Earliest possible date of adoption: November 2, 2025
For further information, please call: (512) 305-7842

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22 TAC §516.3

The Texas State Board of Public Accountancy (Board) proposes a repeal to §516.3 concerning Licensing for Military Veterans.

Background, Justification and Summary

Repeals no longer needed, duplicative language.

Fiscal Note

William Treacy, Executive Director of the Board, has determined that for the first five-year period the proposed repeal is in effect, there will be no additional estimated cost to the state, no estimated reduction in costs to the state and to local governments, and no estimated loss or increase in revenue to the state, as a result of enforcing or administering the repeal.

Public Benefit

The adoption of the proposed repeal will make the rules easier to understand.

Probable Economic Cost and Local Employment Impact

Mr. Treacy, Executive Director, has determined that there will be no probable economic cost to persons required to comply with the repeal and a Local Employment Impact Statement is not required because the proposed repeal will not affect a local economy.

Small Business, Rural Community and Micro-Business Impact Analysis

William Treacy, Executive Director, has determined that the proposed repeal will not have an adverse economic effect on small businesses, rural communities or micro-businesses because the repeal does not impose any duties or obligations upon small businesses, rural communities or micro-businesses; therefore, an Economic Impact Statement and a Regulatory Flexibility Analysis are not required.

Government Growth Impact Statement

William Treacy, Executive Director, has determined that for the first five-year period the repeal is in effect, the proposed repeal: does not create or eliminate a government program; does not create or eliminate employee positions; does not increase or decrease future legislative appropriations to the Board; does not increase or decrease fees paid to the Board; does not create a new regulation; limits the existing regulation; does not increase or decrease the number of individuals subject to the proposed repeal's applicability; and does not positively or adversely affect the state's economy.

Takings Impact Assessment

No takings impact assessment is necessary because there is no proposed use of private real property as a result of the proposed repeal.

The requirement related to a rule increasing costs to regulated persons does not apply to the Texas State Board of Public Accountancy because the rule is being proposed by a self-directed semi-independent agency. (§2001.0045(c)(8))

Public Comment

Written comments may be submitted to J. Randel (Jerry) Hill, General Counsel, Texas State Board of Public Accountancy, 505 E. Huntland Dr., Suite 380, Austin, Texas 78752 or faxed to his attention at (512) 305-7854, no later than noon on November 3, 2025.

The Board specifically invites comments from the public on the issues of whether or not the proposed repeal will have an adverse economic effect on small businesses. If the proposed rule repeal is believed to have an adverse effect on small businesses, estimate the number of small businesses believed to be impacted by the rule, describe and estimate the economic impact of the rule repeal on small businesses, offer alternative methods of achieving the purpose of the rule repeal; then explain how the Board may legally and feasibly reduce that adverse effect on small businesses considering the purpose of the statute under which the proposed rule is to be repealed; and finally, describe how the health, safety, environmental, and economic welfare of the state will be impacted by the various proposed methods. See Texas Government Code, §2006.002(c).

Statutory Authority

The repeal is proposed under the Public Accountancy Act ("Act"), Texas Occupations Code §901.151, which authorizes the Board to adopt rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by this proposed repeal.

§516.3. Licensing for Military Veterans.

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 September 18, 2025.

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J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
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For further information, please call: (512) 305-78422

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22 TAC §516.4

The Texas State Board of Public Accountancy (Board) proposes an amendment to §516.4 concerning Accounting Practice Notification by Military Service Members and Spouses.

Background, Justification and Summary

The proposed rule revision identifies the elements of an acceptable license application for military members, spouses and veterans eligible for the license.

Fiscal Note

William Treacy, Executive Director of the Board, has determined that for the first five-year period the proposed amendment is in effect, there will be no additional estimated cost to the state, no estimated reduction in costs to the state and to local governments, and no estimated loss or increase in revenue to the state, as a result of enforcing or administering the amendment.

Public Benefit

The adoption of the proposed rule amendment will provide greater notice to the public of the accommodations.

Probable Economic Cost and Local Employment Impact

Mr. Treacy, Executive Director, has determined that there will be no probable economic cost to persons required to comply with the amendment and a Local Employment Impact Statement is not required because the proposed amendment will not affect a local economy.

Small Business, Rural Community and Micro-Business Impact Analysis

William Treacy, Executive Director, has determined that the proposed amendment will not have an adverse economic effect on small businesses, rural communities or micro-businesses because the amendment does not impose any duties or obligations upon small businesses, rural communities or micro-businesses; therefore, an Economic Impact Statement and a Regulatory Flexibility Analysis are not required.

Government Growth Impact Statement

William Treacy, Executive Director, has determined that for the first five-year period the amendment is in effect, the proposed rule: does not create or eliminate a government program; does not create or eliminate employee positions; does not increase or decrease future legislative appropriations to the Board; does not increase or decrease fees paid to the Board; does not create a new regulation; limits the existing regulation; does not increase or decrease the number of individuals subject to the proposed rule's applicability; and does not positively or adversely affect the state's economy.

Takings Impact Assessment

No takings impact assessment is necessary because there is no proposed use of private real property as a result of the proposed rule revision.

The requirement related to a rule increasing costs to regulated persons does not apply to the Texas State Board of Public Accountancy because the rule is being proposed by a self-directed semi-independent agency. (§2001.0045(c)(8))

Public Comment

Written comments may be submitted to J. Randel (Jerry) Hill, General Counsel, Texas State Board of Public Accountancy, 505 E. Huntland Dr., Suite 380, Austin, Texas 78752 or faxed to his attention at (512) 305-7854, no later than noon on November 3, 2025.

The Board specifically invites comments from the public on the issues of whether or not the proposed amendment will have an adverse economic effect on small businesses. If the proposed rule is believed to have an adverse effect on small businesses, estimate the number of small businesses believed to be impacted by the rule, describe and estimate the economic impact of the rule on small businesses, offer alternative methods of achieving the purpose of the rule; then explain how the Board may legally and feasibly reduce that adverse effect on small businesses considering the purpose of the statute under which the proposed rule is to be adopted; and finally, describe how the health, safety, environmental, and economic welfare of the state will be impacted by the various proposed methods. See Texas Government Code, §2006.002(c).

Statutory Authority

The amendment is proposed under the Public Accountancy Act ("Act"), Texas Occupations Code §901.151, which authorizes the Board to adopt rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by this proposed amendment.

§516.4. Accounting Practice [~~Notification~~] by Military Service Members and Military Spouses.

(a) This section applies to all board regulated public accountancy practice requirements, other than the examination requirement, by a military service member or military spouse [~~not requiring a license~~].

(b) A military service member or military spouse who holds a license as a Certified Public Accountant from another state in good standing may practice accounting in Texas during the period the military service member or military spouse is stationed at a military installation in Texas if the military service member or military spouse:

(1) submits an application, on a form provided by the board, to practice accounting in Texas;

[~~(1) may practice accounting in Texas during the period the military service member or military spouse is stationed at a military installation in Texas for a period not to exceed the third anniversary of the date the military service member or military spouse receives confirmation of authorization to practice by the board, if the military service member or military spouse:~~]

[~~(A) notifies the board of an intent to practice public accountancy in this state;~~]

[~~(B) submits proof of residency in this state along with a copy of their military identification card;~~]

[~~(C) receives from the board confirmation that the board has verified the license in the other jurisdiction and that the other jurisdiction has licensing requirements that are substantially equivalent to the board's licensing requirements; and~~]

[~~(D) receives confirmation of authorization to practice public accountancy in Texas from the board;~~]

(2) submits a copy of their military orders showing relocation to this state or identification card;

[(2) may not practice in Texas with a restricted license issued by another jurisdiction nor practice with an unacceptable criminal history according to Chapter 53 of the Texas Occupations Code (relating to Consequences of Criminal Conviction); and]

(3) provides a copy of a military spouse's marriage license when the person is a military spouse;

[(3) shall comply with all other laws and regulations applicable to the practice of public accountancy in this state including, but not limited to, providing attest services through a licensed accounting firm.]

(4) provides a notarized affidavit affirming under penalty of perjury that:

(A) the applicant is the person described and identified in the application;

(B) all statements in the application are true, correct and complete;

(C) the applicant understands the scope of the practice for the license and will not perform outside that scope; and

(D) the applicant is in good standing in each state in which the applicant holds or has held a license as a Certified Public Accountant.

(5) receives from the board confirmation that the board has verified the license has been issued in another state and is in good standing; and

(6) receives confirmation of authorization to practice public accountancy in Texas.

[(c) The board, in no less than 30 days following the receipt of notice of intent, will provide confirmation of authorization to practice to a military service member or military spouse, who has satisfied the board's rules.]

[(d) In the event of a divorce or similar event that affects a person's status as a military spouse, the spouse may continue to engage in the business or occupation under the authority of this section until the third anniversary of the date the spouse received the confirmation described by subsection (b)(1)(D) of this section.]

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 September 18, 2025.

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J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Earliest possible date of adoption: November 2, 2025
For further information, please call: (512) 305-7842

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22 TAC §516.5

The Texas State Board of Public Accountancy (Board) proposes new §516.5 concerning Complaints.

Background, Justification and Summary

The new legislation requires to the board to retain a copy of the licensee's complaint and make it available to the public.

Fiscal Note

William Treacy, Executive Director of the Board, has determined that for the first five-year period the proposed new rule is in effect, there will be no additional estimated cost to the state, no estimated reduction in costs to the state and to local governments, and no estimated loss or increase in revenue to the state, as a result of enforcing or administering the new rule.

Public Benefit

The adoption of the proposed new rule will make available to the public of the licensee's disciplinary history.

Probable Economic Cost and Local Employment Impact

Mr. Treacy, Executive Director, has determined that there will be no probable economic cost to persons required to comply with the new rule and a Local Employment Impact Statement is not required because the proposed new rule will not affect a local economy.

Small Business, Rural Community and Micro-Business Impact Analysis

William Treacy, Executive Director, has determined that the proposed new rule will not have an adverse economic effect on small businesses, rural communities or micro-businesses because the new rule does not impose any duties or obligations upon small businesses, rural communities or micro-businesses; therefore, an Economic Impact Statement and a Regulatory Flexibility Analysis are not required.

Government Growth Impact Statement

William Treacy, Executive Director, has determined that for the first five-year period the new rule is in effect, the proposed rule: does not create or eliminate a government program; does not create or eliminate employee positions; does not increase or decrease future legislative appropriations to the Board; does not increase or decrease fees paid to the Board; does not create a new regulation; limits the existing regulation; does not increase or decrease the number of individuals subject to the proposed rule's applicability; and does not positively or adversely affect the state's economy.

Takings Impact Assessment

No takings impact assessment is necessary because there is no proposed use of private real property as a result of the proposed new rule.

The requirement related to a rule increasing costs to regulated persons does not apply to the Texas State Board of Public Accountancy because the rule is being proposed by a self-directed semi-independent agency. (§2001.0045(c)(8))

Public Comment

Written comments may be submitted to J. Randel (Jerry) Hill, General Counsel, Texas State Board of Public Accountancy, 505 E. Huntland Dr., Suite 380, Austin, Texas 78752 or faxed to his attention at (512) 305-7854, no later than noon on November 3, 2025.

The Board specifically invites comments from the public on the issues of whether or not the proposed new rule will have an adverse economic effect on small businesses. If the proposed new rule is believed to have an adverse effect on small businesses, estimate the number of small businesses believed to be impacted by the new rule, describe and estimate the economic impact of the rule on small businesses, offer alternative methods

of achieving the purpose of the rule; then explain how the Board may legally and feasibly reduce that adverse effect on small businesses considering the purpose of the statute under which the proposed rule is to be adopted; and finally, describe how the health, safety, environmental, and economic welfare of the state will be impacted by the various proposed methods. See Texas Government Code, §2006.002(c).

Statutory Authority

The new rule is proposed under the Public Accountancy Act ("Act"), Texas Occupations Code §901.151, which authorizes the Board to adopt rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by this proposed new rule.

§516.5. Complaints.

(a) The board shall maintain a record of each complaint made against a military service member, military veteran, or military spouse to whom the board issues a license.

(b) The board shall publish at least quarterly on the agency's Internet website the information maintained under subsection (a) of this section, including a general description of the disposition of each complaint.

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 September 18, 2025.

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J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
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For further information, please call: (512) 305-7842

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CHAPTER 521. FEE SCHEDULE

22 TAC §521.14

The Texas State Board of Public Accountancy (Board) proposes an amendment to §521.14 concerning Eligibility Fee

Background, Justification and Summary

The proposed revision deletes the four testing sections of licensing which are no longer applicable.

Fiscal Note

William Treacy, Executive Director of the Board, has determined that for the first five-year period the proposed amendment is in effect, there will be no additional estimated cost to the state, no estimated reduction in costs to the state and to local governments, and no estimated loss or increase in revenue to the state, as a result of enforcing or administering the amendment.

Public Benefit

The adoption of the proposed rule amendment will update the basis of the licensing fees.

Probable Economic Cost and Local Employment Impact

Mr. Treacy, Executive Director, has determined that there will be no probable economic cost to persons required to comply with the amendment and a Local Employment Impact Statement is not required because the proposed amendment will not affect a local economy.

Small Business, Rural Community and Micro-Business Impact Analysis

William Treacy, Executive Director, has determined that the proposed amendment will not have an adverse economic effect on small businesses, rural communities or micro-businesses because the amendment does not impose any duties or obligations upon small businesses, rural communities or micro-businesses; therefore, an Economic Impact Statement and a Regulatory Flexibility Analysis are not required.

Government Growth Impact Statement

William Treacy, Executive Director, has determined that for the first five-year period the amendment is in effect, the proposed rule: does not create or eliminate a government program; does not create or eliminate employee positions; does not increase or decrease future legislative appropriations to the Board; does not increase or decrease fees paid to the Board; does not create a new regulation; limits the existing regulation; does not increase or decrease the number of individuals subject to the proposed rule's applicability; and does not positively or adversely affect the state's economy.

Takings Impact Assessment

No takings impact assessment is necessary because there is no proposed use of private real property as a result of the proposed rule revision.

The requirement related to a rule increasing costs to regulated persons does not apply to the Texas State Board of Public Accountancy because the rule is being proposed by a self-directed semi-independent agency. (§2001.0045(c)(8))

Public Comment

Written comments may be submitted to J. Randel (Jerry) Hill, General Counsel, Texas State Board of Public Accountancy, 505 E. Huntland Dr., Suite 380, Austin, Texas 78752 or faxed to his attention at (512) 305-7854, no later than noon on November 3, 2025.

The Board specifically invites comments from the public on the issues of whether or not the proposed amendment will have an adverse economic effect on small businesses. If the proposed rule is believed to have an adverse effect on small businesses, estimate the number of small businesses believed to be impacted by the rule, describe and estimate the economic impact of the rule on small businesses, offer alternative methods of achieving the purpose of the rule; then explain how the Board may legally and feasibly reduce that adverse effect on small businesses considering the purpose of the statute under which the proposed rule is to be adopted; and finally, describe how the health, safety, environmental, and economic welfare of the state will be impacted by the various proposed methods. See Texas Government Code, §2006.002(c).

Statutory Authority

The amendment is proposed under the Public Accountancy Act ("Act"), Texas Occupations Code §901.151, which authorizes the Board to adopt rules deemed necessary or advisable to effectuate the Act.

No other article, statute or code is affected by this proposed amendment.

§521.14. Eligibility Fee.

(a) The board shall determine the UCPAE eligibility fee for each section for which an applicant is eligible and applies.

~~[(1) Auditing and Attestation]~~

~~[(2) Financial Accounting and Reporting]~~

~~[(3) Regulation]~~

~~(4) Business Environment and Concepts]~~

(b) Effective January 1, 2024, the board shall utilize the UCPAE available from the AICPA covering the following sections:

(1) auditing and attestation (AUD);

(2) business analysis and reporting (BAR);

(3) financial accounting and reporting (FAR);

(4) information systems and controls (ISC);

(5) taxation and regulation (REG); and

(6) tax compliance and planning (TCP).

(c) The eligibility fee shall be paid to the Texas State Board of Public Accountancy. This is a non-refundable fee.

(d) An applicant taking a section of the UCPAE shall pay an examination fee to NASBA, when required by NASBA.

(e) The eligibility fee may be paid electronically through the Texas Online system and applicable processing fees for the use of this service will be added to the total fee paid.

(f) Upon receipt by the board of an incomplete application, an applicant has 180 days to complete the application. If the application is not completed within that time, the application is terminated, the eligibility fee is forfeited and the applicant must file a new application and pay a new eligibility fee to continue with the examination process.

(g) The fee paid shall be valid for 180 days after the board determines that an applicant is eligible for a section of the UCPAE. The board may extend the 180-day eligibility to accommodate the psychometric evaluation and performance of test questions by the test provider.

(h) A military service member or military veteran who is eligible to take the UCPAE is exempt from the eligibility fee.

(i) The exemption from the eligibility fee must be evidenced by an active ID, state-issued driver's license with a veteran designation or DD214.

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

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J. Randel (Jerry) Hill
General Counsel
Texas State Board of Public Accountancy
Earliest possible date of adoption: November 2, 2025
For further information, please call: (512) 305-7842

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TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 229. FOOD AND DRUG
SUBCHAPTER X. LICENSING OF DEVICE DISTRIBUTORS AND MANUFACTURERS

The executive commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes amendments to §§229.432 - 229.437, 229.439 - 229.443, concerning Licensing of Device Distributors and Manufacturers, and the repeal of §229.444, concerning Device Distributors and Manufacturers Advisory Committee.

BACKGROUND AND PURPOSE

The purpose of the proposal is to continue adherence with applicable federal laws pertaining to medical devices. The proposed amendments align the minimum standards in the Texas Administrative Code with new device Good Manufacturing Practice requirements under 21 Code of Federal Regulations (CFR) Part 820, which take effect on February 2, 2026. The proposal repeals §229.444 because the advisory committee no longer exists. The proposed amendment to §229.443 adds language relating to enforcement and penalties. The proposed amendments update the licensure fees based on a licensee's gross sales. The proposed amendments update definitions to clarify intent and improve compliance by harmonizing state and federal regulations. Lastly, the proposed amendments update the rules with plain language requirements to improve readability.

SECTION-BY-SECTION SUMMARY

The proposed amendment to §229.432 replaces wording for consistency throughout this section. The proposed amendment updates the link to the DSHS website. The proposed amendment updates a federal reference.

The proposed amendment to §229.433 adds definitions to comply with CFR updates and replaces wording for consistency throughout this section. The proposed amendment provides deleted, revised, and new definitions. The proposed amendment adds clarity to the rule language and ensures consistency in interpretation of the rule. The proposed amendment updates federal reference citations.

The proposed amendment to §229.434 provides revised language to add clarity to the rule language.

The proposed amendment to §229.435 updates wording for clarity and updates DSHS contact information.

The proposed amendment to §229.436 updates the link to the DSHS website and replaces wording for consistency throughout this section.

The proposed amendment to §229.437 replaces wording for consistency throughout this section and adds clarity to rule language.

The proposed amendment to §229.439 replaces wording for consistency throughout this section and adds clarity to rule language. The proposed amendments update the licensure fees based on a licensee's gross sales. The proposed amendment updates the link to the DSHS website.

The proposed amendment to §229.440 replaces wording for consistency throughout this section.

The proposed amendment to §229.441 replaces wording for consistency throughout this section and adds clarity to rule language. The proposed amendment updates federal and state citations throughout this section. The proposed amendment expands on definitions to add clarity to rule interpretation. The proposed amendment corrects grammatical errors.

The proposed amendment to §229.442 replaces wording for consistency throughout this section.

The proposed amendment to §229.443 adds new language on general enforcement actions and penalties, and replaces wording for consistency throughout this section.

The proposed repeal of §229.444 is required because the advisory committee no longer exists.

FISCAL NOTE

Christy Havel-Burton, DSHS Chief Financial Officer, has determined that for each year of the first five years that the rules will be in effect, there will be an increase in revenue to state government because of enforcing or administering the rules as proposed. Enforcing or administering the rules does not have foreseeable implications relating to costs or revenues of local governments.

The effect on state government for each year of the first five years the proposed rules are in effect is an estimated increase in revenue of $224,884 in fiscal year (FY) 2026, $224,884 in FY 2027, $224,884 in FY 2028, $224,884 in FY 2029, and $224,884 in FY 2030.

GOVERNMENT GROWTH IMPACT STATEMENT

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

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

(2) implementation of the proposed rules will not affect the number of DSHS employee positions;

(3) implementation of the proposed rules will result in no assumed change in future legislative appropriations;

(4) the proposed rules will require an increase in fees paid to DSHS;

(5) the proposed rules will not create a new regulation;

(6) the proposed rules will expand and repeal existing regulations;

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

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

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

Christy Havel-Burton has also determined that there will be adverse economic effect on small businesses, micro-businesses, or rural communities because the rules do impose additional costs that are required to comply with the rules. DSHS estimates that the number of small businesses, micro-businesses, and rural communities subject to the proposed rules are approximately 2,480 businesses. The projected economic impact for small businesses, micro-businesses, and rural communities are a 15%-20% increase in licensure fees based on gross annual sales.

LOCAL EMPLOYMENT IMPACT

The proposed rules will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to these rules because the rules are necessary to protect the health, safety, and welfare of the residents of Texas and are necessary to receive a source of federal funds or comply with federal law.

PUBLIC BENEFIT AND COSTS

Timothy Stevenson, Deputy Commissioner, Consumer Protection Division, has determined that for each year of the first five years the rules and repeal are in effect, the public benefit will be improved rule clarity and greater compliance with updated Good Manufacturing Practices, which help ensure that medical devices produced in the state are safe and effective for their intended use.

Christy Havel Burton, Chief Financial Officer, has also determined that for the first five years the rules and repeal are in effect, there are anticipated economic costs to persons who are required to comply with the proposed repeal or the proposed amendments.

TAKINGS IMPACT ASSESSMENT

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

PUBLIC COMMENT

Written comments on the proposal may be submitted to Rules Coordination Office, P.O. Box 13247, Mail Code 4102, Austin, Texas 78711-3247, or street address 4601 West Guadalupe Street, Austin, Texas 78751; or emailed to *HHSRulesCoordinationOffice@hhs.texas.gov*.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register*. Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rules 25R022" in the subject line.

25 TAC §§229.432 - 22.437, 22.439 - 22.443

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §524.0151 and Texas Health and Safety Code §1001.075, which authorize the executive commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and the administration of Texas Health and Safety Code Chapter 1001, and by Texas Health and Safety Code §431.241.

The amendments affect Texas Government Code §524.0151 and Texas Health and Safety Code Chapters 1001 and 431.

§229.432. Applicable Laws and Regulations.

(a) The department adopts by reference the following laws and regulations:

(1) Federal Food, Drug, and Cosmetic Act, 21 United States Code, et seq., as amended;

(2) 21 Code of Federal Regulations (CFR)[,] Part 801, Labeling, as amended;

(3) 21 CFR[,] Part 803, Medical Device Reporting, as amended;

(4) 21 CFR[,] Part 807, Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices, as amended;

(5) 21 CFR[,] Part 814, Premarket Approval of Medical Devices, as amended;

(6) 21 CFR[,] Part 820, Quality Management System Regulation, as amended; and

(7) 21 CFR[,] Subchapter J--Radiological Health, as amended.

(b) Copies of these laws and regulations are indexed and filed at the department, 1100 West 49th Street, Austin, Texas 78756, and are available for inspection during normal working hours. Electronic copies of these laws and regulations are available online at https://www.dshs.texas.gov [~~http://www.dshs.state.tx.us/license.shtm~~].

(c) Nothing in these sections relieves [~~shall relieve~~] any person of the responsibility for compliance with other applicable Texas and federal laws and regulations.

§229.433. Definitions.

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

(1) Act--The Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code (HSC)[,] Chapter 431.

(2) Adulterated Device--Has the meaning specified in the Texas Food, Drug, and Cosmetic Act, HSC [~~Health and Safety Code, Chapter 431,~~] §431.111.

(3) Advertising--All representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

(4) Authorized agent--An employee of the department who is designated by the commissioner to enforce the provisions of this chapter.

(5) Commissioner--The commissioner of the Department of State Health Services, [~~Commissioner of Health~~] or the commissioner's [~~his~~] successor or designee.

(6) Counterfeit device--A device which, or the container, packaging or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark or imprint, or any likeness thereof, or is manufactured using a design, of a device manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, processor, packer, or distributor.

(7) [~~(6)~~] Department--The Department of State Health Services.

(8) [~~(7)~~] Device--An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory[~~, that is~~]:

(A) recognized in the official United States Pharmacopoeia National Formulary or any supplement to it;

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(C) intended to affect the structure or any function of the body of man or other animals and that does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and is not dependent on metabolization for the achievement of any of its principal intended purposes. The term "device" does not include software functions excluded by the Federal Food, Drug, and Cosmetic Act, 21 United States Code §360j(o).

(9) [~~(8)~~] Distributor--A person who furthers the marketing of a finished domestic or imported device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user. The term includes an importer or an own-label distributor. The term does not include a person who repackages a finished device or who otherwise changes the container, wrapper, or labeling of the finished device or the finished device package.

(10) [~~(9)~~] Electronic product radiation--Any ionizing or nonionizing electromagnetic or particulate radiation, or any sonic, infrasonic, or ultrasonic wave, that [~~which~~] is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

(11) [~~(10)~~] Finished device--A device, or any accessory to a device, that [~~which~~] is suitable for use, whether or not packaged or labeled for commercial distribution.

[~~(11) Flea market--A location at which booths or similar spaces are rented or otherwise made available temporarily to two or more persons and at which the persons offer tangible personal property for sale.~~]

(12) Health authority--A physician designated to administer state and local laws relating to public health.

(13) Importer--Any person who initially distributes a device imported into the United States.

(14) Ionizing radiation--Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter. Ionizing radiation includes gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles.

(15) Labeling--All labels and other written, printed, or graphic matter:

(A) upon any article or any of its containers or wrappers; or

(B) accompanying such article.

(16) Manufacture--The making by chemical, physical, biological, or other procedures of any article that meets the definition of device. The term includes the following activities:

(A) repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer; [~~or~~]

(B) initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications; or[.]

(C) sterilization, including contract sterilization services of a device for another establishment's devices.

(17) Manufacturer--A person who manufactures, fabricates, assembles, or processes a finished device. The term includes a person who repackages or relabels a finished device. The term does not include a person who only distributes a finished device.

(18) Misbranded Device--Has the meaning specified in the Texas Food, Drug, and Cosmetic Act, HSC [~~Health and Safety Code, Chapter 431,~~] §431.112.

(19) Person--Includes individual, partnership, corporation, and association.

(20) Place of business--Each location at which a device is manufactured or held for distribution.

(21) Practitioner--As defined in HSC §483.001(12) [~~Means a person licensed by the Texas State Board of Medical Examiners, State Board of Dental Examiners, Texas State Board of Podiatric Medical Examiners, Texas Optometry Board, or State Board of Veterinary Medical Examiners to prescribe and administer prescription devices~~].

(22) Prescription device--A restricted device that [~~which~~], because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which adequate directions for use cannot be prepared.

(23) Radiation machine--Any device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

(24) Radioactive material--Any material (solid, liquid, or gas) that emits radiation spontaneously.

(25) Reconditioning--Any appropriate process or procedure by which distressed merchandise can be brought into compliance with departmental standards as specified in the Texas Food, Drug, Device, and Cosmetic Salvage Act, HSC [~~Health and Safety Code, Chapter 432,~~] §432.003, as defined [~~interpreted~~] in the rules in §229.603 [~~§229.192~~] of this chapter [~~title~~] (relating to Definitions).

(26) Restricted device--A device subject to certain controls related to sale, distribution, or use as specified in the Federal Food, Drug, and Cosmetic Act, 21 United States Code §360(j) [~~as amended, §520(e)(1)~~].

§229.434. Exemptions.

(a) A person is exempt from licensing under §229.435 of this subchapter [~~title~~] (relating to Licensure Requirements) if the person engages only in the following types of device distribution:

(1) intracompany sales;

(2) distribution from a place of business located outside the State of Texas; or

(3) the sale, purchase, or trade of a distressed or reconditioned device by a salvage broker or a salvage operator licensed under §229.605 of this chapter [~~title~~] (relating to Licensing Requirements and Procedures).

(b) A person is exempt from licensing under §229.435 of this subchapter [~~title~~] if the person holds a registration certificate issued under Texas Occupations Code[,] Chapter 266[,] and engages only in conduct within the scope of that registration.

(c) A person is exempt from licensing under §229.435 of this subchapter if the person is exempted from licensing under Texas Occupations Code §605.2515 and engages only in conduct within the scope of that exemption.

(d) [~~(c)~~] This section does not exempt a person from other applicable provisions of the Texas Food, Drug, and Cosmetic Act, HSC [~~Health and Safety Code,~~] Chapter 431; the Texas Dangerous Drug Act, HSC [~~Health and Safety Code,~~] Chapter 483; or the rules adopted to administer and enforce those chapters.

§229.435. Licensure Requirements.

(a) General. A [~~Except as provided by §229.434 of this title (relating to Exemptions), a~~] person may not distribute [~~engage in the distribution~~] or manufacture [~~of~~] devices in Texas unless the person has a valid license from the commissioner [~~Commissioner of the Department of State Health Services (commissioner)~~] for each place of business, unless exempted by §229.434 of this subchapter (relating to Exemptions).

(b) Proof [~~Display~~] of licensure [~~license~~]. The license holder must show proof of licensure in a format readily available to the [~~shall be displayed in an open~~] public [~~area at each place of business~~].

(c) Existing place of business. Each person distributing or manufacturing [~~involved in the distribution or manufacture of~~] devices in Texas on the effective date of these sections must apply for a device distributor or manufacturer license no later than 60 days following the effective date [~~of these sections~~].

(d) New place of business. Each person who acquires or establishes [~~acquiring or establishing~~] a place of business to distribute or manufacture devices must [~~for the purpose of device distribution or manufacturing after the effective date of these sections shall~~] apply to the department [~~Department of State Health Services (department)~~] for a license before [~~of such business prior to~~] beginning operations [~~operation~~].

(e) Two or more places of business. If the device distributor or manufacturer operates more than one place of business, the device distributor or manufacturer must [~~shall~~] license each place of business separately.

(f) Issuance of license. Under [~~In accordance with~~] §229.281 of this chapter [~~title~~] (relating to Processing License/Permit Applications Relating to Food and Drug Operations), the department may issue a license to a device distributor or manufacturer [~~of devices~~] who meets all applicable [~~the~~] requirements [~~of these sections,~~] and pays all fees as required by [~~in compliance with~~] §229.439 of this subchapter (relating to Licensure Fees) [~~title (relating to Licensing Fees)~~].

(g) Transfer of license. A person may not transfer a license to another person or to a different place of business [~~Licenses shall not be transferable from one person to another or from one place of business to another~~].

(h) License term. A license remains valid for two years unless it [~~Unless the license~~] is amended under [~~as provided in~~] subsection (j) of this section or revoked or suspended under [~~as provided in~~] §229.440 of this subchapter (relating to Refusal, Cancellation, Suspension, or Revocation of License [~~title (relating to Refusal, Cancellation, Suspension, or Revocation of a License), the license is valid for two years~~].

(i) Renewal of license.

(1) A person must submit the [~~The~~] license application [~~as~~] outlined in §229.436(b) of this subchapter [~~title~~] (relating to Licensing Procedures) and must pay the nonrefundable license fee [~~licensing fees as outlined in §229.439 of this title (relating to Licensing Fees)~~] for each place of business as outlined in §229.439 of this subchapter before [~~shall be submitted to the department prior to the expiration date of~~] the current license expires. A person who submits [~~files~~] a renewal application after the expiration date must pay a [~~an additional~~] $100 [~~as a~~] delinquency fee.

(2) A licensee who fails to submit a renewal application before the license [~~prior to the current licensure~~] expiration date and continues to operate [~~operations~~] may be subject to [~~the~~] enforcement and penalties under [~~penalty provisions in~~] §229.443 of this subchapter [~~title~~] (relating to Enforcement and Penalties) and to[~~, and/or the~~] revocation or [~~and~~] suspension of the license under [~~provisions in~~] §229.440 of this subchapter [~~title~~].

(3) The department must issue a renewal license only after receiving [~~A renewal license shall only be issued when~~] all past due fees [~~and delinquency fees are paid~~].

(j) Amendment of license. To amend a license, including a name change, or a change in the location of a licensed business, a person must submit [~~A license that is amended, including a change of name, ownership, or a notification of a change in the location of a licensed place of business will require submission of~~] an application as outlined in §229.436 of this subchapter and pay the applicable [~~title (relating to Licensing Procedures) and submission of~~] fees as outlined in §229.439 of this subchapter [~~title (relating to Licensing Fees)~~].

(k) Notification of change of location of place of business. [~~Not fewer than 30 days in advance of the change, the licensee shall notify the commissioner or the commissioner's designee in writing of the licensee's intent to change the location of a licensed place of business. The notice shall include the address of the new location, and the name and residence address of the individual in charge of the business at the new location. Not more than ten days after the completion of the change of location, the licensee shall notify the commissioner or the commissioner's designee in writing to verify the change of location, the specific date of change, the new location, the address of the new location, and the name and residence address of the individual in charge of the business at the new address. Notice will be deemed adequate if the licensee provides the intent and verification notices to the commissioner or the commissioner's designee by certified mail, return receipt requested, mailed to the department, 1100 West 49th Street, Austin, Texas.~~]

(1) At least 30 days before changing the location of place of business, the licensee must notify the commissioner or the commissioner's designee in writing of their intent to change locations of place of business. The notice must include address of new business location; name of person in charge of business at new location; and residence address of person in charge of business at new location.

(2) Within 10 days of completing the move, the licensee must notify the commissioner or the commissioner's designee by submitting an application to verify: change of location; specific date of move; new location; new location's address; name of person in charge of new business location; and residence address of person in charge of new business location.

(3) If the licensee provides the intent and application to the commissioner or commissioner's designee by certified mail (with return receipt requested), the notice will be deemed adequate. The intent and verification notice should be mailed to the department at 1100 West 49th Street, Austin, Texas 78756.

(l) Combination products. If the United States Food and Drug Administration determines that a combination product's [~~, with respect to a product that is a combination of a drug and a device, that the~~] primary mode of action [~~of the product~~] is that of [~~as~~] a device, a distributor or manufacturer of the product is subject to licensure as described in this section.

(m) Texas.gov [~~Texas Online~~]. Applicants may submit initial and renewal license applications electronically at www.texas.gov [~~under these sections electronically by the Internet through Texas Online at www.texasonline.state.tx.us~~]. The department is authorized to collect fees, in amounts determined by the Texas Online Authority, to recover costs of processing applications and renewals through the website [~~associated with application and renewal application processing through Texas Online~~].

§229.436. Licensing Procedures.

(a) License application forms. Applicants may obtain application forms online at www.texas.gov or from the department at [~~License application forms may be obtained from the department,~~] 1100 West 49th Street, Austin, Texas, 78756 [~~or online at http://dshs.state.tx.us/license.shtm~~].

(b) Contents of license application. The applicant must complete and submit a license application form provided by the department. The application must be signed, verified, and include [~~The application for licensure as a device distributor or manufacturer shall be signed and verified, submitted on a license application form furnished by the department, and contain the following information~~]:

(1) the name of the legal entity being [~~to be~~] licensed, including the name under which the business operates [~~is conducted~~];

(2) the address of each licensed place of business [~~that is licensed~~];

(3) the ownership details:

(A) if a proprietorship, the name and residence address of the proprietor;

(B) if a partnership, the names and residence addresses of all partners;

(C) if a corporation, the date and place of incorporation and name and address of its registered agent in the state and corporation charter number; or

(D) if any other type of association, then the names of the principals of such association;

[~~(3) if a proprietorship, the name and residence address of the proprietor; if a partnership, the names and residence addresses of all partners; if a corporation, the date and place of incorporation and name and address of its registered agent in the state and corporation charter number; or if any other type of association, then the names of the principals of such association;~~]

(4) the individual details, including the name, residence address, and valid driver license number for each individual in an [~~actual~~] administrative role: [~~capacity which,~~]

(A) for proprietorships, [~~in the case of proprietorship, shall be~~] the managing proprietor;

(B) for partnerships [~~partnership~~], the managing partner;

(C) for corporations [~~corporation~~], the officers and directors; or

(D) for any other type of association, those in a managerial capacity [~~in any other type of association~~];

(5) [~~for each place of business,~~] the residence address of the individual in charge at each place of business [~~thereof~~];

(6) selection [~~a list~~] of categories for calculation [~~which must be marked and adhered to in the determination~~] and payment of [~~the~~] fee; and

(7) a signature of verification by the applicant [~~statement verified by the applicant's signature~~] that acknowledges the applicant has read, understood, and agrees to abide by the provisions of these sections and those of the Texas Food, Drug, and Cosmetic Act, HSC [~~Health and Safety Code,~~] Chapter 431.

(c) Renewal license application. The renewal application for licensure as a device distributor or manufacturer must [~~shall~~] be made on a license application form furnished by the department.

§229.437. Report of Changes.

The license holder must [~~shall~~] notify the department in writing within 10 [~~ten~~] days of any change that [~~which~~] would render the information contained in the application for the license, as outlined in [~~reported pursuant to~~] §229.436 of this subchapter [~~title~~] (relating to Licensing Procedures), no longer accurate. Failure to notify [~~inform~~] the department within 10 days [~~no later than ten days of a change in the information required in the application for a license~~] may result in administrative penalties [~~a suspension or revocation of the license~~].

§229.439. Licensure Fees.

(a) License fee.

(1) A person must obtain a license from the department before operating or conducting business as a device distributor. [~~No person may operate or conduct business as a device distributor without first obtaining a license from the department.~~] All applicants for a device distributor license or a renewal license must [~~shall~~] pay a non-refundable licensing fee. The department issues licenses for [~~All fees are nonrefundable. Licenses are issued for~~] two-year terms and will [~~. A license shall~~] only issue a license [~~be issued~~] when all past due [~~fees and delinquency~~] fees are paid. License fees are based on gross annual device sales.

(A) For a distributor with gross annual device sales of $0 - $499,999.99, the fees are:

(i) $552 [~~$480~~] for a two-year license;

(ii) $552 [~~$480~~] for a two-year license for [~~that is amended due to~~] a change of ownership; and

(iii) $276 [~~$240~~] for a license [~~that is~~] amended during the current licensure period for [~~due to~~] minor changes.

(B) For a distributor with gross annual device sales of $500,000 - $9,999,999.99, the fees are:

(i) $1,296 [~~$1,080~~] for a two-year license;

(ii) $1,296 [~~$1,080~~] for a two-year license for [~~that is amended due to~~] a change of ownership; and

(iii) $648 [~~$540~~] for a license [~~that is~~] amended during the current licensure period for [~~due to~~] minor changes.

(C) For a distributor with gross annual device sales greater than or equal to $10 million, the fees are:

(i) $2,016 [~~$1,680~~] for a two-year license;

(ii) $2,016 [~~$1,680~~] for a two-year license for [~~that is amended due to~~] a change of ownership; and

(iii) $1,008 [~~$840~~] for a license [~~that is~~] amended during the current licensure period for [~~due to~~] minor changes.

(2) If a [~~A~~] person who is required to be licensed as a device distributor under this section [~~and who~~] is also required to be licensed as a wholesale drug distributor under §229.246(a) of this chapter (relating to Licensure Requirements) [~~§229.252(a)(1) of this title (relating to Licensing Fee and Procedures)~~] or [~~as~~] a wholesale food distributor under §229.182(a)(3) of this chapter (relating to Licensing/Registration Fee and Procedures), the person must [~~title (relating to Licensing Fee and Procedures) shall~~] pay a combined non-refundable [~~licensure~~] fee for each place of business. The department issues licenses for two-year terms and will only issue a license [~~All fees are nonrefundable. Licenses are issued for two-year terms. A license shall only be issued~~] when all past due [~~fees and delinquency~~] fees are paid. License fees are based on [~~the combined~~] gross annual device sales [~~of these regulated products (foods, drugs, and/or devices)~~].

(A) For each place of business having combined gross annual sales of $0 - $199,999.99, the fees are:

(i) $598 [~~$520~~] for a two-year license;

(ii) $598 [~~$520~~] for a two-year license for [~~that is amended due to~~] a change of ownership; and

(iii) $299 [~~$260~~] for a license [~~that is~~] amended during the current licensure period for [~~due to~~] minor changes.

(B) For each place of business having combined gross annual sales of $200,000 - $499,999.99, the fees are:

(i) $897 [~~$780~~] for a two-year license;

(ii) $897 [~~$780~~] for a two-year license for [~~that is amended due to~~] a change of ownership; and

(iii) $449 [~~$390~~] for a license [~~that is~~] amended during the current licensure period for [~~due to~~] minor changes.

(C) For each place of business having combined gross annual sales of $500,000 - $999,999.99, the fees are:

(i) $1,248 [~~$1,040~~] for a two-year license;

(ii) $1,248 [~~$1,040~~] for a two-year license for [~~that is amended due to~~] a change of ownership; and

(iii) $624 [~~$520~~] for a license [~~that is~~] amended during the current licensure period for [~~due to~~] minor changes.

(D) For each place of business having combined gross annual sales of $1 million - $9,999,999.99, the fees are:

(i) $1,560 [~~$1,300~~] for a two-year license;

(ii) $1,560 [~~$1,300~~] for a two-year license for [~~that is amended due to~~] a change of ownership; and

(iii) $780 [~~$650~~] for a license [~~that is~~] amended during the current licensure period for [~~due to~~] minor changes.

(E) For each place of business having combined gross annual sales greater than or equal to $10 million, the fees are:

(i) $2,340 [~~$1,950~~] for a two-year license;

(ii) $2,340 [~~$1,950~~] for a two-year license for [~~that is amended due to~~] a change of ownership; and

(iii) $1,170 [~~$975~~] for a license [~~that is~~] amended during the current licensure period for [~~due to~~] minor changes.

(3) A person must first obtain a license from the department to operate and conduct business as a device manufacturer in Texas [~~No~~

person may operate or conduct business as a device manufacturer in this state without first obtaining a license from the department]. All applicants for a device manufacturer license or renewal license must [shall] pay a nonrefundable licensing fee. The department issues licenses [All fees are nonrefundable. Licenses are issued] for two-year terms and will [. A license shall] only issue a license [be issued] when all past due [fees and delinquency] fees are paid. License fees are based on gross annual device sales.

(A) For a manufacturer with gross annual device sales of $0 - $499,999.99, the fees are:

(i) $552 [$480] for a two-year license;

(ii) $552 [$480] for a two-year license for [that is amended due to] a change of ownership; and

(iii) $276 [$240] for a license [that is] amended during the current licensure period for [due to] minor changes.

(B) For a manufacturer with gross annual device sales of $500,000 - $9,999,999.99, the fees are:

(i) $2,592 [$2,160] for a two-year license;

(ii) $2,592 [$2,160] for a two-year license for [that is amended due to] a change of ownership; and

(iii) $1,296 [$1,080] for a license [that is] amended during the current licensure period for [due to] minor changes.

(C) For a manufacturer with gross annual device sales greater than or equal to $10 million, the fees are:

(i) $4,320 [$3,600] for a two-year license;

(ii) $4,320 [$3,600] for a two-year license for [that is amended due to] a change of ownership; and

(iii) $2,160 [$1,800] for a license [that is] amended during the current licensure period for [due to] minor changes.

(b) Texas.gov [Texas Online]. Applicants may submit initial [applications] and renewal license applications [for a license under these sections] electronically through www.texas.gov [by the Internet through Texas Online at www.texasonline.state.tx.us]. The department is authorized to collect fees, in amounts determined by the Texas Online Authority, to recover costs of [associated with application and renewal application] processing applications and renewals through the website [through Texas Online].

(c) Exemption from licensing fees. A person is exempt from the licensing fees required by this section if the person [is]:

(1) is licensed under §289.252 of this title (relating to Licensing of Radioactive Material) or registered under §289.226 of this title (relating to Registration of Radiation Machine Use and Services) and engages only in the following activities [types of device distribution or manufacturing]:

(A) manufacturing [the manufacture] or distributing [distribution] of radiation machines that [which] are devices; or

(B) manufacturing [the manufacture] or distributing [distribution] of devices that [which] contain radioactive materials; or

(2) is a charitable organization, as described in the Internal Revenue Code of 1986[,] §501(c)(3), or a nonprofit affiliate of one, where [the organization, to the extent otherwise] permitted by law.

(d) Sale of food, drugs, or devices. This section includes the manufacture, production, processing, packaging, exposure, offer, possession, and holding of any of the regulated articles for sale; the sale, dispensing, and giving of any regulated article; and supplying or applying of any regulated articles in the operation of any food, drug, or device place of business.

§229.440. Refusal, Cancellation, Suspension, or Revocation of License.

(a) The commissioner may refuse an application or may suspend or revoke a license if the applicant or licensee:

(1) has been convicted of a felony or misdemeanor that involves moral turpitude;

(2) is an association, partnership, or corporation and the managing officer has been convicted of a felony or misdemeanor that involves moral turpitude;

(3) has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(4) is an association, partnership, or corporation and the managing officer has been convicted in state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(5) has violated any of the provisions of the Texas Food, Drug, and Cosmetic Act, HSC [Health and Safety Code,] Chapter 431 (Act) or these sections;

(6) has failed to pay any fees for licensing [a license fee] or [a] renewal [fee for a license]; [or]

(7) has failed to pay administrative penalties in full more than 30 days after the decision or order assessing the penalty is final, and has not filed a petition for judicial review of the order assessing the penalty; or

(8) [(7)] has obtained or attempted to obtain a license by fraud or deception.

(b) The commissioner may refuse an application for a license or may suspend or revoke a license if the commissioner determines from evidence presented during a hearing that the applicant or licensee:

(1) has violated HSC [the Health and Safety Code,] §431.021(l)(3), concerning the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(2) has violated HSC Chapter 481 (Texas Controlled Substances Act) [the Health and Safety Code, Chapter 481 (Texas Controlled Substance Act)], or HSC Chapter 483 (Texas Dangerous Drug Act) [the Health and Safety Code, Chapter 483 (Dangerous Drugs Act)]; or

(3) has violated [the] rules established by [of] the director of the Department of Public Safety, including being responsible for a significant discrepancy in [the] records the applicant or licensee is required to maintain under state law [that state law requires the applicant or licensee to maintain].

(c) After [The department may, after] providing an opportunity for a hearing, the department may refuse, suspend, or revoke a license for a device distributor or manufacturer if the applicant violates any [refuse to license a distributor or manufacturer of devices, or may suspend or revoke a license for violations of the] requirements in these sections or for any [of the] reasons described in the Act.

(d) Any hearings for the refusal, revocation, or suspension of a license are governed by §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures).

(e) A license issued under these sections must [~~shall~~] be returned to the department if the device distributor's or manufacturer's place of business:

(1) ceases business or otherwise ceases operation on a permanent basis;

(2) relocates; or

(3) changes name or ownership. A corporation transferring 5.0% or more of the share of stock from one person to another is considered to have had an ownership change and must return the license to the department [~~For a corporation, an ownership change is deemed to have occurred, resulting in the necessity to return the license to the department, when 5.0% or more of the share of stock of a corporation is transferred from one person to another~~].

§229.441. Minimum Standards for Licensure.

(a) Minimum requirements. All device distributors or manufacturers [~~of devices~~] engaged in the design, manufacture, packaging, labeling, storage, installation, and servicing of devices must comply with the minimum standards of this section, in addition to the statutory requirements contained in the Texas Food, Drug, and Cosmetic Act, HSC [~~Health and Safety Code,~~] Chapter 431 (Act). For the purpose of this section, the department adopts the policies described in the United States Food and Drug Administration's (FDA's) Compliance Policy Guides relating [~~as they apply~~] to devices [~~shall be the policies of the Department of State Health Services (department)~~].

(b) Federal establishment registration and device listing. All persons who operate as device distributors or manufacturers in Texas must [~~shall~~] meet the applicable requirements in 21 Code of Federal Regulations (CFR)[~~,~~] Part 807, relating to Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices. [~~titled "Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices."~~] Devices distributed by device distributors or manufacturers must [~~shall~~] have met, if applicable, the premarket notification requirements of 21 CFR[~~,~~] Part 807 or the premarket approval provisions of 21 CFR[~~,~~] Part 814, relating to Premarket Approval of Medical Devices. [~~titled "Premarket Approval of Medical Devices."~~]

(c) Good manufacturing practices. Device distributors or manufacturers engaged in the design, manufacture, packaging, labeling, storage, installation, and servicing of finished devices must comply [~~shall be in compliance~~] with the applicable requirements of 21 CFR[~~,~~] Part 820, relating to Quality Management System Regulation. [~~titled "Quality System Regulation."~~] The requirements in this part govern the methods, facilities, and controls used to [~~in, and the facilities and controls used for, the~~] design, manufacture, package, label, store, install, and service [~~packaging, labeling, storage, installation, and servicing of~~] all finished devices intended for human use.

(d) Buildings and facilities.

(1) Manufacturers must conduct all [~~All~~] manufacturing, assembling, packaging, packing, holding, testing, or labeling of devices [~~by manufacturers shall take place~~] in buildings and facilities described in 21 CFR §820.45, relating to Device Labeling and Packaging Controls. [~~21 CFR, Part 820, Subpart L, titled "Handling, Storage, Distribution, and Installation."~~]

(2) Manufacturers and distributors must not conduct any [~~No~~] manufacturing, assembling, packaging, packing, holding, testing, or labeling operations of devices [~~by manufacturers or distributors shall be conducted~~] in any personal residence or any room used as a living area. Manufacturers and distributors must not manufacture or hold devices in any room used as living or sleeping quarters. All device manufacturing and storage must be completely separated from any living or sleeping quarters by a full partition.

(3) Any place of business used by a distributor to store, warehouse, hold, offer, transport, or display devices must [~~shall~~]:

(A) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(B) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, and space;

(C) have a designated quarantine area, physically separate from other devices, for storing [~~storage of devices that are~~] outdated, damaged, deteriorated, misbranded, or adulterated devices until the quarantined devices are destroyed or returned to the supplier;

(D) be maintained in a clean and orderly condition, including keeping walls, ceilings, windows, doors, and floors clean, in good repair, and properly maintained; and

(E) be free from infestation by insects, rodents, birds, or vermin of any kind.

(e) Storage of devices. All devices stored by distributors must [~~shall~~] be in-date, not damaged, and held at appropriate temperatures and in [~~under~~] appropriate conditions under any labeling [~~in accordance with~~] requirements[~~, if any, in the labeling~~] of such devices.

(f) Device labeling. Devices distributed by device distributors or manufacturers must [~~shall~~] meet the labeling requirements of the Act and 21 CFR[~~,~~] Part 801, relating to Labeling. [~~titled "Labeling."~~]

(g) Device labeling exemptions. Exemptions of [~~Device~~] labeling or packaging of devices [~~exemptions~~] adopted under the Federal Food, Drug, and Cosmetic Act must [~~, as amended, shall~~] apply to devices in Texas, unless [~~except insofar as~~] modified or rejected by rules of the executive commissioner [~~Executive Commissioner~~] of the Health and Human Services Commission.

(h) Reconditioned devices. Reconditioned devices must comply with the provisions of the Act and these sections and are subject to the provisions of the Texas Food, Drug, Device, and Cosmetic Salvage Act, HSC [~~Health and Safety Code,~~] Chapter 432.

(i) Medical device reporting. Device distributors or manufacturers must [~~shall~~] meet the applicable medical device reporting requirements of 21 CFR[~~,~~] Part 803, relating to Medical Device Reporting [~~titled "Medical Device Reporting"~~].

(j) Radiation emitting devices. Device distributors or manufacturers that distribute devices emitting [~~Devices which emit~~] electronic product radiation must [~~and are distributed by device distributors or manufacturers shall~~] meet the applicable requirements of the Act and 21 CFR[~~,~~] Subchapter J, relating to Radiological Health. [~~titled "Radiological Health."~~]

(k) Distribution of prescription devices.

(1) A prescription device in the possession of a device distributor or manufacturer licensed under these sections of this subchapter is exempt from HSC §431.112(e)(1) [~~Health and Safety Code, §431.112 (f)(1)~~], relating to labeling bearing adequate directions for use, providing it meets the requirements of 21 CFR §801.109, Prescription Devices, and §801.110, Retail Exemption for Prescription Devices [~~21 CFR, §801.109, titled "Prescription devices" and 801.110, titled "Retail exemption for prescription devices"~~].

(2) Each device distributor or manufacturer who distributes prescription devices must [~~shall~~] maintain a record for every prescription device. The records kept must include the identity of the device, the quantity received or manufactured, and the disposition of each de-

vice [~~, showing the identity and quantity received or manufactured and the disposition of each device~~].

(3) Each device distributor or manufacturer who delivers a prescription device to the ultimate user must [~~shall~~] maintain a record of any prescription [~~or other order lawfully issued by a practitioner in connection with the device~~].

(l) Sale of contact lenses at flea markets. Contact lenses may not be sold by persons at flea markets unless:

(1) the person selling the contact lenses has complied with the requirements of Texas Business and Commerce Code[~~,~~] §35.55; and

(2) the person selling the contact lenses has complied with the requirements of the Texas Occupations Code Chapter 353 [~~Texas Contact Lens Prescription Act, Texas Civil Statutes, Article~~ 4552-A].

(m) Distribution of nonprescription devices. Records must include the identity of each device, the quantity received or manufactured, and the final disposition of each device.

§229.442. Advertising.

(a) An advertisement of a device is [~~shall be~~] deemed [~~to be~~] false if it is false or misleading in any way [~~particular~~].

(b) An advertisement of a device is false if the advertisement represents that the device affects:

(1) infectious and parasitic diseases;

(2) neoplasms;

(3) endocrine, nutritional, and metabolic diseases and immunity disorders;

(4) diseases of blood and blood-forming organs;

(5) mental disorders;

(6) diseases of the nervous system and sense organs;

(7) diseases of the circulatory system;

(8) diseases of the respiratory system;

(9) diseases of the digestive system;

(10) diseases of the genitourinary system;

(11) complications of pregnancy, childbirth, and the puerperium;

(12) diseases of the skin and subcutaneous tissue;

(13) diseases of the musculoskeletal system and connective tissue;

(14) congenital anomalies;

(15) certain conditions originating in the perinatal period;

(16) symptoms, signs, and ill-defined conditions; or

(17) injury and poisoning.

(c) Subsection (b) of this section does not apply to an advertisement of a device if the advertisement does not violate the Act[~~,~~] §431.182(a), and is disseminated:

(1) to the public for self-medication and is consistent with the labeling claims permitted by the United States Food and Drug Administration (FDA);

(2) only to members of the medical, dental, and veterinary professions and appears only in the scientific periodicals of those professions; or

(3) only for the purpose of public health education by a person not commercially interested, directly or indirectly, in the sale of the device.

(d) This section does not indicate that self-medication for a disease, other than a disease listed under subsection (b) of this section, is safe and effective.

§229.443. Enforcement and Penalties.

(a) General enforcement actions. The department may take enforcement action for the following:

(1) failing to comply with Texas Food, Drug, and Cosmetic Act, HSC Chapter 431 (Act) or these sections;

(2) falsifying information provided in an application for a license, or making a false or misleading statement in connection with the initial or renewal application, either in the formal application itself or in any other instrument relating to the application submitted to the department;

(3) refusing to allow the department to conduct an inspection or collect samples;

(4) interfering with the department in the performance of its duties;

(5) removing or disposing a detained device;

(6) misrepresenting any regulated product sold to the public; or

(7) conviction of a felony or misdemeanor that involves moral turpitude.

(b) Administrative penalty. If a person, whether licensed or unlicensed by the department, violates these sections or an order adopted or license issued under the Act, the commissioner may assess an administrative penalty against the person.

(1) The penalty may not exceed $25,000 for each violation. Each day a violation continues is a separate violation.

(2) Violations subject to this subsection must be categorized into severity levels as determined in §229.261 of this chapter (relating to Assessment of Administrative Penalties).

(3) An administrative penalty may be assessed only after the person charged with a violation is given an opportunity for a hearing.

(4) If the person charged with the violation does not request a hearing, or defaults, the commissioner may assess a penalty after determining that a violation has occurred and the amount of the penalty.

(5) After making a determination under this subsection that a penalty is to be assessed, the commissioner must issue an order requiring that the person pay the penalty.

(6) Not later than the 30th calendar day after the date of issuance of an order finding that a violation has occurred, the commissioner must inform the person against whom the order is issued of the amount of the penalty.

(c) Emergency orders.

(1) The commissioner or a person designated by the commissioner may issue a mandatory or prohibitory emergency order, without notice, in relation to the manufacture or distribution of a food, drug, device, or cosmetic upon determination that: the manufacture or distribution creates or poses an immediate and serious threat to human life or health, and other procedures available to the department to remedy

or prevent the occurrence of the situation will result in unreasonable delay.

(2) If an emergency order is issued without a hearing, the department, not later than the 30th day after the date on which the emergency order was issued, must propose a time and place for a hearing at which the emergency order will be affirmed, modified, or set aside. The hearing must be held under departmental formal hearing rules governed by §§1.21, 1.23, 1.25, and 1.27 of this title.

(3) The department must transmit the order in person or by electronic mail or by registered or certified mail to the license or registration holder. If the license or registration holder cannot be located for a notice required under this section, the department must provide notice by posting a copy of the order on the front door of the premises of the license or registration holder.

(d) [~~(a)~~] Inspection.

(1) To enforce these sections or the Act [~~Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act)~~], the department or [~~Commissioner of the Department of State Health Services (commissioner), an~~] authorized agent[~~, or a health authority~~] may, on presenting appropriate credentials to the owner, operator, or agent in charge of a place of business:

(A) enter, at reasonable times, a place of business, including a factory or warehouse, where [~~in which~~] a device is manufactured, assembled, packed, or held for introduction into commerce or held after the introduction;

(B) enter a vehicle being used to transport or hold a device in commerce; or

(C) inspect, at reasonable times, within reasonable limits, and in a reasonable manner, the place of business or vehicle, including [~~and~~] all equipment, finished and unfinished materials, containers, and labeling of any item and obtain samples necessary for the enforcement of these sections or the Act.

(2) The inspection of a place of business, including a factory, warehouse, or consulting laboratory, where [~~in which~~] a restricted device is manufactured, assembled, packed, or held for introduction into commerce may include [~~extends to~~] any place or item, such as [~~thing, including~~] a record, file, paper, process, control, or facility, needed [~~in order~~] to determine whether the device:

(A) is adulterated or misbranded;

(B) is prohibited from being [~~may not be~~] manufactured, introduced into commerce, sold, or offered for sale under the Act; or

(C) is [~~otherwise~~] in violation of these sections or the Act.

(3) An inspection under paragraph (2) of this subsection may not extend to:

(A) financial data;

(B) sales data, except for [~~other than~~] shipment data;

(C) pricing data;

(D) personnel data, except for [~~other than~~] data relating to the qualifications of technical and professional personnel performing functions under the Act; or

(E) research data, except [~~other than~~] data that:

(i) relates [~~relating~~] to devices; and

(ii) is subject to reporting and inspection under regulations issued under [~~§519 or §520(g) of~~] the Federal Food, Drug, and Cosmetic Act, 21 United States Code §360(i) or §360(j), as amended.

(4) An inspection under paragraph (2) of this subsection must [~~shall~~] be started and completed with reasonable promptness.

(e) [~~(b)~~] Receipt for samples. An authorized agent or health authority who inspects [~~makes an inspection of~~] a place of business, including a factory or warehouse, and obtains a sample during [~~or on completion of~~] the inspection must [~~and before leaving the place of business, shall~~] give to the owner, operator, or the owner's or operator's agent a receipt describing the sample before leaving the place of business.

(f) [~~(c)~~] Access to records.

(1) A person who is required to maintain records referenced in these sections, [~~or under~~] the Act, [~~Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act)~~] or [~~§519 or §520(g) of~~] the Federal Food, Drug, and Cosmetic Act, 21 United States Code §360(i), or a person who is in charge or custody of those records must, upon [~~shall, at the~~] request by [~~of~~] an authorized agent or health authority, provide access to the records, [~~permit the authorized agent or health authority~~] at all reasonable times, for copying and verification of [~~access to and to copy and verify~~] the records.

(2) A person who is subject to licensure under these sections of this subchapter must [~~shall~~], at the request of an authorized agent or health authority, provide access to the records, [~~permit the authorized agent or health authority~~] at all reasonable times, for copying and verification of [~~access to and to copy and verify~~] all records showing:

(A) the movement in commerce of any device;

(B) the holding of any device after movement in commerce; and

(C) the quantity, shipper, and consignee of any device.

(g) [~~(d)~~] Retention of records. Records required by these sections of this subchapter must [~~shall~~] be maintained at the place of business or another reasonably accessible [~~other~~] location [~~that is reasonably accessible~~] for a period of at least two [~~2~~] years following disposition of the device, unless a longer retention [~~greater~~] period [~~of time~~] is required by laws and regulations adopted in §229.432 of this subchapter [~~title~~] (relating to Applicable Laws and Regulations).

(h) [~~(e)~~] Adulterated and misbranded device. If the department [~~Department of State Health Services (department)~~] identifies an adulterated or misbranded device, the department may impose the applicable provisions of Subchapter C of the Act,including[~~, but not limited to:~~] detention, emergency order, recall, condemnation, destruction, injunction, civil penalties, criminal penalties, and [~~and/or~~] administrative and civil penalties. Administrative [~~and civil~~] penalties will be assessed using the severity levels [~~Severity Levels~~] contained in §229.261 of this chapter [~~title~~] (relating to Assessment of Administrative [~~or Civil~~] Penalties).

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 September 19, 2025.

TRD-202503316

Cynthia Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: November 2, 2025
For further information, please call: (512) 834-6755

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25 TAC §229.444

STATUTORY AUTHORITY

The repeal is authorized by Texas Government Code §524.0151 and Texas Health and Safety Code §1001.075, which authorize the executive commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and the administration of Texas Health and Safety Code Chapter 1001, and by Texas Health and Safety Code §431.241.

The repeal affects Texas Government Code §524.0151 and Texas Health and Safety Code Chapters 1001 and 431.

§229.444. Device Distributors and Manufacturers Advisory Committee.

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

Filed with the Office of the Secretary of State on September 19, 2025.

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Cynthia Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: November 2, 2025
For further information, please call: (512) 834-6755

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TITLE 28. INSURANCE

PART 1. TEXAS DEPARTMENT OF INSURANCE

CHAPTER 21. TRADE PRACTICES

The Texas Department of Insurance (TDI) proposes amendments to 28 TAC §§21.4902, 21.5002, 21.5003, 21.5010, and 21.5040, concerning out-of-network provider disclosures and the claim dispute resolution process, and §21.5070 and §21.5071, concerning data submission and payment requirements for emergency medical services. Amendments to §§21.4902, 21.5002, 21.5003, and 21.5040 implement Senate Bill 1409, 89th Legislature, 2025. Amendments to §21.5010 implement Senate Bill 2544, 89th Legislature, 2025. Amendments to §21.5070 and §21.5071 implement Senate Bill 916, 89th Legislature, 2025.

EXPLANATION. The amendments to §§21.4902, 21.5002, 21.5003, and 21.5040 are necessary to implement SB 1409, which authorizes postsecondary educational institutions to offer health benefit plans under Insurance Code Chapter 1683. SB 1409 also amends Insurance Code Chapter 1275 to make higher education health benefit plans subject to state balance billing protections and independent dispute resolution processes. Insurance Code Chapter 1275 establishes balance billing protections for plans that are otherwise not subject to state regulation. The protections in Insurance Code Chapter 1275 closely align with the requirements for out-of-network billing that were originally established by Senate Bill 1264, 86th Legislature, 2019, for health maintenance organizations and preferred provider benefit plans, and health benefit plans administered by the Employees Retirement System of Texas and Teacher Retirement System of Texas.

The amendments to §§21.4902, 21.5002, and 21.5003 add health benefit plans offered under Insurance Code Chapter 1683 to the definition and scope sections to clarify that these plans are subject to the rules found in 28 TAC Chapter 21, Subchapters OO and PP. Insurance Code §1275.004 makes Insurance Code Chapter 1467 applicable to health benefit plans identified in Insurance Code Chapter 1275.

In addition, amendments to §21.5040 require health benefit plans offered by postsecondary educational institutions to include additional information in the explanation of benefits (EOB) provided to physicians and providers. Specifically, the EOB must include an instruction that is substantially similar to the following language: "The request for mediation or arbitration must identify the plan type as 'Higher Ed Plan.'" This proposed addition is consistent with the treatment of other plan types under Insurance Code §1275.002 and should assist in identifying and processing eligible mediation and arbitration requests through the Texas IDR process.

Amendments to §21.5010 are necessary to implement SB 2544, which creates a statutory deadline for an out-of-network provider or health benefit plan issuer or administrator to request mandatory mediation under Insurance Code Chapter 1467, Subchapter B. The proposed amendment to §21.5010 adds new subsection (d) to clarify that mediation under Subchapter PP, Division 2 must be requested by the out-of-network provider or health benefit plan issuer or administrator not later than 180 days after the date the initial payment is received. The proposed language in new subsection (d) is consistent with the treatment of arbitration claims under §21.5020(d), except that the mediation deadline is 180 days.

Amendments to §21.5070 and §21.5071 are necessary to implement SB 916, which authorizes political subdivisions to annually adjust rates submitted to TDI under Insurance Code §38.006, subject to certain statutory limits. A political subdivision may not adjust a rate submitted to TDI under Insurance Code §38.006 by more than the lesser of (1) the Medicare Ambulance Inflation Factor, or (2) 10% of the provider's previous calendar year rates.

Political subdivisions first submitted rates under Insurance Code §38.006 for calendar year 2024 to implement Senate Bill 2476, 88th Legislature, 2023, which expired on September 1, 2025. While SB 2476 included a method for rates to increase when plans renewed, it did not give political subdivisions an opportunity to submit rates for calendar year 2025. Since SB 916 is effective for emergency medical services provided on or after September 1, 2025, TDI announced a new reporting opportunity between August 1 and September 1, 2025, to allow political subdivisions to submit adjusted rates. If a political subdivision does not submit a rate adjustment, the rates previously reported will continue to apply. TDI will publish new rate data within 10 days following the September 1, 2025, submission deadline. TDI recognizes the challenges of quickly implementing the published rates but seeks to comply with the statutory deadlines in SB 1409.

Going forward, TDI will provide an annual opportunity for political subdivisions to adjust previously submitted rates. For calendar year 2026, the proposed data submission deadline will be 30 days after the date this rule becomes effective. For subsequent years, the data submission deadline will be December 1 of the year prior to the calendar year for which the data is being reported. For example, a political subdivision that elects to submit a rate adjustment must submit rates applicable for calendar year 2027 by December 1, 2026. TDI will continue to publish data within 10 days of the data submission deadline. Issuers must apply the published rate for the applicable calendar year during which the service or transport was provided or, if rate data is not adjusted for the current year, the most recent available rate.

TDI intends to continue to publish previously submitted data in the four Emergency Services Billing Rates datasets available on the Texas Open Data Portal at data.texas.gov. Information in these datasets include code rates, National Provider Identifier Standard numbers, ZIP codes, and contact lists. For more information about rate data submission, including frequently asked questions and links to other resources, visit www.tdi.texas.gov/health/esbindex.html.

Consistent with SB 916, a political subdivision may annually adjust a rate by not more than the lesser of the Medicare Ambulance Inflation Factor or 10% of the provider's previous calendar rates. For 2025, the Medicare Ambulance Inflation Factor is 2.4%, so an adjusted rate that is submitted by a political subdivision for 2025 may not be more than 2.4% higher than the rate submitted for 2024 for the same service. TDI may audit the data to ensure compliance and will refer rates that violate the statutory limits to the Texas Department of State Health Services for further action as authorized under Health and Safety Code §773.061(a-1), as added by SB 916.

Descriptions of the sections' proposed amendments follow.

Section 21.4902. This section provides definitions for use in Subchapter OO. The amendments to §21.4902 expand the definition of an "administrator" to include an administrator of a health benefit plan offered by a postsecondary educational institution under new Insurance Code Chapter 1683, as added by SB 1409. The amendments also expand the definition of "health benefit plan" to include a plan offered by a postsecondary educational institution under Insurance Code Chapter 1683.

Section 21.5002. This section describes the scope of Subchapter PP. The amendments to §21.5002 expand the applicability of Subchapter PP to a qualified mediation or qualified arbitration claim filed under health benefit plan coverage administered by an administrator of a health benefit plan under new Insurance Code Chapter 1683. The amendments add a citation to Insurance Code Chapter 1683 in §21.5002(c) to reflect this expanded applicability.

Section 21.5003. This section provides definitions for use in Subchapter PP. The amendments to §21.5003 expand the definition of an "administrator" to include an administrator of a health benefit plan offered by a postsecondary educational institution under new Insurance Code Chapter 1683. The proposed amendments also expand the definition of "health benefit plan" to include a plan offered by a postsecondary educational institution under Insurance Code Chapter 1683.

Section 21.5010. The amendment to §21.5010 adds new subsection (d) to narrow the availability of mediation for eligible claim disputes that occur on or after June 20, 2025, consistent with SB 2544. Specifically, proposed new subsection (d) requires the out-of-network provider or health benefit plan issuer or administrator to request mediation under the section not later than 180 days after the date the initial payment is received. The amendment also clarifies that the initial payment made to the out-of-network provider could be zero dollars if the allowable amount was applied to an enrollee's deductible, which is consistent with how arbitration claims are treated in §21.5020(d).

Section 21.5040. This section provides the content required in an explanation of benefits (EOB) provided to an enrollee, physician, and provider. The amendment to §21.5040 adds new subsection (b)(3) to address the specific requirements for EOBs provided by a health benefit plan offered by a postsecondary educational institution under Insurance Code Chapter 1683. Proposed new subsection (b)(3) requires the health benefit plan to include in the EOB to the physician or provider an instruction to identify the plan type as "Higher Ed Plan" when requesting mediation or arbitration.

Section 21.5070. This section provides the requirements for political subdivisions or their designees to submit emergency medical service rates to TDI for publication under Insurance Code §38.006. The amendments to §21.5070 specify the deadlines for submission of a rate based on the calendar year for which the rates apply. For calendar year 2026, the proposed deadline for a political subdivision to submit new or adjusted rates is 30 days after the date §21.5070 becomes effective. The deadline for new or adjusted rates to be filed with TDI for use in a subsequent calendar year is December 1.

Proposed new subsection (g) limits the amount that a political subdivision or their designee may adjust a rate submitted under Insurance Code §38.006 compared to the provider's rate for the previous calendar year. Consistent with SB 916, new subsection (g) states a political subdivision may annually adjust a rate by not more than the lesser of the Medicare Ambulance Inflation Factor, or 10% of the provider's previous calendar year rates.

Section 21.5071. This section outlines the requirements that certain health benefit plan issuers or administrators must meet when making payments to emergency medical services providers. The amendments clarify that the health benefit plan issuer or administrator must pay the lesser of the billed charge or the EMS rate published by TDI in the EMS provider rate database for the calendar year during which the service or transport was provided. The proposed rule specifies that if a new or adjusted rate was not submitted and published in the EMS provider rate database for the calendar year in which the service or transport was provided, the health benefit plan issuer or administrator must use the most recently submitted rate published in the EMS provider rate database established by TDI.

The proposal also deletes subsections (c) - (e), concerning payments by issuers and administrators, and Figure: 28 TAC §21.5071(e), which provides examples illustrating how a health benefit plan should apply published rates to a plan year under subsection (d). Subsections (c) - (e) are no longer necessary because SB 916 removes the requirement that health benefit plans recalculate previously submitted rates and authorizes political subdivisions to submit adjusted rates annually.

FISCAL NOTE AND LOCAL EMPLOYMENT IMPACT STATEMENT. Rachel Bowden, director of the Regulatory Initiatives Office, has determined that during each year of the first five years the proposed amendments are in effect, there will be no measurable fiscal impact on state and local governments as a result of enforcing or administering the amendments, other than that im-

posed by statute. Ms. Bowden made this determination because the proposed amendments do not add to or decrease state revenues or expenditures, and because local governments are not involved in enforcing or complying with the proposed amendments. The rule applies to political subdivisions that choose to submit rates to TDI, but political subdivisions are not required to participate. Any measurable fiscal impact on a political subdivision that voluntarily submits rates to TDI are a result of those requirements imposed by statute when and if a political subdivision chooses to submit rates. Likewise, the rule applies to a postsecondary educational institution, but only if it voluntarily chooses to offer higher education health benefits.

Ms. Bowden does not anticipate any measurable effect on local employment or the local economy as a result of this proposal.

PUBLIC BENEFIT AND COST NOTE. For each year of the first five years the proposed amendments are in effect, Ms. Bowden expects that administering the proposed amendments will have the public benefit of ensuring that TDI's rules conform to Insurance Code Chapters 1275, 1467, and 1683, and §§38.006, 1271.008, 1271.159, 1275.003, 1275.054, 1301.010, 1301.166, 1551.015, 1551.231, 1575.009, 1575.174, 1579.009, and 1579.112.

Ms. Bowden expects that the proposed amendments that implement SB 916 will not increase the cost of compliance with Insurance Code §§38.006, 1271.008, 1271.159, 1275.003, 1275.054, 1301.010, 1301.166, 1551.015, 1551.231, 1575.009, 1575.174, 1579.009, and 1579.112 because the amendments do not impose requirements beyond those in statute. Political subdivisions are authorized, but are not required, to annually adjust an EMS rate submitted to TDI under Insurance Code §38.006. Health benefit plan issuers and administrators are required by statute to cover certain EMS-related claims according to SB 916. As a result, the cost associated with submitting new or adjusted rates or payment of EMS claims does not result from enforcement or administration of the amended sections.

Ms. Bowden expects that the proposed amendments that implement SB 1409 will not increase the cost of compliance with Insurance Code Chapter 1275 because it does not impose requirements beyond those in the statute. Insurance Code §1275.002 states that a health benefit plan offered by a postsecondary educational institute is subject to the requirements in Insurance Code Chapter 1275, including the requirement in Insurance Code §1275.004. Insurance Code §1275.004 requires a health benefit plan or administrator subject to Insurance Code Chapter 1275 to comply with the requirements in Insurance Code Chapter 1467. As a result, the cost associated with complying with the requirement to use the Texas Independent Dispute Resolution system does not result from the enforcement or administration of the proposed amendments.

Ms. Bowden expects that the proposed amendments that implement SB 2544 will not increase the cost of compliance with Insurance Code Chapter 1467, Subchapter B, because it does not impose requirements beyond those in statute. Insurance Code §1467.054 creates a 180-day deadline for an out-of-network provider or health benefit plan issuer or administrator to request mandatory mediation after the date an initial payment is received for a claim. As a result, the cost associated with meeting the 180-day deadline does not result from the enforcement or administration of the proposed amendments.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS. TDI has determined that the proposed amendments will not have an adverse economic effect on small or micro businesses, or on rural communities. As a result, and in accordance with Government Code §2006.002(c), TDI is not required to prepare a regulatory flexibility analysis.

EXAMINATION OF COSTS UNDER GOVERNMENT CODE §2001.0045. TDI has determined that this proposal does not impose a possible cost on regulated persons. However, even if the proposal did impose a cost on regulated persons, Insurance Code §1467.003(b) exempts a rule adopted under Insurance Code Chapter 1467 from Government Code §2001.0045, and the proposed amendments are necessary to implement legislation. The proposed amendments implement Insurance Code Chapter 1683 and §§38.006, 1271.008, 1271.159, 1275.002, 1275.003, 1275.054, 1301.010, 1301.166, 1467.054, 1551.015, 1551.231, 1575.009, 1575.174, 1579.009, and 1579.112 as added or amended by SBs 916, 1409, and 2544.

GOVERNMENT GROWTH IMPACT STATEMENT. TDI has determined that for each year of the first five years that the proposed amendments are in effect, the proposed rule:

- will not create or eliminate a government program;

- will not require the creation of new employee positions or the elimination of existing employee positions;

- will not require an increase or decrease in future legislative appropriations to the agency;

- will not require an increase or decrease in fees paid to the agency;

- will not create a new regulation;

- will expand, limit, or repeal an existing regulation;

- will increase the number of individuals subject to the rule's applicability; and

- will not positively or adversely affect the Texas economy.

TAKINGS IMPACT ASSESSMENT. TDI has determined that no private real property interests are affected by this proposal and that this proposal does not restrict or limit an owner's right to property that would otherwise exist in the absence of government action. As a result, this proposal does not constitute a taking or require a takings impact assessment under Government Code §2007.043.

REQUEST FOR PUBLIC COMMENT. TDI will consider any written comments on the proposal that are received by no later than 5:00 p.m., central time, on November 3, 2025. Consistent with Government Code §2001.024(a)(8), TDI requests public comments on the proposal, including information related to the cost, benefit, or effect of the proposal and any applicable data, research, and analysis. Send your comments to ChiefClerk@tdi.texas.gov or to the Office of the Chief Clerk, MC: GC-CCO, Texas Department of Insurance, P.O. Box 12030, Austin, Texas 78711-2030.

The commissioner of insurance will also consider written and oral comments on the proposal in a public hearing under Docket No. 2855 at 2:00 p.m., central time, on October 21, 2025, in Room 2.035 of the Barbara Jordan State Office Building, 1601 Congress Avenue, Austin, Texas 78701.

SUBCHAPTER OO. DISCLOSURES BY OUT-OF-NETWORK PROVIDERS

28 TAC §21.4902

STATUTORY AUTHORITY. TDI proposes amendments to §21.4902 under Insurance Code §§1275.004, 1467.003, 36.001.

Insurance Code §1275.004 states that Insurance Code Chapter 1467 applies to a health benefit plan to which Insurance Code Chapter 1275 applies, and the administrator of a health benefit plan to which Insurance Code Chapter 1275 applies is an administrator for purposes of Insurance Code Chapter 1467.

Insurance Code §1467.003 requires the commissioner to adopt rules as necessary to implement the commissioner's powers and duties under Insurance Code Chapter 1467.

Insurance Code §36.001 provides that the commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

CROSS-REFERENCE TO STATUTE. Section 21.4902 implements Insurance Code §§1275.002, 1275.003, and 1275.004, and SB 1409.

§21.4902. Definitions.

Words and terms defined in Insurance Code Chapter 1467, concerning Out-of-Network Claim Dispute Resolution, have the same meaning when used in this subchapter unless the context clearly indicates otherwise, and the following words and terms have the following meanings when used in this subchapter unless the context clearly indicates otherwise.

(1) Administrator--Has the meaning assigned by Insurance Code §1467.001, concerning Definitions. The term also includes an administrator of a nonprofit agricultural organization under Insurance Code Chapter 1682, concerning Health Benefits Provided by Certain Nonprofit Agricultural Organizations;[~~, and~~] an administrator of a self-insured or self-funded ERISA plan under Insurance Code Chapter 1275, concerning Balance Billing Prohibitions and Out-of-Network Claim Dispute Resolution for Certain Plans; and an administrator of a postsecondary educational institution under Chapter 1683, concerning Health Benefits Provided by Certain Postsecondary Educational Institutions, offering a health benefit plan.

(2) ERISA--The Employee Retirement Income Security Act of 1974 (29 USC §1001 et seq.).

(3) Health benefit plan--A plan that provides coverage under:

(A) a health benefit plan offered by an HMO operating under Insurance Code Chapter 843, concerning Health Maintenance Organizations;

(B) a preferred provider benefit plan, including an exclusive provider benefit plan, offered by an insurer under Insurance Code Chapter 1301, concerning Preferred Provider Benefit Plans;

(C) a plan, other than an HMO plan, under Insurance Code Chapters 1551, concerning Texas Employees Group Benefits Act; 1575, concerning Texas Public School Employees Group Benefits Program; 1579, concerning Texas School Employees Uniform Group Health Coverage; [~~or~~] 1682; or 1683; or

(D) a self-insured or self-funded plan established by an employer under ERISA (29 USC §1001 et seq.) for which the plan sponsor has elected to apply Insurance Code Chapter 1275 to the plan for the relevant plan year.

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

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Jessica Barta
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Texas Department of Insurance
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For further information, please call: (512) 676-6655

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SUBCHAPTER PP. OUT-OF-NETWORK CLAIM DISPUTE RESOLUTION
DIVISION 1. GENERAL PROVISIONS

28 TAC §21.5002, §21.5003

STATUTORY AUTHORITY. TDI proposes amendments to §21.5002 and §21.5003 under Insurance Code §§1275.004, 1467.003, and 36.001.

Insurance Code §1275.004 states that Insurance Code Chapter 1467 applies to a health benefit plan to which Insurance Code Chapter 1275 applies, and the administrator of a health benefit plan to which Insurance Code Chapter 1275 applies is an administrator for purposes of Insurance Code Chapter 1467.

Insurance Code §1467.003 requires the commissioner to adopt rules as necessary to implement the commissioner's powers and duties under Insurance Code Chapter 1467.

Insurance Code §36.001 provides that the commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

CROSS-REFERENCE TO STATUTE.

Sections 21.5002 and 21.5003 implement Insurance Code §1275.002 and SB 1409.

§21.5002. Scope.

(a) This subchapter applies to a qualified mediation claim or qualified arbitration claim filed under health benefit plan coverage:

(1) issued by an insurer as a preferred provider benefit plan under Insurance Code Chapter 1301, concerning Preferred Provider Benefit Plans, including an exclusive provider benefit plan;

(2) administered by an administrator of a health benefit plan, other than a health maintenance organization (HMO) plan, under Insurance Code Chapters 1551, concerning Texas Employees Group Benefits Act; 1575, concerning Texas Public School Employees Group Benefits Program; 1579, concerning Texas School Employees Uniform Group Health Coverage; [~~or~~] 1682, concerning Health Benefits Provided by Certain Nonprofit Agricultural Organizations; or 1683, concerning Health Benefits Provided by Certain Postsecondary Educational Institutions;

(3) offered by an HMO operating under Insurance Code Chapter 843, concerning Health Maintenance Organizations; or

(4) offered by a self-insured or self-funded plan established by an employer under ERISA if the plan sponsor submitted election according to §21.5060 of this title (relating to Election Submission Requirements).

(b) This subchapter does not apply to a claim for health benefits that is not a covered claim under the terms of the health benefit plan coverage.

(c) Except as provided in §21.5050 of this title (relating to Submission of Information), this subchapter applies to a claim for emergency care or health care or medical services or supplies, provided on or after January 1, 2020. A claim for health care or medical services or supplies provided before January 1, 2020, is governed by the rules in effect immediately before the effective date of this subsection, and those rules are continued in effect for that purpose. This subchapter applies to a claim filed for emergency care or health care or medical services or supplies by the administrator of a health benefit plan under Insurance Code Chapters [~~Chapter~~] 1682 and 1683.

§21.5003. Definitions.

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

(1) Administrator--Has the meaning assigned by Insurance Code §1467.001, concerning Definitions. The term also includes an administrator of a nonprofit agricultural organization under Insurance Code Chapter 1682, concerning Health Benefits Provided by Certain Nonprofit Agricultural Organizations;[~~, and~~] an administrator of a self-insured or self-funded ERISA plan under Insurance Code Chapter 1275, concerning Balance Billing Prohibitions and Out-of-Network Claim Dispute Resolution for Certain Plans; and an administrator of a postsecondary educational institution under Chapter 1683, concerning Health Benefits Provided by Certain Postsecondary Educational Institutions, offering a health benefit plan.

(2) Arbitration--Has the meaning assigned by Insurance Code §1467.001.

(3) Claim--A request to a health benefit plan for payment for health benefits under the terms of the health benefit plan's coverage, including emergency care, or a health care or medical service or supply, or any combination of emergency care and health care or medical services and supplies, provided that the care, services, or supplies:

(A) are furnished for a single date of service; or

(B) if furnished for more than one date of service, are provided as a continuing or related course of treatment over a period of time for a specific medical problem or condition, or in response to the same initial patient complaint.

(4) Diagnostic imaging provider--Has the meaning assigned by Insurance Code §1467.001.

(5) Diagnostic imaging service--Has the meaning assigned by Insurance Code §1467.001.

(6) Emergency care--Has the meaning assigned by Insurance Code §1301.155, concerning Emergency Care.

(7) Emergency care provider--Has the meaning assigned by Insurance Code §1467.001.

(8) ERISA--The Employee Retirement Income Security Act of 1974 (29 USC §1001 et seq.).

(9) Enrollee--Has the meaning assigned by Insurance Code §1467.001.

(10) Facility--Has the meaning assigned by Health and Safety Code §324.001, concerning Definitions.

(11) Health benefit plan--A plan that provides coverage under:

(A) a health benefit plan offered by an HMO operating under Insurance Code Chapter 843, concerning Health Maintenance Organizations;

(B) a preferred provider benefit plan, including an exclusive provider benefit plan, offered by an insurer under Insurance Code Chapter 1301, concerning Preferred Provider Benefit Plans;

(C) a plan, other than an HMO plan, under Insurance Code Chapters 1551, concerning Texas Employees Group Benefits Act; 1575, concerning Texas Public School Employees Group Benefits Program; 1579, concerning Texas School Employees Uniform Group Health Coverage; [~~or~~] 1682; or 1683; or

(D) a self-insured or self-funded plan established by an employer under ERISA for which the plan sponsor has elected to apply Insurance Code Chapter 1275 to the plan for the relevant plan year.

(12) Facility-based provider--Has the meaning assigned by Insurance Code §1467.001.

(13) Insurer--A life, health, and accident insurance company; health insurance company; or other company operating under: Insurance Code Chapters 841, concerning Life, Health, or Accident Insurance Companies; 842, concerning Group Hospital Service Corporations; 884, concerning Stipulated Premium Insurance Companies; 885, concerning Fraternal Benefit Societies; 982, concerning Foreign and Alien Insurance Companies; or 1501, concerning Health Insurance Portability and Availability Act, that is authorized to issue, deliver, or issue for delivery in this state a preferred provider benefit plan, including an exclusive provider benefit plan, under Insurance Code Chapter 1301.

(14) Mediation--Has the meaning assigned by Insurance Code §1467.001.

(15) Mediator--Has the meaning assigned by Insurance Code §1467.001.

(16) Out-of-network claim--A claim for payment for medical or health care services or supplies or both furnished by an out-of-network provider or a non-network provider.

(17) Out-of-network provider--Has the meaning assigned by Insurance Code §1467.001.

(18) Party--Has the meaning assigned by Insurance Code §1467.001.

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

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Jessica Barta
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DIVISION 2. MEDIATION PROCESS

28 TAC §21.5010

STATUTORY AUTHORITY. TDI proposes amendments to §21.5010 under Insurance Code §§1467.003, 1467.0505, and 36.001.

Insurance Code §1467.003 requires the commissioner to adopt rules as necessary to implement the commissioner's powers and duties under Insurance Code Chapter 1467.

Insurance Code §1467.0505 authorizes the commissioner to adopt rules, forms, and procedures necessary for the implementation and administration of the mediation program.

Insurance Code §36.001 provides that the commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

CROSS-REFERENCE TO STATUTE. The proposed amendments to §21.5010 implement Insurance Code §1467.054 and SB 2544.

§21.5010. Qualified Mediation Claim Criteria.

(a) Required criteria. An out-of-network provider that is a facility or a health benefit plan issuer or administrator may request mandatory mediation of an out-of-network claim under §21.5011 of this title (relating to Mediation Request Procedure) if the claim complies with the criteria specified in this subsection. An out-of-network claim that complies with those criteria is referred to as a "qualified mediation claim" in this subchapter.

(1) The out-of-network health benefit claim must be for:

(A) emergency care;

(B) an out-of-network laboratory service provided in connection with a health care or medical service or supply provided by a participating provider; or

(C) an out-of-network diagnostic imaging service provided in connection with a health care or medical service or supply provided by a participating provider.

(2) There is an amount billed by the provider and unpaid by the health benefit plan issuer or administrator after copayments, deductibles, and coinsurance, for which an enrollee may not be billed.

(b) Submission of multiple claim forms. The use of more than one form in the submission of a claim, as defined in §21.5003 of this title (relating to Definitions), does not prevent eligibility of a claim for mandatory mediation under this subchapter if the claim otherwise meets the requirements of this section.

(c) Ineligible claims. This division does not require a health benefit plan issuer or administrator to pay for an uncovered service or supply.

(d) Availability. With respect to a dispute that occurs on or after June 20, 2025, the out-of-network provider or the health benefit plan issuer or administrator may request mediation of a settlement of an out-of-network health benefit claim not later than the 180th day after the date an out-of-network provider receives the initial payment for a health care or medical service or supply. The initial payment could be zero dollars if the allowable amount was applied to an enrollee's deductible.

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

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DIVISION 5. EXPLANATION OF BENEFITS

28 TAC §21.5040

STATUTORY AUTHORITY. TDI proposes amendments to §21.5040 under Insurance Code §§1275.004, 1467.003, and 36.001.

Insurance Code §1275.004 states that Insurance Code Chapter 1467 applies to a health benefit plan to which Insurance Code Chapter 1275 applies, and the administrator of a health benefit plan to which Insurance Code Chapter 1275 applies is an administrator for purposes of Insurance Code Chapter 1467.

Insurance Code §1467.003 requires the commissioner to adopt rules as necessary to implement the commissioner's powers and duties under Insurance Code Chapter 1467.

Insurance Code §36.001 provides that the commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

CROSS-REFERENCE TO STATUTE. Section 21.5040 implements Insurance Code §1275.003 and SB 1409.

§21.5040. Required Explanation of Benefits and Enrollee Identification Card Information.

(a) General requirements for explanation of benefits. A health benefit plan issuer or administrator subject to Insurance Code §1271.008, concerning Balance Billing Prohibition Notice; §1275.003, concerning Balance Billing Prohibition Notice; §1301.010, concerning Balance Billing Prohibition Notice; §1551.015, concerning Balance Billing Prohibition Notice; §1575.009, concerning Balance Billing Prohibition Notice; or §1579.009, concerning Balance Billing Prohibition Notice, must provide written notice in accordance with this section in an explanation of benefits in connection with a health care or medical service or supply or transport provided by a non-network provider or an out-of-network provider:

(1) to the enrollee and physician or provider, which must include:

(A) a statement of the billing prohibition, as applicable; and

(B) the total amount the physician or provider may bill the enrollee under the health benefit plan and an itemization of in-network copayments, coinsurance, deductibles, and other amounts included in that total; and

(2) to the physician or provider, for a claim that is subject to mediation or arbitration under Insurance Code Chapter 1467, concerning Out-of-Network Claim Dispute Resolution, a conspicuous statement in not less than 10-point boldface type that is substantially similar to the following: "If you disagree with the payment amount, you can request mediation or arbitration. To learn more and submit a request, go to www.tdi.texas.gov. After you submit a complete request, you must notify {HEALTH BENEFIT PLAN ISSUER OR ADMINISTRATOR NAME} at {EMAIL}."

(b) Specific requirements for explanation of benefits provided by health benefit plans subject to Insurance Code Chapter 1275. In addition to the requirements in subsection (a) of this section, the following requirements apply.

(1) For a health benefit plan offered by a nonprofit agricultural organization under Insurance Code Chapter 1682, concerning Health Benefits Provided by Certain Nonprofit Agricultural Organizations, the notice to a physician or provider for a claim must also include an [~~the following~~] instruction that is substantially similar to the following: "The request for mediation or arbitration must identify the plan type as 'Ag Plan.'"

(2) For a self-insured or self-funded plan under ERISA where the plan sponsor has elected to apply Insurance Code Chapter 1275, concerning Balance Billing Prohibitions and Out-Of-Network Claim Dispute Resolution for Certain Plans, to the plan for the relevant plan year, the notice to a physician or provider for a claim must also include a statement that is substantially similar to the following: "The plan sponsor has opted in to the Texas Independent Dispute Resolution Process under Insurance Code Chapter 1275 for this plan year. A dispute related to this claim must proceed through the Texas process and may not proceed through the Federal No Surprises Act Independent Dispute Resolution Process. The request for mediation or arbitration must identify the plan type as 'ERISA Opt-In.'"

(3) For a health benefit plan offered by a postsecondary educational institution under Insurance Code Chapter 1683, concerning Health Benefits Provided by Certain Postsecondary Educational Institutions, the notice to a physician or provider for a claim must also include an instruction that is substantially similar to the following: "The request for mediation or arbitration must identify the plan type as 'Higher Ed Plan.'"

(c) Requirements for ID cards issued to enrollees of health benefit plans subject to Insurance Code Chapter 1275. For a plan that is delivered, issued for delivery, or renewed on or after 90 days following the effective date of this section, a health benefit plan issuer or administrator that is subject to Insurance Code §1275.003 must include the letters "TXI" on the front of the ID card issued to enrollees.

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

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Jessica Barta
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DIVISION 8. EMERGENCY MEDICAL SERVICE RATE SUBMISSION AND PAYMENT REQUIREMENTS

28 TAC §21.5070, §21.5071

STATUTORY AUTHORITY. TDI proposes amendments to §21.5070 and §21.5071 under Insurance Code §§38.006, 1301.007, and 36.001.

Insurance Code §38.006 authorizes the commissioner to prescribe the form and manner by which political subdivisions may submit rates for ground ambulance services.

Insurance Code §1301.007 directs the commissioner to adopt rules as necessary to implement Insurance Code Chapter 1301 and ensure reasonable accessibility and availability of preferred provider services to residents of Texas.

Insurance Code §36.001 provides that the commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

CROSS-REFERENCE TO STATUTE. Section 21.5070 and §21.5071 implement Insurance Code §§38.006, 1271.159, 1275.054, 1301.166, 1551.231, 1575.174, and 1579.112, and SB 916.

§21.5070. Rate Database for Emergency Medical Services Providers.

(a) Consistent with Insurance Code §38.006, concerning Emergency Medical Services Provider Balance Billing Rate Database, this section applies to:

(1) a political subdivision that sets, controls, or regulates a rate charged for a health care service, supply, or transport provided by an emergency medical services (EMS) provider, other than an air ambulance; and

(2) an EMS provider or its designee that provides a health care service, supply, or transport on behalf of a political subdivision that sets, controls, or regulates a rate.

(b) A political subdivision or EMS provider subject to this section may not issue a bill for a health care service, supply, or transport that exceeds the amount of the rate set, controlled, or regulated by the political subdivision.

(c) A political subdivision that chooses to submit data to the Texas Department of Insurance (TDI) under this section must submit data using the data submission method available at www.tdi.texas.gov and must include at a minimum:

(1) the political subdivision's name and contact information;

(2) if known, the National Provider Identification (NPI) number of each EMS provider that provides a health care service, supply, or transport that is subject to rates set, controlled, or regulated by the political subdivision;

(3) each ZIP code that is subject to the rates set, controlled, or regulated by the political subdivision; and

(4) the applicable billing code, code type, and dollar amount for each health care service, supply, or transport rate that is set, controlled, or regulated by the political subdivision.

(d) The data submission deadline for a political subdivision that chooses to submit data for calendar year 2026 is 30 days after the date this section becomes effective. For all other data submissions under this section, the data submission deadline is December 1.

(e) TDI will publish data reported by a political subdivision no later than 10 business days after the data reporting deadline specified in subsection (d) of this section.

(f) A claim submitted by an EMS provider or its designee for a health care service, supply, or transport provided on behalf of a political subdivision must include the ZIP code in which the health care service, supply, or transport originated.

(g) For a rate submitted with respect to emergency medical services provided on or after September 1, 2025, the difference between the provider's rate for the previous calendar year and the adjusted rate may not exceed the lesser of:

(1) the Medicare Ambulance Inflation Factor; or

(2) 10%.

§21.5071. Payments to Emergency Medical Services Providers.

(a) This section applies to a health benefit plan issuer or administrator that is subject to one of the following statutes:

(1) Insurance Code §1271.159, concerning Non-Network Emergency Medical Services Provider;

(2) Insurance Code §1275.054, concerning Out-of-Network Emergency Medical Services Provider Payments;

(3) Insurance Code §1301.166, concerning Out-of-Network Emergency Medical Services Provider;

(4) Insurance Code §1551.231, concerning Out-of-Network Emergency Medical Services Provider Payments;

(5) Insurance Code §1575.174, concerning Out-of-Network Emergency Medical Services Provider Payments; or

(6) Insurance Code §1579.112, concerning Out-of-Network Emergency Medical Services Provider Payments.

(b) For a covered health care or medical service, supply, or transport that is provided to an enrollee by an out-of-network emergency medical services (EMS) provider, a health benefit plan issuer or administrator must pay:

(1) for a service or transport that originated in a political subdivision that sets, controls, or regulates the rate, the lesser of the billed charge or the applicable rate for that political subdivision that is published in the EMS provider rate database established by the department for the calendar year during which the service or transport was provided or the most recent rate data submitted [~~and adjusted as required in subsection (d) of this section~~]; or

(2) if there is not a rate published in the EMS provider rate database for the political subdivision in which the service or transport originated, the lesser of:

(A) the provider's billed charge; or

(B) 325% of the current Medicare rate, including any applicable extenders or modifiers.

[~~(c) For claims incurred during a plan year that starts before September 1, 2024, for a claim for emergency medical services that is provided on or after January 1, 2024, and before September 1, 2025, a health benefit plan issuer or administrator that must make a payment consistent with subsection (b)(1) of this section must use the rate data published in the department's EMS provider rate database for calendar year 2024.~~]

[~~(d) For claims incurred during a plan year that starts on or after September 1, 2024, a health benefit plan issuer or administrator that must make a payment consistent with subsection (b)(1) of this section must pay the lesser of:~~]

[~~(1) the billed charge;~~]

[~~(2) (2) the rate published in the department's EMS provider rate database for calendar year 2024 increased by 10%; or~~]

[~~(3) (3) the rate published in the department's EMS provider rate database for calendar year 2024 increased by the Medicare Economic Index rate that applies to the first day of the new plan year.~~]

[~~(e) Figure: 28 TAC §21.5071(e) provides examples illustrating how a health benefit plan should apply published rates to a plan year under subsection (d) of this section.~~]
[~~Figure: 28 TAC §21.5071(e)~~]

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

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TITLE 40. SOCIAL SERVICES AND ASSISTANCE

PART 21. TEXAS COUNCIL FOR DEVELOPMENTAL DISABILITIES

CHAPTER 877. GRANT AWARDS

40 TAC §877.1, §877.2

The Texas Council for Developmental Disabilities (TCDD) proposes amendments to §877.1 concerning General and §877.2 concerning Application and Review Process.

The purpose of the amendments to §877.1 is to clarify language regarding that number of allowable grants from an organization and to §877.2 is to apply consistent language to all sections regarding the Council Request for Applications process.

FISCAL NOTE

Beth Stalvey, PhD, Council Executive Director, has determined for each year of the first five years that the rules will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the rules as proposed.

GOVERNMENT GROWTH IMPACT STATEMENT

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

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

(2) implementation of the proposed rules will not affect the number of TCDD employee positions;

(3) implementation of the proposed rules will result in no assumed change in future legislative appropriations;

(4) the proposed rules will not affect fees paid to the agency;

(5) the proposed rules will not create a new regulation;

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

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

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

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

Dr. Stalvey has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities. The rules do not apply to small or micro-businesses, or rural communities.

PUBLIC BENEFIT

Dr. Stalvey has also determined that for each year of the first five years the rules are in effect, the updates will further efforts to create change so that all people with disabilities are fully included in their communities and exercise control over their own lives.

Comments on the proposal may be submitted to Koren Vogel, 6201 E. Oltorf, Suite 600, Austin, Texas 78741-7509, or e-mail comments to: koren.vogel@tcdd.texas.gov. Comments must be submitted by November 4, 2025, 31 days from publication in the *Texas Register.*

The proposed amendments are authorized under the Texas Human Resources Code, §112.020, which provides authority for the Council to adopt rules as necessary to implement the Council's duties and responsibilities.

The amendments will affect Texas Human Resources Code, Title 7, Chapter 112, Developmental Disabilities.

§877.1. General.

(a) As authorized by Texas Human Resources Code, Title 7, Chapter 112, §112.020(a)(3), the Council may contract or provide grants to public or private organizations to implement the TCDD State Plan for Texans with Developmental Disabilities, if funds are available.

(b) The Council may solicit applications from state agencies, non-profit organizations, or private for profit organizations that have organizational expertise related to the requirements of the solicitation.

(c) The Council may accept unsolicited ideas for future projects consistent with Council policies and procedures.

(d) The Council may develop projects with organizations without competitive applications as allowed by state and federal requirements and Council policies.

(e) All grantees shall comply with applicable state and federal requirements including the Texas Uniform Grant Management Standards. Office of Management and Budget (OMB) circulars, and Council grants procedures.

(f) Independent audits of grantees are required for each year of funding in accordance with the requirements of OMB Circulars and Texas Uniform Grant Management Standards. Project specific independent reviews and other procedures may be required of grantees not subject to annual independent audit requirements of OMB or UGMS consistent with Council policies. The Council shall reimburse the grantees for the reasonable cost of the required audit activities.

(g) Grant awards shall contain appropriate provisions for program and fiscal monitoring and for collection and submission of evaluation data and related reports.

(h) The Council may limit by policy the amount of Council funds allowed to reimburse indirect costs of projects. Any indirect costs of a grantee above those amounts may be allowed as part of the required non-federal participant share.

(i) The Council may by policy reduce reimbursements to grantees when required reports or final expenditure reports are not submitted within at least 60 days following the established due date.

(j) Donated time and services may be included as a financial match contribution unless otherwise restricted by a specific request for applications or by state or federal requirements.

(k) No organization shall receive more than three (3) direct grants from the Council at one [~~any~~] time.

§877.2. Application and Review Process.

(a) All requests for applications will be published in the *Texas Register* and posted on the Council's website, and a notice will be provided to interested parties.

(b) Application instructions [~~information~~] for each request for application shall be available upon request from Council offices and will be made available at the Council's website.

(c) Applications [~~Proposals~~] received after the closing date will not be considered unless an exception is approved in a manner consistent with Council policies.

(d) Projects seeking continuation funding may have separate application forms, instructions, and procedures, as determined by Council staff.

(e) Grants shall be awarded based on guidelines that reflect state and federal mandates. Selection criteria shall be designed to select applications that provide best overall value to the state and to the Council and meet the requirements and intent of the Council as provided in the request for applications.

(f) Final approval of organizations to receive grant funding shall be determined by the Council consistent with Council policies.

(g) Council staff may negotiate with selected applicants to determine the final terms of the award.

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

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Beth Stalvey
Executive Director
Texas Council for Developmental Disabilities
Earliest possible date of adoption: November 2, 2025
For further information, please call: (512) 948-2035

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TITLE 43. TRANSPORTATION

PART 10. TEXAS DEPARTMENT OF MOTOR VEHICLES

CHAPTER 217. VEHICLE TITLES AND REGISTRATION

The Texas Department of Motor Vehicles (department) proposes revisions to 43 Texas Administrative Code (TAC) Chapter 217,

Vehicle Titles and Registration. The department proposes the simultaneous repeal of Subchapter A, Motor Vehicle Titles; §217.10, relating to Appeal to the County, and addition of new Subchapter A, Motor Vehicle Titles; §217.10, relating to Department Decisions on Titles and Appeals to the County. The department additionally proposes amendments to Subchapter B, Motor Vehicle Registration; §217.41, relating to Disabled Person License Plates and Disabled Parking Placards. The department further proposes new Subchapter D, Nonrepairable and Salvage Motor Vehicles; §217.87, relating to Requirements for Certain Vehicles Acquired by a Used Automotive Parts Recycler Without a Title. The proposed amendments, new sections, and repeal are necessary to implement legislation, to clarify existing statutory requirements, and to make nonsubstantive grammatical changes to improve readability.

EXPLANATION.

The repeal of §217.10, relating to Appeal to the County, is proposed because the current language in the section is duplicative of the statutory requirements in Transportation Code, §501.052, and therefore unnecessary as rule text. To replace the proposed repealed section, the department proposes new §217.10, relating to Department Decisions on Titles and Appeals to the County. Proposed new §217.10(a) would clarify what constitutes evidence of a department title refusal or revocation under Transportation Code, §501.051, for purposes of determining eligibility for a hearing by a tax accessor-collector under Transportation Code, §501.052. The proposed language would specify that for purposes of determining whether a person is eligible for a tax accessor-collector hearing under Transportation Code §501.052, the official record of the department's refusal to issue a title is a written notice of determination from the department. Proposed new §217.10(a) would also clarify that the official record of a revoked title is a revocation remark on the motor vehicle record in the department's Registration and Title System. These proposed new provisions are necessary to clarify and prevent confusion about the official records of department action that demonstrate eligibility for an appeal hearing under Transportation Code, §501.052.

Proposed new §217.10(b) would clarify that a department decision that an applicant is ineligible to obtain a bonded title under Transportation Code §501.053 is a not a refusal to issue title under Transportation Code, §501.051, and therefore is not subject to a tax accessor-collector hearing under Transportation Code, §501.052. This proposed new language is necessary to address confusion by some tax accessor-collectors who have incorrectly treated the department's ineligibility determinations under Transportation Code, §501.053 as refusals to title under Transportation Code, §501.051. Proposed new §217.10(b) would also conform the department's rules with recent court rulings, which held that a notice from the department that a vehicle is ineligible for bonded title is not a refusal by the department to issue title under Transportation Code, §501.051.

Proposed amendments to §217.41, relating to Disabled Person License Plates and Disabled Parking Placards, are necessary to implement Senate Bill (SB) 2001, 89th Legislature, Regular Session (2025), which created Transportation Code, §504.2025, relating to Peace Officers with Disabilities. Section 504.2025 established the right of qualifying peace officers to obtain disabled peace officer license plates and disabled parking placards. Proposed amendments to §217.41(b)(1), (b)(2)(A), and (b)(3)(A) would add statutory references to Transportation Code, §504.2025, to include qualifying disabled peace officers as "disabled persons" for purposes of the eligibility for and issuance of disabled person license plates and disabled parking placards under §217.41. Proposed new §217.41(b)(2)(D) would clarify Transportation Code, §504.202(h) and §504.2025(h) by explaining that qualifying disabled veterans and disabled peace officers have the option to obtain general issue license plates at no expense, in lieu of disabled veteran or peace officer license plates.

A proposed amendment to §217.41(b)(1) would also add a reference to the Transportation Code to the citation to §504.202(b-1).

A proposed amendment to §217.41(b)(2)(B) would add the titles to §217.43 and §217.45 for ease of reference to these sections.

A proposed amendment to §217.41(c) would add the title to §217.28 for ease of reference to this section.

Proposed amendments throughout §217.41 would correct punctuation to statutory citations by inserting commas between the Texas code and section number.

Proposed new §217.87, relating to Requirements for Certain Vehicles Acquired by a Used Automotive Parts Recycler Without a Title, would implement House Bill (HB) 5436, 89th Legislature, Regular Session (2025). Transportation Code, §501.098, relating to Exception to Title Requirement for Certain Vehicles, provides a process for a used automotive parts recycler (recycler) to acquire motor vehicles without titles for the purpose of dismantling, scraping and parting them, without incurring the cost and delay of going through the bonded title process. Proposed new §217.87(a)(1) would inform a recycler of their obligation to determine if a motor vehicle acquired without a title under Transportation Code, §501.098(a) has been reported stolen or is subject to a recorded lien or security interest by submitting a form to the department within the time prescribed by Transportation Code, §501.098(c) and §501.098(g). Proposed new §217.87(a)(2) would require the recycler to separately report this information to the National Motor Vehicle Title Information System (NMVTIS), to comply with Transportation Code, §501.098(c) and to clarify that the department will not be reporting information to NMVTIS on the recycler's behalf.

Proposed new §217.87(b) would describe the information that the recycler must submit on a department form to ascertain whether a vehicle was reported stolen or is subject to any recorded liens, consistent with the information specified under 28 C.F.R. §25.56, to implement the requirements provided in Transportation Code, §501.098(c) and §501.098(g). Proposed new §217.87(b)(5) would require recyclers to attest that the vehicle meets the requirements of Transportation Code, §501.098(a)(1) and (2), in order to ensure that the vehicle is eligible for a recycler to purchase without obtaining title, so that the department can avoid wasting resources by processing forms for ineligible vehicles. Proposed new §217.87(c) would specify that a recycler must submit the form in person at one of the department's 16 regional service centers, to allow for an immediate response from the department and to reduce implementation costs for the department by not requiring additional coding in the department's Registration and Title System. Recyclers have previously gone to the department's regional service centers to process title transactions, so submitting the form in person will take the place of the title transaction with no increased inefficiency for the recycler.

Proposed new §217.87(d) would describe the actions the department will take in response to receiving the recycler's form under subsection (b) of this section. Proposed new §217.87(d)(1)(A) would require the department to provide the recycler with no-

tice of whether the motor vehicle has been reported stolen either in person or by email, to assure that the department meets the 48-hour deadline for issuing the notice in accordance with Transportation Code, §501.098(d). Proposed new §217.87(d)(1)(B) would describe the department's method of informing the recycler in person or by email if the vehicle is subject to a recorded lien or security interest in the department's Registration and Title System, to expedite the notice required under Transportation Code, §501.098(g). Proposed new §217.87(d)(1)(B) would also inform the recycler of the process of obtaining from the department the contact information for a recorded lien holder, which is information that Transportation Code, §501.098(h)(2) requires the recycler provide to the county tax accessor-collector. Proposed new §217.87(d)(2) would clarify that if there is a motor vehicle record for the vehicle in the department's Registration and Title System, the department will make a notation in the motor vehicle record that the motor vehicle has been dismantled, scrapped or destroyed, and cancel the title issued by the department for the motor vehicle, in accordance with Transportation Code, §501.098(f).

Proposed new §217.87(e) would describe the process for a lienholder or last registered owner of a motor vehicle acquired by a recycler under Transportation Code, §501.098 to request that the department reinstate the title and remove a notation in the department's records for the motor vehicle made under Transportation Code, §501.098(f)(1) and proposed new §217.87(b)(2), indicating that the vehicle had been dismantled, scrapped or destroyed. Proposed new §217.87(e) would describe the process of making the request to the department by presenting valid proof of identification and submitting a receipt received from the recycler transferring the motor vehicle back to the lienholder or last registered owner. The proposed new provisions for §217.87(e) are necessary to implement and administer Transportation Code, §501.098(j), which provides a lienholder or last registered owner the right to retrieve the motor vehicle acquired by the recycler under Transportation Code, §501.098. Additionally, proposed new §217.87(e) would avoid subjecting the lienholder or last registered owner to any additional costs, such as the bonded title process would require.

Proposed new §217.87(f) would describe the form and format for the records a recycler is required to compile under Transportation Code, §501.098(b) and have available for inspection by law enforcement or department personnel under Transportation Code, §501.098(m). Proposed new §217.87(f)(1) would require a recycler to collect and record the information specified under Transportation Code, §501.098(b)(1)-(9) on a department form made available on the department's website, and to maintain that form together with the identification documents under Transportation Code, §501.098(b)(10) and the department's response under proposed new §217.87(d). Proposed new §217.87(f)(2) would allow a recycler the option to maintain the records in an electronic format. The proposed new provisions to §217.87(f) are necessary to implement Transportation Code, §501.098(b), to clarify the manner in which a recycler is to compile and maintain the information specified in Transportation Code, §501.098(b) and (c), for inspection under Transportation Code, §501.098(m).

FISCAL NOTE AND LOCAL EMPLOYMENT IMPACT STATEMENT. Glenna Bowman, Chief Financial Officer, has anticipated that for each year of the first five years that the proposal will be in effect, there will be no significant fiscal impact to state or local governments as a result of the enforcement or administration of the proposal.

Annette Quintero, Director of the Vehicle Titles and Registration Division, has determined that there will be no measurable effect on local employment or the local economy as a result of the proposal.

PUBLIC BENEFIT AND COST NOTE. Ms. Quintero and Ms. Bowman have also determined that, for each year of the first five years the proposal is in effect, there are several public benefits anticipated and economic costs for persons required to comply with the rules.

Anticipated Public Benefits. The proposed repeal of §217.10 would remove any perceived conflict with Transportation Code, §501.052 by eliminating text that is duplicative of the statute thereby lessening any confusion by the public of the county tax assessor-collector's role in conducting hearings under Transportation Code, §501.052. Proposed new §217.10 would provide clarity to the public on what documents constitute a department decision on a vehicle title for purposes of applying for a hearing with a county assessor-collector's office, preventing any confusion or unnecessary and costly litigation. The proposed amendments to §217.41 would clarify that qualifying disabled veterans and peace officers have the option to select general issue license plates instead of disabled license plates without incurring the three-dollar fee associated with the disabled license plates.

Proposed new §217.87 would provide clarity to a recycler on the process for fulfilling their obligations under Transportation Code, §501.098 to thereby allow a recycler to acquire a vehicle for scrapping, dismantling, or parting that would not otherwise be authorized without a title. Proposed new §217.87 would also provide clarity for the public in how to reinstate and correct a title that has been marked dismantled, scrapped or destroyed, when the vehicle was later transferred back to the lienholder or last registered owner.

Anticipated Costs to Comply with the Proposal. Ms. Quintero anticipates that proposed new §217.87 will create a cost to comply. Proposed new §217.87 would require a recycler's staff to compile information and complete forms along with the acquisition of storage equipment to store the documentation if maintained in physical form, or computer equipment to store the documents in an electronic format. While proposed new §217.87(c) would require a recycler to travel to a regional service center to deliver the form necessary to confirm the status of any vehicles purchased for dismantling, scrapping or parting under Transportation Code, §501.098, the travel costs associated with delivering the form to a regional service center would be offset directly by the reduction in costs caused by the elimination of the requirement that a recycler travel to a regional service center to surrender titles for motor vehicles that are dismantled, scrapped or destroyed by the recycler. The proposed repeal of §217.10, proposed new §217.10, and the proposed amendments to §217.41 do not create any costs.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS. The department does not anticipate an adverse economic impact to small business, micro-businesses or rural communities as a result of the proposed repeal of §217.10, proposed new §217.10, and the proposed amendments to §217.41. Regarding the proposed new §217.87, the department anticipates an adverse economic effect on small businesses and micro-businesses that operate as recyclers.

There are approximately 646 recyclers operating in Texas, according to the Texas Department of Licensing and

Regulation Staff Report for the Used Auto Parts Recycling Board Meeting, dated March 6, 2025, available at https://www.tdlr.texas.gov/parts/aprboard.htm#past-meetings. Of that number, most are likely to be micro-business or small businesses for purposes of Government Code, §2006.002. As noted in the Public Benefit and Cost Note, proposed new §217.87 would require a recycler to travel to a regional service center to submit the form under §217.87(c), use a department form to compile information required by Transportation Code, §501.098(b), and maintain that documentation either in hard-copy or in electronic format for inspection by the department or law enforcement.

Under Government Code, §2006.002, the department must perform a regulatory flexibility analysis for proposed new §217.87. The department considered alternatives to not adopting §217.87, exempting small and micro-businesses from this new section, and adopting separate compliance or reporting requirements for small and micro-businesses. The department rejected all three options. Foregoing the adoption of §217.87 is not acceptable because Transportation Code, §501.098(b), (c) and (m) require that the department codify a process for recyclers to comply with the statutory requirements of compiling, submitting, and maintaining data on vehicle purchases for inspection purposes and to verify a vehicle's stolen or lien status with the department. The statute also requires all recyclers regardless of their business profile to comply with these requirements, so the department would not be authorized to exempt micro or small businesses from these requirements. Finally, the department considered the option of micro or small businesses to compile their vehicle purchase data under Transportation Code, §501.098(b) using their own forms and to submit their requests to the department under §501.098(c) by email or mail as opposed to an in-person visit to a regional service center, but it was determined that department forms available on the department's website are just as economical as a form created by the recycler and that the cost of travelling to a regional service center to submit forms is offset by the efficiency of an immediate response from the department that either email or mail would not permit under the department's current systems. In addition, allowing recyclers to create their own forms would increase the cost to the department significantly, as it would require significantly more department staff time to hunt through each unique form in search of the information required by Transportation Code, §501.098(b). Allowing recyclers to submit their forms under §501.098(c) electronically would significantly increase costs to the department to recode the Registration and Title System or to hire additional staff to monitor and process forms submitted by email or mail. The proposed new rule provides flexibility for recyclers to decide whether to store the records in hard-copy or electronic form, so recyclers will be able to limit the cost and impact of the proposed rule by choosing between electronic and hard-copy depending on whether hard-copy or electronic format is better and less costly for their particular circumstances. Finally, the travel costs associated with delivering the form under §501.098(c) in person will coincide with the reduction in costs for the recyclers that result from the statutory change to no longer require a title transfer.

TAKINGS IMPACT ASSESSMENT. The department has determined that no private real property interests are affected by this proposal and that this proposal does not restrict or limit an owner's right to property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking or require a takings impact assessment under Government Code, §2007.043.

GOVERNMENT GROWTH IMPACT STATEMENT. The department has determined that each year of the first five years the proposal is in effect, no government program would be created or eliminated. Implementation of the proposal would not require the creation of new employee positions or elimination of existing employee positions. Implementation would not require an increase or decrease in future legislative appropriations to the department or have a significant impact on fees paid to the department. The proposal repeals an existing regulation, §217.10, that is duplicative of the requirements provided in Transportation Code, §501.052 and creates new regulations, §217.10 and §217.87, that clarify department decisions under Transportation Code, §501.052 and §501.053 and the process for compiling data on vehicle purchases without titles and verifying statuses under Transportation Code, §501.098, respectively. Proposed new §217.87 would limit existing regulations by allowing recyclers a process to avoid titling a vehicle they purchased. The proposed amendments to §217.41 expand an existing regulation and would increase the number of individuals subject to its applicability by including qualifying disabled peace officers as disabled persons under the regulation for purposes of being issued disabled license plates and disabled parking placards, as is required by Transportation Code, §504.2025. Lastly, the proposal will not affect this state's economy.

REQUEST FOR PUBLIC COMMENT.

If you want to comment on the proposal, submit your written comments by 5:00 p.m. CST on November 3, 2025. The department requests information related to the cost, benefit, or effect of the proposed rule, including any applicable data, research, or analysis, from any person required to comply with the proposed rule or any other interested person. A request for a public hearing must be sent separately from your written comments. Send written comments or hearing requests by email to *rules@txdmv.gov* or by mail to Office of General Counsel, Texas Department of Motor Vehicles, 4000 Jackson Avenue, Austin, Texas 78731. If a hearing is held, the department will consider written comments and public testimony presented at the hearing.

SUBCHAPTER A. MOTOR VEHICLE TITLES

43 TAC §217.10

STATUTORY AUTHORITY. The department proposes the repeal of §217.10 under Transportation Code, §501.0041, which gives the department authority to adopt rules to administer Transportation Code, Chapter 501, Certificate of Title Act; Transportation Code, §501.051, which gives the department authority to refuse, cancel, suspend or revoke a title; Transportation Code, §501.052, which provides an interested person aggrieved by a refusal, rescission, cancellation, suspension, or revocation under Transportation Code, §501.051, the right to apply for hearing to the county assessor-collector; and Transportation Code, §1002.001, which authorizes the board to adopt rules that are necessary and appropriate to implement the powers and the duties of the department.

CROSS REFERENCE TO STATUTE. The proposed repeal would implement Transportation Code, Chapters 501 and 1002.

§217.10. Appeal to the County.

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 September 19, 2025.

TRD-202503320
Laura Moriaty
General Counsel
Texas Department of Motor Vehicles
Earliest possible date of adoption: November 2, 2025
For further information, please call: (512) 465-5665

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43 TAC §217.10

STATUTORY AUTHORITY. The department proposes new §217.10 under Transportation Code, §501.0041, which gives the department authority to adopt rules to administer Transportation Code, Chapter 501, Certificate of Title Act; Transportation Code, §501.051, which gives the department authority to refuse, cancel, suspend or revoke a title; Transportation Code, §501.053, which gives the department authority to determine the eligibility for a bonded title; Transportation Code, §1002.001, which authorizes the board to adopt rules that are necessary and appropriate to implement the powers and the duties of the department; and the statutory authority referenced throughout the preamble and in the rule text.

CROSS REFERENCE TO STATUTE. The proposed new section would implement Transportation Code, Chapters 501 and 1002.

§217.10. Department Decisions on Titles and Appeals to the County.

(a) Department refusal or revocation of title. For purposes of Transportation Code, §501.052, the official record of the department's refusal to issue a title under its authority in Transportation Code, §501.051 is the department's notice of determination regarding the application. The official record of the department's revocation of a title is the entry of a revocation remark on the motor vehicle record in the department's Registration and Title System.

(b) Department determination of ineligibility for bonded title. A department determination of ineligibility for bonded title is made under the authority of Transportation Code, §501.053 and is not a refusal to issue a title under Transportation Code, §501.051. An applicant that receives a notice of ineligibility for bonded title from the department is not eligible to pursue a hearing under Transportation Code, §501.052.

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

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Laura Moriaty
General Counsel
Texas Department of Motor Vehicles
Earliest possible date of adoption: November 2, 2025
For further information, please call: (512) 465-5665

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SUBCHAPTER B. MOTOR VEHICLE REGISTRATION

43 TAC §217.41

STATUTORY AUTHORITY. The department proposes amendments to §217.41 under Transportation Code, §504.0011, which gives the board authority to adopt rules to implement and administer Transportation Code, Chapter 504, License Plates; Transportation Code, §504.010, which authorizes the board to adopt rules governing the placement of license plates on motor vehicles; Transportation Code, §504.202, entitling a qualifying disabled veteran to elect for license plates issued under Transportation Code, Chapter 502 in lieu of disabled veteran license plates; Transportation Code, §504.2025, as created by Senate Bill 2001, 89th Legislature, Regular Session (2025), providing a qualifying peace officer with the option to obtain disabled peace officer license plates and disabled parking placards; Transportation Code, §1002.001, which authorizes the board to adopt rules that are necessary and appropriate to implement the powers and the duties of the department; and the statutory authority referenced throughout the preamble and in the rule text.

CROSS REFERENCE TO STATUTE. The proposed amendments would implement Transportation Code, Chapters 504 and 1002.

§217.41. Disabled Person License Plates and Disabled Parking Placards.

(a) Purpose. Transportation Code, Chapters 504 and 681, charge the department with the responsibility for issuing specially designed license plates and disabled parking placards for disabled persons. For the department to perform these duties efficiently and effectively, this section prescribes the policies and procedures for the application, issuance, and renewal of disabled person license plates and disabled parking placards.

(b) Issuance.

(1) For purposes of this section, "disabled person" means a person eligible for issuance of a license plate bearing the International Symbol of Access under Transportation Code, §504.201, including a qualifying disabled veteran under Transportation Code, §504.202(b-1) and a qualifying disabled peace officer under Transportation Code, §504.2025.

(2) Disabled person license plates.

(A) Eligibility. In accordance with Transportation Code, §504.201; [~~and~~] §504.202(b-1) and (b-2); and §504.2025, the department will issue specially designed license plates displaying the International Symbol of Access to permanently disabled persons or their transporters instead of general issue license plates. As satisfactory proof of eligibility, an organization that transports disabled veterans who would qualify for license plates issued under Transportation Code, §504.202(b-1) must provide a written statement from the veteran's county service officer of the county in which a vehicle described by Transportation Code, §504.202(c) is registered or by the Department of Veterans Affairs that:

(i) the vehicle is used exclusively to transport veterans of the United States armed forces who have suffered, as a result of military service, a service-connected disability;

(ii) the vehicle regularly transports veterans who are eligible to receive license plates under Subsection (b-1); and

(iii) the veterans are not charged for the transportation.

(B) Specialty license plates. The department will issue disabled person specialty license plates displaying the International Symbol of Access that can accommodate the identifying insignia and that are issued in accordance with §217.43 of this title (relating to Mil-

itary Specialty License Plates) or §217.45 of this title (relating to Specialty License Plates, Symbols, Tabs, and Other Devices).

(C) License plate number. Disabled person license plates will bear a license plate number assigned by the department or will bear a personalized license plate number issued in accordance with §217.43 or §217.45 of this title.

(D) General issue license plate option for qualifying disabled veterans and disabled peace officers. In accordance with Transportation Code, §504.202(h) and §504.2025(h), qualifying disabled veterans and disabled peace officers may elect to receive general issue license plates without paying license plate fees.

(3) Windshield disabled parking placards.

(A) Issuance. The department will issue removable windshield disabled parking placards to temporarily or permanently disabled persons and to the transporters of permanently disabled persons, as provided under Transportation Code, §§504.201, 504.202 (b-1) and (b-2), 504.2025, and 681.004.

(B) Display. A person who has been issued a windshield disabled parking placard shall hang the placard from a vehicle's rearview mirror when the vehicle is parked in a disabled person parking space or shall display the placard on the center portion of the dashboard if the vehicle does not have a rearview mirror.

(c) Renewal of disabled person license plates. Disabled person license plates are valid for a period of 12 months from the date of issuance and are renewable as specified in §§217.28 of this title (relating to Vehicle Registration Renewal), 217.43, and 217.45 of this title.

(d) Replacement.

(1) License plates. If a disabled person metal license plate is lost, stolen, or mutilated, the owner may obtain a replacement metal license plate by applying with a county tax assessor-collector.

(A) Accompanying documentation. To replace disabled person metal license plates, the owner must present the current year's registration receipt and personal identification acceptable to the county tax assessor-collector.

(B) Absence of accompanying documentation. If the current year's registration receipt is not available and the county tax assessor-collector cannot verify that the disabled person metal license plates were issued to the owner, the owner must reapply in accordance with this section.

(2) Disabled parking placards. If a disabled parking placard becomes lost, stolen, or mutilated, the owner may obtain a new disabled parking placard in accordance with this section.

(e) Transfer of disabled person license plates and disabled parking placards.

(1) License plates.

(A) Transfer between persons. Disabled person license plates may not be transferred between persons. An owner who sells or trades a vehicle to which disabled person license plates have been issued shall remove the disabled person license plates from the vehicle. The owner shall return the license plates to the department and shall obtain appropriate replacement license plates to place on the vehicle prior to any transfer of ownership.

(B) Transfer between vehicles. Disabled person license plates may be transferred between vehicles if the county tax assessor-collector or the department can verify the plate ownership and the owner of the vehicle is a disabled person or the vehicle is used to transport a disabled person.

(i) Plate ownership verification may include:

(I) a Registration and Title System (RTS) inquiry;

(II) a copy of the department application for disabled person license plates; or

(III) the owner's current registration receipt.

(ii) An owner who sells or trades a vehicle with disabled person license plates must remove the plates from the vehicle.

(iii) The department will provide a form that persons may use to facilitate a transfer of disabled person license plates between vehicles.

(2) Disabled parking placards.

(A) Transfer between vehicles. Disabled parking placards may be displayed in any vehicle driven by the disabled person or in which the disabled person is a passenger.

(B) Transfer between persons. Disabled parking placards may not be transferred between persons.

(f) Seizure and revocation of disabled parking placard.

(1) If a law enforcement officer seizes and destroys a disabled parking placard under Transportation Code, §681.012, the officer shall notify the department by email.

(2) The person to whom the seized disabled parking placard was issued may apply for a new disabled parking placard by submitting an application to the county tax assessor-collector of the county in which the person with the disability resides or in which the applicant is seeking medical treatment.

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

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Laura Moriaty
General Counsel
Texas Department of Motor Vehicles
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SUBCHAPTER D. NONREPAIRABLE AND SALVAGE MOTOR VEHICLES

43 TAC §217.87

STATUTORY AUTHORITY. The department proposes new §217.87 under Transportation Code, §501.0041, which gives the department authority to adopt rules to administer Transportation Code, Chapter 501, Certificate of Title Act; Transportation Code, §501.098, as created by House Bill 5436, 89th Legislature, Regular Session (2025), which gives the department authority to prescribe the manner in which a used automotive parts recycler compiles the information required under Transportation Code, §501.098(b) on motor vehicles purchased without title for purposes of dismantling, scrapping or parting; the authority to prescribe the manner in which a used automotive parts recycler submits to the department any information necessary to satisfy

any applicable requirement for reporting information to the National Motor Vehicle Title Information System; the authority to inspect records under Transportation Code, §501.098(m); and Transportation Code, §1002.001, which authorizes the board to adopt rules that are necessary and appropriate to implement the powers and the duties of the department; and the statutory authority referenced throughout the preamble and in the rule text.

CROSS REFERENCE TO STATUTE. The proposed new section would implement Transportation Code, Chapters 501 and 1002.

§217.87. Requirements for Certain Vehicles Acquired by a Used Automotive Parts Recycler Without a Title.

(a) Reporting requirements.

(1) A used automotive parts recycler (recycler), as defined in Occupations Code §2309.002, that purchases a motor vehicle without a title, in accordance with Transportation Code, §501.098(a), shall determine if the motor vehicle is reported stolen and if the motor vehicle is the subject of any recorded security interests or liens by completing and submitting the form described in subsection (b) of this section to the department within the time provided under Transportation Code, §501.098(c) and §501.098(g).

(2) A recycler must separately report the information specified under Transportation Code, §501.098(c) to the National Motor Vehicle Title Information System.

(b) Information on form. A recycler shall submit a form containing the following information:

(1) name, mailing address, email address and phone number of the recycler;

(2) the vehicle identification number for the motor vehicle;

(3) the date the motor vehicle was obtained;

(4) the name of the individual or entity from whom the motor vehicle was obtained;

(5) A statement that the vehicle:

(A) is at least 13 years old,

(B) is purchased solely for parts, dismantling, or scrap, and

(C) has not been registered for at least seven years; and

(6) the signature of the recycler or the recycler's authorized agent.

(c) Submittal of form. The form shall be submitted to the department in person at one of the department's regional offices.

(d) Department response.

(1) Upon receipt of a completed and signed form under subsection (b) of this section, the department shall:

(A) notify the recycler, in person or via the email address specified on the form, within the time specified under Transportation Code, §501.098(d), whether the motor vehicle has been reported stolen; and

(B) notify the recycler, in person or via the email address specified on the form, whether the motor vehicle is the subject of a recorded security interest or lien in the department's Registration and Title System. If the vehicle has a recorded lien or security interest, the recycler may obtain the contact information of the holder of that recorded lien or security interest from the department by submitting a request in accordance with §217.123 of this title (relating to Access to Motor Vehicle Records).

(2) If the motor vehicle has a motor vehicle record in the department's Registration and Title System, the department shall:

(A) add a notation to the motor vehicle record that the motor vehicle has been dismantled, scrapped, or destroyed; and

(B) cancel the title issued by the department for the motor vehicle.

(e) Vehicles retrieved from recycler. The department shall reinstate the title and remove the notation in the department's records specified under subsection (d)(2) of this section and Transportation Code, §501.098(f)(1) at the request of a lienholder or last registered owner of a vehicle that is retrieved from a recycler under Transportation Code, §501.098(j). The request must include:

(1) a receipt from the recycler transferring the vehicle to the lienholder or last registered owner that includes the vehicle identification number, year and make; and

(2) valid proof of identification as provided in §217.7 of this title (relating to Replacement of Title).

(f) Records.

(1) A recycler shall collect and record the information specified in Transportation Code, §501.098(b)(1)-(9) on a form available on the department's website and maintain that form with the identification documents under Transportation Code, §501.098(b)(10) and the department's response under subsection (d) of this section.

(2) The records may be maintained in an electronic format.

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

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