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

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

TITLE 1. ADMINISTRATION

PART 15. TEXAS HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 353. MEDICAID MANAGED CARE

SUBCHAPTER Q. PROCESS TO RECOUP CERTAIN OVERPAYMENTS

1 TAC §§353.1451 - 353.1454

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) proposes new §353.1451, concerning Purpose and Authority; §353.1452, concerning Definitions; §353.1453, concerning Due Process Procedures to Recoup an Overpayment Related to an EVV Visit Transaction that is not Fraud or Abuse and Limitation on Audit Period; and §353.1454, concerning Due Process Procedures to Recoup an Overpayment Because of a Discovery of Fraud or Abuse, in Chapter 353, new Subchapter Q, Process to Recoup Certain Overpayments.

BACKGROUND AND PURPOSE

Senate Bill 1991, 86th Legislature, Regular Session, 2019, amended Texas Government Code by adding new §§531.1131(f) and 531.1135 requiring HHSC to adopt rules describing the due process procedures a managed care organization (MCO) must follow to recoup an overpayment made to a health care provider related to missing electronic visit verification (EVV) information; and requiring that, as part of the process to recoup such an overpayment, an MCO give a provider at least 60 days to correct a deficiency in a claim before the MCO begins any efforts to recoup overpayments.

Texas Government Code, §531.1131(e) requires HHSC to adopt rules describing the due process procedures an MCO must follow when engaging in recoupment efforts related to fraud or abuse.

The purpose of the proposal is to implement Texas Government Code, §§531.1131(e) and (f) and 531.1135.

SECTION-BY-SECTION SUMMARY

Proposed new §353.1451 describes the purpose of new Subchapter Q and explains that Texas Government Code, §531.1131 and §531.1135 provide the statutory basis for the new subchapter.

Proposed new §353.1452 defines the terms used in the subchapter.

Proposed new §353.1453(a) requires an MCO to, in an audit of a provider or financial management services agency (FMSA), limit the review of EVV visit transactions to those that occurred during the 24 months prior to the audit. Subsection (b) of the proposed rule requires that if, based on an audit or investigation, an MCO identifies a deficiency related to an EVV visit transaction that is not fraud or abuse and the MCO decides to recoup an overpayment because of the deficiency, the MCO gives a provider or FMSA written notice of the MCO's intent to recoup overpayments not later than the 30th day after the date the audit or investigation is completed. Subsection (c) of the proposed rule describes the information that must be in the written notice, including the specific number of days allowed to correct and explain the deficiency before the MCO begins any efforts to collect overpayments, which must be no fewer than 60 days from the notice date; the provider's or FMSA's option to seek an informal resolution with the MCO of the intended recoupment; and the MCO's process to appeal the intended recoupment. Subsection (d) of the proposed rule provides that a corrected deficiency is one that a provider or FMSA makes by performing visit maintenance to correct an EVV visit transaction in accordance with HHSC EVV policy or correcting and resubmitting a claim in accordance with MCO policies and procedures. Subsection (e) of the proposed rule allows an MCO to recoup an overpayment only if a provider or FMSA does not correct the deficiency related to an EVV visit transaction and does not appeal the alleged overpayment or appeals the alleged overpayment and the final decision from the appeal is favorable to the MCO. Subsection (f) of the proposed rule requires an MCO to comply with the proposed new §353.1454 if the MCO determines that a deficiency related to an EVV visit transaction is fraud or abuse.

Proposed new §353.1454(a) requires an MCO to have due process procedures in place if the MCO decides to recoup an overpayment from a provider or FMSA because of a discovery of fraud or abuse, as permitted by §353.505 (relating to Recovery of Funds). Subsection (a) also requires that the due process procedures include a written notice to the provider or FMSA of the MCO's intent to recoup overpayments and that such notice include a description of the basis for the intended recoupment; the provider's or FMSA's option to seek an informal resolution with the MCO of the intended recoupment; and the MCO's process for the provider or FMSA to appeal the intended recoupment. Subsection (b) of the proposed rule allows an MCO to recoup an overpayment only if the provider or FMSA does not appeal the alleged overpayment or appeals the alleged overpayment and the final decision from the appeal is favorable to the MCO.

FISCAL NOTE

Trey Wood, HHSC Chief Financial Officer has determined that for each year of the first five years that the rules will be in effect, enforcing or administering the rules does not have foreseeable

implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

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

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

(2) implementation of the proposed rules will not affect the number of HHSC employee positions;

(3) implementation of the proposed rules will result in no assumed change in future legislative appropriations;

(4) the proposed rules will not affect fees paid to HHSC;

(5) the proposed rules will create new rules;

(6) the proposed rules will expand existing rules;

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

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

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

Trey Wood has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities. There are no Texas Medicaid MCOs that fall into the category of small businesses, micro-businesses, or rural communities.

LOCAL EMPLOYMENT IMPACT

The proposed rules will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code, §2001.0045 does not apply to these rules because the rules are necessary to implement legislation that does not specifically state that §2001.0045 applies to the rules.

PUBLIC BENEFIT AND COSTS

Stephanie Stephens, State Medicaid Director, has determined that for each year of the first five years the rules are in effect, the public will benefit from rules that require MCOs to have due process procedures in place regarding recoupment of overpayments from providers and FMSAs because of errors related to an EVV visit transaction or because of fraud or abuse.

Trey Wood has also determined that for the first five years the rules are in effect, persons who are required to comply with the proposed rules may incur economic costs. An MCO may incur costs developing the written notice required, training staff responsible for implementing the new requirements, and making any necessary information systems changes. HHSC lacks sufficient data to determine an estimate of these costs.

TAKINGS IMPACT ASSESSMENT

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

PUBLIC COMMENT

Written comments on the proposal may be submitted to Rules Coordination Office, P.O. Box 13247, Mail Code 4102, Austin, Texas 78711-3247, or street address 4900 North Lamar Boulevard, 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 Rule 20R082" in the subject line.

STATUTORY AUTHORITY

The new sections are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; Texas Government Code, §531.033, which provides the Executive Commissioner of HHSC with broad rulemaking authority; Human Resources Code, §32.021, which provides that HHSC shall adopt necessary rules for the proper and efficient operation of the Medicaid program; Texas Government Code, §531.1131(e) which provides that the Executive Commissioner of HHSC shall adopt rules describing the due process procedures an MCO must follow when engaging in recoupment efforts related to fraud or abuse; and Texas Government Code, §531.1135 which provides that the Executive Commissioner of HHSC shall adopt rules to standardize the process an MCO must follow to recoup an overpayment made to a health care provider related to missing electronic visit verification information.

The new sections affect Texas Government Code, §531.0055, §531.033, §531.1131(e), and §531.1135 and Texas Human Resources Code, §32.021.

§353.1451. Purpose and Authority.

The purpose of this subchapter is to describe the due process a managed care organization (MCO) must give to recoup an overpayment related to an electronic visit verification visit transaction in accordance with Texas Government Code, §531.1135 and the due process an MCO must give to recoup an overpayment related to a determination of fraud or abuse in accordance with Texas Government Code, §531.1131.

§353.1452. Definitions.

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

(1) Abuse--This term has the meaning set forth in §371.1 of this title (relating to Definitions).

(2) EVV visit transaction--Electronic visit verification visit transaction. This term has the meaning set forth in §354.4003 of this title (relating to Definitions).

(3) FMSA--Financial management services agency. An entity that contracts with a managed care organization to provide financial management services to a consumer directed services employer as described in Title 40, Texas Administrative Code, Chapter 41 (relating to Consumer Directed Services Option).

(4) Fraud--This term has the meaning set forth in §371.1 of this title.

§353.1453. Due Process Procedures to Recoup an Overpayment Related to an EVV Visit Transaction that is not Fraud or Abuse and Limitation on Audit Period.

(a) In an audit of a provider or FMSA conducted by a managed care organization (MCO), the MCO must limit the review of EVV visit transactions to those that occurred during the 24 months prior to the audit.

(b) If, based on an audit or investigation of a provider or FMSA, an MCO identifies a deficiency related to an EVV visit transaction that is not fraud or abuse and the MCO decides to recoup an overpayment because of the deficiency, the MCO must give the provider or FMSA written notice of the MCO's intent to recoup overpayments not later than the 30th day after the date the audit or investigation is completed.

(c) An MCO must include the following in the written notice required by subsection (b) of this section:

(1) a description of the basis for the intended recoupment;

(2) if the basis of the intended recoupment is an EVV visit transaction, the specific EVV visit transaction and associated claim that are the basis of the intended recoupment;

(3) if the basis of the intended recoupment is a missing EVV visit transaction, the claim for which there is no associated EVV visit transaction;

(4) that the MCO must receive a response to the notice from the provider or FMSA no later than the 30th day after the date the provider or FMSA receives the written notice, if the provider or FMSA intends to respond;

(5) the specific number of days allowed to correct and explain the deficiency before the MCO begins any efforts to collect overpayments, which must be no fewer than 60 days from the notice date;

(6) the process by which the provider or FMSA should communicate with and send information to the MCO about the EVV visit transactions that are the basis of the intended recoupment;

(7) the provider's or FMSA's option to seek an informal resolution with the MCO of the intended recoupment; and

(8) the MCO's process for the provider or FMSA to appeal the intended recoupment.

(d) A corrected deficiency is one that a provider or FMSA makes by doing one or both of the following:

(1) performing visit maintenance to correct an EVV visit transaction in accordance with HHSC EVV policy; or

(2) correcting and resubmitting a claim in accordance with MCO policies and procedures.

(e) An MCO may recoup an overpayment only if a provider or FMSA:

(1) does not correct the deficiency and does not appeal the alleged overpayment; or

(2) appeals the alleged overpayment and the final decision from the appeal is favorable to the MCO.

(f) If an MCO determines that a deficiency related to an EVV visit transaction is fraud or abuse, the MCO must comply with §353.1454 of this subchapter (relating to Due Process Procedures to Recoup an Overpayment Because of a Discovery of Fraud or Abuse).

§353.1454. Due Process Procedures to Recoup an Overpayment Because of a Discovery of Fraud or Abuse.

(a) If a managed care organization (MCO) decides to recoup an overpayment from a provider or FMSA because of a discovery of fraud or abuse as permitted by §353.505 of this chapter (relating to Recovery of Funds), the MCO must have due process procedures that include the following:

(1) written notice to the provider or FMSA of the MCO's intent to recoup overpayments that includes the following:

(A) a description of the basis for the intended recoupment;

(B) the specific claims that are the basis of the intended recoupment;

(C) the process by which the provider or FMSA should send information to the MCO about claims that are the basis of the intended recoupment;

(D) the provider's or FMSA's option to seek an informal resolution with the MCO of the intended recoupment; and

(E) the MCO's process for the provider or FMSA to appeal the intended recoupment;

(2) a process for the provider or FMSA to seek informal resolution; and

(3) a process for the provider or FMSA to appeal the intended recoupment.

(b) An MCO may recoup an overpayment only if a provider or FMSA:

(1) does not appeal the alleged overpayment; or

(2) appeals the alleged overpayment and the final decision from the appeal is favorable to the MCO.

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 10, 2021.

TRD-202103592
Karen Ray
Chief Counsel
Texas Health and Human Services Commission
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 707-6132

♦ ♦ ♦

TITLE 7. BANKING AND SECURITIES

PART 6. CREDIT UNION DEPARTMENT

CHAPTER 91. CHARTERING, OPERATIONS, MERGERS, LIQUIDATIONS

SUBCHAPTER A. GENERAL RULES

7 TAC §91.121

The Credit Union Commission (the Commission) proposes amendments to 7 TAC, Chapter 91, §91.121 concerning complaint notices and procedures. The purpose of the proposed amendments is to implement amendments to Finance Code

Section 15.408 that resulted from the passage of SB 707. Finance Code Section 15.408 provides that the Commission shall maintain a system to promptly and efficiently act on complaints filed with the Credit Union Department (Department).

The proposed rule changes are intended to incorporate SB 707's redesign of Finance Code Section 15.408 from provisions previously found in Section 15.409 and further amendments providing for additional data element tracking and annual reporting related to complaints filed with the Department against chartered credit unions.

The proposed amendments to paragraph (a) amends the legal citation to reflect the redesign of the Finance Code created by the passage of SB 707.

The proposed amendments to paragraph (c)(2) represents a grammar correction.

The proposed amendments to paragraph (c)(4) address grammar corrections and incorporate language added to the Finance Code by the passage of SB 707.

The proposed amendments to paragraph (c)(5) address grammar changes to clarify the paragraphs meaning.

The proposed amendments to (c)(7) address language changes required by the passage of SB 707 which specifically involves additional data elements to be tracked in the complaint process.

The proposed amendments to paragraph (d) addresses a grammar edit.

The proposed new paragraph (f) incorporates the Departments annual reporting requirement initiated as a result of the passage of SB 707.

STATE AND LOCAL GOVERNMENTS

John J. Kolhoff, Commissioner, has determined that for the first five-year period that the rule changes are in effect there will be no fiscal implications for state and local government as a result of enforcing or administering the rule changes.

STATEMENT OF PUBLIC COST AND BENEFITS

Mr. Kolhoff has also determined that for each year of the first five years the rules are in effect, the public will benefit from the adoption of the proposed amendments because they will have access to information which will assist them in making complaints and will allow a better understanding of the process by which complaints are reviewed by the Department. There will be no anticipated cost to persons who are required to comply with the proposed amendments.

SMALL AND MICRO BUSINESSES AND RURAL COMMUNITIES

Mr. Kolhoff has also determined that for each year of the first five years the rule changes are in effect, there will be no adverse economic effect on small businesses, micro-businesses, or rural communities. There is no economic cost anticipated to the credit union system or to individuals required to comply with the rule changes as proposed.

GOVERNMENT GROWTH IMPACT STATEMENT

Except as may be described below to the contrary, for each year of the first five years that the rules will be in effect, the rules will not:

--Create or eliminate a government program;

--Require the creation of new employee positions or the elimination of existing employee positions;

--Require an increase or decrease in future legislative appropriations to the agency;

--Create new regulations;

--Expand, limit, or repeal an existing regulation;

--Increase fees paid to the department;

--Increase or decrease the number of individuals subject to the rule's applicability; or

--Positively or adversely affect this state's economy.

Written comments on the proposed amendments may be submitted to John J. Kolhoff, Commissioner, Credit Union Department, 914 East Anderson Lane, Austin, Texas 78752-1699 or by email to CUDMail@cud.texas.gov. To allow the Commission sufficient time to fully address all the comments it receives, all comments must be received on or before 5:00 p.m. on the 31st day after the date the proposal is published in the *Texas Register.*

The rule changes are proposed under Texas Finance Code, Section 15.402, which authorizes the Commission to adopt reasonable rules for administering Texas Finance Code Title 2, Chapter 15 and Title 3, Subtitle D.

The statutory provision affected by the proposed amendments is Texas Finance Code, Section 15.408, regarding consumer information and complaints.

§91.121. Complaint Notices and Procedures.

(a) Purpose. This section implements Finance Code §15.408 [~~§15.409~~], which requires the Department to maintain a system to promptly and efficiently act on each complaint filed with the Department.

(b) Required Notice.

(1) Credit unions must provide their members with a notice that substantially conforms to the language and form of the following notice in order to let its members know how to file complaints: "If you have a problem with the services provided by this credit union, please contact us at: (Your Name) Credit Union Mailing Address Telephone Number or e-mail address. The credit union is incorporated under the laws of the State of Texas and under state law is subject to regulatory oversight by the Texas Credit Union Department. If any dispute is not resolved to your satisfaction, you may also file a complaint against the credit union by contacting the Texas Credit Union Department through one of the means indicated below: In Person or U.S. Mail: 914 East Anderson Lane, Austin, Texas 78752-1699, Telephone Number: (512) 837-9236, Facsimile Number: (512) 832-0278; email: complaints@cud.texas.gov., Website: www.cud.texas.gov."

(2) The title of this notice shall be "COMPLAINT NOTICE" and must be in all capital letters and boldface type.

(3) The credit union must provide the notice as follows:

(A) In each area where a credit union typically conducts business on a face-to-face basis, the required notice must be conspicuously posted. A notice is deemed to be conspicuously posted if a member with 20/20 vision can read it from the place where he or she would typically conduct business or if it is included in plain view on a bulletin board on which required communications to the membership (such as equal housing posters) are posted.

(B) If a credit union maintains a website, the required notice or a link to the required notice must be conspicuously posted on the homepage of the website.

(C) If a credit union distributes a newsletter, it must include the notice on approximately the same date at least once each year in any newsletter distributed to its members.

(D) If a credit union does not distribute a newsletter, the notice must be included with any privacy notice the credit union is required to provide or send its members.

(c) Filing, Receipt, and Handling of Complaints.

(1) The Department shall make available, on its public website (www.cud.texas.gov) and at its office, information on how to file a complaint.

(2) A person who alleges that a credit union has committed an act[,] or failed to perform an act that may constitute a violation of the Texas Credit Union Act or Department rules may file a complaint in writing with the Department. The complainant may complete and submit to the Department the complaint form the Department maintains at the Department's office and on its public website, or the complainant may submit a complaint in a letter that addresses the matters covered by the complaint form. At a minimum, all complaints should contain information necessary for the proper processing of the complaint by the Department, including, but not limited to:

(A) complainant's name and how the complainant may be contacted;

(B) name and address of the credit union against whom the complaint is made;

(C) a brief statement of the nature of the complaint and relevant facts, including names of persons with knowledge, times, dates, and location; and

(D) Copies of any documents or records related to the complaint (original records should not be sent with a complaint).

(3) Anonymous complaints may be accepted by the Department, but the lack of a witness or the inability of the Department to secure additional information from the anonymous complainant may result in the Department's inability to secure sufficient evidence to pursue action against a credit union.

(4) The Department will review all complaints to determine whether they are within the Department's jurisdiction or authority to resolve[,] and will send an acknowledgement letter to the complainant within five (5) business days of receipt of a complaint. At least quarterly until final disposition of the complaint, the Department shall provide status updates to the complainant and respondent credit union, orally or in writing, unless the notice would jeopardize an investigation.

(5) Upon determining that a complaint is within the Department's jurisdiction, the Department will inform the credit union respondent of the complaint and will request a written response from the credit union. Along with a request for response, the Department will transmit to the credit union a copy of the complaint and any attachments. Within fifteen (15) days from the date of the request for response, unless the period is extended by the Department, the credit union shall provide a substantive response and set forth the credit union's position with respect to the allegations in the complaint, which shall include all data, information and documentation supporting its position, or a description of corrective measures taken or intended to be taken. The Department may request, and the complainant and respondent shall provide, [~~to the Department~~] additional information or further explanation at any time during the review of the complaint.

(6) Once the Department has received the documentation from both parties, the Department will review the information and will process the complaint in accordance with the rules of the Department. The Department will advise both parties in writing of the final disposition of the complaint.

(7) The Department shall maintain a file on each complaint filed with the agency. The file shall include:

(A) the complainant's name and relationship to the institution [~~of the complainant~~];

(B) the date the complaint is received and resolved or closed by the Department;

(C) the basis [~~subject matter~~] of the complaint;

(D) a summary of the results of the review of the complaint including issuance of any enforcement action; and

(E) an explanation of the reason the file was closed, if the Department closed the file without taking action other than to review the complaint.

(8) The Department will maintain a database of complaints in order to identify trends or issues related to violations of state laws under the Department's jurisdiction.

(d) Complaints Closed with No Action Beyond Review. Certain complaints and disputes may be closed with no action taken other than to review the complaint. Such complaints may include those that are not within the Department authority to investigate or adjudicate, and which may be referred to as non-jurisdictional complaints. The Department, for example, will not address complaints concerning contractual matters or internal credit union practices that are not governed by the statutes or rules that the Department implements or enforces. The Department also may close without taking action other types of complaints, including undocumented factual disputes between a person and a credit union and complaints involving matters that are the subject of a pending lawsuit. The Department does not offer legal assistance and cannot represent individuals in settling claims or recovering damages. The Department does not own, operate, or control credit unions, and the Department does not establish their operating policies and procedures. Therefore, the Department may close without taking action complaints concerning the range of services a credit union offers, complaints about bad customer service, and disagreements over specific credit union policies, practices, or procedures, or about other matters that are not governed by a law or rule under the Department's jurisdiction. The Department will inform the complainant and respondent credit union when a complaint is closed with no action taken[,] and will inform them of the reason for closing the case.

(e) Privacy. The information collected from complainants and respondents is solicited to provide the Department with information that is necessary and useful in reviewing complaints received from persons regarding their interactions with a credit union. A complainant is not required to give the Department any information; however, without such information, the Department's ability to complete a review, to investigate, or to prosecute a matter may be hindered. It is intended that the information a person provides to the Department will be used within the Department and for the purpose of investigating and prosecuting a complaint. A person should not include personal or confidential information such as social security, credit card, or account numbers, or dates of birth when corresponding with the Department. If it is necessary to supply a document that contains personal or confidential information,

the information should be redacted before the document is submitted to the Department.

(f) The Department will annually produce a statistical analysis of complaints processed and related enforcement actions for the preceding fiscal year which must include at a minimum:

(1) total complaints filed, closed and outstanding;

(2) resolved complaints aggregated by source, basis of complaint, disposition, jurisdictional vs. non-jurisdiction, regulatory vs. non-regulatory penalties or fees assessed and the average number of days to resolve.

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 9, 2021.

TRD-202103580
John J. Kolhoff
Commmissioner
Credit Union Department
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 837-9236

♦ ♦ ♦

SUBCHAPTER C. MEMBERS

7 TAC §91.301

The Credit Union Commission (the Commission) proposes amendments to 7 TAC, Chapter 91, Subchapter C, §91.301, concerning field of membership. The amended rule is proposed to ensure consistency with the field of membership language provided by Texas Finance Code Section 122.051, to recognize the growing consumer expectation of, operational efficiencies obtained through and safety and soundness implications of, digital delivery of financial services, and ensure competitiveness with the National Credit Union Administration (NCUA) field of membership rules.

On March 19, 2020, the State of Texas issued its first Declaration of a Public Health Disaster in response to the Covid-19 Pandemic. Similar declarations occurred throughout the country at the national, state, county and municipal level, and indeed throughout the world. As a result, the delivery of financial services under appropriate safety standards, including significant restrictions on physical interaction, made providing services through digital channels an important component of the credit union industry's ability to continue their statutory mission of providing convenient, safe and competitive financial services to their memberships.

Texas chartered credit unions worked diligently to utilize digital channels in conjunction with their diverse physical presence to ensure Texas consumers had full and unfettered access to their funds and necessary loan products. Further, access through digital channels was a major contributor toward the implementation of national, state and local programs designed to assist various economically impacted groups and provide broad support to mitigate the negative impact of the pandemic to the overall economy. Finally, the ability to react appropriately during a disaster using digital services evidenced itself as an important component of an institution's ability to maintain itself as a safe, sound and viable entity. As a result, the digital delivery of financial services was proven to be not only a matter of consumer convenience, but one of safety and soundness relating to the diversity of programs available to meet the industry's mission as well as public policy relating to the ability to react to significant adverse scenarios and maintain a viable industry.

As the Commission reviewed TAC 91.301 it noted that the rule does not consider digital delivery channels as a component of an institution's ability to serve its membership despite the safety and soundness, public policy and consumer convenience implications. It was also noted that the limitation in recognizing digital financial services imposed by TAC 91.301 is beyond the field of membership requirements outlined by Texas Finance Code Section 122.051, and in direct contravention to the legislative intent outlined by Texas Finance Code Section 15.402 (b-1).

The purpose of the proposed amendments to §91.301 are to remove the local service area definition which exceeds the legislative requirements found in Texas Finance Code Section 122.051 and to allow the commissioner to consider an institution's ability to provide financial services through digital channels to meet the needs of its membership. The proposed amendments will provide credit unions the full extent of the field of membership provisions found in the Texas Finance Code and will help ensure parity with both federal and foreign state credit unions doing business in Texas.

The proposed changes within §91.301(a) removes the definition of local service area and related physical office requirement to allow the commissioner to consider the ability of an institution to provide digital delivery channels as a viable option in its ability to serve its membership.

The proposed deletion of §91.301(e)(2) removes the related physical office requirements for an approved underserved community field of membership to ensure the same consideration of digital delivery of financial services is available to the commissioner.

STATE AND LOCAL GOVERNMENTS

John J. Kolhoff, Commissioner, has determined that for the first five-year period the rule changes are in effect there will be no fiscal implications for state or local government as a result of enforcing or administering the rule changes.

STATEMENT OF PUBLIC COST AND BENEFITS

Mr. Kolhoff has also determined that for each year of the first five years the rule changes are in effect, the public benefits anticipated as a result of the changes will be greater clarity regarding the rule's requirements and significant regulatory relief for credit unions. There will be no anticipated cost to persons who are required to comply with the proposed amendments. There will be no adverse economic effect on small businesses, micro-businesses, or rural communities, as compared to large businesses. There is no economic cost anticipated to the credit union system or to individuals required to comply with the rule changes as proposed.

SMALL AND MICRO BUSINESSES AND RURAL COMMUNITIES

Mr. Kolhoff has also determined that for each year of the first five years the rule changes are in effect, there will be no adverse economic effect on small businesses, micro-businesses, or rural communities. There is no economic cost anticipated to the credit

union system or to individuals required to comply with the rule changes as proposed.

GOVERNMENT GROWTH IMPACT STATEMENT

Except as may be described below to the contrary, for each year of the first five years that the rules will be in effect, the rules will not:

--Create or eliminate a government program;

--Require the creation of new employee positions or the elimination of existing employee positions;

--Require an increase or decrease in future legislative appropriations to the agency;

--Create new regulations;

--Expand or repeal an existing regulation;

--Increase fees paid to the department;

--Increase or decrease the number of individuals subject to the rule's applicability; or

--Positively or adversely affect this state's economy.

Written comments on the proposed amendments may be submitted in writing to John J. Kolhoff, Commissioner, Credit Union Department, 914 East Anderson Lane, Austin, Texas 78752-1699 or by email to CUDMail@cud.texas.gov. To be considered, a written comment must be received on or before 5:00 p.m. on the 31st day after the date the proposal is published in the *Texas Register.* At the conclusion of business on the 31st day after the proposal is published in the *Texas Register,* no further written comments will be considered or accepted by the commission.

The rule changes are proposed under Texas Finance Code Section 15.402, which authorizes the Commission to adopt reasonable rules for administering Title 3, Subtitle D of the Texas Finance Code.

The statutory provisions affected by the proposed amendments are contained in Texas Finance Code Section 122.051.

§91.301. Field of Membership.

(a) General. Membership in a credit union shall be limited to one or more groups, each of which (the Group) has its own community of interest as outlined under Texas Finance Code Section 122.051. [and is within the credit unions local service area. In this section, local service area generally consists of one or more contiguous political subdivisions that are within reasonable proximity of a credit union's offices. Political subdivision has the meaning assigned by TEX. LOCAL GOV'T CODE §172.003(3). For purposes of field of membership, the Group as a whole will be considered to be within the local service area when:]

[(1) a majority of the persons in the Group live, work, or gather regularly within the local service area;]

[(2) the Group's headquarters is located within the local service area; or]

[(3)] [the persons in the Group are "paid from" or "supervised from" an office or facility located within the local service area]. The commissioner may impose a geographical limitation on any Group if the commissioner reasonably determines that the applicant credit union does not have the ability [facilities and staffing] to serve a larger group or there are other operational or management concerns.

(b) Other persons eligible for membership. A number of persons by virtue of their close relationship to a Group may be included in the field of membership at the option of the applicant credit union. These include:

(1) members of the family or household of a member of the Group;

(2) volunteers performing services for or on behalf of the Group;

(3) organizations owned or controlled by a member or members of the Group, and any employees and members of those organizations;

(4) spouses of persons who died while in the Group;

(5) employees of the credit union; and

(6) subsidiaries of the credit union and their employees; and businesses and other organizations whose employees or members are within the Group.

(c) Multiple-groups.

(1) The commissioner may approve a credit union's original articles of incorporation and bylaws or a request for approval of an amendment to a credit union's bylaws to serve one or more communities of interest or a combination of types of communities of interest.

(2) In addition to general requirements, special requirements pertaining to multiple-Group applications may be required before the commissioner will grant such a certificate or approve such an amendment.

(A) Each Group to be included in the proposed field of membership of the credit union must have its own community of interest.

(B) Each associational or occupational Group must individually request inclusion in the proposed credit union's field of membership.

(d) Overlap protection.

(1) The commissioner will only consider the financial effect of an overlap proposed by an application to expand a credit union's field of membership or when a charter application proposes an overlap for a Group of 3,000 members or more.

(2) The commissioner will weigh the information in support of the application and any information provided by a protesting or affected credit union. If the applicant has the financial capacity to serve the financial needs of the proposed members, demonstrates economic feasibility, complies with the requirements of this rule, and no protestant reasonably establishes a basis for denying the request, it shall be approved.

(3) If a finding is made that overlap protection is warranted, the commissioner shall reject the application or require the applicant to limit or eliminate the overlap by adding exclusionary language to the text of the amendment, e.g., "excluding persons eligible for primary membership in any occupation or association based credit union that has an office within a specified proximity of the applicant credit union at the time membership is sought." Exclusionary clauses are rarely appropriate for inclusion on a geographic community of interest.

(4) Generally, if the overlapped credit union does not submit a notice of protest form, and the department determines that there is no safety and soundness problem, an overlap will be permitted. If, however, a notice of protest is filed, the commissioner will consider the following in performing an overlap analysis:

(A) whether the overlap is incidental in nature, i.e., the group(s) in question is so small as to have no material effect on the overlapped credit union;

(B) whether there is limited participation by members of the group(s) in the overlapped credit union after the expiration of a reasonable period of time;

(C) whether the overlapped credit union provides requested service;

(D) the financial effect on the overlapped credit union;

(E) the desires of the group(s); and

(F) the best interests of the affected group(s) and the credit union members involved.

(5) Where a sponsor organization expands its operations internally, by acquisition or otherwise, the credit union may serve these new entrants to its field of membership if they are part of the community of interest described in the credit union's bylaws. Where acquisitions are made which add a new subsidiary or affiliate, the group cannot be served until the entity is included in the field of membership through the application process.

(6) Credit unions affected by the organizational restructuring or merger of a group within its field of membership must apply for a modification of their fields of membership to reflect the group to be served.

(e) Underserved communities.

(1) All credit unions may include underserved areas or areas designated as a credit union development district in accordance with Subchapter K (related to Credit Union Development Districts) in their fields of membership, without regard to location. More than one credit union can serve the same underserved community.

~~[(2) Once an underserved community has been added to a credit union's field of membership, the credit union must establish and maintain an office or facility in the area under this subsection.]~~

(2) [~~(3)~~] A credit union desiring to add an underserved community must document that the area meets the applicable definition in §91.101 (relating to Definitions and Interpretations). In addition, the credit union must develop a business plan specifying how it will serve the community. The business plan, at a minimum, must identify the credit and depository needs of the community and detail how the credit union plans to serve those needs. The credit union will be expected to regularly review the business plan to determine if the community is being adequately served. The commissioner may require periodic service status reports from a credit union pertaining to the underserved area to ensure that the needs of the area are being met, as well as requiring such reports before allowing a credit union to add an additional underserved area.

(f) Parity with Federal Credit Unions.
Credit unions will be allowed to have, at a minimum, at least as much flexibility as federal credit unions have in field of membership regulation. If a credit union proposes a type of Group that the National Credit Union Administration has previously determined meets the Federal requirements, the commissioner shall approve the application unless the commissioner finds that the credit union has not demonstrated sufficient managerial and financial capacity to safely and soundly serve such expanded membership.

(g) Application. In order to request the approval of the commissioner to add a Group to its bylaws, a credit union must submit a written application to the Department. The applicant credit union shall have the burden to show to the Department such facts and data that support the requirements and considerations in this rule. In reviewing such application, the commissioner shall consider:

(1) Whether the Group has adequate unifying characteristics or a mutual interest such that the safety and soundness of the credit union is maintained;

(2) The ability of credit unions to maintain parity and to compete fairly with their counterparts;

(3) Service by the credit union that is responsive to the convenience and needs of prospective members;

(4) Protection for the interest of current and future members of the credit union; and

(5) The encouragement of economic progress in this State by allowing opportunity to expand services and facilities.

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 9, 2021.

TRD-202103579
John J. Kolhoff
Commissioner
Credit Union Department
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 837-9236

♦ ♦ ♦

TITLE 16. ECONOMIC REGULATION

PART 4. TEXAS DEPARTMENT OF LICENSING AND REGULATION

CHAPTER 62. CODE ENFORCEMENT OFFICERS

16 TAC §62.20, §62.80

The Texas Department of Licensing and Regulation (Department) proposes amendments to existing rules at 16 Texas Administrative Code (TAC), Chapter 62, §62.20 and §62.80, regarding the Code Enforcement Officers program. These proposed changes are referred to as "proposed rules."

EXPLANATION OF AND JUSTIFICATION FOR THE RULES

The rules under 16 TAC Chapter 62 implement Texas Occupations Code, Chapter 1952, Code Enforcement Officers.

The proposed rules are necessary to amend the registration term for a Code Enforcement Officer in Training who upgrades to a Code Enforcement Officer from the remainder of the training registration to a full two-year registration from the date of issuance of the upgrade. The proposed amendment eliminates the need for the newly upgraded Code Enforcement Officer to then have to renew the new registration, sometimes within days of the upgrade, when the initial one-year registration expires.

The proposed amendment also combines the upgrade and renewal of the Code Enforcement Officer registration, resulting in the elimination of a second application having to be filed and processed so soon after the upgrade.

The proposed rules were presented to and discussed by the Code Enforcement Officers Advisory Committee (Advisory Committee) at its meeting on September 1, 2021. The Advisory Committee did not make any changes to the proposed rules. The Advisory Committee voted and recommended that the proposed rules be published in the *Texas Register* for public comment.

SECTION-BY-SECTION SUMMARY

The proposed rules amend §62.20, Registration Requirements--Applicant and Experience Requirements. The proposed rules amend subsection (c) to improve readability through the use of the plain talk guidelines. The proposed rules also provide a two-year registration term from the date of issuance to be consistent with the Code Enforcement Officer registration term.

The proposed rules amend §62.80, Fees. The proposed rules amend subsection (d) to include the renewal fee into the upgrade process.

FISCAL IMPACT ON STATE AND LOCAL GOVERNMENT

Tony Couvillon, Policy Research and Budget Analyst, has determined that for each year of the first five years the proposed rules are in effect, there are no estimated additional costs or reductions in costs to state or local government as a result of enforcing or administering the proposed rules.

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

Mr. Couvillon has determined that for each year of the first five years the proposed rules are in effect, enforcing or administering the proposed rules does not have foreseeable implications relating to costs or revenues of state governments.

Mr. Couvillon has determined that for each year of the first five years the proposed rules are in effect, enforcing or administering the proposed rules does not have foreseeable implications relating to costs or revenues of local governments.

LOCAL EMPLOYMENT IMPACT STATEMENT

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

PUBLIC BENEFITS

Mr. Couvillon also has determined that for each year of the first five-year period the proposed rules are in effect, the public benefit will be that the proposed rules eliminate a Code Enforcement Officer in Training having to submit a Code Enforcement Officer renewal application in a short period of time after submitting an upgrade application, removing the impediment to becoming a registered Code Enforcement Officer of additional paperwork, fee payment, and processing time.

PROBABLE ECONOMIC COSTS TO PERSONS REQUIRED TO COMPLY WITH PROPOSAL

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

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

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

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

The proposed rules do not have a fiscal note that imposes a cost on regulated persons, including another state agency, a special district, or a local government. Therefore, the agency is not required to take any further action under Government Code §2001.0045.

GOVERNMENT GROWTH IMPACT STATEMENT

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

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

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

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

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

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

6. The proposed rules do expand, limit, or repeal an existing regulation. The proposed changes expand the rules to now require the agency to issue a two-year registration when an upgrade applicant for a Code Enforcement Officer registration is approved by the agency, instead of the new registration only lasting through the end of the Code Enforcement Officer in Training registration term.

Although the proposed rules increase the upgrade fee to $100 from $25, the resulting issuance of a two-year Code Enforcement Officer registration eliminates the need for an almost immediate renewal, with a fee of $75. The net result of fees paid is zero.

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

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

TAKINGS IMPACT ASSESSMENT

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

PUBLIC COMMENTS

Comments on the proposed rules may be submitted electronically on the Department's website at https://ga.tdlr.texas.gov:1443/form/gcerules; by facsimile to (512) 475-3032; or by mail to Monica Nuñez, Legal Assistant, Texas Department of Licensing and Regulation, P.O. Box 12157, Austin, Texas 78711. The deadline for comments is 30 days after publication in the *Texas Register.*

STATUTORY AUTHORITY

The proposed rules are proposed under Texas Occupations Code, Chapters 51 and 1952, which authorize the Texas Commission of Licensing and Regulation, the Department's governing body, to adopt rules as necessary to implement these chapters and any other law establishing a program regulated by the Department.

The statutory provisions affected by the proposed rules are those set forth in Texas Occupations Code, Chapters 51 and 1952. No other statutes, articles, or codes are affected by the proposed rules.

§62.20. Registration Requirements--Applicant and Experience Requirements.

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

(c) A registered code enforcement officer in training who has obtained the experience necessary to qualify as a code enforcement officer may file an application to upgrade a registration to that of code enforcement officer. Upon payment of the required fee and approval by the department, the applicant must [~~shall~~] be granted registration as a code enforcement officer for a term of two years from the date of issuance.

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

§62.80. Fees.

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

(d) The fee to upgrade a registration from code enforcement officer in training to code enforcement officer pursuant to 16 TAC §62.20(c)--$100 [~~$25~~] .

(e) - (h) (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 13, 2021.

TRD-202103608
Brad Bowman
General Counsel
Texas Department of Licensing and Regulation
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 475-4879

♦ ♦ ♦

TITLE 22. EXAMINING BOARDS

PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 283. LICENSING REQUIREMENTS FOR PHARMACISTS

22 TAC §283.12

The Texas State Board of Pharmacy proposes amendments to 22 TAC §283.12, concerning Licenses for Military Service Members, Military Veterans, and Military Spouses. The amendments, if adopted, specify that a copy of a permanent change of station order may be used as proof of a military spouse's residency and add a new service branch to the definition of armed forces of the United States, in accordance with House Bill 139.

Timothy L. Tucker, 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. Mr. Tucker has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide consistency between state law and Board rules and clear licensing requirements for military spouse pharmacists to request an interim pharmacist license. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

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

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

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

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

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

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

(6) The proposed amendments do limit an existing regulation in order to be consistent with state law;

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

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

Written comments on the amendments may be submitted to Eamon D. Briggs, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., October 25, 2021.

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

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

§283.12. Licenses for Military Service Members, Military Veterans, and Military Spouses.

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

(1) Active duty--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, or similar military service of another state.

(2) Armed forces of the United States--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--A person who is on active duty.

(4) Military spouse--A person who is married to a military service member.

(5) Military veteran--A person who has served on active duty and who was discharged or released from active duty.

(b) Alternative licensing procedure. For the purpose of §55.004, Occupations Code, an applicant for a pharmacist license who is a military service member, military veteran, or military spouse may complete the following alternative procedures for licensing as a pharmacist.

(1) Requirements for licensing by reciprocity. An applicant for licensing by reciprocity who meets all of the following requirements may be granted a temporary license as specified in this subsection prior to completing the NABP application for pharmacist license by reciprocity, and taking and passing the Texas Pharmacy Jurisprudence Examination. The applicant shall:

(A) complete the Texas application for pharmacist license by reciprocity that includes the following:

(i) name;

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

(iii) any other information requested on the application;

(B) meet the educational and age requirements as set forth in §283.3 of this title (relating to Educational and Age Requirements);

(C) present to the board proof of initial licensing by examination and proof that any current licenses and any other licenses granted to the applicant by any other state have not been suspended, revoked, canceled, surrendered, or otherwise restricted for any reason;

(D) meet all requirements necessary for the board to access the criminal history records information, including submitting fingerprint information, and such criminal history check does not reveal any disposition for a crime specified in §281.64 of this title (relating to Sanctions for Criminal Offenses) indicating a sanction of denial, revocation, or suspension; [~~and~~]

(E) be exempt from the application and examination fees paid to the board set forth in §283.9(a)(2)(A) and (b) of this title (relating to Fee Requirements for Licensure by Examination, Score Transfer and Reciprocity); and

(F) provide documentation of eligibility, including:

(i) military identification indicating that the applicant is a military service member, military veteran, or military dependent, if a military spouse; and

(ii) marriage certificate, if a military spouse.

(2) Requirements for an applicant whose Texas pharmacist license has expired. An applicant whose Texas pharmacist license has expired within five years preceding the application date:

(A) shall complete the Texas application for licensing that includes the following:

(i) name;

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

(iii) any other information requested on the application;

(B) shall provide documentation of eligibility, including:

(i) military identification indicating that the applicant is a military service member, military veteran, or military dependent, if a military spouse; and

(ii) marriage certificate, if a military spouse;

(C) shall pay the renewal fee specified in §295.5 of this title (relating to Pharmacist License or Renewal Fees); however, the applicant shall be exempt from the fees specified in §295.7(3) of this title (relating to Pharmacist License Renewal); [.]

(D) shall complete approved continuing education requirements according to the following schedule:

(i) if the Texas pharmacist license has been expired for more than one year but less than two years, the applicant shall complete 15 contact hours of approved continuing education;

(ii) if the Texas pharmacist license has been expired for more than two years but less than three years, the applicant shall complete 30 contact hours of approved continuing education; or

(iii) if the Texas pharmacist license has been expired for more than three years but less than five years, the applicant shall complete 45 contact hours of approved continuing education; and

(E) is not required to take the Texas Pharmacy Jurisprudence Examination.

(3) A temporary license issued under this section is valid for no more than six months and may be extended, if disciplinary action is pending, or upon request, as otherwise determined reasonably necessary by the executive director of the board.

(4) A temporary license issued under this section expires within six months of issuance if the individual fails to pass the Texas Pharmacy Jurisprudence Examination within six months or fails to take the Texas Pharmacy Jurisprudence Examination within six months.

(5) An individual may not serve as pharmacist-in-charge of a pharmacy with a temporary license issued under this subsection.

(c) Expedited licensing procedure. For the purpose of §55.005, Occupations Code, an applicant for a pharmacist license who is a military service member, military veteran, or military spouse and who holds a current license as a pharmacist issued by another state may complete the following expedited procedures for licensing as a pharmacist. The applicant shall:

(1) meet the educational and age requirements specified in §283.3 of this title (relating to Educational and Age Requirements);

(2) meet all requirements necessary in order for the board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs;

(3) complete the Texas and NABP applications for reciprocity. Any fraudulent statement made in the application for reciprocity is grounds for denial of the application. If such application is granted, any fraudulent statement is grounds for suspension, revocation, and/or cancellation of any license so granted by the board. The Texas application includes the following information:

(A) name;

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

(C) any other information requested on the application; [;]

(4) present to the board proof of initial licensing by examination and proof that their current license and any other license or licenses granted to the applicant by any other state have not been suspended, revoked, canceled, surrendered, or otherwise restricted for any reason;

(5) pass the Texas Pharmacy Jurisprudence Examination with a minimum grade of 75. (The passing grade may be used for the purpose of licensure by reciprocity for a period of two years from the date of passing the examination.) Should the applicant fail to achieve a minimum grade of 75 on the Texas Pharmacy Jurisprudence Examination, such applicant, in order to be licensed, shall retake the Texas Pharmacy Jurisprudence Examination as specified in §283.11 of this title (relating to Examination Retake Requirements) until such time as a minimum grade of 75 is achieved; and

(6) be exempt from the application and examination fees paid to the board set forth in §283.9(a)(2)(A) and (b).

(d) License renewal. As specified in §55.003, Occupations Code, a military service member who holds a pharmacist license is entitled to two years of additional time to complete any requirements related to the renewal of the military service member's license as follows:

(1) A military service member who fails to renew their pharmacist license in a timely manner because the individual was serving as a military service member shall submit to the board:

(A) name, address, and license number of the pharmacist;

(B) military identification indicating that the individual is a military service member; and

(C) a statement requesting up to two years of additional time to complete the renewal.

(2) A military service member specified in paragraph (1) of this subsection shall be exempt from fees specified in §295.7(3) of this title (relating to Pharmacist License Renewal).

(3) A military service member specified in paragraph (1) of this subsection is entitled to two additional years of time to complete the continuing education requirements specified in §295.8 of this title (relating to Continuing Education Requirements).

(e) Inactive status. The holder of a pharmacist license who is a military service member, a military veteran, or a military spouse who holds a pharmacist license and who is not engaged in the practice of pharmacy in this state may place the license on inactive status as specified in §295.9 of this title (relating to Inactive License). The inactive license holder:

(1) shall provide documentation to include:

(A) military identification indicating that the pharmacist is a military service member, military veteran, or military dependent, if a military spouse; and

(B) marriage certificate, if a military spouse;

(2) shall be exempt from the fees specified in §295.9(a)(1)(C) and §295.9(a)(2)(C) of this title;

(3) shall not practice pharmacy in this state; and

(4) may reactivate the license as specified in §295.9 of this title (relating to Inactive License).

(f) Interim license for military spouse. In accordance with §55.0041, Occupations Code, a military spouse who is currently licensed in good standing by a jurisdiction with licensing requirements that are substantially equivalent to the licensing requirements in this state may be issued an interim pharmacist license. The military spouse:

(1) shall provide documentation to include:

(A) a notification of intent to practice form including any additional information requested;

(B) proof of the military spouse's residency in this state including a copy of the permanent change of station order for the military service member to whom the spouse is married;

(C) a copy of the military spouse's military identification card; and

(D) verification from the jurisdiction in which the military spouse holds an active pharmacist license that the military spouse's license is in good standing;

(2) may not practice pharmacy in this state until issued an interim pharmacist license;

(3) may hold an interim pharmacist license only for the period during which the military service member to whom the military spouse is married is stationed at a military installation in this state, but not to exceed three years from the date of issuance of the interim license; and

(4) may not renew the interim pharmacist license.

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

Filed with the Office of the Secretary of State on September 3, 2021.

TRD-202103534
Timothy L. Tucker, Pharm.D.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 305-8010

♦ ♦ ♦

CHAPTER 291. PHARMACIES
SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

22 TAC §291.34

The Texas State Board of Pharmacy proposes amendments to 22 TAC §291.34, concerning Records. The amendments, if adopted, clarify that a pharmacist may provide an emergency refill of insulin or insulin-related equipment or supplies under certain conditions, in accordance with House Bill 1935.

Timothy L. Tucker, 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. Mr. Tucker has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide consistency between state law and Board rules and clear procedures for a pharmacist to provide an emergency refill of insulin or insulin-related equipment or supplies. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

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

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

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

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

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

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

(6) The proposed amendments do limit an existing regulation in order to be consistent with state law;

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

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

Written comments on the amendments may be submitted to Eamon D. Briggs, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., October 25, 2021.

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.

§291.34. Records.

(a) Maintenance of records.

(1) Every inventory or other record required to be kept under the provisions of Subchapter B of this chapter (relating to Community Pharmacy (Class A)) shall be:

(A) kept by the pharmacy at the pharmacy's licensed location and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative and 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 must be provided in a mutually agreeable electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this 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) Records of controlled substances listed in Schedule II shall be maintained separately from all other records of the pharmacy.

(3) Records of controlled substances, other than prescription drug orders, listed in Schedules III-V shall be maintained separately or readily retrievable from all other records of the pharmacy. For purposes of this subsection, readily retrievable means that the controlled substances shall be asterisked, red-lined, or in some other manner readily identifiable apart from all other items appearing on the record.

(4) Records, except when specifically required to be maintained in original or hard copy form, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(A) the records maintained in the alternative system contain all of the information required on the manual record; and

(B) 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) Prescriptions.

(1) Professional responsibility.

(A) Pharmacists shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order they dispense. If the pharmacist questions the accuracy or authenticity of a prescription drug order, he/she shall verify the order with the practitioner prior to dispensing.

(B) Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. A pharmacist may not dispense a prescription drug unless the pharmacist complies with the requirements of §562.056 and §562.112 of the Act, and §291.29 of this title (relating to Professional Responsibility of Pharmacists).

(C) Subparagraph (B) of this paragraph does not prohibit a pharmacist from dispensing a prescription when a valid patient-practitioner relationship is not present in an emergency situation (e.g., a practitioner taking calls for the patient's regular practitioner).

(D) The owner of a Class A pharmacy shall have responsibility for ensuring its agents and employees engage in appropriate decisions regarding dispensing of valid prescriptions as set forth in §562.112 of the Act.

(2) Written prescription drug orders.

(A) Practitioner's signature.

(i) Dangerous drug prescription orders. Written prescription drug orders shall be:

(I) manually signed by the practitioner; or

(II) electronically signed by the practitioner using a system that electronically replicates the practitioner's manual signature on the written prescription, provided:

(-a-) that security features of the system require the practitioner to authorize each use; and

(-b-) the prescription is printed on paper that is designed to prevent unauthorized copying of a completed prescription and to prevent the erasure or modification of information written on the prescription by the prescribing practitioner. (For example, the paper contains security provisions against copying that results in some indication on the copy that it is a copy and therefore render the prescription null and void.)

(ii) Controlled substance prescription orders. Prescription drug orders for Schedules II, III, IV, or V controlled substances shall be manually signed by the practitioner. Prescription drug orders for Schedule II controlled substances shall be issued on an official prescription form as required by the Texas Controlled Substances Act, §481.075.

(iii) Other provisions for a practitioner's signature.

(I) A practitioner may sign a prescription drug order in the same manner as he would sign a check or legal document, e.g., J.H. Smith or John H. Smith.

(II) Rubber stamped signatures may not be used.

(III) The prescription drug order may not be signed by a practitioner's agent but may be prepared by an agent for the signature of a practitioner. However, the prescribing practitioner is responsible in case the prescription drug order does not conform in all essential respects to the law and regulations.

(B) Prescription drug orders written by practitioners in another state.

(i) Dangerous drug prescription orders. A pharmacist may dispense prescription drug orders for dangerous drugs issued by practitioners in a state other than Texas in the same manner as prescription drug orders for dangerous drugs issued by practitioners in Texas are dispensed.

(ii) Controlled substance prescription drug orders.

(I) A pharmacist may dispense prescription drug orders for Schedule II controlled substances issued by a practitioner in another state provided:

(-a-) the prescription is dispensed as specified in §315.9 of this title (relating to Pharmacy Responsibility - Out-of-State Practitioner - Effective September 1, 2016);

(-b-) the prescription drug order is an original written prescription issued by a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration (DEA) registration number, and who may legally prescribe Schedule II controlled substances in such other state; and

(-c-) the prescription drug order is not dispensed after the end of the twenty-first day after the date on which the prescription is issued.

(II) A pharmacist may dispense prescription drug orders for controlled substances in Schedules III, IV, or V issued by a physician, dentist, veterinarian, or podiatrist in another state provided:

(-a-) the prescription drug order is issued by a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal DEA registration number, and who may legally prescribe Schedules III, IV, or V controlled substances in such other state;

(-b-) the prescription drug order is not dispensed or refilled more than six months from the initial date of issuance and may not be refilled more than five times; and

(-c-) if there are no refill instructions on the original prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original prescription drug order have been dispensed, a new prescription drug order is obtained from the prescribing practitioner prior to dispensing any additional quantities of controlled substances.

(C) Prescription drug orders written by practitioners in the United Mexican States or the Dominion of Canada.

(i) Controlled substance prescription drug orders. A pharmacist may not dispense a prescription drug order for a Schedule II, III, IV, or V controlled substance issued by a practitioner in the Dominion of Canada or the United Mexican States.

(ii) Dangerous drug prescription drug orders. A pharmacist may dispense a dangerous drug prescription issued by a person licensed in the Dominion of Canada or the United Mexican States as a physician, dentist, veterinarian, or podiatrist provided:

(I) the prescription drug order is an original written prescription; and

(II) if there are no refill instructions on the original written prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original written prescription drug order have been dispensed, a new written prescription drug order shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of dangerous drugs.

(D) Prescription drug orders issued by an advanced practice registered nurse, physician assistant, or pharmacist.

(i) A pharmacist may dispense a prescription drug order that is:

(I) issued by an advanced practice registered nurse or physician assistant provided the advanced practice registered nurse or physician assistant is practicing in accordance with Subtitle B, Chapter 157, Occupations Code; and

(II) for a dangerous drug and signed by a pharmacist under delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations Code.

(ii) Each practitioner shall designate in writing the name of each advanced practice registered nurse or physician assistant authorized to issue a prescription drug order pursuant to Subtitle B, Chapter 157, Occupations Code. A list of the advanced practice registered nurses or physician assistants designated by the practitioner must be maintained in the practitioner's usual place of business. On request by a pharmacist, a practitioner shall furnish the pharmacist with a copy of the written authorization for a specific advanced practice registered nurse or physician assistant.

(E) Prescription drug orders for Schedule II controlled substances. No Schedule II controlled substance may be dispensed without a written prescription drug order of a practitioner on an official prescription form as required by the Texas Controlled Substances Act, §481.075.

(3) Oral prescription drug orders.

(A) An oral prescription drug order for a controlled substance from a practitioner or a practitioner's designated agent may only

be received by a pharmacist or a pharmacist-intern under the direct supervision of a pharmacist.

(B) A practitioner shall designate in writing the name of each agent authorized by the practitioner to communicate prescriptions orally for the practitioner. The practitioner shall maintain at the practitioner's usual place of business a list of the designated agents. The practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a specific agent on the pharmacist's request.

(C) A pharmacist may not dispense an oral prescription drug order for a dangerous drug or a controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(4) Electronic prescription drug orders.

(A) Dangerous drug prescription orders.

(i) An electronic prescription drug order for a dangerous drug may be transmitted by a practitioner or a practitioner's designated agent:

(I) directly to a pharmacy; or

(II) through the use of a data communication device provided:

(-a-) the confidential prescription information is not altered during transmission; and

(-b-) confidential patient information is not accessed or maintained by the operator of the data communication device other than for legal purposes under federal and state law.

(ii) A practitioner shall designate in writing the name of each agent authorized by the practitioner to electronically transmit prescriptions for the practitioner. The practitioner shall maintain at the practitioner's usual place of business a list of the designated agents. The practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a specific agent on the pharmacist's request.

(B) Controlled substance prescription orders. A pharmacist may only dispense an electronic prescription drug order for a Schedule II, III, IV, or V controlled substance in compliance with federal and state laws and the rules of the Drug Enforcement Administration outlined in Part 1300 of the Code of Federal Regulations.

(C) Prescriptions issued by a practitioner licensed in the Dominion of Canada or the United Mexican States. A pharmacist may not dispense an electronic prescription drug order for a dangerous drug or controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(5) Facsimile (faxed) prescription drug orders.

(A) A pharmacist may dispense a prescription drug order for a dangerous drug transmitted to the pharmacy by facsimile.

(B) A pharmacist may dispense a prescription drug order for a Schedule III-V controlled substance transmitted to the pharmacy by facsimile provided the prescription is manually signed by the practitioner and not electronically signed using a system that electronically replicates the practitioner's manual signature on the prescription drug order.

(C) A pharmacist may not dispense a facsimile prescription drug order for a dangerous drug or controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(6) Original prescription drug order records.

(A) Original prescriptions may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order, including clarifications to the order given by the practitioner or the practitioner's agent and recorded on the prescription.

(B) Notwithstanding subparagraph (A) of this paragraph, a pharmacist may dispense a quantity less than indicated on the original prescription drug order at the request of the patient or patient's agent.

(C) Original prescriptions shall be maintained by the pharmacy in numerical order and remain legible for a period of two years from the date of filling or the date of the last refill dispensed.

(D) If an original prescription drug order is changed, such prescription order shall be invalid and of no further force and effect; if additional drugs are to be dispensed, a new prescription drug order with a new and separate number is required. However, an original prescription drug order for a dangerous drug may be changed in accordance with paragraph (10) of this subsection relating to accelerated refills.

(E) Original prescriptions shall be maintained in three separate files as follows:

(i) prescriptions for controlled substances listed in Schedule II;

(ii) prescriptions for controlled substances listed in Schedules III-V; and

(iii) prescriptions for dangerous drugs and nonprescription drugs.

(F) Original prescription records other than prescriptions for Schedule II controlled substances may be stored in a system that is capable of producing a direct image of the original prescription record, e.g., a digitalized imaging system. If original prescription records are stored in a direct imaging system, the following is applicable:

(i) the record of refills recorded on the original prescription must also be stored in this system;

(ii) the original prescription records must be maintained in numerical order and separated in three files as specified in subparagraph (D) of this paragraph; and

(iii) the pharmacy must provide immediate access to equipment necessary to render the records easily readable.

(7) Prescription drug order information.

(A) All original prescriptions shall bear:

(i) the name of the patient, or if such drug is for an animal, the species of such animal and the name of the owner;

(ii) the address of the patient; provided, however, that a prescription for a dangerous drug is not required to bear the address of the patient if such address is readily retrievable on another appropriate, uniformly maintained pharmacy record, such as medication records;

(iii) the name, address and telephone number of the practitioner at the practitioner's usual place of business, legibly printed or stamped, and if for a controlled substance, the DEA registration number of the practitioner;

(iv) the name and strength of the drug prescribed;

(v) the quantity prescribed numerically, and if for a controlled substance:

(I) numerically, followed by the number written as a word, if the prescription is written;

(II) numerically, if the prescription is electronic; or

(III) if the prescription is communicated orally or telephonically, as transcribed by the receiving pharmacist;

(vi) directions for use;

(vii) the intended use for the drug unless the practitioner determines the furnishing of this information is not in the best interest of the patient;

(viii) the date of issuance;

(ix) if a faxed prescription:

(I) a statement that indicates that the prescription has been faxed (e.g., Faxed to); and

(II) if transmitted by a designated agent, the name of the designated agent;

(x) if electronically transmitted:

(I) the date the prescription drug order was electronically transmitted to the pharmacy, if different from the date of issuance of the prescription; and

(II) if transmitted by a designated agent, the name of the designated agent; and

(xi) if issued by an advanced practice nurse or physician assistant in accordance with Subtitle B, Chapter 157, Occupations Code:

(I) the name, address, telephone number, and if the prescription is for a controlled substance, the DEA number of the supervising practitioner; and

(II) the address and telephone number of the clinic where the prescription drug order was carried out or signed; and

(xii) if communicated orally or telephonically:

(I) the initials or identification code of the transcribing pharmacist; and

(II) the name of the prescriber or prescriber's agent communicating the prescription information.

(B) At the time of dispensing, a pharmacist is responsible for documenting the following information on either the original hardcopy prescription or in the pharmacy's data processing system:

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

(ii) the initials or identification code of the dispensing pharmacist;

(iii) the initials or identification code of the pharmacy technician or pharmacy technician trainee performing data entry of the prescription, if applicable;

(iv) the quantity dispensed, if different from the quantity prescribed;

(v) the date of dispensing, if different from the date of issuance; and

(vi) the brand name or manufacturer of the drug or biological product actually dispensed, if the drug was prescribed by generic name or interchangeable biological name or if a drug or interchangeable biological product other than the one prescribed was dispensed pursuant to the provisions of the Act, Chapters 562 and 563.

(C) Prescription drug orders may be utilized as authorized in Title 40, Part 1, Chapter 19 of the Texas Administrative Code.

(i) A prescription drug order is not required to bear the information specified in subparagraph (A) of this paragraph if the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital). Such prescription drug orders must contain the following information:

(I) the full name of the patient;

(II) the date of issuance;

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

(IV) directions for use; and

(V) the signature(s) required by 40 TAC §19.1506.

(ii) Prescription drug orders for dangerous drugs shall not be dispensed following one year after the date of issuance unless the authorized prescriber renews the prescription drug order.

(iii) Controlled substances shall not be dispensed pursuant to a prescription drug order under this subparagraph.

(8) Refills.

(A) General information.

(i) Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order except as authorized in paragraph (10) of this subsection relating to accelerated refills.

(ii) If there are no refill instructions on the original prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original prescription drug order have been dispensed, authorization from the prescribing practitioner shall be obtained prior to dispensing any refills and documented as specified in subsection (l) of this section.

(B) Refills of prescription drug orders for dangerous drugs or nonprescription drugs.

(i) Prescription drug orders for dangerous drugs or nonprescription drugs may not be refilled after one year from the date of issuance of the original prescription drug order.

(ii) If one year has expired from the date of issuance of an original prescription drug order for a dangerous drug or nonprescription drug, authorization shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of the drug.

(C) Refills of prescription drug orders for Schedules III-V controlled substances.

(i) Prescription drug orders for Schedules III-V controlled substances may not be refilled more than five times or after six months from the date of issuance of the original prescription drug order, whichever occurs first.

(ii) If a prescription drug order for a Schedule III, IV, or V controlled substance has been refilled a total of five times or if six months have expired from the date of issuance of the original prescrip-

tion drug order, whichever occurs first, a new and separate prescription drug order shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of controlled substances.

(D) Pharmacist unable to contact prescribing practitioner. If a pharmacist is unable to contact the prescribing practitioner after a reasonable effort, a pharmacist may exercise his or her professional judgment in refilling a prescription drug order for a drug, other than a Schedule II controlled substance, without the authorization of the prescribing practitioner, provided:

(i) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(ii) the quantity of prescription drug dispensed does not exceed a 72-hour supply;

(iii) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided without such authorization and that authorization of the practitioner is required for future refills;

(iv) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable time;

(v) the pharmacist maintains a record of the emergency refill containing the information required to be maintained on a prescription as specified in this subsection;

(vi) the pharmacist affixes a label to the dispensing container as specified in §291.33(c)(7) of this title (relating to Operational Standards); and

(vii) if the prescription was initially filled at another pharmacy, the pharmacist may exercise his or her professional judgment in refilling the prescription provided:

(I) the patient has the prescription container, label, receipt or other documentation from the other pharmacy that contains the essential information;

(II) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription;

(III) the pharmacist, in his or her professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of clause (i) of this subparagraph; and

(IV) the pharmacist complies with the requirements of clauses (ii) - (vi) of this subparagraph.

(E) Natural or man-made disasters. If a natural or man-made disaster has occurred that prohibits the pharmacist from being able to contact the practitioner, a pharmacist may exercise his or her professional judgment in refilling a prescription drug order for a drug, other than a Schedule II controlled substance, without the authorization of the prescribing practitioner, provided:

(i) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(ii) the quantity of prescription drug dispensed does not exceed a 30-day supply;

(iii) the governor of Texas has declared a state of disaster;

(iv) the board, through the executive director, has notified pharmacies that pharmacists may dispense up to a 30-day supply of prescription drugs;

(v) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided without such authorization and that authorization of the practitioner is required for future refills;

(vi) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable time;

(vii) the pharmacist maintains a record of the emergency refill containing the information required to be maintained on a prescription as specified in this subsection;

(viii) the pharmacist affixes a label to the dispensing container as specified in §291.33(c)(7) of this title; and

(ix) if the prescription was initially filled at another pharmacy, the pharmacist may exercise his or her professional judgment in refilling the prescription provided:

(I) the patient has the prescription container, label, receipt or other documentation from the other pharmacy that contains the essential information;

(II) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription;

(III) the pharmacist, in his or her professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of clause (i) of this subparagraph; and

(IV) the pharmacist complies with the requirements of clauses (ii) - (viii) of this subparagraph.

(F) Emergency Refills of Insulin and Insulin-Related Equipment or Supplies.

(i) A pharmacist may exercise the pharmacist's professional judgment in refilling a prescription for insulin or insulin-related equipment or supplies without the authorization of the prescribing practitioner if the pharmacist:

(I) is unable to contact the practitioner after reasonable effort;

(II) is provided with documentation showing that the patient was previously prescribed insulin or insulin-related equipment or supplies by a practitioner;

(III) assesses the patient to determine whether the emergency refill is appropriate;

(IV) creates a record that documents the patient's visit that includes a notation describing the documentation provided under subclause (II) of this clause; and

(V) makes a reasonable attempt to inform the practitioner of the emergency refill at the earliest reasonable time.

(ii) The quantity of an emergency refill of insulin may not exceed a 30-day supply. The quantity of an emergency refill of insulin-related equipment or supplies may not exceed the lesser of a 30-day supply or the smallest available package.

(G) [~~(F)~~] Auto-Refill Programs. A pharmacy may use a program that automatically refills prescriptions that have existing refills available in order to improve patient compliance with and adherence to prescribed medication therapy. The following is applicable in order to enroll patients into an auto-refill program:

(i) Notice of the availability of an auto-refill program shall be given to the patient or patient's agent, and the patient

or patient's agent must affirmatively indicate that they wish to enroll in such a program and the pharmacy shall document such indication.

(ii) The patient or patient's agent shall have the option to withdraw from such a program at any time.

(iii) Auto-refill programs may be used for refills of dangerous drugs, and Schedules IV and V controlled substances. Schedules II and III controlled substances may not be dispensed by an auto-refill program.

(iv) As is required for all prescriptions, a drug regimen review shall be completed on all prescriptions filled as a result of the auto-refill program. Special attention shall be noted for drug regimen review warnings of duplication of therapy and all such conflicts shall be resolved with the prescribing practitioner prior to refilling the prescription.

(9) Records Relating to Dispensing Errors. If a dispensing error occurs, the following is applicable.

(A) Original prescription drug orders:

(i) shall not be destroyed and must be maintained in accordance with subsection (a) of this section; and

(ii) shall not be altered. Altering includes placing a label or any other item over any of the information on the prescription drug order (e.g., a dispensing tag or label that is affixed to back of a prescription drug order must not be affixed on top of another dispensing tag or label in such a manner as to obliterate the information relating to the error).

(B) Prescription drug order records maintained in a data processing system:

(i) shall not be deleted and must be maintained in accordance with subsection (a) of this section;

(ii) may be changed only in compliance with subsection (e)(2)(B) of this section; and

(iii) if the error involved incorrect data entry into the pharmacy's data processing system, this record must be either voided or cancelled in the data processing system, so that the incorrectly entered prescription drug order may not be dispensed, or the data processing system must be capable of maintaining an audit trail showing any changes made to the data in the system.

(10) Accelerated refills. In accordance with §562.0545 of the Act, a pharmacist may dispense up to a 90-day supply of a dangerous drug pursuant to a valid prescription that specifies the dispensing of a lesser amount followed by periodic refills of that amount if:

(A) the total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the original prescription, including refills;

(B) the patient consents to the dispensing of up to a 90-day supply and the physician has been notified electronically or by telephone;

(C) the physician has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary;

(D) the dangerous drug is not a psychotropic drug used to treat mental or psychiatric conditions; and

(E) the patient is at least 18 years of age.

(c) Patient medication records.

(1) A patient medication record system shall be maintained by the pharmacy for patients to whom prescription drug orders are dispensed.

(2) The patient medication record system shall provide for the immediate retrieval of information for the previous 12 months that is necessary for the dispensing pharmacist to conduct a prospective drug regimen review at the time a prescription drug order is presented for dispensing.

(3) The pharmacist-in-charge shall assure that a reasonable effort is made to obtain and record in the patient medication record at least the following information:

(A) full name of the patient for whom the drug is prescribed;

(B) address and telephone number of the patient;

(C) patient's age or date of birth;

(D) patient's gender;

(E) any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs currently being used by the patient which may relate to prospective drug regimen review;

(F) pharmacist's comments relevant to the individual's drug therapy, including any other information unique to the specific patient or drug; and

(G) a list of all prescription drug orders dispensed (new and refill) to the patient by the pharmacy during the last two years. Such lists shall contain the following information:

(i) date dispensed;

(ii) name, strength, and quantity of the drug dispensed;

(iii) prescribing practitioner's name;

(iv) unique identification number of the prescription; and

(v) name or initials of the dispensing pharmacists.

(4) A patient medication record shall be maintained in the pharmacy for two years. If patient medication records are maintained in a data processing system, all of the information specified in this subsection shall be maintained in a retrievable form for two years and information for the previous 12 months shall be maintained online. A patient medication record must contain documentation of any modification, change, or manipulation to a patient profile.

(5) Nothing in this subsection shall be construed as requiring a pharmacist to obtain, record, and maintain patient information other than prescription drug order information when a patient or patient's agent refuses to provide the necessary information for such patient medication records.

(d) Prescription drug order records maintained in a manual system.

(1) Original prescriptions shall be maintained in three files as specified in subsection (b)(6)(D) of this section.

(2) Refills.

(A) Each time a prescription drug order is refilled, a record of such refill shall be made:

(i) on the back of the prescription by recording the date of dispensing, the written initials or identification code of the dis-

pensing pharmacist, the initials or identification code of the pharmacy technician or pharmacy technician trainee preparing the prescription label, if applicable, and the amount dispensed. (If the pharmacist merely initials and dates the back of the prescription drug order, he or she shall be deemed to have dispensed a refill for the full face amount of the prescription drug order); or

(ii) on another appropriate, uniformly maintained, readily retrievable record, such as medication records, that indicates by patient name the following information:

(I) unique identification number of the prescription;

(II) name and strength of the drug dispensed;

(III) date of each dispensing;

(IV) quantity dispensed at each dispensing;

(V) initials or identification code of the dispensing pharmacist;

(VI) initials or identification code of the pharmacy technician or pharmacy technician trainee preparing the prescription label, if applicable; and

(VII) total number of refills for the prescription.

(B) If refill records are maintained in accordance with subparagraph (A)(ii) of this paragraph, refill records for controlled substances in Schedules III-V shall be maintained separately from refill records of dangerous drugs and nonprescription drugs.

(3) Authorization of refills. Practitioner authorization for additional refills of a prescription drug order shall be noted on the original prescription, in addition to the documentation of dispensing the refill as specified in subsection (l) of this section.

(4) Each time a modification, change, or manipulation is made to a record of dispensing, documentation of such change shall be recorded on the back of the prescription or on another appropriate, uniformly maintained, readily retrievable record, such as medication records. The documentation of any modification, change, or manipulation to a record of dispensing shall include the identification of the individual responsible for the alteration.

(e) Prescription drug order records maintained in a data processing system.

(1) General requirements for records maintained in a data processing system.

(A) Compliance with data processing system requirements. If a Class A pharmacy's data processing system is not in compliance with this subsection, the pharmacy must maintain a manual record keeping system as specified in subsection (d) of this section.

(B) Original prescriptions. Original prescriptions shall be maintained in three files as specified in subsection (b)(6)(D) of this section.

(C) Requirements for backup systems.

(i) The pharmacy shall maintain a backup copy of information stored in the data processing system using disk, tape, or other electronic backup system and update this backup copy on a regular basis, at least monthly, to assure that data is not lost due to system failure.

(ii) Data processing systems shall have a workable (electronic) data retention system that can produce an audit trail of drug usage for the preceding two years as specified in paragraph (2)(H) of this subsection.

(D) Change or discontinuance of a data processing system.

(i) Records of dispensing. A pharmacy that changes or discontinues use of a data processing system must:

(I) transfer the records of dispensing to the new data processing system; or

(II) purge the records of dispensing to a printout that contains the same information required on the daily printout as specified in paragraph (2)(C) of this subsection. The information on this hard copy printout shall be sorted and printed by prescription number and list each dispensing for this prescription chronologically.

(ii) Other records. A pharmacy that changes or discontinues use of a data processing system must:

(I) transfer the records to the new data processing system; or

(II) purge the records to a printout that contains all of the information required on the original document.

(iii) Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(E) Loss of data. The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(2) Records of dispensing.

(A) Each time a prescription drug order is filled or refilled, a record of such dispensing shall be entered into the data processing system.

(B) Each time a modification, change or manipulation is made to a record of dispensing, documentation of such change shall be recorded in the data processing system. The documentation of any modification, change, or manipulation to a record of dispensing shall include the identification of the individual responsible for the alteration. Should the data processing system not be able to record a modification, change, or manipulation to a record of dispensing, the information should be clearly documented on the hard copy prescription.

(C) The data processing system shall have the capacity to produce a daily hard copy printout of all original prescriptions dispensed and refilled. This hard copy printout shall contain the following information:

(i) unique identification number of the prescription;

(ii) date of dispensing;

(iii) patient name;

(iv) prescribing practitioner's name and the supervising physician's name if the prescription was issued by an advanced practice registered nurse, physician assistant or pharmacist;

(v) name and strength of the drug product actually dispensed; if generic name, the brand name or manufacturer of drug dispensed;

(vi) quantity dispensed;

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

(viii) initials or an identification code of the pharmacy technician or pharmacy technician trainee performing data entry of the prescription, if applicable;

(ix) if not immediately retrievable via computer display, the following shall also be included on the hard copy printout:

(I) patient's address;

(II) prescribing practitioner's address;

(III) practitioner's DEA registration number, if the prescription drug order is for a controlled substance;

(IV) quantity prescribed, if different from the quantity dispensed;

(V) date of issuance of the prescription drug order, if different from the date of dispensing; and

(VI) total number of refills dispensed to date for that prescription drug order; and

(x) any changes made to a record of dispensing.

(D) The daily hard copy printout shall be produced within 72 hours of the date on which the prescription drug orders were dispensed and shall be maintained in a separate file at the pharmacy. Records of controlled substances shall be readily retrievable from records of non-controlled substances.

(E) Each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document (e.g., J.H. Smith, or John H. Smith) within seven days from the date of dispensing.

(F) In lieu of the printout described in subparagraph (C) of this paragraph, the pharmacy shall maintain a log book in which each individual pharmacist using the data processing system shall sign or electronically sign a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is correct as entered. Such log book shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing; provided, however, that the data processing system can produce the hard copy printout on demand by an authorized agent of the Texas State Board of Pharmacy. If no printer is available on site, the hard copy printout shall be available within 72 hours with a certification by the individual providing the printout, stating that the printout is true and correct as of the date of entry and such information has not been altered, amended, or modified.

(G) The pharmacist-in-charge is responsible for the proper maintenance of such records, for ensuring that such data processing system can produce the records outlined in this section, and that such system is in compliance with this subsection.

(H) The data processing system shall be capable of producing a hard copy printout of an audit trail for all dispensing (original and refill) of any specified strength and dosage form of a drug (by either brand or generic name or both) during a specified time period.

(i) Such audit trail shall contain all of the information required on the daily printout as set out in subparagraph (C) of this paragraph.

(ii) The audit trail required in this subparagraph shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy.

(I) Failure to provide the records set out in this subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(J) The data processing system shall provide online retrieval (via computer display or hard copy printout) of the information set out in subparagraph (C) of this paragraph of:

(i) the original controlled substance prescription drug orders currently authorized for refilling; and

(ii) the current refill history for Schedules III, IV, and V controlled substances for the immediately preceding six-month period.

(K) In the event that a pharmacy using a data processing system experiences system downtime, the following is applicable:

(i) an auxiliary procedure shall ensure that refills are authorized by the original prescription drug order and that the maximum number of refills has not been exceeded, or authorization from the prescribing practitioner shall be obtained prior to dispensing a refill; and

(ii) all of the appropriate data shall be retained for online data entry as soon as the system is available for use again.

(3) Authorization of refills. Practitioner authorization for additional refills of a prescription drug order shall be noted as follows:

(A) on the hard copy prescription drug order;

(B) on the daily hard copy printout; or

(C) via the computer display.

(f) Limitation to one type of recordkeeping system. When filing prescription drug order information a pharmacy may use only one of the two systems described in subsection (d) or (e) of this section.

(g) Transfer of prescription drug order information. For the purpose of initial or refill dispensing, the transfer of original prescription drug order information is permissible between pharmacies, subject to the following requirements:

(1) The transfer of original prescription drug order information for controlled substances listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(2) The transfer of original prescription drug order information for dangerous drugs is permissible between pharmacies without limitation up to the number of originally authorized refills.

(3) The transfer is communicated orally by telephone or via facsimile:

(A) directly by a pharmacist or pharmacist-intern to another pharmacist or pharmacist-intern for prescription drug order information for controlled substances; or

(B) directly by a pharmacist, pharmacist-intern, or pharmacy technician to another pharmacist, pharmacist-intern, or pharmacy technician for prescription drug order information for dangerous drugs.

(4) Both the original and the transferred prescription drug orders are maintained for a period of two years from the date of last refill.

(5) The individual transferring the prescription drug order information shall:

(A) write the word "void" on the face of the invalidated prescription or the prescription is voided in the data processing system;

(B) record the name, address, and if for a controlled substance, the DEA registration number of the pharmacy to which it was transferred, and the name of the receiving individual on the reverse of the invalidated prescription or stored with the invalidated prescription drug order in the data processing system;

(C) record the date of the transfer and the name of the individual transferring the information; and

(D) if the prescription is transferred electronically, provide the following information:

(i) date of original dispensing and prescription number;

(ii) number of refills remaining and if a controlled substance, the date(s) and location(s) of previous refills;

(iii) name, address, and if a controlled substance, the DEA registration number of the transferring pharmacy;

(iv) name of the individual transferring the prescription; and

(v) if a controlled substance, the name, address, DEA registration number, and prescription number from the pharmacy that originally dispensed the prescription, if different.

(6) The individual receiving the transferred prescription drug order information shall:

(A) write the word "transfer" on the face of the prescription or indicate in the prescription record that the prescription was a transfer; and

(B) reduce to writing all of the information required to be on a prescription as specified in subsection (b)(7) of this section, and the following:

(i) date of issuance and prescription number;

(ii) original number of refills authorized on the original prescription drug order;

(iii) date of original dispensing;

(iv) number of valid refills remaining, and if a controlled substance, the date(s) and location(s) of previous refills;

(v) name, address, and if for a controlled substance, the DEA registration number of the transferring pharmacy;

(vi) name of the individual transferring the prescription; and

(vii) name, address, and if for a controlled substance, the DEA registration number, of the pharmacy that originally dispensed the prescription, if different; or

(C) if the prescription is transferred electronically, create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription including all of the information required to be on a prescription as specified in subsection (b)(7) of this section, and the following:

(i) date of original dispensing;

(ii) number of refills remaining and if a controlled substance, the prescription number(s), date(s) and location(s) of previous refills;

(iii) name, address, and if for a controlled substance, the DEA registration number;

(iv) name of the individual transferring the prescription; and

(v) name, address, and if for a controlled substance, the DEA registration number, of the pharmacy that originally filled the prescription.

(7) Both the individual transferring the prescription and the individual receiving the prescription must engage in confirmation of the prescription information by such means as:

(A) the transferring individual faxes the hard copy prescription to the receiving individual; or

(B) the receiving individual repeats the verbal information from the transferring individual and the transferring individual verbally confirms that the repeated information is correct.

(8) Pharmacies transferring prescriptions electronically shall comply with the following:

(A) Prescription drug orders may not be transferred by non-electronic means during periods of downtime except on consultation with and authorization by a prescribing practitioner; provided, however, that during downtime, a hard copy of a prescription drug order may be made available for informational purposes only, to the patient or a pharmacist, and the prescription may be read to a pharmacist by telephone;

(B) The original prescription drug order shall be invalidated in the data processing system for purposes of filling or refilling, but shall be maintained in the data processing system for refill history purposes;

(C) If the data processing system does not have the capacity to store all the information as specified in paragraphs (5) and (6) of this subsection, the pharmacist is required to record this information on the original or transferred prescription drug order;

(D) The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance prescription drug orders that have been previously transferred; and

(E) Pharmacies electronically accessing the same prescription drug order records may electronically transfer prescription information if the following requirements are met:

(i) The original prescription is voided and the pharmacies' data processing systems store all the information as specified in paragraphs (5) and (6) of this subsection;

(ii) Pharmacies not owned by the same entity may electronically access the same prescription drug order records, provided the owner, chief executive officer, or designee of each pharmacy signs an agreement allowing access to such prescription drug order records; and

(iii) An electronic transfer between pharmacies may be initiated by a pharmacist intern, pharmacy technician, or pharmacy technician trainee acting under the direct supervision of a pharmacist.

(9) An individual may not refuse to transfer original prescription information to another individual who is acting on behalf of a patient and who is making a request for this information as specified in this subsection. The transfer of original prescription information must be completed within four business hours of the request.

(10) When transferring a compounded prescription, a pharmacy is required to provide all of the information regarding the

compounded preparation, including the formula, unless the formula is patented or otherwise protected, in which case, the transferring pharmacy shall, at a minimum, provide the quantity or strength of all of the active ingredients of the compounded preparation.

(11) The electronic transfer of multiple or bulk prescription records between two pharmacies is permitted provided:

(A) a record of the transfer as specified in paragraph (5) of this subsection is maintained by the transferring pharmacy;

(B) the information specified in paragraph (6) of this subsection is maintained by the receiving pharmacy; and

(C) in the event that the patient or patient's agent is unaware of the transfer of the prescription drug order record, the transferring pharmacy must notify the patient or patient's agent of the transfer and must provide the patient or patient's agent with the telephone number of the pharmacy receiving the multiple or bulk prescription drug order records.

(h) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practitioner, another pharmacy, or other registrant, without being registered to distribute, under the following conditions.

(1) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to dispense that controlled substance.

(2) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed and distributed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled substances.

(3) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained that indicates:

(A) the actual date of distribution;

(B) the name, strength, and quantity of controlled substances distributed;

(C) the name, address, and DEA registration number of the distributing pharmacy; and

(D) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

(4) A pharmacy shall comply with 21 CFR 1305 regarding the DEA order form (DEA 222) requirements when distributing a Schedule II controlled substance.

(i) Other records. Other records to be maintained by a pharmacy:

(1) a log of the initials or identification codes that will identify each pharmacist, pharmacy technician, and pharmacy technician trainee who is involved in the dispensing process, in the pharmacy's data processing system (the initials or identification code shall be unique to ensure that each individual can be identified, i.e., identical initials or identification codes shall not be used). Such log shall be maintained at the pharmacy for at least seven years from the date of the transaction;

(2) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify that the controlled substances listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances;

(3) suppliers' credit memos for controlled substances and dangerous drugs;

(4) a copy of inventories required by §291.17 of this title (relating to Inventory Requirements);

(5) reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;

(6) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(7) a copy of any notification required by the Texas Pharmacy Act or the sections in this chapter, including, but not limited to, the following:

(A) reports of theft or significant loss of controlled substances to the DEA and the board;

(B) notifications of a change in pharmacist-in-charge of a pharmacy; and

(C) reports of a fire or other disaster that may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and disease.

(j) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for invoices and financial data shall comply with the following procedures.

(1) Controlled substance records. Invoices and financial data for controlled substances may be maintained at a central location provided the following conditions are met:

(A) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of the Drug Enforcement Administration as required by Title 21, Code of Federal Regulations, §1304.04(a), and submits a copy of this written notification to the board. Unless the registrant is informed by the divisional director of the Drug Enforcement Administration that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director;

(B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this paragraph; and

(C) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories that shall be maintained at the pharmacy;

(2) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location;

(3) Access to records. If the records are kept on microfilm, computer media, or in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records; and

(4) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy location within two business days of written request of a board agent or any other authorized official.

(k) Ownership of pharmacy records. For the purposes of these sections, a pharmacy licensed under the Act is the only entity that may legally own and maintain prescription drug records.

(l) Documentation of consultation. When a pharmacist, pharmacist-intern, or pharmacy technician consults a prescriber as described in this section, the individual shall document such occurrences on the hard copy or in the pharmacy's data processing system associated with the prescription and shall include the following information:

(1) date the prescriber was consulted;

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

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

(4) initials or identification code of the pharmacist, pharmacist-intern, or pharmacy technician performing the consultation clearly recorded for the purpose of identifying the individual who performed the consultation if the information is recorded on the hard copy prescription.

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 3, 2021.

TRD-202103535
Timothy L. Tucker, Pharm.D.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 305-8010

♦ ♦ ♦

22 TAC §291.36

The Texas State Board of Pharmacy proposes amendments to §291.36, concerning Pharmacies Compounding Sterile Preparations (Class A-S). The amendments, if adopted, create the designation of Class A-N for community pharmacies engaged in the compounding of certain non-sterile preparations and Class A-SN for community pharmacies engaged in the compounding of both sterile preparations and certain non-sterile preparations.

Timothy L. Tucker, 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. Mr. Tucker 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 that community pharmacies engaged in compounding are properly licensed and regulated in order to protect the public. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

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

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

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

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

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

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

(6) The proposed amendments do expand an existing regulation by creating new pharmacy license designations and license requirements for each designation;

(7) The proposed amendments do increase the number of individuals subject to the rule's applicability; and

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

Written comments on the amendments may be submitted to Eamon D. Briggs, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., October 25, 2021.

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.

§291.36. Pharmacies Compounding [~~Sterile~~] Preparations (Class A-S, Class A-N, and Class A-SN).

(a) Licensing Requirements for Class A-S. A community pharmacy engaged in the compounding of sterile preparations shall be designated as a Class A-S pharmacy.

(1) A Class A-S pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures as specified in §291.1 of this title (relating to Pharmacy License Application). A Class A-S license may not be issued unless the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(2) A Class A-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board within the last renewal period.

(3) A Class A-S pharmacy shall comply with the provisions of §291.3 of this title (relating to Required Notifications), §291.5 of this title (relating to Closing a Pharmacy), and §291.6 of this title (relating to Pharmacy License Fees). [~~A Class A-S pharmacy which changes ownership shall notify the board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).~~]

[~~(4) A Class A-S pharmacy which changes location and/or name shall notify the board within ten days of the change and file for an amended license as specified in §291.3 of this title.~~]

[~~(5) A Class A-S pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures as specified in §291.3 of this title.~~]

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

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

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

(5) [(9)] A Class A-S pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) concerning Community Pharmacy (Class A) is required to comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), §291.35 of this title (relating to Official Prescription Requirements), and §291.133 of this title.

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

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

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

(b) Licensing Requirements for Class A-N. A community pharmacy engaged in the compounding of non-sterile preparations that use bulk API or excipients or manipulation beyond the FDA labeling of a commercial product (e.g., crushing a tablet or opening a capsule) shall be designated as a Class A-N pharmacy.

(1) A Class A-N pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures as specified in §291.1 of this title. A Class A-N license may not be issued unless the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(2) A Class A-N pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board within the last renewal period.

(3) A Class A-N pharmacy shall comply with the provisions of §§291.3, 291.5, and 291.6 of this title.

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

(5) A Class A-N pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) concerning Community Pharmacy (Class A) is required to comply with the provisions of §§291.31, 291.32, 291.33, 291.34, 291.35, and 291.131 of this title.

(6) A Class A-N pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title.

(7) A Class A-N pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title and/or §291.125 of this title.

(c) Licensing Requirements for Class A-SN. A community pharmacy engaged in the compounding of sterile preparations and non-sterile preparations that use bulk API or excipients or manipulation beyond the FDA labeling of a commercial product (e.g., crushing a tablet or opening a capsule) shall be designated as a Class A-SN pharmacy.

(1) A Class A-SN pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures as specified in §291.1 of this title. A Class A-SN license may not be issued unless the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as specified in §291.131 of this title and §291.133 of this title.

(2) A Class A-SN pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board within the last renewal period.

(3) A Class A-SN pharmacy shall comply with the provisions of §§291.3, 291.5, and 291.6 of this title.

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

(5) A Class A-SN pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) concerning Community Pharmacy (Class A) is required to comply with the provisions of §§291.31, 291.32, 291.33, 291.34, 291.35, 291.131, and 291.133 of this title.

(6) A Class A-SN pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title.

(7) A Class A-SN pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title and/or §291.125 of this title.

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 10, 2021.

TRD-202103593
Timothy L. Tucker, Pharm.D.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 305-8010

♦ ♦ ♦

SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)

22 TAC §291.77

The Texas State Board of Pharmacy proposes amendments to 22 TAC §291.77, concerning Pharmacies Compounding Sterile

Preparations (Class C-S). The amendments, if adopted, create the designation of Class C-N for institutional or ASC pharmacies engaged in the compounding of certain non-sterile preparations and Class C-SN for institutional or ASC pharmacies engaged in the compounding of both sterile preparations and certain non-sterile preparations.

Timothy L. Tucker, 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. Mr. Tucker 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 that institutional or ASC pharmacies engaged in compounding are properly licensed and regulated in order to protect the public. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

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

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

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

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

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

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

(6) The proposed amendments do expand an existing regulation by creating new pharmacy license designations and license requirements for each designation;

(7) The proposed amendments do increase the number of individuals subject to the rule's applicability; and

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

Written comments on the amendments may be submitted to Eamon D. Briggs, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., October 25, 2021.

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.

§291.77. Pharmacies Compounding [~~Sterile~~] Preparations (Class C-S, Class C-N, and Class C-SN).

(a) Licensing requirements for Class C-S. An institutional or ASC pharmacy engaged in the compounding of sterile preparations shall be designated as a Class C-S pharmacy.

(1) A Class C-S pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application). A Class C-S license may not be issued unless the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(2) A Class C-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board within the last renewal period.

(3) A Class C-S pharmacy shall comply with the provisions of §291.3 of this title (relating to Required Notifications), §291.5 of this title (relating to Closing a Pharmacy), and §291.6 of this title (relating to Pharmacy License Fees). [~~A Class C-S pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).~~]

[~~(4) A Class C-S pharmacy which changes location and/or name shall notify the board within 10 days of the change and file for an amended license as specified in §291.3 of this title.~~]

[~~(5) A Class C-S pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change following the procedures in §291.3 of this title.~~]

[~~(6) A Class C-S pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).~~]

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

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

(5) [~~(9)~~] A Class C-S pharmacy, licensed under the Act, §560.051(a)(3), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) concerning Community Pharmacy (Class A) [~~(Community Pharmacy (Class A))~~] or the Act, §560.051(a)(2) concerning Nuclear Pharmacy (Class B) [~~(Nuclear Pharmacy (Class B))~~], is not required to secure a license for the such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Requirements), contained in Community Pharmacy (Class A), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy, and §291.133 of this title.

[~~(10) A Class C-S pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).~~]

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

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

(8) [~~(13)~~] A Class C-S pharmacy with an ongoing clinical pharmacy program that proposes to allow a pharmacy technician to verify the accuracy of work performed by another pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a patient admitted to the hospital if the patient's orders have previously been reviewed and approved by a pharmacist shall make application to the board and submit any information specified on the application [~~as follows~~.

[~~(A) The pharmacist-in-charge must submit an application on a form provided by the board, containing the following information:~~]

~~(i)~~ ~~name, address, and pharmacy license number;~~]

~~(ii)~~ ~~name and license number of the pharmacist-in-charge;~~]

~~(iii)~~ ~~name and registration numbers of the pharmacy technicians;~~]

~~(iv)~~ ~~anticipated date the pharmacy plans to begin allowing a pharmacy technician to verify the accuracy of work performed by another pharmacy technician;~~]

~~(v)~~ ~~documentation that the pharmacy has an ongoing clinical pharmacy program; and~~]

~~(vi)~~ ~~any other information specified on the application.~~]

[~~(B) The pharmacy may not allow a pharmacy technician to check the work of another pharmacy technician until the board has reviewed and approved the application and issued an amended license to the pharmacy.~~]

[~~(C) Every two years, in connection with the application for renewal of the pharmacy license, the pharmacy shall provide updated documentation that the pharmacy continues to have an ongoing clinical pharmacy program as specified in subparagraph (A)(v) of this paragraph.~~]

(9) [~~(14)~~] A rural hospital that wishes to allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title (relating to Personnel) shall make application to the boardand submit any information specified on the application [~~as follows~~].

[~~(A) Prior to allowing a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title, the pharmacist-in-charge must submit an application on a form provided by the board, containing the following information:~~]

~~(i)~~ ~~name, address, and pharmacy license number;~~]

~~(ii)~~ ~~name and license number of the pharmacist-in-charge;~~]

~~(iii)~~ ~~name and registration number of the pharmacy technicians;~~]

~~(iv)~~ ~~proposed date the pharmacy wishes to start allowing pharmacy technicians to perform the duties specified in §291.73(e)(2)(D) of this title;~~]

~~(v)~~ ~~documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural hospital is either:~~]

~~(I)~~ ~~located in a county with a population of 50,000 or less as defined by the United States Census Bureau in the most recent U.S. census; or~~]

~~(II)~~ ~~designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital; and~~]

~~(vi)~~ ~~any other information specified on the application.~~]

(A) [~~(B)~~] A rural hospital may not allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title until the board has reviewed and approved the application and issued an amended license to the pharmacy.

(B) [~~(C)~~] Every two years in conjunction with the application for renewal of the pharmacy license, the pharmacist-in-charge shall update the application for pharmacy technicians to perform the duties specified in §291.73(e)(2)(D) of this title and shall attest as required on the application.

(b) Licensing Requirements for Class C-N. An institutional or ASC pharmacy engaged in the compounding of non-sterile preparations that use bulk API or excipients or manipulation beyond the FDA labeling of a commercial product (e.g., crushing a tablet or opening a capsule) shall be designated as a Class C-N pharmacy.

(1) A Class C-N pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title. A Class C-S license may not be issued unless the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(2) A Class C-N pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board within the last renewal period.

(3) A Class C-N pharmacy shall comply with the provisions of §§291.3, 291.5, and 291.6 of this title.

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

(5) A Class C-N pharmacy, licensed under the Act, §560.051(a)(3), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) concerning Community Pharmacy (Class A) or the Act, §560.051(a)(2) concerning Nuclear Pharmacy (Class B), is not required to secure a license for the such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of §§291.31, 291.32, 291.33, 291.34, and 291.35 of this title, contained in Community Pharmacy (Class A), or §§291.51, 291.52, 291.53, 291.54, and 291.55 of this title, contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy, and with the provisions of §291.131 of this title.

(6) A Class C-N pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title.

(7) A Class C-N pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title and/or §291.125 of this title.

(8) A Class C-N pharmacy with an ongoing clinical pharmacy program that proposes to allow a pharmacy technician to verify the accuracy of work performed by another pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a patient admitted to the hospital if the patient's orders have previously been reviewed and approved by a pharmacist shall make application to the board and submit any information specified on the application.

(9) A rural hospital that wishes to allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title shall make application to the board and submit any information specified on the application.

(A) A rural hospital may not allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title until the board has reviewed and approved the application and issued an amended license to the pharmacy.

(B) Every two years in conjunction with the application for renewal of the pharmacy license, the pharmacist-in-charge shall update the application for pharmacy technicians to perform the duties specified in §291.73(e)(2)(D) of this title and shall attest as required on the application.

(c) Licensing Requirements for Class C-SN. An institutional or ASC pharmacy engaged in the compounding of sterile preparations and non-sterile preparations that use bulk API or excipients or manipulation beyond the FDA labeling of a commercial product (e.g., crushing a tablet or opening a capsule) shall be designated as a Class C-SN pharmacy.

(1) A Class C-SN pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title. A Class C-SN license may not be issued unless the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as specified in §291.131 and §291.133 of this title.

(2) A Class C-SN pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board within the last renewal period.

(3) A Class C-SN pharmacy shall comply with the provisions of §§291.3, 291.5, and 291.6 of this title.

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

(5) A Class C-SN pharmacy, licensed under the Act, §560.051(a)(3), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) concerning Community Pharmacy (Class A) or the Act, §560.051(a)(2) concerning Nuclear Pharmacy (Class B), is not required to secure a license for the such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of §§291.31, 291.32, 291.33, 291.34, and 291.35 of this title, contained in Community Pharmacy (Class A), or §§291.51, 291.52, 291.53, 291.54, and 291.55 of this title, contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy, and with the provisions of §291.131 and §291.133 of this title.

(6) A Class C-SN pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title.

(7) A Class C-SN pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title and/or §291.125 of this title.

(8) A Class C-SN pharmacy with an ongoing clinical pharmacy program that proposes to allow a pharmacy technician to verify the accuracy of work performed by another pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a patient admitted to the hospital if the patient's orders have previously been reviewed and approved by a pharmacist shall make application to the board and submit any information specified on the application.

(9) A rural hospital that wishes to allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title shall make application to the board and submit any information specified on the application.

(A) A rural hospital may not allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title until the board has reviewed and approved the application and issued an amended license to the pharmacy.

(B) Every two years in conjunction with the application for renewal of the pharmacy license, the pharmacist-in-charge shall update the application for pharmacy technicians to perform the duties specified in §291.73(e)(2)(D) of this title and shall attest as required on the application.

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 10, 2021.

TRD-202103601
Timothy L. Tucker, Pharm.D.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 305-8010

♦ ♦ ♦

SUBCHAPTER F. NON-RESIDENT PHARMACY (CLASS E)

22 TAC §291.106

The Texas State Board of Pharmacy proposes amendments to §291.106, concerning Pharmacies Compounding Sterile Preparations (Class E-S). The amendments, if adopted, create the designation of Class E-N for non-resident pharmacies engaged in the compounding of certain non-sterile preparations and Class E-SN for non-resident pharmacies engaged in the compounding of both sterile preparations and certain non-sterile preparations.

Timothy L. Tucker, 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. Mr. Tucker 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 that non-resident pharmacies engaged in compounding are properly licensed and regulated in order to protect the public. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

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

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

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

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

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

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

(6) The proposed amendments do expand an existing regulation by creating new pharmacy license designations and license requirements for each designation;

(7) The proposed amendments do increase the number of individuals subject to the rule's applicability; and

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

Written comments on the amendments may be submitted to Eamon D. Briggs, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., October 25, 2021.

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.

§291.106. Pharmacies Compounding [~~Sterile~~] Preparations (Class E-S, Class E-N, and Class E-SN).

(a) Licensing requirements for Class E-S. A non-resident pharmacy engaged in the compounding of sterile preparations shall be licensed as a Class E-S pharmacy.

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

(2) A Class E-S license may not be issued unless the pharmacy has been inspected by the board or its designee to ensure the pharmacy meets the requirements as specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations). A Class E-S pharmacy shall reimburse the board for all expenses, including travel, related to the inspection of the Class E-S pharmacy.

(3) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this title and then provide the following additional information specified in §560.052(c) and (f) of the Act (relating to Qualifications):

(A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the state in which the pharmacy is located;

(B) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;

(C) evidence of the applicant's ability to provide to the board a record of a prescription drug order dispensed by the applicant to a resident of this state not later than 72 hours after the time the board requests the record;

(D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read and understands the laws and rules relating to a Class E pharmacy; and

(E) proof of creditworthiness.

(4) A Class E-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board or its designee within the last renewal period.

(5) A Class E-S pharmacy shall comply with the provisions of §291.3 of this title (relating to Required Notifications), §291.5 of this title (relating to Closing a Pharmacy), and §291.6 of this title (relating to Pharmacy License Fees). [~~A Class E-S pharmacy which changes ownership shall notify the board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).~~]

[~~(6) A Class E-S pharmacy which changes location and/or name shall notify the board as specified in §291.3 of this title.~~]

[~~(7) A Class E-S pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, as specified in §291.3 of this title.~~]

[~~(8) A Class E-S pharmacy shall notify the board in writing within ten days of closing.~~]

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

[~~(10) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.~~]

(7) [~~(11)~~] The board may grant an exemption from the licensing requirements of this Act on the application of a pharmacy located in a state of the United States other than this state that restricts its dispensing of prescription drugs or devices to residents of this state to isolated transactions.

(8) [~~(12)~~] A Class E-S pharmacy engaged in the centralized dispensing of prescription drug or medication orders shall comply with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

(9) [~~(13)~~] A Class E-S pharmacy engaged in central processing of prescription drug or medication orders shall comply with the provisions of §291.123 of this title (relating to Central Prescription or Medication Order Processing).

[~~(14) A Class E-S pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of~~

§291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).]

(10) [(15)] A Class E-S pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133 of this title.

(11) [(16)] A Class E-S pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(5) concerning Non-Resident Pharmacy (Class E) is required to comply with the provisions of §291.101 of this title (relating to Purpose), §291.102 of this title (relating to Definitions), §291.103 of this title (relating to Personnel), §291.104 of this title (relating to Operational Standards) and §291.105 of this title (relating to Records).

(b) Licensing Requirements for Class E-N. A non-resident pharmacy engaged in the compounding of non-sterile preparations that use bulk API or excipients or manipulation beyond the FDA labeling of a commercial product (e.g., crushing a tablet or opening a capsule) shall be designated as a Class E-N pharmacy.

(1) A Class E-N pharmacy shall register with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title.

(2) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this title and then provide the following additional information specified in §560.052(c) and (f) of the Act:

(A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the state in which the pharmacy is located;

(B) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;

(C) evidence of the applicant's ability to provide to the board a record of a prescription drug order dispensed by the applicant to a resident of this state not later than 72 hours after the time the board requests the record;

(D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read and understands the laws and rules relating to a Class E pharmacy; and

(E) proof of creditworthiness.

(3) A Class E-N pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board or its designee within the last renewal period.

(4) A Class E-N pharmacy shall comply with the provisions of §§291.3, 291.5, and 291.6.

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

(6) The board may grant an exemption from the licensing requirements of this Act on the application of a pharmacy located in a state of the United States other than this state that restricts its dispensing of prescription drugs or devices to residents of this state to isolated transactions.

(7) A Class E-N pharmacy engaged in the centralized dispensing of prescription drug or medication orders shall comply with the provisions of §291.125 of this title.

(8) A Class E-N pharmacy engaged in central processing of prescription drug or medication orders shall comply with the provisions of §291.123 of this title.

(9) A Class E-N pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(5) concerning Non-Resident Pharmacy (Class E) is required to comply with the provisions of §§291.101, 291.102, 291.103, 291.104, 291.105, and 291.131 (relating to Pharmacies Compounding Non-Sterile Preparations) of this title.

(c) Licensing Requirements for Class E-SN. A non-resident pharmacy engaged in the compounding of sterile preparations and non-sterile preparations that use bulk API or excipients or manipulation beyond the FDA labeling of a commercial product (e.g., crushing a tablet or opening a capsule) shall be designated as a Class E-SN pharmacy.

(1) A Class E-SN pharmacy shall register with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title.

(2) A Class E-SN license may not be issued unless the pharmacy has been inspected by the board or its designee to ensure the pharmacy meets the requirements as specified in §291.133 of this title. A Class E-SN pharmacy shall reimburse the board for all expenses, including travel, related to the inspection of the Class E-SN pharmacy.

(3) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this title and then provide the following additional information specified in §560.052(c) and (f) of the Act:

(A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the state in which the pharmacy is located;

(B) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;

(C) evidence of the applicant's ability to provide to the board a record of a prescription drug order dispensed by the applicant to a resident of this state not later than 72 hours after the time the board requests the record;

(D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read and understands the laws and rules relating to a Class E pharmacy; and

(E) proof of creditworthiness.

(4) A Class E-SN pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board or its designee within the last renewal period.

(5) A Class E-N pharmacy shall comply with the provisions of §§291.3, 291.5, and 291.6 of this title.

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

(7) The board may grant an exemption from the licensing requirements of this Act on the application of a pharmacy located in a state of the United States other than this state that restricts its dispensing of prescription drugs or devices to residents of this state to isolated transactions.

(8) A Class E-SN pharmacy engaged in the centralized dispensing of prescription drug or medication orders shall comply with the provisions of §291.125 of this title.

(9) A Class E-SN pharmacy engaged in central processing of prescription drug or medication orders shall comply with the provisions of §291.123 of this title.

(10) A Class E-SN pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(5) concerning Non-Resident Pharmacy (Class E) is required to comply with the provisions of §§291.101, 291.102, 291.103, 291.104, 291.105, 291.131, and 291.133 of this title.

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 10, 2021.

TRD-202103602
Timothy L. Tucker, Pharm.D.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 305-8010

♦ ♦ ♦

SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES

22 TAC §291.131

The Texas State Board of Pharmacy proposes amendments to 22 TAC §291.131, concerning Pharmacies Compounding Non-Sterile Preparations. The amendments, if adopted, add definitions of "cleaning" and "sanitizing", update requirements for all personnel engaged in non-sterile compounding, add additional requirements for personnel engaged in certain types of non-sterile compounding, and update environmental and equipment requirements for non-sterile compounding.

Timothy L. Tucker, 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. Mr. Tucker 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 non-sterile compounded preparations for patients, improve the health, safety, and welfare of patients by ensuring that Class A, Class C, and Class E pharmacies engaged in non-sterile compounding operate in a safe and sanitary environment, and provide clearer regulatory language.

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 §291.131. The Board currently does not have information on the number of pharmacies that compound non-sterile preparations that use bulk active pharmaceutical ingredient (API) or excipients or manipulation beyond the U.S. Food and Drug Administration (FDA) labeling of a commercial product and therefore would be subject to the proposed amendments. The Board is unable to estimate the number of small or micro-businesses subject to the proposed amendments. The Board estimates that 468 rural communities contain pharmacies, of which approximately 365 contain pharmacies that perform some form of non-sterile compounding, that could potentially be impacted by the proposed amendments if the pharmacy compounds non-sterile preparations that use bulk API or excipients or manipulation beyond the FDA labeling of a commercial product. 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 non-sterile preparations. The estimated cost of testing a non-sterile compounded preparation is $200 per compounded preparation. The estimated cost of a prescription balance inspection is $50 to $100 per scale. The estimated cost of a closed system processing device is $1,000 to $11,000 depending on the size and quality of the unit. The estimated cost of a space specifically designated for non-sterile compounding that is kept clean, does not have carpet, and is arranged to minimize cross-contamination is dependent on the anticipated scope and volume of the pharmacy's compounding operation. If a pharmacy chose to pay for their employee's ACPE-accredited in-person experiential training, the estimated cost ranges from $1,000 to $5,000 depending on the course chosen.

The Board has established an ongoing Compounding Advisory Group (Group), and the proposed amendments are based on the recommendations of the Group. Alternative methods of achieving the purpose of the proposed amendments were considered by the Group and the proposed amendments reflect the Group's recommendation of the least restrictive methods of ensuring the safety and efficacy of non-sterile compounded preparations for patients.

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 §291.131. The Board has established an ongoing Compounding Advisory Group (Group), and the proposed amendments are based on the recommendations of the Group. The Group discussed updating non-sterile compounding requirements to ensure patient safety and possible methods of achieving this purpose at the November 18, 2020, January 13, 2021, and June 24, 2021, meetings. The Group discussed differing options and levels of training, process validation testing, and environmental requirements in determining recommendations for the least restrictive methods of ensuring the safety and efficacy of non-sterile compounded preparations for patients. The Group chose to limit the applicability of the recommended requirements in the proposed amendments to pharmacies that compound non-sterile preparations that use bulk active pharmaceutical ingredient or excipients or manipulation beyond the U.S. Food and Drug Administration labeling of a commercial product so that the requirements would apply to types of non-sterile compounding that posed a greater risk to patient safety. 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, Mr. Tucker has determined the following:

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

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

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

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

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

(6) The proposed amendments do expand an existing regulation by adding new operational requirements for Class A, Class C, and Class E pharmacies engaged in non-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 do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Eamon D. Briggs, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., October 25, 2021.

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.

§291.131. Pharmacies Compounding Non-Sterile Preparations.

(a) Purpose. Pharmacies compounding non-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 non-sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies;

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

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

(4) compounding of non-sterile preparations by a Class C (Institutional) pharmacy and the distribution of the compounded preparations to other Class C (Institutional) 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) Beyond-use date--The date or time after which the compounded non-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 when the preparation was compounded.

(2) Cleaning--The process of removing soil (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.

(3) [~~(2)~~] Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.

(4) [~~(3)~~] 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.

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

(6) [~~(5)~~] 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 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 Pharmacopoeia guidelines and accreditation practices.

(7) Sanitizing--A process for reducing on inanimate surfaces the number of all forms of microbial life including fungi, viruses, and bacteria using an agent such as isopropyl alcohol.

(8) [~~(6)~~] SOPs--Standard operating procedures.

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

(c) Personnel.

(1) Pharmacist-in-charge. 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 non-sterile compounding:

(A) determining that all personnel involved in non-sterile compounding possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised;

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

(C) assuring that the equipment used in compounding is properly maintained;

(D) maintaining an appropriate environment in areas where non-sterile compounding occurs; and

(E) assuring that effective quality control procedures are developed and followed.

(2) Pharmacists. Special requirements for non-sterile compounding.

(A) All pharmacists involved [~~engaged~~] in the preparation and handling of compounded non-sterile preparations [~~compounding~~] shall:

(i) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised; and

(ii) obtain one hour of ACPE accredited continuing education during each renewal period as appropriate for the type of compounding done by the pharmacist.

(B) All pharmacists involved in the preparation and mixing of compounded non-sterile preparations that use bulk API or excipients or manipulation beyond the FDA labeling of a commercial product (e.g., crushing a tablet or opening a capsule) shall, in addition to the requirements above in subparagraph (A) of this paragraph:

(i) complete testing of three preparations compounded by the pharmacist for accuracy of correct identities and amounts of ingredients within the first six months of engaging in compounding non-sterile preparations intended for patient use; and

(ii) demonstrate and document competency and undergo re-evaluation every 12 months.

(C) [~~(B)~~] A pharmacist shall inspect and approve all components, drug product containers, closures, labeling, and any other materials involved in the compounding process.

(D) [~~(C)~~] A pharmacist shall review all compounding records for accuracy and conduct in-process and final checks to ensure that errors have not occurred in the compounding process.

(E) [~~(D)~~] A pharmacist is responsible for the proper maintenance, cleanliness, and use of all equipment used in the compounding process.

(3) Pharmacy technicians and pharmacy technician trainees.

(A) All pharmacy technicians and pharmacy technician trainees engaged in non-sterile compounding shall:

(i) [~~(A)~~] possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken;

(ii) [~~(B)~~] obtain one hour of ACPE accredited continuing education during each renewal period as appropriate for the type of compounding done by the pharmacy technician or pharmacy technician trainee; and

(iii) [~~(C)~~] perform compounding duties under the direct supervision of and responsible to a pharmacist.

(B) All pharmacy technicians and pharmacy technician trainees involved in the preparation and mixing of compounded non-sterile preparations that use bulk API or excipients or manipulation beyond the FDA labeling of a commercial product (e.g., crushing a tablet or opening a capsule) shall, in addition to the requirements above in subparagraph (A) of this paragraph:

(i) complete testing of three preparations compounded by the pharmacy technician or pharmacy technician trainee for accuracy of correct identities and amounts of ingredients within the first six months of engaging in compounding non-sterile preparations intended for patient use; and

(ii) demonstrate and document competency and undergo re-evaluation every 12 months.

(4) Training.

(A) All training activities shall be documented and covered by appropriate SOPs as outlined in subsection (d)(8)(A) of this section.

(B) All personnel involved in non-sterile compounding shall be well trained and must participate in continuing relevant training programs.

(C) All personnel involved in the preparation and mixing of compounded non-sterile preparations that use bulk API or excipients or manipulation beyond the FDA labeling of a commercial product (e.g., crushing a tablet or opening a capsule) shall complete initial training in the areas listed in subparagraph (D) of this paragraph through:

(i) a single course with a minimum of 40 hours for the pharmacy technician or 20 hours for the pharmacist of instruction and hands-on, in-person experience. 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; or

(ii) a structured on-the-job didactic and hands-on, in-person experiential training program at the pharmacy where the individual is involved in non-sterile compounding. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program.

(D) Training shall include instruction, experience and demonstrated proficiency in the following areas:

(i) hand hygiene;

(ii) garbing;

(iii) cleaning and sanitizing;

(iv) handling and transporting components and compounded non-sterile preparations;

(v) measuring and mixing;

(vi) proper use of equipment and devices selected to compound non-sterile preparations; and

(vii) documentation of the compounding process (e.g., Master Formulation Records and Compounding Records).

(E) All training shall be completed and documented prior to engaging in compounding non-sterile preparations intended for patient use.

(F) The required experiential portion of the training programs must be supervised by an individual who is actively engaged in performing non-sterile compounding and is qualified and has completed training as specified in this paragraph.

(d) Operational Standards.

(1) General requirements.

(A) Non-sterile drug preparations may be compounded in licensed pharmacies:

(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) Non-sterile compounding in anticipation of future prescription drug or medication orders 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.

(i) The pharmacist's professional judgment shall be based on the criteria used to determine a beyond-use date outlined in paragraph (5)(C) of this subsection.

(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time 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) pharmacy [~~facility's~~] lot number;

(III) beyond-use date as determined by the pharmacist using appropriate documented criteria as outlined in paragraph (5)(C) of this subsection; and

(IV) quantity or amount in the container.

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

(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet 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 patient needs 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 product 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 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 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/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 non-sterile prescription compounding services, which may include specific drug products 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) A pharmacist may add flavoring to a prescription at the request of a patient, the patient's agent, or the prescriber. The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise documented. Documentation of beyond-use-dates longer than fourteen days shall be maintained by the pharmacy electronically or manually and made available to agents of the board on request. A pharmacist may not add flavoring to an over-the-counter product at the request of a patient or patient's agent unless the pharmacist obtains a prescription for the over-the-counter product from the patient's practitioner.

(2) Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain a current copy, in hard-copy or electronic format, of Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations.

(3) Environment.

(A) Pharmacies regularly engaging in compounding shall have a designated and adequate area for the safe and orderly compounding of non-sterile preparations, including the placement of equipment and materials. Space in the pharmacy shall be specifically designated for non-sterile compounding. The method of designation (e.g., visible perimeter) must be described in the pharmacy's SOP. Other activities shall not occur in the space at the same time as compounding. The compounding space shall be secure, well-lighted and shall be maintained in a clean, orderly, and sanitary condition, and in a good state of repair. Carpet is not allowed in the compounding space. Surfaces should be resistant to damage by cleaning and sanitizing agents. The space shall allow for the orderly placement of equipment and materials to prevent confusion among components, containers, labels, in-process materials, and finished compounded non-sterile preparations. The space shall be designed, arranged, and used in a way that minimizes cross-contamination from non-compounding areas.

(B) Pharmacies involved in occasional compounding shall prepare an area prior to each compounding activity which is adequate for safe and orderly compounding.

(C) [~~(B)~~] Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of a drug compounding operation.

(D) [~~(C)~~] A sink with hot and cold running water, exclusive of rest room facilities, shall be accessible to the compounding areas and be maintained in a sanitary condition. Supplies necessary for adequate washing shall be accessible in the immediate area of the sink and include:

(i) soap or detergent; and

(ii) disposable [~~air-driers or single-use~~] towels.

(E) [~~(D)~~] If drug products which require special precautions to prevent contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its use for the preparation of other drug products, must be used in order to prevent cross-contamination.

(F) Cleaning and sanitizing of the surfaces including ceilings, walls, floors, work surfaces, and storage shelving in the non-sterile compounding area(s) shall occur on a regular basis as defined in SOPs.

(4) Equipment and Supplies. The pharmacy shall:

(A) have a Class A prescription balance, or analytical balance and weights which shall be:

(i) properly maintained; [~~and subject to periodic inspection by the Texas State Board of Pharmacy;~~ ~~and~~]

(ii) inspected and calibrated at least every 12 months by a qualified independent individual. The balance shall not be used to weigh any amount less than the minimum accurate weighable quantity (MAWQ) of that balance or the manufacturer's specifications for the smallest weighable quantity; and

(iii) calibrated and have the accuracy of the balance verified by the pharmacy on a routine basis as specified in the pharmacy's SOPs. The pharmacy shall document the calibration and verification;

(B) have equipment and utensils necessary for the proper compounding of prescription drug or medication orders. Such equipment and utensils used in the compounding process shall be:

(i) of appropriate design and 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 product beyond the desired result;

(iii) cleaned and sanitized immediately prior and after to each use; and

(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance; and [.]

(C) use a closed system processing device, used to reduce the potential exposure to personnel, or contamination of the pharmacy, or compounded non-sterile preparations, to perform activities such as weighing, measuring, or otherwise manipulating components that generate airborne chemical particles (e.g., active pharmaceutical ingredients (APIs), added substances, conventionally manufactured products). Examples of closed system processing devices include containment ventilated enclosures (CVEs), 249 biological safety cabinets (BSCs), powder containment hoods, or single-use containment glove bags. If a BSC or CVE is used, the BSC or CVE shall be certified every 12 months by a qualified independent individual.

(5) Labeling. In addition to the labeling requirements of the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following.

(A) The generic name(s) or the official name(s) of the principal active ingredient(s) of the compounded preparation.

(B) A statement that the preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement).

(C) A beyond-use date after which the compounded preparation should not be used. The beyond-use date shall be determined as outlined in Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations including the following:

(i) The pharmacist shall consider:

(I) physical and chemical properties of active ingredients;

(II) use of preservatives and/or stabilizing agents;

(III) dosage form;

(IV) storage containers and conditions; and

(V) scientific, laboratory, or reference data from a peer reviewed source and retained in the pharmacy. The reference data should follow the same preparation instructions for combining raw materials and packaged in a container with similar properties.

(ii) In the absence of stability information applicable for a specific drug or preparation, the following maximum beyond-use dates are to be used when the compounded preparation is packaged in tight, light-resistant containers and stored at controlled room temperatures.

(I) Nonaqueous liquids and solid formulations (Where the manufactured drug product is the source of active ingredient): 25% of the time remaining until the product's expiration date or 6 months, whichever is earlier.

(II) Water-containing formulations (Prepared from ingredients in solid form): Not later than 14 days when refrigerated between 2 - 8 degrees Celsius (36 - 46 degrees Fahrenheit).

(III) All other formulations: Intended duration of therapy or 30 days, whichever is earlier.

(iii) Beyond-use date limits may be exceeded when supported by valid scientific stability information for the specific compounded preparation.

(6) Written drug information. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing. A statement which indicates that the preparation was compounded by the pharmacy must be included in this written information. If there is no written information available, the patient should be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate the prescriber, concerning the drug.

(7) Drugs, components, and materials used in non-sterile compounding.

(A) Drugs used in non-sterile compounding shall be a USP/NF grade substances manufactured in an FDA-registered facility.

(B) If USP/NF grade substances are not available, or when food, cosmetics, or other substances are, or must be used, the substance shall be of a chemical grade in one of the following categories:

(i) Chemically Pure (CP);

(ii) Analytical Reagent (AR); [~~or~~]

(iii) American Chemical Society (ACS); or

(iv) Food Chemical Codex. [; or]

(C) The [If a drug, component or material is not purchased from a FDA-registered facility, the] pharmacist shall establish purity and stability of each component by obtaining a Certificate of Analysis from the supplier and ensure that the component meets the acceptance criteria in a USP/NF monograph, if one exists [the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis] .

(D) A manufactured drug product may be a source of active ingredient. Only manufactured drugs from containers labeled with a batch control number and a future expiration date are acceptable as a potential source of active ingredients. When compounding with manufactured drug products, the pharmacist must consider all ingredients present in the drug product relative to the intended use of the compounded preparation.

(E) All components shall be stored in properly labeled containers in a clean, dry area, under proper temperatures.

(F) Drug product 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 product beyond the desired result.

(G) Components, drug product containers, and closures shall be rotated so that the oldest stock is used first.

(H) 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 product.

(I) 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.

(8) Compounding process.

(A) 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 for:

(i) the pharmacy compounding area [facility];

(ii) equipment;

(iii) personnel, including training and personal protective equipment;

(iv) preparation evaluation;

(v) quality assurance;

(vi) preparation recall;

(vii) packaging; and

(viii) storage of compounded preparations.

(B) Any compounded preparation 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) Any person with an apparent illness or open lesion that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, any materials involved in the compounding process, and drug products until the condition is corrected. Personnel engaged in compounding shall perform hand hygiene procedure when entering the designated compounding area. Personnel shall wash hands and forearms up to the elbows with soap and running warm water for at least 30 seconds. Dry hands and forearms to the elbows completely with disposable towels. Allow hands and forearms to dry thoroughly before donning gloves.

(D) Gloves and other garb (e.g., shoe covers, head and facial hair covers, face masks, gowns) shall be worn for all compounding activities for prevention of preparation and facility contamination and must be appropriate for the type of compounding performed. The garbing requirements and frequency of changing the garb shall be determined by the pharmacy and documented in the pharmacy's SOPs. Garb shall be stored in a manner that minimizes contamination (e.g., away from sinks to avoid splashing). Visibly soiled garb or garb with tears or punctures, including gloves, shall be changed immediately. Gloves, shoe covers, hair covers, facial hair covers, face masks, or head coverings may not be re-used if worn outside of the compounding area and must be replaced with new ones. To minimize the risk of cross-contaminating other compounded non-sterile preparations and contaminating other objects (e.g., pens and keyboards), gloves should be wiped with 70% isopropyl alcohol or replaced before beginning a compounded non-sterile preparation with different components. [Personnel engaged in the compounding of drug preparations shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, hair nets, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug preparations from contamination].

(E) 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.

(9) Quality Assurance.

(A) Initial formula validation. Prior to routine compounding of a non-sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a product that contains the stated amount of active ingredient(s).

(B) Finished preparation checks. The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded non-sterile preparations shall be inspected for accuracy of correct identities and amounts of ingredients, packaging, labeling, and expected physical appearance before the non-sterile preparations are dispensed.

(C) The pharmacy shall develop and implement SOPs for complaint, variance, and adverse event report receipt, acknowledgment, handling and documentation. Complaints or variances may include reports on the quality, labeling, or possible adverse reactions to a compounded non-sterile preparation.

(10) Quality Control.

(A) The pharmacy shall follow established quality control procedures to monitor the quality of compounded drug preparations for uniformity and consistency such as capsule weight variations, adequacy of mixing, clarity, or pH of solutions. When developing these procedures, pharmacy personnel shall consider the provisions of Chapter 795, concerning Pharmacy Compounding Non-Sterile Preparations[, Chapter 1075, concerning Good Compounding Practices,] and Chapter 1160, concerning Pharmaceutical Calculations in Prescription Compounding contained in the current USP/NF. Such procedures shall be documented and be available for inspection.

(B) Compounding procedures that are routinely performed, including batch compounding, shall be completed and verified according to written procedures. The act of verification of a com-

pounding procedure involves checking to ensure that calculations, weighing and measuring, order of mixing, and compounding techniques were appropriate and accurately performed.

(C) Unless otherwise indicated or appropriate, compounded preparations are to be prepared to ensure that each preparation shall contain not less than 90.0 percent and not more than 110.0 percent of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume and not less than 90.0 percent and not more than 110.0 percent of the theoretically calculated weight or volume per unit of the preparation.

(e) Records.

(1) Maintenance of records. Every record required by this section shall 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 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 or medication orders. Compounding records for all compounded preparations shall be maintained by the pharmacy electronically or manually as part of the prescription drug or medication order, formula record, formula book, or compounding log and shall include:

(i) the date 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) and name(s) of the manufacturer(s) of the raw materials and the quantities of each;

(iii) signature or initials of the pharmacist or pharmacy technician or pharmacy technician trainee performing the compounding;

(iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting in-process and final checks of compounded preparations if pharmacy technicians or pharmacy technician trainees perform the compounding function;

(v) the quantity in units of finished preparations or amount of raw materials;

(vi) the container used and the number of units prepared; and

(vii) 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. Documentation of the performance of quality control procedures is not required if the compounding process is done pursuant to a patient specific order and involves the mixing of two or more commercially available oral liquids or commercially available preparations when the final product is intended for external use.

(B) Compounding records when batch compounding or compounding in anticipation of future prescription drug or medication orders.

(i) Master work sheet. A master work sheet shall be 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) the formula;

(II) the components;

(III) the compounding directions;

(IV) a sample label;

(V) evaluation and testing requirements;

(VI) specific equipment used during preparation; and

(VII) storage requirements.

(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 or each component;

(III) component manufacturer/distributor or suitable identifying number;

(IV) container specifications;

(V) unique lot or control number assigned to batch;

(VI) beyond use 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 Compounded Preparations to Class C Pharmacies or Veterinarians in Accordance With §563.054 of the Act.

(1) General.

(A) A pharmacy may dispense and deliver a reasonable quantity of a compounded preparation to a practitioner for office use by the practitioner in accordance with this subsection.

(B) A Class A pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations to a Class C pharmacy.

(C) A Class C pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations that the Class C pharmacy has compounded for other Class C pharmacies under common ownership.

(D) To dispense and deliver a compounded preparation under this subsection, a pharmacy must:

(i) verify the source of the raw materials to be used in a compounded drug;

(ii) comply with applicable United States 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.

(2) Written Agreement. A pharmacy that provides non-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 preparations may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except as authorized by §563.054 of the Act;

(B) state that the practitioner or receiving pharmacy should include on a separate log or in 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 non-sterile compounded preparations to a practitioner for office use or to a Class C 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) maintained separately from the records of products dispensed pursuant to a prescription or medication order; and

(III) 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 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 non-sterile compounded preparations ordered by a practitioner for office use or by a Class C 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 Class C pharmacy ordering the preparation; and

(iii) name, strength, and quantity of the preparation ordered.

(C) Distributions. The pharmacy shall maintain a record of all non-sterile compounded preparations distributed pursuant to an order to a practitioner for office use or by a Class C 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 Class C pharmacy to whom the preparation is distributed.

(D) Audit Trail.

(i) The pharmacy shall store the order and distribution records of preparations for all non-sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a Class C pharmacy for administration to a patient in such a manner as to be able to provide a 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 Class C 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.

(1) The pharmacy shall have written procedures for the recall of any compounded non-sterile preparations provided to a patient, to a practitioner for office use, or a pharmacy for administration. 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 non-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) each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;

(B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;

(C) if the preparation is prepared as a batch, the board is notified of the recall, in writing;

(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;

(E) the preparation is quarantined; and

(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) 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.

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 10, 2021.

TRD-202103603
Timothy L. Tucker, Pharm.D.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 305-8010

♦ ♦ ♦

CHAPTER 297. PHARMACY TECHNICIANS AND PHARMACY TECHNICIAN TRAINEES

22 TAC §297.10

The Texas State Board of Pharmacy proposes amendments to 22 TAC §297.10, concerning Registration for Military Service Members, Military Veterans, and Military Spouses. The amendments, if adopted, specify that a copy of a permanent change of station order may be used as proof of a military spouse's residency and add a new service branch to the definition of armed forces of the United States, in accordance with House Bill 139.

Timothy L. Tucker, 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. Mr. Tucker has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide consistency between state law and Board rules and clear registration requirements for military spouse pharmacy technicians to request an interim pharmacy technician registration. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

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

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

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

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

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

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

(6) The proposed amendments do limit an existing regulation in order to be consistent with state law;

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

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

Written comments on the amendments may be submitted to Eamon D. Briggs, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., October 25, 2021.

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.

§297.10. Registration for Military Service Members, Military Veterans, and Military Spouses.

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

(1) Active duty--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, or similar military service of another state.

(2) Armed forces of the United States--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--A person who is on active duty.

(4) Military spouse--A person who is married to a military service member.

(5) Military veteran--A person who has served on active duty and who was discharged or released from active duty.

(b) Alternative registration procedure. For the purpose of §55.004, Occupations Code, an applicant for a pharmacy technician registration who is a military service member, military veteran, or military spouse may complete the following alternative procedures for registering as a pharmacy technician.

(1) An applicant who holds a current registration as a pharmacy technician issued by another state but does not have a current pharmacy technician certification certificate shall meet the requirements for registration as a pharmacy technician trainee as specified in §297.3 of this chapter (relating to Registration Requirements).

(2) An applicant who held a pharmacy technician registration in Texas that expired within the five years preceding the application date who meets the following requirements may be granted a pharmacy technician registration. The applicant:

(A) shall complete the Texas application for registration that includes the following:

(i) name;

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

(iii) any other information requested on the application;

(B) shall provide documentation to include:

(i) military identification indicating that the applicant is a military service member, military veteran, or military dependent, if a military spouse; and

(ii) marriage certificate, if the applicant is a military spouse; applicant's spouse is on active duty status;

(C) be exempt from the application fees paid to the board set forth in §297.4(a) and (b)(2) of this chapter (relating to Fees);

(D) shall meet all necessary requirements in order for the board to access the criminal history records information, including submitting fingerprint information and such criminal history check does not reveal any charge or conviction for a crime that §281.64 of this title (relating to Sanctions for Criminal Offenses) indicates a sanction of denial, revocation, or suspension; and

(E) is not required to have a current pharmacy technician certification certificate.

(c) Expedited registration procedure. For the purpose of §55.005, Occupations Code, an applicant for a pharmacy technician registration who is a military service member, military veteran or military spouse and who holds a current registration as a pharmacy technician issued by another state or who held a pharmacy technician registration in Texas that expired within the five years preceding the application date may complete the following expedited procedures for registering as a pharmacy technician.

(1) The applicant shall:

(A) have a high school or equivalent diploma (e.g., GED), or be working to achieve a high school or equivalent diploma. For the purpose of this clause, an applicant for registration may be working to achieve a high school or equivalent diploma for no more than two years; [~~and~~]

(B) have taken and passed a pharmacy technician certification examination approved by the board and have a current certification certificate; [~~and~~]

(C) complete the Texas application for registration that includes the following information:

(i) name;

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

(iii) any other information requested on the application; [~~.~~]

(D) meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and paying the required fees; and

(E) shall be exempt from the registration fee as specified in §297.4(b)(2) of this chapter.

(2) Once an applicant has successfully completed all requirements of registration, and the board has determined there are no grounds to refuse registration, the applicant will be notified of registration as a registered pharmacy technician and of his or her pharmacy technician registration number.

(3) All applicants for renewal of an expedited pharmacy technician registration issued to a military service member, military veteran, or military spouse shall comply with the renewal procedures as specified in §297.3 of this chapter.

(d) License renewal. As specified in §55.003, Occupations Code, a military service member who holds a pharmacy technician registration is entitled to two years of additional time to complete any

requirements related to the renewal of the military service member's registration as follows:

(1) A military service member who fails to renew their pharmacy technician registration in a timely manner because the individual was serving as a military service member shall submit to the board:

(A) name, address, and registration number of the pharmacy technician;

(B) military identification indicating that the individual is a military service member; and

(C) a statement requesting up to two years of additional time to complete the renewal.

(2) A military service member specified in paragraph (1) of this subsection shall be exempt from fees specified in §297.3(d)(3) of this chapter.

(3) A military service member specified in paragraph (1) of this subsection is entitled to two additional years of time to complete the continuing education requirements specified in §297.8 of this title (relating to Continuing Education Requirements).

(e) Interim registration for military spouse. In accordance with §55.0041, Occupations Code, a military spouse who is currently registered in good standing by a jurisdiction with registration requirements that are substantially equivalent to the registration requirements in this state may be issued an interim pharmacy technician registration. The military spouse:

(1) shall provide documentation to include:

(A) a notification of intent to practice form including any additional information requested;

(B) proof of the military spouse's residency in this state including a copy of the permanent change of station order for the military service member to whom the spouse is married;

(C) a copy of the military spouse's military identification card; and

(D) verification from the jurisdiction in which the military spouse holds an active pharmacy technician registration that the military spouse's registration is in good standing;

(2) may not engage in pharmacy technician duties in this state until issued an interim pharmacy technician registration;

(3) may hold an interim pharmacy technician registration only for the period during which the military service member to whom the military spouse is married is stationed at a military installation in this state, but not to exceed three years from the date of issuance of the interim registration; and

(4) may not renew the interim pharmacy technician registration.

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 3, 2021.

TRD-202103536

Timothy L. Tucker, Pharm.D.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 305-8010

♦ ♦ ♦

TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 157. EMERGENCY MEDICAL CARE

SUBCHAPTER G. EMERGENCY MEDICAL SERVICES TRAUMA SYSTEMS

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes the repeal of §157.132, concerning the Regional Trauma Account; the repeal and replace with new §157.122, concerning Trauma Service Areas; and the repeal and replace with new §157.133, concerning Requirements for Stroke Facility Designation.

BACKGROUND AND PURPOSE

The purpose of the proposal is to update the content and processes with the advances and practices that have developed since these rules were last revised. The repeal and new §157.122, Trauma Service Areas (TSAs), updates the geographic alignment change to a TSA and the process for realignment of a county to a TSA.

House Bill (H.B.) 7, 84th Legislature, Regular Session, 2015, removed the funds from regional trauma account No. 5137 and reallocated the funds to the designated trauma facility and emergency medical services (EMS) account No. 5111. The repeal of §157.132 removes the regional trauma account in order to align with the legislative direction of H.B. 7.

The repeal and new §157.133 aligns the Texas systems with national stroke standards. Per Texas Health and Safety Code §773.024, the Governor's EMS and Trauma Advisory Council Stroke Committee shall consult the criteria for stroke facilities established by national medical organizations, such as The Joint Commission, in developing the stroke emergency transport plan and stroke facility criteria. The extensive revisions to the rule text and reorganization of the subsections necessitate repeal and replacement, rather than an amendment to this section.

SECTION-BY-SECTION SUMMARY

The proposed repeal and replace with new §157.122, is necessary due to the number of amendments to the rule that was last amended in 2004. The proposed new §157.122 describes the geographic regions of the TSAs and the process for realignment. The individual counties were removed from the rule text.

The proposed repeal of §157.132, is necessary because H.B. 7 removed the funds from regional trauma account No. 5137 and reallocated the funds to designated trauma facility and EMS account No 5111.

The proposed repeal and replace with new §157.133, is necessary because of the number of updates to the rule. It was

adopted in 2006 and is inconsistent with the current national stroke standards. The proposed new §157.133 describes the levels of stroke facility designation, the requirements for each designation, and process for designation.

FISCAL NOTE

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

GOVERNMENT GROWTH IMPACT STATEMENT

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

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

(2) implementation of the proposed rules will not affect the number of DSHS employee positions;

(3) implementation of the proposed rules will result in no assumed change in future legislative appropriations;

(4) the proposed rules will not affect fees paid to DSHS;

(5) the proposed rules will create new rules;

(6) the proposed rules will repeal existing rules;

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

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

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

Donna Shepperd has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities.

LOCAL EMPLOYMENT IMPACT

The proposed rules will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to these rules because the rules are necessary to protect the health, safety, and welfare of the residents of Texas. The repeal of §157.132 is necessary to implement legislation that does not specifically state that §2001.0045 applies to the rule.

PUBLIC BENEFIT AND COSTS

Luis Morales, Interim Associate Commissioner, Consumer Protection Division, has determined that for each year of the first five years the sections are in effect the public benefit will be improved continuity and outcomes of stroke care by bringing the Texas systems current with national standards and updates to the TSAs.

Donna Shepperd has also determined that for the first five years the rules are in effect, any economic costs to persons who are required to comply with the proposed rules are related to upgrading to the national standards of care for stroke management. Stroke facility designation is voluntary and the choice of the facility.

TAKINGS IMPACT ASSESSMENT

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

PUBLIC COMMENT

Written comments on the proposal may be submitted to Robert Friedrich, Program Specialist, EMS/Trauma Systems, Attn: Proposed Rule 20R100, P.O. Box 149347 MC 1876, Austin, Texas 78714; or by e-mail to DSHS.EMS-TRAUMA@dshs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 20R100" in the subject line.

25 TAC §§157.122, 157.132, 157.133

STATUTORY AUTHORITY

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

The repeals are authorized by Texas Government Code, Chapter 551; and Texas Health and Safety Code, Chapters 773 and 1001.

§157.122. Trauma Service Areas.

§157.132. Regional Trauma Account.

§157.133. Requirements for Stroke Facility Designation.

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 10, 2021.

TRD-202103588
Scott A. Merchant
Interim General Counsel
Department of State Health Services
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 535-8538

♦ ♦ ♦

25 TAC §157.122, §157.133

STATUTORY AUTHORITY

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

The new sections are authorized by Texas Government Code, Chapter 551; and Texas Health and Safety Code, Chapters 773 and 1001.

§157.122. Trauma Service Areas.

(a) Trauma service areas (TSAs) are established for effective coordination, oversight, system development and enhancements, and delivery of trauma, stroke, perinatal, acute care, disaster response, and emergency medical services (EMS) in geographical regions consistent with national standards.

(b) Texas is geographically divided into defined TSAs. Each TSA shall:

(1) contain no fewer than three Texas counties;

(2) use county borders to geographically define the TSA boundaries; and

(3) have at least one designated trauma facility within its boundaries that has or exceeds the advanced Level III trauma facility designation requirements as defined in §157.125 of this title (relating to Requirements for Trauma Facility Designation) .

(c) The Department of State Health Services (department) shall maintain the current list of counties included in each TSA and make the list available on the department's website: dshs.texas.gov.

(d) The realignment of a county to a different TSA may be initiated by the department or at the request of the Regional Advisory Council (RAC), provided the transferring county is contiguous to the county in the receiving TSA.

(1) The requesting RAC shall submit a request to the Director of EMS/Trauma Systems Section specifying:

(A) reasons for realignment request such as a decrease in EMS transport time, access to higher levels of care, or access to additional resources;

(B) existing patient routing patterns used by both EMS providers and health care facilities, including distances and transport times involved in this patient routing;

(C) a list of all health care facilities and all first responder organizations, EMS providers, and county governments affected by the requested realignment; and

(D) documentation that the RAC of the receiving TSA agrees with the proposed re-alignment.

(2) The requesting RAC shall forward copies of the request to all impacted health care facilities' chief executive officer, first responder organizations, EMS provider medical directors, and county governments.

(3) The department evaluates the re-alignment request based on the impact to patient care, including transport times, access to higher levels of care facilities, or resources.

§157.133. Requirements for Stroke Facility Designation.

(a) The department ensures that stroke facility designation promotes the goal, objective, and purpose of the stroke system.

(1) The goal of the stroke system is to reduce the morbidity and mortality of the stroke victim, subsequently referred to as a stroke patient.

(2) The objective of the stroke system is to improve the overall care of stroke patients by rapidly recognizing the signs of a stroke and transporting the potential stroke patient to the appropriate level of stroke facility, in the appropriate time, with the appropriate level of resources.

(b) The department determines requirements for the levels of stroke facility designation. Hospitals seeking stroke facility designation must demonstrate compliance to department-approved national stroke standard requirements located on the DSHS EMS/Trauma Systems Stroke Designation Webpage: https://dshs.texas.gov/emstraumasystems/stroke.shtm. Hospitals must have compliance with the requirements validated by a department-approved survey organization. The hospital must submit:

(1) a completed application for the stroke facility designation, and an annual summary of the stroke Quality Assessment and Performance Improvement (QAPI) plan;

(2) the documented stroke designation site survey summary that includes the requirement compliance findings and the medical record summaries;

(3) evidence of successful verification issued by the survey organization; and

(4) full payment of the non-refundable, non-transferrable designation fee located on the DSHS EMS/Trauma Systems Stroke Designation Webpage: https://dshs.texas.gov/emstraumasystems/stroke.shtm.

(c) Minimum requirements for stroke designation.

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

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

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

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

(2) Each hospital shall demonstrate the capability to provide stabilization and transfer or treatment for an acute stroke patient, written stroke standards of care, and a written stroke QAPI plan.

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

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

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

(C) Each emergency department of a hospital operating on a single hospital license must provide the same level of emergency stroke care for patients.

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

(4) If applicable, the designated stroke facility shall include stroke patients received at the non-contiguous departments in the facility's stroke database and stroke performance improvement process.

(d) The four levels of stroke designation and the requirements for each are:

(1) Comprehensive (Level I) stroke designation. The hospital must meet the department-approved national stroke standards of care for a Comprehensive Stroke Center, participate in the hospital's Regional Advisory Council (RAC) and regional stroke plan, and submit data to the department as requested.

(2) Advanced (Level II) stroke designation. The hospital must meet the department-approved national stroke standards of care for a non-Comprehensive Thrombectomy Stroke Center, participate in the hospital's RAC and regional stroke plan, and submit data to the department as requested.

(3) Primary (Level III) stroke designation. The hospital must meet the department-approved national stroke standards of care for a Primary Stroke Center, participate in the hospital's RAC and regional stroke plan, and submit data to the department as requested.

(4) Acute Stroke-Ready (Level IV) stroke designation. The hospital must meet the department-approved national stroke standards of care for an Acute Stroke-Ready Center, participate in the hospital's RAC and regional stroke plan, and submit data to the department as requested.

(e) Designation of a hospital as a stroke facility is valid for the length of the approved stroke survey organization's stroke certification.

(f) A hospital seeking stroke facility designation must undergo an onsite or virtual survey as outlined in this section.

(1) The hospital is responsible for scheduling a stroke designation survey through a department-approved survey organization. Approved survey organizations are located on the DSHS EMS/Trauma Systems Stroke Designation Webpage: https://dshs.texas.gov/emstraumasystems/stroke.shtm.

(2) The hospital notifies the department of the stroke designation survey date.

(3) The hospital is responsible for expenses associated with the stroke designation survey.

(4) The hospital does not accept surveyors with any conflict of interest. If a conflict of interest is present, the hospital must decline the assigned surveyor through the surveying organization. A conflict of interest exists when the surveyor has a current or past relationship with the hospital or key hospital staff members to the degree that the relationship may appear to cause bias. The conflict of interest includes a previous working relationship, residency training, or participation in a consultation program for the hospital within the past five years.

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

(6) The survey team evaluates the hospital's compliance with the department-approved national stroke standards of care requirements and documents all noncompliance issues identified in the survey report and patient care reviews. The surveyors must review ten stroke patient medical record reviews and the associated QAPI related documents and summarize these reviews to include in the hospital's stroke facility designation application.

(7) The hospital shall provide the survey team access to records regarding the QAPI plan to include peer review activities related to the stroke patient. Failure to provide access to these records will result in a determination by the department that the hospital seeking stroke facility designation is not in compliance with Texas Health and Safety Code, Chapter 773, and the rules in this chapter.

(g) A hospital seeking stroke facility designation must submit a completed application packet.

(1) The completed application packet includes:

(A) an accurate and complete stroke designation application for the requested level of designation and an annual summary of the stroke QAPI plan;

(B) full payment of the non-refundable, non-transferrable designation fee located on the DSHS EMS/Trauma Systems Stroke Designation Webpage: https://dshs.texas.gov/emstraumasystems/stroke.shtm;

(C) the documented stroke designation site survey summary that includes the requirement compliance findings and the medical record summaries, and the report is submitted to the department no later than 60 days after the stroke site survey date;

(D) evidence of successful verification issued by the survey organization;

(E) if required by the department, a plan of correction (POC) that addresses all requirements with identified non-compliance findings in the survey report and the POC shall include:

(i) a statement identifying the specific designation requirement the facility has not met or is in non-compliance;

(ii) a statement describing the corrective action by the facility seeking stroke facility designation to ensure compliance with the defined requirement;

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

(iv) the date the corrective actions will be implemented;

(v) how the corrective actions will be monitored;

(vi) supporting documentation of the requirement reaching compliance; and

(vii) corrective actions that will be implemented within 60 days from the date the facility seeking stroke facility designation received the official survey summary report;

(F) written evidence of participation in the applicable RACs; and

(G) any additional documents requested by the department.

(2) If a hospital seeking stroke facility designation fails to submit the required application documents and fee listed in paragraph (1) of this subsection, the application will not be processed.

(3) The stroke facility designation renewal process, a request to change the level of designation, or a change in ownership requiring re-designation follows the same requirements outlined in paragraph (1) of this subsection.

(A) The hospital must submit the required documents described in paragraph (1) of this subsection to the department no later than 90 days before the facility's stroke designation expiration date.

(B) The hospital must submit the stroke designation fee in full payment with the required application documents.

(4) The hospital has the right to withdraw its application for stroke facility designation any time before being recommended for designation by the department.

(5) The hospital must submit an application packet to renew its stroke facility designation no later than 90 days before the facility's stroke designation expiration date.

(6) The facility's stroke designation will expire if the facility fails to provide a complete stroke designation application packet to the department by its current designation's expiration date.

(7) The stroke designation application packet, in its entirety, must be written as an element of the facility's QAPI plan and subject to confidentiality as described in Texas Health and Safety Code, §773.095.

(8) The department reviews the application packet to determine the recommended stroke facility designation.

(9) The department determines the final stroke facility designation level awarded to the hospital. The designation level may be different than the level requested based on the documented stroke designation site survey summary that includes the requirement compliance findings and the medical record summaries.

(10) If the department determines the hospital meets the requirements for stroke facility designation, the department provides the hospital with a designation award letter and a designation certificate.

(A) The hospital shall display its stroke facility designation certificate in a public area of the licensed premises that is readily visible to patients, employees, and visitors.

(B) The hospital shall not alter the stroke facility designation certificate. Any alteration voids stroke designation for the remainder of that designation period.

(h) If a hospital disagrees with the department's decision regarding its designation status, the hospital has a right to a hearing, in accordance with Texas Government Code, Chapter 2001.

(i) Exceptions and Notifications.

(1) A designated stroke facility must provide written notification of any temporary event or decision preventing the facility from complying with requirements of its current stroke designation level. This notification shall outline the stroke facility requirements the facility is not able to maintain compliance with and be provided to the following:

(A) all emergency medical services (EMS) providers that transfer stroke patients to or from the designated stroke facility;

(B) the health care facilities to which it customarily transfers-out or transfers-in stroke patients;

(C) applicable RACs; and

(D) the department.

(2) If the designated stroke facility has an interruption in capabilities or capacity critical to the evaluation and treatment of a stroke patient, the facility will immediately notify local EMS providers, referring facilities, and their RAC by written notification to include electronic written communication with time-stamp capabilities, a phone call to their local medical control, and change their status through the RAC communication system such as EMResources or WEBEOC. This notification must occur within 60 minutes of the recognition of the loss in capabilities.

(3) If the designated stroke facility is unable to comply with requirements to maintain its current designation status, it shall submit to the department a POC as described in subsection (g)(1)(E) of this section, and a request for a temporary exception to the requirements. Any request for an exception shall be submitted in writing from the chief executive officer of the facility and define the facility's plan of correction with a timeline to become compliant with the stroke facility requirements. The department shall review the request and the POC, and either grant the exception, with a specific timeline based on the public interest, or deny the exception. If the facility is not granted an exception, or it is not compliant to the requirements at the end of the exception period, the department shall elect one of the following:

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

(B) accept the facility's surrender of its stroke facility designation certificate and designation award letter after the requirements in subsection (k) of this section have been completed.

(j) An application for a higher or lower level of stroke facility designation may be submitted to the department at any time.

(1) A designated stroke facility that is increasing its stroke capabilities may choose to apply for a higher level of designation at any time. The facility must follow the designation process as described in subsection (g)(1) of this section to apply for the higher level.

(2) A designated stroke facility that is unable to maintain compliance with the facility's current level of stroke designation may choose to apply for a lower level of designation at any time.

(k) If the facility chooses to relinquish its stroke facility designation, the facility shall provide a 30 days written, advance notice prior to the relinquishment of the designation to the department, the applicable RACs, EMS providers, and health care facilities it customarily transfers-out or transfers-in stroke patients. The facility is responsible to continue providing stroke care services and ensure that stroke care continuity for the region remains in place for the 30 days following the notice of relinquishing its stroke designation.

(l) A hospital shall not use or authorize the use of any public communication or advertising containing false, misleading, or deceptive claims regarding its stroke designation status. Public communication or advertising shall be deemed false, misleading, or deceptive if the facility uses these terms:

(1) "stroke facility," "stroke hospital," "stroke center," or similar terminology and the facility is not currently designated as a stroke facility in accordance with this section; or

(2) "comprehensive Level I stroke center," "advanced Level II stroke center," "primary Level III stroke center," "acute stroke ready hospital," "acute stroke ready Level III center," or similar terminology in its signs, advertisements or in the printed materials the facility provides to the public, unless the hospital is currently designated at that defined level of stroke facility in accordance with this section.

(m) The department has the right to review, inspect, evaluate, and audit all stroke patient records, stroke multidisciplinary QAPI plan documents, and peer review activities, as well as, any other documents relevant to stroke care in a designated stroke facility or facility seeking stroke facility designation at any time to verify compliance with the Texas Health and Safety Code, Chapter 773 and this section.

(n) The department maintains confidentiality of such records to the extent authorized by Texas Government Code, Chapter 552.

(o) Stroke designation site review of the hospital applying for stroke facility designation will be scheduled with the department-approved survey organization and follow the department survey guidelines.

(p) The department may deny, suspend, or revoke a stroke facility designation if a designated stroke facility ceases to provide services to meet or maintain compliance with the requirements of this section or if it violates the Chapter 133 of this title, concerning requirements resulting in enforcement action.

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 10, 2021.

TRD-202103589
Scott A. Merchant
Interim General Counsel
Department of State Health Services
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 535-8538

♦ ♦ ♦

TITLE 31. NATURAL RESOURCES AND CONSERVATION

PART 2. TEXAS PARKS AND WILDLIFE DEPARTMENT

CHAPTER 53. FINANCE

The Texas Parks and Wildlife Department proposes amendments to 31 TAC §§53.2 - 53.4, concerning Fees, and §53.60, concerning Stamps. The amendments would function, in conjunction with proposed amendments to §§57.981, 65.7, 65.8. 65.10, 65.42, and 65.64 published elsewhere in this issue of the *Texas Register,* to implement digital versions of the super combination hunting and "all water" fishing license package, a virtual license that does not utilize physical tags, and provide for the digital issuance of tags to holders of a lifetime super combination hunting and "all water" fishing license package.

The 87th Texas Legislature enacted House Bill (H.B.) 3081, which authorized the commission to develop and implement a program for the issuance of digital tags for animals, including birds, to holders of hunting licenses authorizing the taking of those animals. In light of the passage of H.B. 3081, the department has determined that it is appropriate to initiate a pilot program to determine the public receptivity to and logistical feasibility of the concept of digital licenses and tags for hunting and fishing. The department currently offers a wide variety of physical hunting and fishing licenses; however, those licenses are issued via a computerized point-of-sale system operated by an outside vendor and the majority of license sales are consummated at retail locations where licenses are sold. Thus, there are many factors for the department to consider and significant potential for unforeseen circumstances to present themselves. Therefore, rather than offering digital versions of every type of hunting and fishing license all at once, the department has determined that it is prudent to begin with a pilot program to provide a real-world test of the parameters and customer experiences to be considered in any enlargement of the program. The super combination hunting and "all water" fishing license package is a suitable candidate for the pilot program.

The proposed amendment to §53.2, concerning License Issuance Procedures, Fees, Possession, and Exemption Rules, would prescribe the requirements for providing proof of licensure for persons who purchase a digital license. Because the digital license is not a physical thing, the department has determined that it is necessary to prescribe how a person who has purchased a digital license may prove to law enforcement personnel that the person is legally engaging in hunting or fishing activities authorized under a digital license. The proposed amendment also makes clarifying changes to prevent conflicts between components of current rules applicable to physical licenses with provisions governing digital licenses and clarifies that license fees are not affected by the rulemaking. Finally, the proposed amendment would allow the holder of a lifetime resident super combination hunting and "all water" fishing package to select, beginning the year following the year of purchase and each year thereafter, whether to receive digital or physical tags. The proposed provision would provide that such a selection is final and could not be altered for the rest of the license year, which is necessary to prevent misunderstandings and confusion with respect to enforcement and compliance.

The proposed amendment to §53.3, concerning Combination Hunting and Fishing License Packages, would provide for the issuance of a digital version of the resident super combination hunting and "all water" fishing package, a digital version of the resident senior super combination hunting and "all water" fishing package, and digital tags for the lifetime resident super combination hunting and "all water" fishing package.

The proposed amendment to §53.4, concerning Lifetime Licenses, would alter that section to provide for the optional issuance of digital tags.

The proposed amendment to §53.60, concerning Stamps, would create exceptions to the current rules regarding possession of required stamps necessary to accommodate the creation of digital licenses.

Robin Riechers, Coastal Fisheries Division Director, has determined that for each of the first five years that the rules as proposed are in effect, there will be minimal fiscal implications to the department, if any, and those fiscal implications will be positive.

There will be no implications for other units of state or local governments as a result of administering or enforcing the rules.

Mr. Riechers also has determined that for each of the first five years that the rules as proposed are in effect, the public benefit anticipated as a result of enforcing or administering the proposed rules will be the provision of a new type of license for public enjoyment.

Under the provisions of Government Code, Chapter 2006, a state agency must prepare an economic impact statement and a regulatory flexibility analysis for a rule that may have an adverse economic effect on small businesses, micro-businesses, or rural communities. As required by Government Code, §2006.002(g), the Office of the Attorney General has prepared guidelines to assist state agencies in determining a proposed rule's potential adverse economic impacts to small businesses, micro-businesses, or rural communities. Those guidelines state that an

agency need only consider a proposed rule's "direct adverse economic impacts" to small businesses and micro-businesses to determine if any further analysis is required. For that purpose, the department considers "direct economic impact" to mean a requirement that would directly impose recordkeeping or reporting requirements; impose taxes or fees; result in lost sales or profits; adversely affect market competition; or require the purchase or modification of equipment or services.

The department has determined that the proposed amendments will not result in direct adverse impacts on small businesses, micro-businesses, or rural communities because the proposed rules regulate various aspects of recreational license privileges that allow individual persons to pursue and harvest public wildlife resources in this state and therefore do not directly affect small businesses, micro-businesses, or rural communities. Therefore, neither the economic impact statement nor the regulatory flexibility analysis described in Government Code, Chapter 2006, is required.

The department has not drafted a local employment impact statement under the Administrative Procedures Act, §2001.022, as the agency has determined that the rules as proposed will not impact local economies.

The department has determined that Government Code, §2001.0225 (Regulatory Analysis of Major Environmental Rules), does not apply to the proposed rules.

The department has determined that there will not be a taking of private real property, as defined by Government Code, Chapter 2007, as a result of the proposed rules.

In compliance with the requirements of Government Code, §2001.0221, the department has prepared the following Government Growth Impact Statement (GGIS). The rules as proposed, if adopted, will neither create nor eliminate a government program; not result in an increase or decrease in the number of full-time equivalent employee needs; not result in a need for additional General Revenue funding; not affect the amount of any fee; create a new regulation (governing digital licenses and tagging); not repeal, expand, or limit a regulation; neither increase nor decrease the number of individuals subject to regulation; and not positively or adversely affect the state's economy.

Comments on the proposal may be submitted to Robin Riechers at (512) 389-4636, e-mail: robin.riechers@tpwd.texas.gov. Comments also may be submitted via the department's website at http://www.tpwd.texas.gov/business/feedback/public_comment/.

SUBCHAPTER A. FEES
DIVISION 1. LICENSE, PERMIT, AND BOAT AND MOTOR FEES

31 TAC §§53.2 - 53.4

The amendments are proposed under the authority of Parks and Wildlife Code, §42.010, which requires the commission to prescribe the form and issuance of hunting licenses authorized under Parks and Wildlife Code, Chapter 42; §42.0101, which authorizes the commission to promulgate rules for the issuance of digital tags for animals, including birds, to holders of hunting licenses authorizing the taking of those animals, including rules allowing a person using a digital tag to create a digital record at the time of the taking of an animal that includes information required by the department as soon as possible after the taking of the animal and requiring a person using a digital tag to retain in the person's possession documentation of a required digital record at all times before the carcass is finally processed; §42.0177, which authorizes the commission to modify or eliminate the tagging, carcass, final destination, and final processing requirements of Chapter 42; §42.006, which authorizes the commission to prescribe requirements relating to possessing a license issued under Chapter 42 by rule; §46.0085, which authorizes the department to issue tags for finfish species allowed by law to be taken during each year or season from coastal waters of the state to holders of licenses authorizing the taking of finfish species; §46.0086, which authorizes the commission to prescribe tagging requirements for the take of finfish; §50.004, which requires the department to issue and prescribe the form and manner of issuance for combination hunting and fishing licenses, including identification and compliance requirements; and Chapter 61, which requires the commission to regulate the periods of time when it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the means, methods, and places in which it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the species, quantity, age or size, and, to the extent possible, the sex of the game animals, game birds, or aquatic animal life authorized to be hunted, taken, or possessed; and the region, county, area, body of water, or portion of a county where game animals, game birds, or aquatic animal life may be hunted, taken, or possessed.

The proposed amendment affects Parks and Wildlife Code, Chapters 42, 46, 50, and 61.

§53.2. License Issuance Procedures, Fees, Possession, and Exemption Rules.

(a) Hunting license possession.

(1) Except as provided in [~~by subsection (g) of~~] this section, no person may hunt [~~turkey~~] in this state without having a valid physical hunting license in immediate possession.

(2) A person may hunt [~~species other than turkey~~] in this state without having a valid physical hunting license in immediate possession if that person has acquired a license electronically [~~(including by telephone)~~] and has either:

(A) a receipt, notification, or application data from the department on a smart phone, computer, tablet, or similar device indicating acquisition of a digital license described in §53.3(a)(12) of this title (relating to Super Combination Hunting and Fishing License Packages) or §53.4(a)(1) of this title (relating to Lifetime Licenses); or

(B) a valid confirmation number in [~~his~~] possession while awaiting fulfilment of the physical license. Confirmation numbers shall only be valid for 20 days from date of purchase.

(3) Except as provided in [~~by subsection (g) of~~] this section, a person may hunt deer in this state without having a valid physical hunting license in immediate possession only if that person:

(A) has acquired a license electronically [~~(including by telephone)~~] and has a valid confirmation number in [~~his~~] possession while awaiting fulfilment of the physical license; and

(B) (No change.)

(4) (No change.)

(b) Fishing license possession.

(1) A person may fish in this state without having a valid physical fishing license in immediate possession if that person:

(A) (No change.)

(B) has acquired a license electronically [~~(including by telephone)~~] and has either:

(i) a receipt, notification, or application data from the department on a smart phone, computer, tablet, or similar device indicating acquisition of a digital license described in §53.3(a)(12) of this title or §53.4(a)(1) of this title; or

(ii) a valid confirmation number in possession while awaiting fulfilment of the physical license. Confirmation numbers shall only be valid for 20 days from date of purchase.

(2) No person may catch and retain a red drum over 28 inches in length in the coastal waters of this state without having a valid fishing license, saltwater sportfishing stamp (unless exempt), and valid red drum tag in immediate possession, unless the person has purchased a valid digital license described in §53.3(a)(12) of this title or a valid license with digital tags under §53.4(a)(1) of this title.

(c) Issuance of licenses and stamp endorsements electronically (on-line or by telephone).

(1) - (2) (No change.)

(3) The fees established by this subsection apply to the electronic acquisition of a digital license identified in §53.3(a)(12) of this title or §53.4(a)(1) of this title.

(d) - (g) (No change.)

§53.3. Combination Hunting and Fishing License Packages.

(a) Combination hunting and fishing license packages may be priced at an amount less than the sum of the license and stamp prices of the individual licenses and stamps included in the package.

(1) - (11) (No change.)

(12) Digital super combination hunting and "all water" fishing license package. The licenses listed in paragraphs (7) and (8) of this subsection are available in a digital version that does not include the license log or the physical license tags found on the physical license.

(A) The fee for a digital license identified in this paragraph shall be the same as the fee specified for that license in paragraphs (7) and (8) of this section.

(B) A person who acquires a digital license is ineligible to acquire any other form of recreational hunting or fishing license in the same license year.

(C) The digital licenses identified in this paragraph are available only through the department's website at www.tpwd.texas.gov.

(D) The provisions of §65.8 of this title (relating to Alternative Licensing System) do not apply to a digital license.

(13) [~~(12)~~] Replacement combination or replacement super combination packages--$10 except for a replacement disabled veteran super combination hunting and "all water" fishing package or a Texas resident active duty military super combination hunting and "all water" fishing package, which shall be replaced at no charge.

(b) (No change.)

§53.4. Lifetime Licenses.

(a) Fees.

(1) lifetime resident super combination hunting and "all water" fishing package--$1,800;

(A) includes the digital tag option that does not require the license log or the physical license tags found on the physical license. The digital tag option is available beginning the year after the year of purchase of the license (and each year thereafter); and

(B) the provisions of §53.3(12)(B) - (D) of this title (relating to Combination Hunting and Fishing License Packages) apply;

(2) - (5) (No change.)

(b) - (c) (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 10, 2021.

TRD-202103583
James Murphy
General Counsel
Texas Parks and Wildlife Department
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 389-4775

♦ ♦ ♦

SUBCHAPTER B. STAMPS

31 TAC §53.60

The amendment is proposed under the authority of Parks and Wildlife Code, §42.010, which requires the commission to prescribe the form and issuance of hunting licenses authorized under Parks and Wildlife Code, Chapter 42; §42.0101, which authorizes the commission to promulgate rules for the issuance of digital tags for animals, including birds, to holders of hunting licenses authorizing the taking of those animals, including rules allowing a person using a digital tag to create a digital record at the time of the taking of an animal that includes information required by the department as soon as possible after the taking of the animal and requiring a person using a digital tag to retain in the person's possession documentation of a required digital record at all times before the carcass is finally processed; §42.0177, which authorizes the commission to modify or eliminate the tagging, carcass, final destination, and final processing requirements of Chapter 42; §42.006, which authorizes the commission to prescribe requirements relating to possessing a license issued under Chapter 42 by rule; §46.0085, which authorizes the department to issue tags for finfish species allowed by law to be taken during each year or season from coastal waters of the state to holders of licenses authorizing the taking of finfish species; §46.0086, which authorizes the commission to prescribe tagging requirements for the take of finfish; §50.004, which requires the department to issue and prescribe the form and manner of issuance for combination hunting and fishing licenses, including identification and compliance requirements; and Chapter 61, which requires the commission to regulate the periods of time when it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the means, methods, and places in which it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the species, quantity, age or size, and, to the extent possible, the sex of the game animals, game birds, or aquatic animal life authorized to be hunted, taken, or possessed; and the region, county, area, body of water, or portion of a county

where game animals, game birds, or aquatic animal life may be hunted, taken, or possessed.

The proposed amendment affects Parks and Wildlife Code, Chapters 42, 46, 50, and 61.

§53.60. Stamps.

(a) Stamp Form, Design and Manner of Issuance.

(1) Except as provided in paragraph (2) of this subsection, a [~~A~~] required stamp shall be issued as an endorsement noted on the license issued through the department's automated system.

(2) A digital license issued under the provisions of §53.3(a)(12) of this title (relating to Combination Hunting and Fishing License Packages) includes all required endorsements.

(b) Stamp Purchase Identification and Possession Requirements.

(1) A person may hunt without a required state hunting stamp in immediate possession if the person:

(A) possesses a valid digital license issued under the provisions of §53.3(a)(12) of this title or a valid license with digital tags under §53.4(a)(1) of this title (relating to Lifetime Licenses); or

(B) has acquired a stamp electronically [~~(including by telephone)~~] and has a valid authorization number in possession while awaiting fulfilment of the physical tag. Authorization numbers shall only be valid for 20 days from purchase date.

(2) A person may fish without a required fishing stamp in immediate possession if the person:

(A) possesses a valid digital license issued under the provisions of §53.3(a)(12) of this title or a valid license with digital tags under §53.4(a)(1) of this title; or

(B) has acquired a stamp electronically [~~(including by telephone)~~] and has a valid authorization number in possession while awaiting fulfilment of the physical tag. Authorization numbers shall only be valid for 20 days from purchase date.

(c) - (e) (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 10, 2021.

TRD-202103584
James Murphy
General Counsel
Texas Parks and Wildlife Department
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 389-4775

♦ ♦ ♦

CHAPTER 57. FISHERIES
SUBCHAPTER A. HARMFUL OR POTENTIALLY HARMFUL FISH, SHELLFISH, AND AQUATIC PLANTS
31 TAC §57.113, §57.116

The Texas Parks and Wildlife Department (the department) proposes amendments to 31 TAC §57.113 and §57.116, concerning Harmful or Potentially Harmful Fish, Shellfish and Aquatic Plants. The proposed amendments clarify the period of validity for the permit for stocking of triploid grass carp in private or public waters, lawful transfer of these fish with any change in ownership of a property, and harvest of stocked triploid grass carp from public waters.

The proposed amendment to §57.113(b)(2), concerning General Provisions and Exceptions, would alter subsection (b)(2) to clarify the process by which the department designates public water bodies where triploid grass carp have been stocked for aquatic vegetation management purposes and may not be taken. This language is more consistent with current procedure whereby the department designates these water bodies by listing on the department website.

The proposed amendment to §57.116, concerning Special Provisions - Triploid Grass Carp, would alter subsection (g)(3) to clarify that the stocking authority under a permit issued under the subsection is specific to the pond for which it issued (i.e., cannot be used on any other pond) and is valid for 18 months from the date of issuance. Current §57.116(g)(3) unintentionally mixes provisions regarding the transfer of property with provisions regarding the applicability and period of validity of a permit. Therefore, provisions regarding transfer of property would be relocated to proposed new paragraph (8) and the remaining provisions reworded for the sake of clarity. Additionally, the department has determined there is a need for a defined permit expiration date to accommodate administrative document archiving schedules and prevent potential permit reuse. A period of 18 months provides for adequate flexibility for adaptive management practices, if needed. The amendment would also relocate the provision pertaining to modification of ponds in such a way that could result in increased risk of escape, release, or discharge of controlled exotic species to new paragraph (8) as it relates to conditions for possession rather than permit period of validity.

The proposed amendment also would add new paragraph (8) to relocate provisions governing the transfer of properties where triploid grass carp are present. Proposed new §57.116(g)(8) provides that documentation required to be retained by persons in possession of triploid grass carp (i.e., transport invoice and proof of triploid status certification) shall be transferred with the change of ownership of a property to the new property owner as proof of lawful possession of transferred triploid grass carp. This amendment clarifies that this documentation authorizes lawful possession by the new owner to facilitate such transfers.

The proposed amendment would also relocate the provision from paragraph (3) pertaining to modification of ponds in such a way that could result in increased risk of escape, release, or discharge of controlled exotic species to new paragraph (10) as it relates to conditions for possession rather than permit period of validity.

The proposed amendment to §57.116(g)(9), concerning transfer of triploid grass carp, clarifies that live triploid grass carp stocked in a pond may be transferred to the new owner of a property.

Monica McGarrity, Senior Scientist for Aquatic Invasive Species in the Inland Fisheries Division, has determined that for each of the first five years that the rules as proposed are in effect, there will be no fiscal implications to state or local governments as a result of administering or enforcing the rules.

Ms. McGarrity also has determined that for each of the first five years that the rules as proposed are in effect, the public benefit anticipated as a result of enforcing or administering the proposed rules will be accurate and effective rules governing the possession of harmful or potentially harmful species.

Under provisions of Government Code, Chapter 2006, a state agency must prepare an economic impact statement and a regulatory flexibility analysis for a rule that may have an adverse economic effect on small businesses and micro-businesses. Those guidelines state that an agency need only consider a proposed rule's "direct adverse economic impacts" to small businesses and micro-businesses to determine if any further analysis is required. For that purpose, the department considers "direct economic impact" to mean a requirement that would directly impose recordkeeping or reporting requirements; impose taxes or fees; result in lost sales or profits; adversely affect market competition; or require the purchase or modification of equipment or services. The department has determined that the proposed rules will not result in any direct economic costs to any small businesses, micro-businesses, or rural communities; therefore, the department has a determined that neither the economic impact statement nor the regulatory flexibility analysis described in Government Code, Chapter 2006, is required.

The department has not drafted a local employment impact statement under the Administrative Procedures Act, §2001.022, as the agency has determined that the rules as proposed will not impact local economies.

The department has determined that Government Code, §2001.0225 (Regulatory Analysis of Major Environmental Rules), does not apply to the proposed rules.

The department has determined that there will not be a taking of private real property, as defined by Government Code, Chapter 2007, as a result of the proposed rules.

In compliance with the requirements of Government Code, §2001.0221, the department has prepared the following Government Growth Impact Statement (GGIS). The rules as proposed, if adopted, will neither create nor eliminate a government program; not result in an increase or decrease in the number of full-time equivalent employee needs; not result in a need for additional General Revenue funding; not affect the amount of any fee; not create a new regulation; not expand an existing regulation; neither increase nor decrease the number of individuals subject to regulation; and not positively or adversely affect the state's economy.

Comments on the proposed rule may be submitted to Monica McGarrity, Texas Parks and Wildlife Department, 4200 Smith School Road, Austin, Texas 78744; (512) 552-3465; email: monica.mcgarrity@tpwd.texas.gov or via the department website at http://www.tpwd.texas.gov/business/feedback/public_comment/.

The amendments are proposed under the authority of Parks and Wildlife Code, §66.007, which authorizes the department to make rules necessary to authorize the import, possession, sale, or introduction of harmful or potentially harmful exotic fish.

The proposed amendments affect Parks and Wildlife Code, Chapter 66.

§57.113. General Provisions and Exceptions.

(a) (No change.)

(b) Except as provided by Parks and Wildlife Code or this subchapter, no person shall:

(1) (No change.)

(2) take or possess a [~~live~~] grass carp from public water designated by the department where grass carp have been introduced by the department or under a permit issued by the department[~~, unless the department has specifically authorized removal or the permit is no longer in effect~~].

(c) - (p) (No change.)

§57.116. Special Provisions--Triploid Grass Carp.

(a) - (f) (No change.)

(g) Stocking in private ponds.

(1) - (2) (No change.)

(3) A permit [~~Permits~~] for stocking of triploid grass carp into private ponds is [~~are~~] specific to the pond or ponds for which it is issued and shall remain valid for a period of 18 months from the date of issuance. All stocking must take place within the period of permit validity established by this paragraph. [~~on a property, transferrable with the sale of the property, and shall not expire or require renewal provided that the ponds are not modified in any way that could result in increased risk of escape, release, or discharge of controlled exotic species into public water.~~]

(4) - (7) (No change.)

(8) A person in possession of live triploid grass carp shall provide the documentation required by paragraph (7) of this subsection to the new property owner upon change of ownership of the property as proof of lawful possession of triploid grass carp. Possession of the documentation described in paragraph (7) of this subsection shall be maintained so long as a person possesses any live triploid grass carp.

(9) [~~(8)~~] Except as provided in paragraph (8) of this subsection, triploid [~~Triploid~~] grass carp stocked in a private pond must be killed in accordance with the provisions of §57.113 of this title (relating to General Provisions and Exceptions) prior to being transported or transferred to another person.

(10) A person in possession of live triploid grass carp may not modify the pond or ponds for which stocking was permitted in any way that could result in increased risk of escape, release, or discharge of controlled exotic species into public water.

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 10, 2021.

TRD-202103582
James Murphy
General Counsel
Texas Parks and Wildlife Department
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 389-4775

♦ ♦ ♦

SUBCHAPTER N. STATEWIDE RECREATIONAL AND COMMERCIAL FISHING PROCLAMATION

DIVISION 1. GENERAL PROVISIONS

31 TAC §57.975

The Texas Parks and Wildlife Department proposes an amendment to 31 TAC §57.975, concerning Freeze Event Closures.

The proposed amendment would alter definitions and provide for the declaration of freeze closures in advance of expected severe cold weather.

The current rule was promulgated in 2005 to protect vulnerable fish populations during periods of intense cold weather. Department data indicate that extensive fish mortality can occur, and has, as a result of unseasonable cold weather and freeze events. During such events, prolonged periods of freezing or near-freezing air temperatures can cause water temperatures to exceed lethal thresholds for numerous marine fish species. As water temperatures fall, fish tend to congregate in areas of deeper water that serve as temporary thermal refuges because they do not cool as quickly as shallower waters. As fish become concentrated in the thermal refugia, they are vulnerable to overharvest, which could result in depletion of the resource. Following the severe freeze event of February 2021, the department assessed its ability to effectively respond to such events. Department social dimension and outreach activities indicate not only support for freeze closures, but a desire for them to be declared pre-emptively and in areas where they currently are not declared. The proposed amendment is intended to optimize the effectiveness of the current rule.

The definition of "affected area" in current rule is restricted to areas of coastal water "where fishing from the bank is possible." The department has determined that during freeze events, fish can congregate in thermal refugia at various distances from the bank or shore, including distances beyond which it is possible to fish from the bank or shore; therefore, the proposed amendment would remove that qualification from the definition, which would allow freeze event closures to be declared in any coastal waters rather than restricting the closures to only those areas where bank fishing is possible. The proposed amendment also makes nonsubstantive changes for clarity.

Under current rule, a freeze is defined as "a period of cold weather that begins when the air temperature drops below 32 degrees Fahrenheit." The department has determined that the current rule should be modified to reflect the fact that water temperature is a more important factor than air temperature in terms of direct environmental impact on fish. Species such as spotted seatrout and red drum begin to suffer cold-related mortality at 40° F; therefore, the proposed amendment would establish a 40° F water temperature as the new threshold for environmental conditions necessary to trigger a potential freeze event closure. Current rules do not provide the criteria to be used by the department for determining when a freeze closure will be rescinded. Proposed new subsection (c) would authorize the Executive Director to allow fishing in affected areas to resume when water temperatures, as measured by select National Oceanic and Atmospheric Administration (NOAA) tide stations, reach a minimum of 50° F and are expected to remain above 40° F for at least 48 hours. The department has determined that fish begin to disperse from thermal refugia and become less vulnerable to overharvest when water temperatures reach 50° F and do not drop below 40° F for at least 48 hours. The proposed amendment also makes nonsubstantive changes for clarity.

The current rule provides for the declaration of freeze event closures when a freeze "has occurred." The department has determined that because the purpose of the rule is to prevent overharvest of vulnerable fish populations, the optimal use of the closure mechanism would be to allow areas to be closed in advance of expected unfavorable environmental conditions rather than after those conditions already exist. Therefore, the proposed amendment would allow the declaration of freeze event closures in anticipation of freeze events. The proposed amendment also makes changes to subsection (d) to comport the contents of that section with alterations made elsewhere regarding the timeframes for freeze closure declarations.

Dakus Geeslin, Science and Policy Branch Chief, Coastal Fisheries Division, has determined that for each of the first five years that the rule as proposed is in effect, there will be no fiscal implications to state or local governments as a result of administering or enforcing the rule.

Mr. Geeslin also has determined that for each of the first five years that the rule as proposed is in effect, the public benefit anticipated as a result of enforcing or administering the proposed rule will be the dispensation of the agency's statutory duty to protect and conserve the fisheries resources of this state by protecting fisheries resources from depletion.

Under the provisions of Government Code, Chapter 2006, a state agency must prepare an economic impact statement and a regulatory flexibility analysis for a rule that may have an adverse economic effect on small businesses, micro-businesses, or rural communities. As required by Government Code, §2006.002(g), the Office of the Attorney General has prepared guidelines to assist state agencies in determining a proposed rule's potential adverse economic impacts to small businesses, micro-businesses, or rural communities. Those guidelines state that an agency need only consider a proposed rule's "direct adverse economic impacts" to small businesses and micro-businesses to determine if any further analysis is required. For that purpose, the department considers "direct economic impact" to mean a requirement that would directly impose recordkeeping or reporting requirements; impose taxes or fees; result in lost sales or profits; adversely affect market competition; or require the purchase or modification of equipment or services.

The department has determined that the proposed amendment will not result in direct adverse impacts on small businesses, micro-businesses, or rural communities because it will not result in either more frequent or more prolonged freeze event closures, and in any case the department notes that the proposed rule will result in an overall positive economic impact because it optimizes the department's ability to protect stocks and allow them to recover more quickly after population impacts from freeze events, which would have the effect of minimizing the adverse economic impacts of freeze events. Additionally, the department expects that closures will continue to be infrequent, as freezes are rare and brief events on the coast, and closures typically apply to limited areas.

The department has not drafted a local employment impact statement under the Administrative Procedures Act, §2001.022, as the agency has determined that the rule as proposed will not impact local economies.

The department has determined that Government Code, §2001.0225 (Regulatory Analysis of Major Environmental Rules), does not apply to the proposed rule.

The department has determined that there will not be a taking of private real property, as defined by Government Code, Chapter 2007, as a result of the proposed rule.

In compliance with the requirements of Government Code, §2001.0221, the department has prepared the following Government Growth Impact Statement (GGIS). The rule as proposed, if adopted, will neither create nor eliminate a government program; not result in an increase or decrease in the number of full-time equivalent employee needs; not result in a need for additional General Revenue funding; not affect the amount of any fee; not create a new regulation; not repeal, expand, or limit a regulation; neither increase nor decrease the number of individuals subject to regulation; and not positively or adversely affect the state's economy.

The department has determined that the proposed rule is in compliance with Government Code, §505.11 (Actions and Rule Amendments Subject to the Coastal Management Program).

Comments on the proposal may be submitted to Dakus Geeslin (Coastal Fisheries) at (512) 389-8734, e-mail: dakus.geeslin@tpwd.texas.gov. Comments also may be submitted via the department's website at http://www.tpwd.texas.gov/business/feedback/public_comment/.

The amendment is proposed under the authority of Parks and Wildlife Code, Chapter 61, which requires the commission to regulate the periods of time when it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the means, methods, and places in which it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the species, quantity, age or size, and, to the extent possible, the sex of the game animals, game birds, or aquatic animal life authorized to be hunted, taken, or possessed; and the region, county, area, body of water, or portion of a county where game animals, game birds, or aquatic animal life may be hunted, taken, or possessed.

The proposed amendment affects Parks and Wildlife Code, Chapter 61.

§57.975. Freeze Event Closures.

(a) Definitions. For purposes of this section, the following terms shall have the following meanings:

(1) Affected area--an area of coastal water [~~where fishing from the bank is possible and~~] where game fish are known or expected to congregate in response to [~~take refuge from~~] cold weather conditions, making them vulnerable to overharvest.

(2) Freeze--a period of cold weather during which air temperatures are expected to cause coastal water temperatures to fall below 40° F, creating [~~that begins when the air temperature drops to or below 32 degrees Fahrenheit and creates~~] a risk of depletion of one or more game fish species.

(b) The Executive Director shall provide appropriate notice to the public that a closure in anticipation of a freeze has been declared [~~freeze has occurred~~] and fishing in the affected area or areas is prohibited. The Executive Director shall provide appropriate public notice as to when fishing in the affected area or areas is allowed to resume.

(c) The Executive Director may allow fishing in affected areas to resume when water temperatures, as measured by select National Oceanic and Atmospheric Administration (NOAA) tide stations, reach a minimum of 50° F and are expected to remain above 40° F for at least 48 hours.

(d) [~~(c)~~] No person shall take or attempt to take any aquatic life by any means in an affected area [~~during a freeze~~] after the Executive Director has given notice to the public that [~~a freeze has occurred and~~] fishing in the affected area is prohibited and before the Executive Director gives notice that fishing may resume.

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 10, 2021.

TRD-202103581
James Murphy
General Counsel
Texas Parks and Wildlife Department
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 389-4775

♦ ♦ ♦

DIVISION 2. STATEWIDE RECREATIONAL FISHING PROCLAMATION

31 TAC §57.981

The Texas Parks and Wildlife Department proposes an amendment to 31 TAC §57.981, concerning Bag, Possession, and Length Limits. The amendment would function, in conjunction with proposed amendments to §§53.2 - 53.4, 53.60, 65.7, 65.8. 65.10, 65.42, and 65.64 published elsewhere in this issue of the *Texas Register,* to implement a digital version of the super combination hunting and "all water" fishing license package, a virtual license that does not utilize physical tags, and provide for the digital issuance of tags to holders of a lifetime super combination hunting and "all water" fishing license package.

Under current rule, the super combination hunting and "all water" fishing license entitles a person to retain a red drum exceeding the maximum length limit only if the person has attached a properly executed red drum tag, exempt angler red drum tag, or bonus red drum tag to the harvested red drum. The 87th Texas Legislature enacted House Bill (H.B.) 3081, which authorized the commission to develop and implement a program for the issuance of digital tags for animals, including birds, to holders of hunting licenses authorizing the taking of those animals. In light of the passage of H.B. 3081, the department has determined that it is appropriate to initiate a pilot program to determine the public receptivity for and logistical feasibility of the concept of digital licenses for hunting and fishing. The department currently offers a wide variety of physical hunting and fishing licenses; however, those licenses are issued via a computerized point-of-sale system operated by an outside vendor and the majority of license sales are consummated at retail locations where licenses are sold. Thus, there are many factors for the department to consider and significant potential for unforeseen circumstances to present themselves. Therefore, rather than offering digital versions of every hunting and fishing license all at once, the department has determined that it is prudent to begin with a pilot program to provide a real-world test of the parameters and customer experiences to be considered in any enlargement of the program. The super combination hunting and fishing license is a suitable candidate for the pilot program.

The proposed amendment would prescribe tagging requirements for holders of digital licenses with respect to oversized red drum. As noted earlier, current rule requires a person who retains an oversized red drum to execute and attach a

physical tag from the person's fishing license. A person who retains an oversized red drum under a license that does not contain tags cannot comply with current rule; therefore, the proposed amendment would create an exception to the current requirements for physical licenses and prescribe digital tagging provisions. The proposed amendment would require the holder of a digital license to immediately report the retention of an oversized red drum via an electronic application developed by the department for that purpose and receive a confirmation number. Additionally, the proposed rule would prescribe the requirements for situations in which data connectivity prevents the required harvest report from being uploaded (i.e., preventing a confirmation number from being obtained). Specifically, a person who retains an oversized red drum and reports via the electronic application as required but cannot receive a confirmation number because of data connectivity issue would be required to upload the harvest report immediately upon reaching data connectivity. Finally, the proposed amendment would require persons in possession of an oversized red drum under a digital license to be in possession of an appropriate electronic device. It is or should be intuitively obvious that compliance with the requirement for digital tagging immediately upon harvest cannot take place in the absence of a functioning smartphone, computer, or other device capable of reporting; thus, the proposed rule would require that the capability for compliance be present. The department acknowledges that situations may arise in which electronic devices are damaged, lost, or lose power and notes that Parks and Wildlife Code, §46.015, provides for the dismissal of charges for persons charged with fishing license violations if the person is able to produce for the court or the prosecuting attorney the proper fishing license issued to the person and valid at the time of the offense. The department notes that persons who purchase a lifetime super combination hunting and "all water" fishing license and choose to have the department fulfil a physical red drum tag would be required to follow current rules regarding tagging.

Robin Riechers, Coastal Fisheries Division Director, has determined that for each of the first five years that the rule as proposed is in effect, there will be minimal fiscal implications to the department, if any, and those fiscal implications will be positive.

There will be no implications for other units of state or local governments as a result of administering or enforcing the rule.

Mr. Riechers also has determined that for each of the first five years that the rule as proposed is in effect, the public benefit anticipated as a result of enforcing or administering the proposed rule will be the provision of a new type of license for public use.

Under the provisions of Government Code, Chapter 2006, a state agency must prepare an economic impact statement and a regulatory flexibility analysis for a rule that may have an adverse economic effect on small businesses, micro-businesses, or rural communities. As required by Government Code, §2006.002(g), the Office of the Attorney General has prepared guidelines to assist state agencies in determining a proposed rule's potential adverse economic impacts to small businesses, micro-businesses, or rural communities. Those guidelines state that an agency need only consider a proposed rule's "direct adverse economic impacts" to small businesses and micro-businesses to determine if any further analysis is required. For that purpose, the department considers "direct economic impact" to mean a requirement that would directly impose recordkeeping or reporting requirements; impose taxes or fees; result in lost sales or profits; adversely affect market competition; or require the purchase or modification of equipment or services.

The department has determined that the proposed amendment will not result in direct adverse impacts on small businesses, micro-businesses, or rural communities because the proposed rule regulates various aspects of recreational license privileges that allow individual persons to pursue and harvest public fisheries resources in this state and therefore do not directly affect small businesses, micro-businesses, or rural communities. Therefore, neither the economic impact statement nor the regulatory flexibility analysis described in Government Code, Chapter 2006, is required.

The department has not drafted a local employment impact statement under the Administrative Procedures Act, §2001.022, as the agency has determined that the rule as proposed will not impact local economies.

The department has determined that Government Code, §2001.0225 (Regulatory Analysis of Major Environmental Rules), does not apply to the proposed rule.

The department has determined that there will not be a taking of private real property, as defined by Government Code, Chapter 2007, as a result of the proposed rule.

In compliance with the requirements of Government Code, §2001.0221, the department has prepared the following Government Growth Impact Statement (GGIS). The rule as proposed, if adopted, will neither create nor eliminate a government program; not result in an increase or decrease in the number of full-time equivalent employee needs; not result in a need for additional General Revenue funding; not affect the amount of any fee; create a new regulation (governing digital licenses and tagging); not repeal, expand, or limit a regulation; neither increase nor decrease the number of individuals subject to regulation; and not positively or adversely affect the state's economy.

Comments on the proposal may be submitted to Robin Riechers at (512) 389-4636, e-mail: robin.riechers@tpwd.texas.gov. Comments also may be submitted via the department's website at http://www.tpwd.texas.gov/business/feedback/public_comment/.

The amendment is proposed under the authority of Parks and Wildlife Code, §46.0085, which authorizes the department to issue tags for finfish species allowed by law to be taken during each year or season from coastal waters of the state to holders of licenses authorizing the taking of finfish species; §46.0086, which authorizes the commission to prescribe tagging requirements for the take of finfish; §50.004, which requires the department to issue and prescribe the form and manner of issuance for combination hunting and fishing licenses, including identification and compliance requirements; and Chapter 61, which requires the commission to regulate the periods of time when it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the means, methods, and places in which it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the species, quantity, age or size, and, to the extent possible, the sex of the game animals, game birds, or aquatic animal life authorized to be hunted, taken, or possessed; and the region, county, area, body of water, or portion of a county where game animals, game birds, or aquatic animal life may be hunted, taken, or possessed.

The proposed amendment affects Parks and Wildlife Code, Chapters 46, 50, and 61.

§57.981. Bag, Possession, and Length Limits.

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

(c) There are no bag, possession, or length limits on game or non-game fish, except as provided in this subchapter.

(1) - (4) (No change.)

(5) Except as provided in subsection (d) of this section, the statewide daily bag and length limits shall be as follows.

(A) - (F) (No change.)

(G) Drum, red.

(i) - (iii) (No change.)

(iv) During a license year, one red drum exceeding [~~over~~] the [~~stated~~] maximum length limit established by this subparagraph may be retained when affixed with a properly executed Red Drum Tag, a properly executed Exempt Angler Red Drum Tag or with a properly executed Duplicate Exempt Red Drum Tag and one red drum over the stated maximum length limit may be retained when affixed with a properly executed Bonus Red Drum Tag. Any fish retained under authority of a Red Drum Tag, an Exempt Angler Red Drum Tag, a Duplicate Exempt Red Drum Tag, or a Bonus Red Drum Tag may be retained in addition to the daily bag and possession limit as provided [~~stated~~] in this section.

(v) A person who lawfully takes a red drum under a digital license issued under the provisions of §53.3(a)(12) this title (relating to Super Combination Hunting and Fishing License Packages) or under a lifetime license with the digital tagging option provided by §53.4(a)(1) of this title (relating to Lifetime Licenses) that exceeds the maximum length limit established by this subparagraph is exempt from any requirement of Parks and Wildlife Code or this subchapter regarding the use of license tags for that species; however, that person shall immediately upon take ensure that a harvest report is created and submitted via a mobile or web application provided by the department for that purpose. If the absence of data connectivity prevents the receipt of a confirmation number from the department following the report required by this subparagraph, the person who took the red drum is responsible for ensuring that the report required by this subparagraph is uploaded to the department immediately upon the availability of network connectivity.

(vi) It is an offense for any person to possess a red drum exceeding the maximum length established by this subparagraph under a digital license or digital tagging option without being in immediate physical possession of an electronic device that is:

(I) loaded with the mobile or web application designated by the department for harvest reporting under this subsection; and

(II) capable of uploading the harvest report required by this subsection.

(vii) A person who is fishing under a license identified in §53.4(a)(1) of this title and selected the fulfilment of physical tags must comply with the tagging requirements of this chapter that are applicable to the tagging of red drum under a license that is not a digital license.

(H) - (X) (No change.)

(d) (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 10, 2021.

TRD-202103587
James Murphy
General Counsel
Texas Parks and Wildlife Department
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 389-4775

CHAPTER 65. WILDLIFE
SUBCHAPTER A. STATEWIDE HUNTING PROCLAMATION

The Texas Parks and Wildlife Department proposes amendments to 31 TAC §§65.7, 65.8. 65.10, 65.42, and 65.64, concerning the Statewide Hunting Proclamation. The amendments would function, in conjunction with proposed amendments to §§53.2 - 53.4, 53.60, and 57.981 published elsewhere in this issue of the *Texas Register,* to implement a digital version of the super combination hunting and "all water" fishing license package, a virtual license that does not utilize physical tags, and provide for the digital issuance of tags to holders of a lifetime super combination hunting and "all water" fishing license package.

Under Parks and Wildlife Code, Chapter 42, no person may possess a deer or turkey unless a properly executed tag from the person's hunting license has been attached to the deer or turkey, except as provided by commission rule. The 87th Texas Legislature enacted House Bill (H.B.) 3081, which authorized the commission to develop and implement a program for the issuance of digital tags for animals, including birds, to holders of hunting licenses authorizing the taking of those animals. In light of the passage of H.B. 3081, the department has determined that it is appropriate to initiate a pilot program to determine the public receptivity to and logistical feasibility of the concept of digital licenses and tags for hunting and fishing. The department currently offers a wide variety of physical hunting and fishing licenses; however, those licenses are issued via a computerized point-of-sale system operated by an outside vendor and the majority of license sales are consummated at retail locations where licenses are sold. Thus, there are many factors for the department to consider and significant potential for unforeseen circumstances to present themselves. Therefore, rather than offering digital versions of every hunting and fishing license all at once, the department has determined that it is prudent to begin with a pilot program to provide a real-world test of the parameters and customer experiences to be considered in any enlargement of the program. The super combination hunting and "all water" fishing license package is a suitable candidate for the pilot program.

The proposed amendment to §65.7, concerning Harvest Log, would create an exception for the holders of a digital license or lifetime license with digital tags to provisions requiring the completion of the license log that is contained on the physical hunting license. Because the digital license and digital tags would not be physical things and harvest reporting via an electronic applica-

tion would be required, it is unnecessary for the department to require utilization of a license log to capture that information.

The proposed amendment to §65.8, concerning Alternative Licensing System, would create an exception to the provisions of that section for holders of a digital license or lifetime license with digital tags. The section was adopted in 2007 to address the possibilities presented by the hypothetical unavailability or failure of the department's computerized point-of-sale system at critical seasonal times when almost all hunting and fishing licenses are sold. Under such a scenario, the department would issue licenses online, but without tags, and the various provisions governing tagging would be waived. Since digital licenses would be issued without tags and lifetime licensees would have the option of digital tags, the provisions of the section waiving requirements for tagless licenses would apply unless an exception is created.

The proposed amendment to §65.10, concerning Possession of Wildlife Resources, would prescribe tagging requirements for holders of digital licenses and lifetime licenses with digital tags. As noted earlier, current law requires a person who kills a deer or turkey to execute and attach a physical tag from the person's hunting license, unless the commission provides otherwise by rule. A person who kills a deer or turkey under a license that does not contain tags cannot comply with current rule; therefore, the proposed amendment would create an exception to the current requirements for physical licenses and prescribe digital tagging provisions. The proposed amendment would require the holder of a digital license or lifetime license with digital tags to immediately report the harvest of a deer or turkey via an electronic application developed by the department for that purpose and receive a confirmation number, which would then be required to be reproduced on some sort of durable media and attached to the carcass of the deer or turkey, where it would be required to remain until reaching a final destination. The purpose of tagging is to allow department law enforcement personnel to quickly and easily determine that deer or turkey have been legally harvested. Unless there is some sort of physical documentation present on a carcass, particularly when the carcass is unattended or the person who harvested the deer or turkey is not present, that process can become problematic, time consuming, and inconvenient. By requiring the confirmation number of the harvest report to be attached to a carcass, the rule would allow game wardens to efficiently check harvested deer or turkey for tags. In instances in which a game warden encounters deer or turkey harvested under a digital license or tag, the warden would either check the smartphone, computer, tablet, or other device to verify that the required harvest report has been submitted, or query the license system to verify that the hunter, the deer or turkey, and the location of harvest have been reported. Additionally, the proposed rule would prescribe the requirements for situations in which data connectivity prevents the required harvest report from being uploaded (i.e., preventing a confirmation number from being obtained). Specifically, a person who harvests a deer or turkey and reports via the electronic application as required but cannot receive a confirmation number because of data connectivity issue would be required to complete a hunter's document and attach it to the carcass of the deer or turkey until reaching data connectivity and obtaining a confirmation number. The hunter's document would contain the same information required to be reported via the electronic application, and could be replaced with documentation of the confirmation number once the confirmation number is received. Finally, the proposed amendment would require persons hunting deer or turkey under a digital license or tag to be in possession of an appropriate electronic device while hunting. It is or should be intuitively obvious that compliance with the requirement for digital tagging immediately upon harvest cannot take place in the absence of a functioning smartphone, computer, or other device capable of reporting; thus, the proposed rule would require that the capability for compliance be present. The department acknowledges that situations may arise in which electronic devices are damaged, lost, or lose power and notes that Parks and Wildlife Code, §42.004, provides for the dismissal of charges for persons charged with hunting license violations if the person is able to produce for the court or the prosecuting attorney the proper hunting license issued to the person and valid at the time of the offense. The department notes that persons who purchase a digital lifetime super combination hunting and "all water" fishing license and choose to have the department fulfil physical deer and turkey tags would be required to follow current rules regarding tagging.

The proposed amendment to §65.42, concerning Deer, would remove a potential conflict with current rule for persons who harvest antlerless deer under a digital license or tag in specific counties in the Oak Prairies region. Current rule requires antlerless harvest in those counties to be electronically reported to the department within 24 hours, which is necessary because of department research into antlerless deer harvest in those counties. The proposed amendment would have the effect of requiring immediate harvest reporting of antlerless deer in the affected counties if the harvest is under a digital license or tag.

The proposed amendment to §65.64, concerning Turkey, would accomplish the same objectives as the proposed amendment to §65.42 and for the same reasons, only with respect to turkey rather than deer.

Robin Riechers, Coastal Fisheries Division Director, has determined that for each of the first five years that the rules as proposed are in effect, there will be minimal fiscal implications to the department, if any, and those fiscal implications will be positive.

There will be no implications for other units of state or local governments as a result of administering or enforcing the rules.

Mr. Riechers also has determined that for each of the first five years that the rules as proposed are in effect, the public benefit anticipated as a result of enforcing or administering the proposed rules will be the provision of a new type of license for public use.

Under the provisions of Government Code, Chapter 2006, a state agency must prepare an economic impact statement and a regulatory flexibility analysis for a rule that may have an adverse economic effect on small businesses, micro-businesses, or rural communities. As required by Government Code, §2006.002(g), the Office of the Attorney General has prepared guidelines to assist state agencies in determining a proposed rule's potential adverse economic impacts to small businesses, micro-businesses, or rural communities. Those guidelines state that an agency need only consider a proposed rule's "direct adverse economic impacts" to small businesses and micro-businesses to determine if any further analysis is required. For that purpose, the department considers "direct economic impact" to mean a requirement that would directly impose recordkeeping or reporting requirements; impose taxes or fees; result in lost sales or profits; adversely affect market competition; or require the purchase or modification of equipment or services.

The department has determined that the proposed amendments will not result in direct adverse impacts on small businesses, micro-businesses, or rural communities because the proposed rules regulate various aspects of recreational license privileges

that allow individual persons to pursue and harvest public wildlife resources in this state and therefore do not directly affect small businesses, micro-businesses, or rural communities. Therefore, neither the economic impact statement nor the regulatory flexibility analysis described in Government Code, Chapter 2006, is required.

The department has not drafted a local employment impact statement under the Administrative Procedures Act, §2001.022, as the agency has determined that the rules as proposed will not impact local economies.

The department has determined that Government Code, §2001.0225 (Regulatory Analysis of Major Environmental Rules), does not apply to the proposed rules.

The department has determined that there will not be a taking of private real property, as defined by Government Code, Chapter 2007, as a result of the proposed rules.

In compliance with the requirements of Government Code, §2001.0221, the department has prepared the following Government Growth Impact Statement (GGIS). The rules as proposed, if adopted, will neither create nor eliminate a government program; not result in an increase or decrease in the number of full-time equivalent employee needs; not result in a need for additional General Revenue funding; not affect the amount of any fee; create a new regulation (governing digital licenses and tagging); not repeal, expand, or limit a regulation; neither increase nor decrease the number of individuals subject to regulation; and not positively or adversely affect the state's economy.

Comments on the proposal may be submitted to Robin Riechers at (512) 389-4636, e-mail: robin.riechers@tpwd.texas.gov. Comments also may be submitted via the department's website at http://www.tpwd.texas.gov/business/feedback/public_comment/.

DIVISION 1. GENERAL PROVISIONS

31 TAC §§65.7, 65.8, 65.10

The amendments are proposed under the authority of Parks and Wildlife Code, §42.010, which, which requires the commission to prescribe the form and issuance of hunting licenses authorized under Parks and Wildlife Code, Chapter 42; §42.0101, which authorizes the commission to promulgate rules for the issuance of digital tags for animals, including birds, to holders of hunting licenses authorizing the taking of those animals, including rules allowing a person using a digital tag to create a digital record at the time of the taking of an animal that includes information required by the department as soon as possible after the taking of the animal and requiring a person using a digital tag to retain in the person's possession documentation of a required digital record at all times before the carcass is finally processed; §42.0177, which authorizes the commission to modify or eliminate the tagging, carcass, final destination, and final processing requirements of Chapter 42; §42.006, which authorizes the commission to prescribe requirements relating to possessing a license issued under Chapter 42 by rule; §50.004, which requires the department to issue and prescribe the form and manner of issuance for combination hunting and fishing licenses, including identification and compliance requirements; and Chapter 61, which requires the commission to regulate the periods of time when it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the means, methods, and places in which it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the species, quantity, age or size, and, to the extent possible, the sex of the game animals, game birds, or aquatic animal life authorized to be hunted, taken, or possessed; and the region, county, area, body of water, or portion of a county where game animals, game birds, or aquatic animal life may be hunted, taken, or possessed.

The proposed amendment affects Parks and Wildlife Code, Chapters 42, 50, and 61.

§65.7. Harvest Log.

(a) The provisions of this subsection apply only to a person in possession of a license purchased through an automated point-of-sale system and do not apply to a digital license issued by the department pursuant to §53.3(a)(12) of this title (relating to Super Combination Hunting and Fishing License Packages) or §53.4(a)(1) of this title (relating to Lifetime Licenses).

(1) - (2) (No change.)

(b) (No change.)

§65.8. Alternative Licensing System.

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

(d) This section does not apply to the digital licenses identified in §53.3(a)(12) of this title (relating to Super Combination Hunting and Fishing License Packages) or §53.4(a)(1) of this title (relating to Lifetime Licenses).

§65.10. Possession of Wildlife Resources.

(a) (No change.)

(b) Under authority of Parks and Wildlife Code, §42.0177, the tagging requirements of Parks and Wildlife Code, §42.018, are modified as follows.

(1) - (2) (No change.)

(3) Except as provided in paragraph (4) of this subsection, the tagging requirements for deer and turkey taken under a digital license issued under the provisions of §53.3(a)(12) of this title (relating to Super Combination Hunting and Fishing License Packages) or under the digital tagging option of §53.4(a)(1) of this title (relating to Lifetime Licenses) are prescribed in subsection (e) of this section.

(4) A person who has purchased a digital license identified in §53.4(a)(1) of this title and selected the fulfilment of physical tags must comply with the tagging requirements of Parks and Wildlife Code, Chapter 42, and this chapter that are applicable to the tagging of deer and turkey under a license that is not a digital license.

(5) [~~(3)~~] The provisions of this subsection do not modify or eliminate any requirement of this subchapter or the Parks and Wildlife Code applicable to a carcass before it is at a final destination.

(c) - (d) (No change.)

(e) A person who lawfully kills a deer or turkey under a digital license issued under the provisions of §53.3(a)(12) of this title or the digital tagging option under §53.4(a)(1) of this title is exempt from any requirement of Parks and Wildlife Code or this subchapter regarding the use or possession of license tags for those species; however, that person shall ensure that immediately upon take a harvest report is created and submitted via a mobile or web application provided by the department for that purpose.

(1) Upon receipt of a confirmation number sent by the department in response to the harvest report required by this subsection,

the person who took the deer or turkey is responsible for ensuring that the confirmation number is legibly reproduced on a reasonably durable media, which shall immediately be attached to the carcass of the deer or turkey. The confirmation number shall remain attached to the carcass until the applicable requirements of subsection (b) of this section have been satisfied.

(2) If the absence of network data connectivity prevents the receipt of a confirmation number from the department following the report required by this subsection, the person who took the deer or turkey is responsible for the preparation of a hunter's document which shall immediately be attached to the carcass of the deer or turkey and remain attached to the carcass until the harvest report required by this subsection is uploaded to the department. The hunter's document shall be made of reasonably durable media and shall contain:

(A) the first and last name of the person who took the deer or turkey;

(B) the customer number of the license of the person who took the deer or turkey; and

(C) the date and time the deer or turkey was taken.

(D) A person who documents the take of a deer or turkey under the provisions of this paragraph shall ensure that the harvest report required by this subsection is uploaded to the department immediately upon the availability of network connectivity, at which time the hunter's document may be replaced with documentation meeting the requirements of paragraph (1) of this subsection, which shall remain attached to the carcass of the deer or turkey until the applicable requirements of subsection (b) of this section have been satisfied.

(3) It is an offense for any person to hunt deer or turkey under a digital license or digital tagging option without being in immediate physical possession of an electronic device that is:

(A) loaded with the mobile or web application designated by the department for harvest reporting under this subsection; and

(B) capable of uploading the harvest report required by this subsection.

(f) [~~(e)~~] Proof of sex for deer and antelope must remain with the carcass until tagging requirements cease.

(1) - (2) (No change.)

(g) [~~(f)~~] During a season in which the bag composition for turkey is restricted to gobblers only or gobblers and bearded hens, proof of sex must remain with a harvested turkey (attached or detached from the bird) until it reaches either the possessor's permanent residence or a cold storage/processing facility and is finally processed. Proof of sex for turkey is as follows:

(1) - (2) (No change.)

(h) [~~(g)~~] Proof of sex for pheasant consists of: one leg, including the spur, attached to the bird or the entire plumage attached to the bird.

(i) [~~(h)~~] No additional proof of sex is required for a deer that is lawfully tagged in accordance with:

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

(j) [~~(i)~~] In lieu of proof of sex, the person who killed the wildlife resource may:

(1) - (2) (No change.)

(k) [~~(j)~~] A person may give, leave, receive, or possess any species of legally taken wildlife resource, or a part of the resource, that is required to have a tag or permit attached or is protected by a bag or possession limit, if the wildlife resource is accompanied by a wildlife resource document from the person who killed or caught the wildlife resource. A wildlife resource may be possessed without a WRD by the person who took the wildlife resource, provided the person is in compliance with all other applicable provisions of this subchapter and the Parks and Wildlife Code.

(1) - (5) (No change.)

(l) [~~(k)~~] It is a defense to prosecution if the person receiving the wildlife resource does not exceed any possession limit or possesses a wildlife resource or a part of a wildlife resource that is required to be tagged if the wildlife resource or part of the wildlife resource is tagged.

(m) [~~(l)~~] The identification requirements for desert bighorn sheep skulls are as follows.

(1) - (4) (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 10, 2021.

TRD-202103585
James Murphy
General Counsel
Texas Parks and Wildlife Department
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 389-4775

♦ ♦ ♦

DIVISION 2. OPEN SEASONS AND BAG LIMITS

31 TAC §65.42, §65.64

The amendments are proposed under the authority of Parks and Wildlife Code, §42.010, which, which requires the commission to prescribe the form and issuance of hunting licenses authorized under Parks and Wildlife Code, Chapter 42; §42.0101, which authorizes the commission to promulgate rules for the issuance of digital tags for animals, including birds, to holders of hunting licenses authorizing the taking of those animals, including rules allowing a person using a digital tag to create a digital record at the time of the taking of an animal that includes information required by the department as soon as possible after the taking of the animal and requiring a person using a digital tag to retain in the person's possession documentation of a required digital record at all times before the carcass is finally processed; §42.0177, which authorizes the commission to modify or eliminate the tagging, carcass, final destination, and final processing requirements of Chapter 42; §42.006, which authorizes the commission to prescribe requirements relating to possessing a license issued under Chapter 42 by rule; §50.004, which requires the department to issue and prescribe the form and manner of issuance for combination hunting and fishing licenses, including identification and compliance requirements; and Chapter 61, which requires the commission to regulate the periods of time when it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the means, methods,

and places in which it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the species, quantity, age or size, and, to the extent possible, the sex of the game animals, game birds, or aquatic animal life authorized to be hunted, taken, or possessed; and the region, county, area, body of water, or portion of a county where game animals, game birds, or aquatic animal life may be hunted, taken, or possessed.

The proposed amendments affect Parks and Wildlife Code, Chapters 42, 50, and 61.

§65.42. Deer.

(a) General.

(1) - (4) (No change.)

(5) In the counties or portions of counties listed in subsection (b)(2)(H) of this section, antlerless deer harvested on properties not subject to the provisions of §65.29 of this title (relating to Managed Lands Deer (MLD) Programs) must be reported via the department's internet or mobile application within 24 hours of the time of kill, including antlerless deer harvested during the special seasons established by subsection (b)(5) - (7) of this section. This paragraph does not apply to antlerless deer harvested under a digital license issued by the department pursuant to §53.2(a)(12) of this title (relating to Super Combination Hunting and Fishing Packages) or a valid license with digital tags under §53.4(a)(12) of this title (relating to Lifetime Licenses) of this title, which must be reported as required under §65.11 of this title (relating to Possession of Wildlife Resources).

(b) - (c) (No change.)

§65.64. Turkey.

(a) (No change.)

(b) Rio Grande Turkey. The open seasons and bag limits for Rio Grande turkey shall be as follows.

(1) - (2) (No change.)

(3) Spring season and bag limits.

(A) - (B) (No change.)

(C) In Bastrop, Caldwell, Colorado, Fayette, Jackson, Lavaca, Lee, Matagorda, Milam, and Wharton counties, there is a spring general open season.

(i) - (ii) (No change.)

(iii) Except as provided by §65.10 of this title (relating to Possession of Wildlife Resources) for turkeys harvested under a digital license issued by the department pursuant to §53.3(a)(12) of this title (relating to Super Combination Hunting and Fishing License Packages) or a valid license with digital tags under §53.4(a)(1) of this title (relating to Lifetime Licenses), all ~~[All]~~ turkeys harvested during the open season established under this subparagraph must be reported within 24 hours of the time of kill via an internet or mobile application designated by the department for that purpose.

(4) (No change.)

(c) Eastern turkey. The open seasons and bag limits for Eastern turkey shall be as follows. In Bowie, Cass, Fannin, Grayson, Jasper (other than the Angelina National Forest), Lamar, Marion, Nacogdoches, Newton, Polk, Red River, and Sabine counties, there is a spring season during which both Rio Grande and Eastern turkey may be lawfully hunted.

(1) - (2) (No charge.)

(3) In the counties listed in this subsection:

(A) - (B) (No change.)

(C) except as provided by §65.10 of this title for turkeys harvested under a digital license issued pursuant to §53.3 of this title or a valid license with digital tags under §53.4(a)(1) of this title, all turkeys harvested during the open season must be registered via the department's internet or mobile application within 24 hours of the time of kill. The department will publish the internet address and information on obtaining the mobile application in generally accessible locations, including the department internet web site (www.tpwd.texas.gov). Harvested turkeys may be field dressed but must otherwise remain intact.

(d) (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 10, 2021.

TRD-202103586
James Murphy
General Counsel
Texas Parks and Wildlife Department
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 389-4775

♦ ♦ ♦

TITLE 34. PUBLIC FINANCE

PART 1. COMPTROLLER OF PUBLIC ACCOUNTS

CHAPTER 3. TAX ADMINISTRATION

SUBCHAPTER O. STATE AND LOCAL SALES AND USE TAXES

34 TAC §3.276

The Comptroller of Public Accounts proposes new §3.276, concerning surveying services. This section memorializes existing comptroller policy, implements House Bill 3319, 80th Legislature, 2007, and defines terms in Tax Code, §151.0048 (Real Property Service) which were not previously defined. The comptroller intends for the information in this rule to be consistent with the surveying services information currently in §3.356 (relating to Real Property Service). Portions of §3.356 regarding surveying services will be repealed after the adoption of this new rule. To the extent the information in this section differs from the information concerning surveying services contained in other sections of this title, it is the comptroller's intent that this section control.

Subsection (a) defines terms used in this section. Paragraph (1) defines the term "confirm" based on guidance provided in Comptroller's Decision No. 101,058 (2011) and the requirements for boundary construction stated in the Texas Administrative Code, Title 22, Part 29, Chapter 663, Subchapter B, §663.16 (relating to Boundary Construction).

Paragraph (2) defines the term "contractor" as stated in Tax Code, §151.0048(c).

Paragraph (3) defines the term "determine" based on guidance provided in Comptroller's Decision No. 101,058 (2011) and the requirements for boundary construction stated in Administrative

Code, Title 22, Part 29, Chapter 663, Subchapter B, §663.16 (relating to Boundary Construction).

Paragraph (4) defines the term "landman." The definition is taken from Occupations Code, §1702.324(a) (Certain Occupations).

Paragraph (5) defines the term "surveying service" based on the definition of "surveying of real property" in §3.356(a)(9) of this title (relating to Real Property Service).

Subsection (b) restates agency policy that a person who performs a surveying service defined in subsection (a)(5) performs a taxable surveying service and lists some examples. The examples are for illustration purposes only and are not exhaustive.

Subsection (c) lists examples of surveying activities that are not taxable as real property services. Prior comptroller rulings have held that the surveying and marking of proposed improvements and natural features are not taxable as real property services. *See* e.g., Comptroller Decision No. 101,058 (2011); STAR Accession Nos. 9207L1186C04 (July 30, 1992); 9004L0996E11 (April 4, 1990); and 8901T0920C10 (Jan. 23, 1989). Although these activities could be considered "surveying" within the meaning of the statute, subsection (c) memorializes the prior comptroller rulings.

Subsection (d) implements Tax Code, §151.0048(b) and (b-1), which exclude surveying services from taxable real property services when purchased by a contractor building a new residential improvement or when performed by a landman.

Subsection (e) explains the sales tax permitting and reporting responsibilities of a person who performs a surveying service.

Subsection (f) restates agency policy regarding when a taxpayer may issue a resale or exemption certificate in lieu of paying tax on a taxable surveying service or for tangible personal property used in performing a taxable surveying service. This information is currently found in §3.356(c) and (d) of this title and §3.287 of this title (relating to Exemption Certificates).

Subsection (g) restates agency policy regarding the taxability of an unrelated service. This information is found in §3.356(i) of this title.

Subsection (h) refers to §3.334 of this title for guidance relating to local sales and use taxes.

Tom Currah, Chief Revenue Estimator, has determined that during the first five years that the proposed amendment is in effect, the amendment: will not create or eliminate a government program; will not require the creation or elimination of 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 increase or decrease the number of individuals subject to the rules' applicability; and will not positively or adversely affect this state's economy. This proposal is a new rule.

Mr. Currah also has determined that for each year of the first five years the rule is in effect, proposed amendment would benefit the public by conforming the rule to current statutes and agency policy. This rule is proposed under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. The proposed amendment would have no significant fiscal impact on the state government, units of local government, or individuals. There would be no anticipated significant economic costs to the public.

Comments on the proposal may be submitted to Teresa G. Bostick, Director, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711-3528. Comments must be received no later than 30 days from the date of publication of the proposal in the *Texas Register.*

This section is proposed under Tax Code, §111.002 (Comptroller's Rules; Compliance; Forfeiture), which provides the comptroller with the authority to prescribe, adopt, and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2 (State Taxation).

The proposal implements Tax Code, §151.0101 (Taxable Services) and §151.0048 (Real Property Services).

§3.276. Surveying Services.

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

(1) Confirm--To perform any act, at a location or remotely, to reestablish or verify boundaries of real property or the location of a real property improvement. The term includes reestablishing or verifying the location of a boundary used as a reference point to locate or measure to another point, such as the location of an improvement in relation to the boundaries of real property.

(2) Contractor--A person who makes an improvement on real property and who, as a necessary or incidental part of the service, incorporates tangible personal property into the real property improved. For the purposes of this section, the term includes a builder, developer, speculative builder, or other person acting as a builder to improve residential real property.

(3) Determine--To perform any act, at a location or remotely, to establish, mark, or set the boundaries of real property or the location of an improvement. The term includes ascertaining the location of a boundary used as a reference point to locate or to measure another point, such as the location of an improvement in relation to the boundaries of real property.

(4) Landman--An individual who, in the course and scope of the individual's business:

(A) acquires or manages petroleum or mineral interests; or,

(B) performs title or contract functions related to the exploration, exploitation, or disposition of petroleum or mineral interests.

(5) Surveying service--An activity performed on land, from the air, under water or remotely that uses relevant elements of law, research, measurement, analysis, computation, mapping, and land description to determine or confirm the boundaries of real property or to determine or confirm the location of an improvement in relation to the boundaries of real property. Professional surveying subject to regulation under Occupations Code, Chapter 1071 (Land Surveyors), is presumed to be a surveying service.

(b) Taxable surveying services. Except as provided in subsection (d) of this section, surveying activities described in subsection (a)(5) of this section that are performed for real property located in Texas are taxable as real property services, including the preparation of the following types of surveys:

(1) As-built survey. A survey to depict the relationship of improvements to property boundary lines.

(2) Boundary survey. A survey to determine or confirm a boundary line on real property, or to obtain data for constructing a map or description showing a boundary line.

(3) Easement survey. A survey to determine or confirm by map or description, the boundaries of a tract of real property used in granting the right, privilege, or liberty given to a person or group to use land belonging to another for a specific and definite purpose. An easement survey may document existing easements or be used to establish a new easement.

(4) Land title survey. A boundary survey to determine or confirm boundary locations for title transfer of real property.

(5) Right-of-way survey. A survey to determine or confirm right-of way-lines, center lines, or reference lines, including surface, overhead and underground lines. Such surveys typically document the route of highways, railroads, pipelines, waterways or canals, and transmission lines for electrical or communication purposes.

(6) Subdivision plat. A survey to divide a tract of real property into parcels or lots, and may include the location of items such as street rights-of-ways or easements. The survey is often performed to meet subdivision statutes or county and municipal regulations. This survey may also be referred to as a lot survey.

(7) Title survey. A survey to investigate and evaluate factors affecting and influencing boundary locations, ownership lines, rights-of-way, and easements within or immediately surrounding a tract of real property. A title survey is commonly performed to locate, determine, or reestablish property boundaries for title insurance purposes.

(8) Staking and placement services. A survey that establishes, remotely or on the ground, the location and position of various structures or construction projects in relation to the boundaries of the involved site. The survey is used for defining the positions of buildings, structures, wells, canals, fences, walls, and other physical facilities in relation to the boundaries or property lines of the site.

(c) Nontaxable surveying services. Surveying activities not described in subsection (a)(5) of this section are not taxable as real property services. Examples of nontaxable surveying services include:

(1) As-built verification survey. A survey after construction is completed to determine characteristics of an improvement other than its relationship to property boundary lines, such as principal horizontal and vertical control points, and the dimensions of the finished structures and/or infrastructures.

(2) Construction survey. Activities prior to and during a construction project to measure aspects of an improvement other than its relationship to property boundary lines, such as activities to control elevation, horizontal location, dimensions, or configuration; to determine if the construction was adequately completed; and to obtain dimensions for calculating quantities used in construction.

(3) Design survey. A survey to obtain information that is essential for planning an engineering project or development and estimating its cost.

(4) Existing oil, gas, or oil and gas well ties survey. A survey to gather the locations of existing oil or gas wells in relation to the location of proposed wells.

(5) Geodetic/Control survey. A survey to provide horizontal and/or vertical coordinates of fixed points on the surface of the earth to which supplementary surveys or mapping efforts are adjusted.

(6) Hydrographic survey. A survey to determine the geometric and dynamic characteristics of bodies of water, including a record of a survey, of a given date, of a water covered region, with particular attention to the relief of the bottom and features under the surface.

(7) Monitoring deformation survey. A survey to periodically measure the horizontal and vertical movement or warpage of the surface of the earth or a physical object or structure.

(8) Oil or gas drilling unit, proration unit, and pooled unit plats. A drilling unit, proration unit, or pooled unit plat submitted to the Railroad Commission.

(9) Seismic survey. A survey to determine the subterranean composition and structure in an area, generally by using a vibroseis or small explosives to measure vibrations.

(10) Topographic survey. A survey to determine the configuration, relief, or elevations of a portion of the earth's surface, including the location of natural features.

(11) Tree survey. A survey to locate and identify existing trees on real property. If services are performed to evaluate the health of a tree, to remove a tree, or to prune a tree, those services are taxable landscaping services. See §3.356 of this title (relating to Real Property Service).

(12) Building elevation survey. A survey to certify building elevations that is issued for completion of the National Flood Insurance Program Elevation Certificate. If the survey or certificate issued is used to evaluate risks to property, is used to determine an individual's eligibility for insurance coverage, is used to determine the proper insurance premium rate, or for determining the payment of insurance policy benefits, the survey provided is taxable as an insurance service. See §3.355 of this title (relating to Insurance Services).

(13) Archaeological or historic significance survey. A survey to identify items of archaeological or historic significance performed after boundary surveying has been completed.

(14) Staking and placement services. A survey which gathers identified surface locations that are used to mark or locate proposed improvements. For example, a separate charge for staking or re-staking a centerline of pipeline is not taxable.

(d) Excluded surveying services. A person performing a surveying service described in subsection (a)(5) of this section is not performing a taxable real property service if:

(1) a contractor purchases the surveying service as part of the construction of a new improvement to residential real property or other improvement immediately adjacent to a new improvement to residential real property; or

(2) a landman performs the surveying service and it is necessary to negotiate or secure land or mineral rights for acquisition or trade, including:

(A) determining ownership;

(B) negotiating a trade or agreement regarding land or mineral rights;

(C) drafting and administering contractual agreements;

(D) ensuring that all governmental regulations are complied with; and

(E) any other action necessary to complete the transaction related to a service described by this subsection, other than an information service described by Tax Code, §151.0038 (Information Service).

(e) Responsibilities of persons providing surveying services.

(1) A person who performs a surveying service described in subsection (a)(5) of this section for consideration must obtain a sales

and use tax permit and collect and remit sales or use taxes on all charges for taxable surveying services.

(2) A person who performs a surveying service for a contractor who claims the service is excluded from tax as described in subsection (d)(1) of this section must obtain documentation from the contractor demonstrating the surveying service is being purchased as part of the construction of a new improvement to residential real property or other improvement immediately adjacent to a new improvement to residential real property. The contractor and the person who performs the surveying service must retain a copy of these records in accordance with §3.281 of this title (relating to Records Required; Information Required). If the comptroller later determines that the surveying service purchased by the contractor was taxable, the contractor will be liable for the tax due on the purchase including any related penalty and interest.

(3) A landman who performs a surveying service defined in subsection (a)(5) of this section that is excluded from tax because it meets the requirements in subsection (d)(2) of this section must retain documentation demonstrating the surveying service provided was not taxable. The landman and purchaser must retain these records in accordance with §3.281 of this title.

(4) If a purchaser or seller of a nontaxable surveying service described in subsection (d)(1) or (2) of this section does not maintain the documentation demonstrating that the service is nontaxable, the comptroller may proceed against either the seller or the purchaser, or both until the tax, penalty, and interest have been paid. See §3.282(m) of this title (relating to Auditing Taxpayer Records.)

(f) Resale and exemption certificates. The sale of a surveying service described in subsection (a)(5) of this section is presumed taxable.

(1) Resale certificates. A person who performs a taxable surveying service may issue a resale certificate to a supplier in lieu of paying tax on purchases of tangible personal property if care, custody, and control of the property transfers to the purchaser as part of the taxable surveying service. The care, custody, and control of tangible personal property is transferred to the purchaser of the service when the purchaser has primary possession of the tangible personal property. For example, a person who performs a taxable surveying service may issue a resale certificate to a supplier when purchasing metal pins or PK nails used to mark boundary lines. A person who performs a taxable surveying service may also issue a resale certificate in lieu of paying tax on purchases of taxable services the person intends to transfer to the purchaser as an integral part of the taxable surveying service. A person who performs taxable surveying services owes tax on tangible personal property, such as supplies, machinery and equipment, used or consumed in performing the service.

(A) A person who performs a taxable surveying service may not accept a resale certificate in lieu of collecting tax on a taxable surveying service sold to a purchaser who acquires the service for the purpose of providing a nontaxable service. For example, a person performing taxable surveying services may not accept a resale certificate from a title company on taxable surveying services used in performing nontaxable real estate closing services, even if the title company transfers the survey to the real estate purchaser after the closing. Similarly, a person performing taxable surveying services may not accept a resale certificate from an engineering firm on taxable surveying services acquired for the purpose of providing nontaxable engineering services to either an exempt or non-exempt customer. The engineer owes tax on the purchase of the taxable surveying service used in the provision of the nontaxable engineering service. The engineering firm and the title company are the end-consumers of the taxable surveying services purchased to provide their respective nontaxable services.

(B) A person who performs a nontaxable surveying service may not issue a resale certificate in lieu of paying tax on taxable items used or consumed in performing the nontaxable surveying service. A person who performs a nontaxable surveying service is the end-consumer of all taxable items purchased, leased, or rented to perform the nontaxable service. A person who performs a nontaxable surveying service owes tax on all taxable items purchased to perform the service, unless the items are otherwise exempt.

(2) Exemption certificates. A person who performs a taxable surveying service may accept a properly completed exemption certificate in lieu of collecting tax if an exempt entity directly contracts for and purchases the surveying service. See §3.322 of this title (relating to Exempt Organizations), §3.287 of this title (relating to Exemption Certificates). See also §3.288 of this title (relating to Direct Payment Procedures and Qualifications) regarding purchasers who may issue a direct payment exemption certificate. Purchase vouchers that are issued by governmental entities exempted under Tax Code, §151.309, are acceptable documentation of exempt transactions. See §3.322(g)(3) of this title.

(A) Except as provided by subparagraph (B) of this paragraph, a person who performs a taxable surveying service may not accept an exemption certificate from a person performing nontaxable services for an exempt entity described in Tax Code, §151.309 or §151.310. The person providing the nontaxable services is the end consumer and owes tax on the purchase of the taxable surveying service, even if the person providing the nontaxable services provides a copy of the survey to the exempt entity upon completion of its nontaxable services.

(B) A person who performs a taxable surveying service may accept an exemption certificate from a contractor under Tax Code, §151.311, on a purchase of a taxable item for use under a contract to improve realty for an organization that is exempt under Tax Code, §151.309 or §151.310.

(g) Unrelated services.

(1) A service is an unrelated service if:

(A) it is not a taxable surveying service nor a service or labor taxable under another provision of Tax Code, Chapter 151 (Limited Sales, Excise, and Use Tax);

(B) it is not provided as a part of the taxable surveying service and is of a type that is commonly provided on a stand-alone basis; and

(C) the performance of the unrelated service is distinct and identifiable. Examples of services that are distinct and identifiable from taxable surveying services include nontaxable surveying services, such as a topographical survey, engineering services and architectural or landscaping design services.

(2) Unrelated nontaxable services and taxable surveying services sold or purchased for a single charge. When an unrelated nontaxable service and a taxable surveying service are sold together for a single charge, the total amount charged is presumed to be taxable. This presumption does not apply if the portion of the charge attributable to the taxable surveying service represents 5.0% or less of the total charge.

(A) The person performing the taxable surveying service with an unrelated nontaxable service may overcome the presumption of taxability by separately stating a reasonable charge for the taxable surveying service to the purchaser at the time of the transaction. A purchaser may presume, in the context of this section, that the service

provider's separately stated charge for a taxable surveying service is reasonable. If the charge attributable to the taxable surveying service is not separately stated at the time of the transaction, the service provider or the purchaser may later establish for the comptroller, through documentary evidence, the portion of the total charge that is attributable to an unrelated service.

(B) The taxable surveying service provider's books must support the apportionment of the total charge between a taxable surveying service and an unrelated nontaxable service based on either the cost of providing the taxable surveying service or a comparison to the normal charge for each service if it had been performed on a stand-alone basis. If, after reviewing the transaction, the comptroller determines the charge for a taxable surveying service is unreasonable, considering the cost of providing the service or a comparable charge made in the industry for the service, the comptroller may adjust the charges and assess against the person performing the taxable surveying service any additional tax, penalty, and interest due on the taxable surveying service.

(h) Local taxes. See §3.334 of this title (relating to Local Sales and Use Taxes) for additional guidance related to local sales and use tax responsibilities.

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 13, 2021.

TRD-202103607
William Hamner
Special Counsel for Tax Administration
Comptroller of Public Accounts
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 475-0387

♦ ♦ ♦

34 TAC §3.302

The Comptroller of Public Accounts proposes amendments to 34 TAC §3.302, concerning accounting methods, credit sales, bad debt deductions, repossessions, interest on sales tax, and trade-ins. The comptroller amends the section to incorporate longstanding agency guidance on bad debts, to revise agency requirements with respect to taking credits on sales and use tax reports and requesting refunds, and to define key terms used in the Tax Code and this section that are undefined.

Throughout the section, the comptroller inserts the phrase "sales and use" before the term "tax;" replaces the term "section" with the term "subsection," where appropriate; and replaces the term "customer" with the term "purchaser" for consistency within the section and with other sections of this title.

The comptroller adds new subsection (a), titled "definitions," to define key terms used but not defined within the section. The proposed amendments also relocate terms defined within the current section to new subsection (a). Subsequent subsections are relettered accordingly.

New paragraph (1) defines the term "affiliate" based on the meaning assigned by Tax Code, §151.426(j) (Credits and Refunds for Bad Debts, Returned Merchandise, and Repossessions), and current subsection (d)(8).

New paragraph (2) defines the term "assignee" as the person who acquires the right to claim a credit or refund related to a bad debt through a written assignment executed by the retailer who made the sale or the private label credit provider.

New paragraph (3) defines the term "bad debt" based on its use in Tax Code, §151.426(a), and its definition in current subsection (d)(1), with minor revisions to provide clarity.

New paragraph (4) defines the term "credit sale" based on the term's definition in current subsection (b)(1), which is being deleted.

New paragraphs (5) and (6) define the terms "private label credit agreement" and "private label credit provider," respectively. The terms appear in the current section but are undefined. The comptroller bases the new definitions on their common industry usage and on definitions of similar terms in other states that permit tax credits or refunds for bad debts. *See, e.g.,* 35 Ill. Comp. Stat. Ann. 120/6d(c); Wis. Stat. Ann., §77.585(1)(a) (West) (both relating to deductions for bad debt).

New paragraph (7) defines the term "trade-in" based on its definition in current subsection (g) of this section and on Tax Code, §151.007(c)(5) ("Sales Price" or "Receipts").

The comptroller reletters current subsection (a), regarding accounting methods, as subsection (b). The comptroller amends paragraph (1) by giving it the heading "Reporting sales and use tax, " and by replacing the term "correctly" in the first sentence with the term "accurately" to adhere more closely to the language in Tax Code, §151.408 (Accounting Basis for Reports). The amendment also replaces the term "should" in the second sentence with the term "must." A retailer must obtain prior written approval from the comptroller before the retailer can report its sales and use tax using an accounting system that is not a generally recognized accounting system. *See* Comptroller's Decision No. 26,487 (1990). In addition, the comptroller amends the second sentence to replace the phrase "commonly recognized accounting system" with the phrase "generally recognized accounting system" to more closely track the language of Tax Code, §151.408 (Accounting Basis for Reports).

The comptroller amends paragraph (2) by giving it the heading "Reporting sales and use tax on rentals and leases," and correcting the reference to §3.294 of this title (relating to Rental and Lease of Tangible Personal Property).

The comptroller reletters current subsection (b), regarding credit sales, as subsection (c). The comptroller deletes current paragraph (1), defining the term "credit sale," because the definition now appears in new subsection (a)(5). The comptroller renumbers subsequent paragraphs accordingly.

The comptroller amends renumbered paragraph (1) by giving it the heading, "Service charges." The comptroller also makes nonsubstantive changes to improve readability.

The comptroller amends renumbered paragraph (2) by giving it the heading, "Accounting methods." The comptroller also adds the phrase "for its regular books and records" at the end of the paragraph to adhere more closely to the language in Tax Code, §151.408.

The comptroller amends subparagraph (A) by giving it the heading "Accrual basis," and subparagraph (B) by giving it the heading, "Cash basis." The comptroller further amends subparagraph (B) by inserting the terms "insurance" and "interest" in the second sentence to be consistent with the language in relettered

subsection (c)(1). The comptroller makes other nonsubstantive changes to subparagraphs (A) and (B) to improve readability and consistency within this section.

The comptroller amends subparagraph (C) by giving it the heading, "Modified basis." The comptroller further amends the subparagraph to add a sentence requiring a retailer to obtain written approval from the comptroller before using any accounting method other than a generally recognized accounting method to be consistent with relettered subsection (b)(1).

The comptroller adds new subparagraph (D), giving it the heading, "Cash basis reporting option." The new subparagraph informs retailers whose regular books are kept on an accrual basis of accounting that they can elect to use the cash basis of accounting for sales and use tax reporting purposes. This amendment reflects long-standing agency policy. *See, e.g.,* Comptroller's Decision No. 38,886 (2002) ("[T]he method used to report sales tax is not controlled by whether [the retailer's] books are generally maintained on an accrual or cash basis...").

The comptroller redesignates current subsection (c), titled "Transfer or sale of sales contracts and accounts receivable," as paragraph (3). The comptroller makes nonsubstantive changes to improve readability and consistency with other subsections of this section.

The comptroller amends subsection (d) to revise and reorganize the existing information on bad debts and to add the content from current subsection (e) on repossessions. The comptroller amends the heading of subsection (d) to read, "Bad debts and repossessions."

The comptroller deletes paragraph (1), defining bad debt, because the term is now defined in new subsection (a).

The comptroller redesignates subparagraph (A) as paragraph (1) and gives it the heading, "Bad debts during a reporting period." The comptroller further amends renumbered paragraph (1) by adding language clarifying that the retailer must report on its federal income tax return the amount entered in the retailer's books as a bad debt. Finally, the comptroller deletes subparagraphs (B) and (C).

The comptroller deletes the content of paragraph (2), regarding the amount of a bad debt, because the information now appears in new subparagraphs (3)(A) and (3)(B). The comptroller further amends paragraph (2) by giving it the heading, "Persons who may claim a credit or refund. "

The comptroller adds new subparagraph (A) based on the language of deleted paragraph (1)(C) and subsection (e)(1). The new subparagraph explains that only a retailer, private label credit provider, or an assignee or affiliate of either are entitled to a credit or refund for bad debts or repossessed items under Tax Code, §151.426.

The comptroller adds new subparagraph (B), which explains that only one person is entitled to a credit or refund for each bad debt or repossession.

The comptroller deletes the content of paragraph (3), regarding expenses to collect a bad debt, because the information now appears in new paragraph (3)(D). The comptroller further amends paragraph (3) by giving it the heading, "Determining the amount of a bad debt or the unpaid portion of the sales price of a taxable item repossessed under a conditional sales contract. "

The comptroller adds new subparagraph (A), which states that the amount of a bad debt or unpaid portion of the sales price of a taxable item repossessed under a conditional sales contract is the sales price of the taxable item less all payments and recoveries, including payments applied to interest, fees, and other expenses relating to the sales price of the taxable item under the credit agreement and proceeds from the sale of an account to a third party. This subparagraph is based on language from deleted subsection (d)(2) and subsection (e)(1).

The comptroller adds new subparagraph (B), which explains that the sales price of a taxable item does not include nontaxable separately stated charges such as finance and carrying charges or charges for interest or insurance. The comptroller derives the language of the new subparagraph from deleted subsection (d)(2) and subsection (e)(1).

The comptroller adds new subparagraph (C), which provides guidance on how payments should be applied to determine the amount of a bad debt in accordance with Tax Code, §151.426(e)(2), and Comptroller's Decision No. 101,531 (2010). The comptroller clarifies that payments on an account are applied to the charges occurring first in time and are prorated between taxable and nontaxable charges.

The comptroller adds new subparagraph (D), which addresses expenses to collect a bad debt or repossess an item. The comptroller derives this language from the content deleted from current subsection (d)(3) and (e)(2) and reorganizes it into new clauses (i) through (iii) to improve readability.

The comptroller adds new subparagraph (E) to explain the requirement that the claimant account for all payments and recoveries of a debt. If the claimant does not have the actual payment or recovery amounts the comptroller will estimate this amount. For claims that include accounts sold to a third party, the comptroller will use an industry average for post-sale collections, which is 2.5 times the amount paid to acquire the account. *See* Federal Trade Commission, The Structure and Practices of the Debt Buying Industry, 23 n.99 (January 2013), available at https://www.ftc.gov/sites/default/files/documents/reports/structure-and-practices-debt-buying-industry/debtbuyingreport.pdf (internal citations omitted).

The comptroller deletes the content of paragraph (4), regarding required records, because the information is now in amended paragraph (7). The comptroller also amends the paragraph to address local sales and use tax. The comptroller derives the language from subsection (d)(7) and Tax Code, §151.426(i). This amendment also clarifies that only the retailer that made the sale is entitled to a refund of tax paid on a bad debt or the unpaid portion of the sales price of a taxable item repossessed under a conditional sales contract. A person who is not a retailer is entitled to a credit or refund under this subsection only for state sales and use tax, unless the retailer expressly assigned its rights to a credit or refund.

The comptroller deletes the content of paragraph (5), regarding alternative reporting and recordkeeping methods, because the information is now in amended paragraph (8). The comptroller further amends paragraph (5) and gives it the heading, "Statute of limitations. " The comptroller adds language addressing the statute of limitations based, in part, on the content deleted from subsection (d)(1)(B) and on STAR Accession No. 200203888L (March 22, 2002) (explaining that the assignee of a bad debt deduction is limited to the assignor's time period for claiming a refund). Due to the different reporting timeframes for sales and use tax and federal income taxes, the comptroller clarifies that a claim for a bad debt refund must be made within four years

from the date the account was claimed as a bad debt for federal income tax purposes.

The comptroller deletes the content of paragraph (6), regarding revocation of an alternative reporting or recordkeeping method, because the information is now in amended paragraph (8). The comptroller further amends the paragraph and gives it the heading, "Post refund collection on a bad debt or sale of a repossessed item." The comptroller amends the paragraph to address the taxability of collections on an account after a credit has been taken or a refund has been issued by the comptroller. The comptroller derives this language from current paragraph (9) and Tax Code, §151.426(h).

The comptroller deletes the content of paragraph (7), regarding local taxes, because the information now appears in amended subsection (d)(4). The comptroller further amends paragraph (7) by giving it the title, "Claiming a credit or refund," and providing information on how a person may seek a credit or refund for bad debts and repossessions.

The comptroller adds new subparagraph (A), labeled "Permitted persons," which provides that a person who holds, or held at the time of the sale, a valid Texas sales and use tax permit can take a credit on the person's sales tax report for taxes paid on a sale determined to be a bad debt only if the person files the report electronically. A person who does not file electronically may request a refund of tax paid on a sale determined to be a bad debt by submitting a written refund request. The comptroller derives this language based, in part, on the content deleted from subsection (d)(1)(B) and (C); Tax Code, §§151.426(c) and (e), 111.0626 (Electronic Filing of Certain Reports), 111.104(b) (Refunds); and §3.325 of this title (relating to Refunds and Payments Under Protest).

The comptroller adds new subparagraph (B), labeled "Nonpermitted persons," which provides that a person who does not hold a valid Texas sales and use tax permit may not take a credit on a future sales tax report. Instead, the person may only file a written request for a refund of taxes paid on a sale later determined to be a bad debt or an item repossessed under a conditional sales contract.

The comptroller adds new subparagraph (C), labeled "Records required," which explains that a person claiming a credit or refund under this subsection must provide specific information regarding the claim. The comptroller derives this language from Tax Code, §151.426(e), the content deleted from subsection (d)(4), and current subsection (e)(3).

The comptroller adds new subparagraph (D), labeled "Records required for bad debts acquired by assignment or purchase," which provides that a claimant must maintain and make available to the comptroller additional records when a claim includes tax paid on bad debt accounts acquired from a third party. To provide clarification for auditors and others processing the refund, the comptroller requires an express assignment of the right to a refund of tax paid on a bad debt from the retailer or private label credit provider who transferred the bad debt accounts to the claimant. An assignee who acquires a bad debt account from a third party without an express assignment of the third party's right to a refund is not entitled to a refund under this subsection. New subparagraph (D) also implements the updated Webfile requirements for returns that include credits for tax paid on a bad debt.

The comptroller deletes the content of paragraph (8), defining the term "affiliate," because the definition now appears in new subsection (a). The comptroller amends paragraph (8), by giving it the title "Alternative recordkeeping and tax calculation methods." This paragraph explains how to request comptroller approval to use an alternative method of maintaining necessary records or calculating the amount of a bad debt credit or refund. The comptroller derives the content of amended paragraph (8) from language deleted from subsection (d)(5) and (6). The comptroller also amends the paragraph by adding new subparagraphs (A) through (G) to improve readability, and by correcting internal cross references.

New subparagraph (A) addresses alternative recordkeeping methods, formerly addressed in subsection (d)(5)(A).

New subparagraph (B) addresses alternative methods of reporting sales and use tax responsibilities, formerly addressed in subsection (d)(5)(B).

New subparagraph (C) explains that the comptroller may revoke an approved alternative method. The comptroller derives this language from the content deleted from subsection (d)(6).

New subparagraph (D) provides that if there is a change in the circumstances on which an approved alternative method was based, or if the alternative method used differs from the alternative method that was approved in writing, the person may submit a new written request.

New subparagraph (E) provides that the comptroller's approval of a request for an alternative method is prospective only. See Tax Code, §151.022, which gives the comptroller the authority to prescribe the extent to which a rule shall be applied without retroactive effect.

New subparagraphs (F) and (G) provide that the comptroller's approval of an alternative method does not apply to any other person or any other types of records required to be maintained for any other purpose.

The comptroller deletes paragraph (9), regarding amounts collected on a bad debt after a credit or refund has been issued, because this information now appears in subsection (d)(6).

The comptroller deletes paragraph (10). The principle expressed in the current paragraph remains true that credit or installment sales may not be labeled as bad debts merely for the purpose of delaying the payment of the tax due, but the comptroller has determined that it is not necessary to include this statement in light of the additional guidance provided on bad debts by the other proposed amendments to this section.

The comptroller deletes subsection (e), regarding repossessions, because the amendments to subsection (d) incorporate the information on repossessions. Those amendments are intended to consolidate existing provisions regarding repossessions with the bad debt provisions in subsection (d).

The comptroller reletters subsection (f), regarding interest on sales and use tax, as subsection (e). The comptroller deletes the first sentence of the subsection and relocates it to the end of paragraph (1). The comptroller deletes the statement that the term "credit" includes all deferred payment agreements because new subsection (a)(5) defines the term "credit sale" to include deferred payment agreements. The comptroller makes other nonsubstantive changes for consistency within this section.

The comptroller amends paragraph (1) by giving it the heading, "Cash basis of accounting." The comptroller replaces the phrase "on credit" with the phrase "by means of a credit sale" to use the defined term in new subsection (a)(5).

The comptroller redesignates current paragraphs (2) and (3) as new subparagraphs (A) and (B) without substantive change. The comptroller amends the format of the listed percentages for consistency with other sections of this title. The comptroller renumbers the remaining paragraphs accordingly.

The comptroller amends renumbered paragraph (2) by giving it the heading, "Determining the amount of interest."

The comptroller amends renumbered paragraph (3) by giving it the heading, "Penalty and interest." The comptroller further amends the paragraph to delete the word "Texas" and to add titles of the cited statutes to maintain consistency with citations throughout this title.

The comptroller adds new paragraph (4), labeled "Reporting interest," to provide guidance regarding the reporting of interest charged on the financing of sales and use taxes.

The comptroller reletters subsection (g), regarding trade-ins, as subsection (f). The comptroller deletes the definition of the term "trade-in" because the definition now appears in new subsection (a).

The comptroller amends paragraphs (1), (2), and (3) of this subsection to add headings to make the subsection easier to navigate. The comptroller further amends paragraph (1) by adding the term "seller's" before the phrase "regular course of business" for consistency with existing comptroller guidance. *See* Comptroller's Decision No. 104,720 (2013). The comptroller makes a similar change to paragraph (2). The comptroller amends paragraph (3) to incorporate a reference to §3.336 (Currency, Certain Coins, and Gold, Silver, and Platinum Bullion) of this title.

The comptroller deletes paragraph (4), referring taxpayers to §3.336 of this title for information on bartering for taxable items, because the information now appears in paragraph (3).

The comptroller reletters subsection (h), regarding interest on tax paid in error, as subsection (g). The comptroller amends relettered subsection (g) by adding a statement that tax paid on a bad debt is not tax paid in error and does not accrue interest.

The comptroller deletes paragraph (1), regarding interest on refunds of tax paid on a bad debt, because the information now appears in relettered subsection (g).

The comptroller deletes paragraph (2), regarding interest on bad debt refunds for periods before January 1, 2000, because it is obsolete.

Tom Currah, Chief Revenue Estimator, has determined that during the first five years that the proposed amendment is in effect, the amendment: will not create or eliminate a government program; will not require the creation or elimination of 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 increase or decrease the number of individuals subject to the rules' applicability; and will not positively or adversely affect this state's economy. This proposal amends a current rule.

Mr. Currah also has determined that for each year of the first five years the rule is in effect, the proposed amendment would benefit the public by conforming the rule to current agency policy. This rule is proposed under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses or rural communities The proposed amendment would have no significant fiscal impact on the state government, units of local government, or individuals. There would be no anticipated significant economic cost to the public.

Comments on the proposal may be submitted to Teresa G. Bostick, Director, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711-3528. Comments must be received no later than 30 days from the date of publication of the proposal in the *Texas Register.*

This amendment is proposed under Tax Code, §111.002 (Comptroller's Rules; Compliance; Forfeiture), which provides the comptroller with the authority to prescribe, adopt, and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

The proposed amendments implement Tax Code, §§111.0041 (Records; Burden To Produce and Substantiate Claims), 111.104 (Refunds), 111.1042 (Tax Refund: Informal Review), 111.107 (When Refund Or Credit Is Permitted), 151.007 ("Sales Price" or "Receipts"), 151.408 (Accounting Basis for Reports), 151.426 (Credits and Refunds for Bad Debts, Returned Merchandise, and Repossessions), and 151.428 (Interest Charged by Retailer on Amounts of Taxes).

§3.302. Accounting Methods, Credit Sales, Bad Debt Deductions, Repossessions, Interest on Sales Tax, and Trade-Ins.

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

(1) Affiliate--Any entity that would be classified as a member of an affiliated group under 26 U.S.C. §1504 (Definitions).

(2) Assignee--A person to whom either a retailer who made the sale or a private label credit provider transfers the right to claim a credit or refund of Texas sales or use tax paid on a bad debt via a written assignment with specific language transferring the right to claim a credit or refund under this section.

(3) Bad debt--Any portion of the sales price of a taxable item that a retailer or private label credit provider cannot collect, and that has been determined to be worthless and actually charged off for federal income tax purposes , provided that the bad debt amount for calculation of the refund or credit is limited to bad debts related to sales that were made by the retailer with whom the person that extended credit entered into the private label credit agreement.

(4) Credit sale--Any sale in which the terms of the sale provide for deferred payment of the sales price. Credit sales include installment sales, sales under conditional sales contracts and revolving credit accounts, and sales for which another person extends credit to the purchaser under a private label credit agreement.

(5) Private label credit agreement--An agreement by which a person agrees to extend to purchasers for credit sales with a retailer or the retailer's affiliates, or franchisees, often using a credit card or other instrument bearing the name or logo of the retailer or the retailer's affiliates or franchisees.

(6) Private label credit provider--A person who extends credit to a purchaser under a private label credit agreement.

(7) Trade-in--Tangible personal property taken by a seller as all or a part of the consideration for the sale of a taxable item when the property is of a type normally sold by the seller in the regular course of business, and the seller separately states the value of the property to the purchaser by means of an invoice, billing, sales slip, ticket, or contract.

(b) [~~(a)~~] Accounting methods.

(1) Reporting sales and use tax. For sales and use tax purposes, retailers may use a cash basis, an accrual basis, or any generally recognized accounting basis that accurately [~~correctly~~] reflects the operation of their business. A retailer [~~Retailers~~] who wants [~~wish~~] to use an accounting method [~~system~~] to report tax that is not on a pure cash or accrual basis or that is not a generally [~~commonly~~] recognized accounting method must [~~system should~~] obtain prior written approval from the comptroller.

(2) Reporting sales and use tax on rentals and leases. Paragraph (1) of this subsection does not apply to the reporting of sales and use tax on rentals and leases of tangible personal property. See §3.294 of this title (relating to Rental and Lease of Tangible Personal Property [~~Rentals and Leases of Taxable Items~~]) for the accounting of rentals and leases.

(c) [~~(b)~~] Credit sales.

[~~(1) Credit sales include all sales in which the terms of the sale provide for deferred payments of the purchase price. Credit sales include installment sales, sales under conditional sales contracts and revolving credit accounts, and sales by a retailer for which another person extends credit to the purchaser under a retailer's private label credit agreement.~~]

(1) [~~(2)~~] Service charges. Sales and use tax is due on insurance, interest, finance and carrying charges, and all other service charges incurred as a part of a credit sale unless these charges are stated separately to the purchaser [~~customer~~] by such means as an invoice, billing, sales slip or [~~,~~] ticket, or contract.

(2) [~~(3)~~] Accounting methods. Except as provided by paragraph (D), sales and use tax must [~~Tax is to~~] be reported on a credit sale based upon the accounting method that the retailer uses for its regular books and records.

(A) Accrual basis. If a [~~the~~] retailer uses [~~is on~~] an accrual basis of accounting for sales and use tax purposes, the entire amount of sales and use tax is due and must be reported in the reporting period in which [~~at the time~~] the sale occurs [~~is made~~].

(B) Cash basis. If a [~~the~~] retailer uses [~~is on~~] a cash basis of accounting for sales and use tax purposes, the payment received from the purchaser [~~customer~~] includes a proportionate amount of sales and use tax, sales price [~~receipts~~], and may [~~also~~] include finance charges. Sales and use tax is due and [~~Tax~~] must be reported in the reporting period in which the payment is received based upon the [~~actual~~] cash collected [~~during the reporting period~~], excluding separately stated insurance, interest, or finance and carrying charges.

(C) Modified basis. If a [~~the~~] retailer uses an accounting method [~~basis~~] that is not a pure cash or accrual basis, sales and use tax must be reported in a consistent manner that accurately reflects the realization of income from the credit sales on the retailer's books and records. The retailer must obtain prior written approval from the comptroller to use an accounting method that is not a generally recognized method.

(D) Cash basis reporting option. A retailer who uses the accrual basis of accounting for its books and records may elect to use the cash basis of accounting for sales and use tax reporting purposes as long as the retailer reports the tax in a manner that accurately reflects the realization of income from cash and credit sales on the retailer's books and records. A change from the accrual basis to the cash basis for reporting sales and use tax is prospective only, and the retailer must establish a procedure to accurately account for sales and use tax received from purchasers during the transition period.

(3) [~~(c)~~] Transfer or sale of sales contracts and accounts receivable. At the time a retailer sells, factors, or assigns [~~A retailer may sell, factor, or assign~~] to a third party the retailer's right to receive all payments due under a credit sale[~~. At the time the contract or receivable is sold, factored, or assigned~~], the unpaid sales and use tax on all remaining payments becomes due immediately [~~on all remaining payments~~]. The retailer is responsible for reporting all remaining sales and use tax due on a [~~under the~~] credit sale to the comptroller in the reporting period in which the contract or receivable is sold, factored, or assigned. No reduction in the amount of sales and use tax to be reported and paid by the retailer is allowed if the transfer to the third party is for a discounted amount. This paragraph [~~section~~] does not apply to a retailer's [~~seller's~~] assignment or pledge of contracts or accounts receivable to a third party as loan collateral.

(d) Bad debts and repossessions.

[~~(1) Any portion of the sales price of a taxable item that the retailer or private label credit provider cannot collect is considered to be a bad debt.~~]

(1) [~~(A)~~] Bad debts during a reporting period. A retailer is not required to report sales and use tax on any amount that has been entered in the retailer's books as a bad debt during the same reporting period in which the sale occurred [~~was made~~], and that will be taken as a deduction for federal income tax purposes on the retailer's federal income tax return during the same or subsequent reporting period.

[~~(B) A retailer is entitled to a credit for tax reported and paid on an account later determined to be a bad debt. A retailer may take a deduction on the retailer's report form, or obtain a refund from the comptroller, in the reporting period in which the retailer's books reflect the bad debt. Deductions and refunds due to bad debts are limited to four years from the date the account is entered in the retailer's books as a bad debt.~~]

[~~(C) A retailer who extends credit to a purchaser on an account that is later determined to be a bad debt, a person who extends credit to a purchaser under a retailer's private label credit agreement on an account that is later determined to be a bad debt, or an assignee or affiliate of either who extends credit on an account that is later determined to be a bad debt, is entitled to a credit or refund for the tax paid to the comptroller on the bad debt.~~]

(2) Persons who may claim a credit or refund. [~~The amount of the bad debt may include both the sales price of the taxable item and nontaxable charges, such as finance charges, late charges, or interest that were separately billed to the customer. A deduction may only be claimed on that portion of the bad debt that represents the amount reported as subject to tax. In determining that amount, all payments and credits to the account may be applied ratably against the various charges that comprise the bad debt, except as provided by paragraph (3) of this subsection.~~]

(A) Only a retailer, private label credit provider, or assignee or affiliate of either may claim a credit or refund for sales and use tax paid on the bad debt or the unpaid portion of the sales price of a taxable item repossessed under a conditional sales contract.

(B) Only one person is entitled to a credit or refund for sales and use tax paid to the comptroller on each bad debt or repossession.

(3) Determining the amount of the bad debt or the unpaid portion of the sales price of a taxable item repossessed under a conditional sales contract. [~~A retailer, private label credit provider, or assignee or affiliate may not deduct from the amount subject to tax to be reported the expense of collecting a bad debt, or the amount that a third~~

party has retained or which has been paid to a third party for the service of collecting a bad debt.]

(A) The amount is the sales price of the taxable item less all payments and recoveries, including payments applied to interest, fees, and other expenses relating to the sales price of the taxable item under the credit agreement and the proceeds from the sale of an account to a third party.

(B) The sales price does not include nontaxable separately stated charges such as finance, carrying, insurance or service charges; or interest from credit extended on sales of taxable items under a conditional sales contract or other contract providing for the deferred payment of the sales price.

(C) For a worthless account that includes charges for taxable and nontaxable items, payments on the account are applied to the charges occurring first in time and prorated between taxable and nontaxable charges occurring at the same time.

(D) Expenses to collect a bad debt or repossess an item. A person claiming a credit or refund under this subsection cannot add to the credit or refund amount:

(i) the expense of collecting a bad debt;

(ii) the expense of repossessing or selling a repossessed item; or

(iii) the amount that a third party has retained or which has been paid to a third party for the service of collecting a bad debt or the service of repossessing or selling a repossessed item.

(E) Any person claiming a bad debt refund or credit must also account for all recoveries on an account. If the retailer or private label credit provider claims a refund that includes accounts sold to a third party, the retailer or private label credit provider must provide the detailed collection amounts for sold accounts. If the person claiming the refund does not have the actual collection information, the comptroller will estimate the post-sale collections in calculating the amount eligible for a refund. The comptroller will estimate the post-sale collections at a rate of 2.5 times the proceeds from the sale of the account.

(4) Local sales and use tax. Only the retailer who made the sale, or an affiliate or assignee of the retailer, is entitled to a credit or refund for local sales and use tax paid on a bad debt or the unpaid portion of the sales price of a taxable item repossessed under a conditional sales contract. A person who is not the retailer who made the sale is entitled to a credit or refund under this subsection only for state sales and use tax imposed by Tax Code, §151.051 (Sales Tax Imposed), or §151.101 (Use Tax Imposed), unless the retailer who made the sale expressly assigned its rights to a credit or refund under this subsection. [To claim bad debt deductions, the records of the person who claims the bad debt deduction must show:]

[(A) date of original sale and name and Texas sales tax permit number of the retailer;]

[(B) name and address of purchaser;]

[(C) amount that the purchaser contracted to pay;]

[(D) taxable and nontaxable charges;]

[(E) amount on which the retailer reported and paid Texas tax;]

[(F) all payments or other credits applied to the account of the purchaser;]

[(G) evidence that the uncollected amount has been designated as a bad debt in the books and records of the person who claims the bad debt deduction, and that the amount has been or will be claimed as a bad debt deduction for income tax purposes;]

[(H) city, county, transit authority, or special purpose district to which local taxes were reported; and]

[(I) the unpaid portion of the assigned sales price.]

(5) Statute of limitations. A claim for a credit or a refund under this subsection must be submitted within four years from the date a bad debt is actually charged off for federal income tax purposes or the date the taxable item is repossessed, whichever is applicable. [A person who is otherwise qualified to claim a bad debt deduction, and whose volume and character of uncollectible accounts warrants an alternative method of substantiating the reimbursement or credit, may:]

[(A) maintain records other than the records specified in paragraph (4) of this subsection if:]

[(i) the records fairly and equitably apportion taxable and nontaxable elements of a bad debt, and substantiate the amount of Texas sales tax imposed and remitted to the comptroller with respect to the taxable charges that remain unpaid on the debt; and]

[(ii) the comptroller approves the procedures used; or]

[(B) implement a system to report its future tax responsibilities based on a historical percentage calculated from a sample of transactions if:]

[(i) the system utilizes records provided by the person claiming the credit or reimbursement and the person who reported and remitted such tax to the comptroller; and]

[(ii) the comptroller approves the procedures used.]

(6) Post refund collection on a bad debt or sale of a repossessed item. A person who later collects any payment on a bad debt or sells a repossessed item for which a credit or refund was claimed must report the total amount collected or received from the sale as a taxable sale in the reporting period in which the collection or sale occurs. [The comptroller may revoke the authorization to report under paragraph (5)(B) of this subsection if the comptroller determines that the percentage being used is no longer representative because of:]

[(A) a change in law, including a change in the interpretation of an existing law or rule; or]

[(B) a change in the taxpayer's business operations.]

(7) Claiming a credit or refund. [A person who is not a retailer may claim a credit or reimbursement authorized by paragraph (1)(C) of this subsection only for taxes imposed by Tax Code, §151.051 or §151.101.]

(A) Permitted persons. A person who holds, or held at the time of the sale, a valid Texas sales and use tax permit and who is otherwise entitled to claim a credit or refund authorized under this subsection may:

(i) claim a credit on the person's sales and use tax report for tax paid on a bad debt only if the person files the tax report electronically and claims the credit in the reporting period in which the person's books reflect the bad debt or subsequent reporting periods; or

(ii) request a refund in writing from the comptroller for sales and use tax paid on a bad debt.

(B) Non-permitted persons. A person who does not hold a valid Texas sales and use tax permit but is otherwise entitled

to a credit or refund under this subsection can only request a refund in writing from the comptroller for sales and use tax paid to the comptroller on the bad debt or the unpaid portion of the sales price of a taxable item repossessed.

(C) Records required. A person claiming a credit or requesting a refund for sales and use taxes paid on a bad debt or the unpaid portion of the sales price of a taxable item repossessed must maintain and make available to the comptroller:

(i) date of original credit sale and name and Texas sales and use tax permit number of the retailer who collected and remitted the sales and use tax to the comptroller;

(ii) amount that the purchaser contracted to pay;

(iii) taxable and nontaxable charges;

(iv) all other payments or other credits applied to the account of the purchaser;

(v) evidence that the uncollected amount has been designated as a bad debt in the books and records of the person who claims the bad debt deduction, and that the amount has been claimed as a bad debt deduction for federal income tax purposes;

(vi) identification of each city, county, transit authority, or special purpose district to which local taxes were reported if the claimant is claiming a refund or credit of local taxes;

(vii) the sales and use tax collected and remitted to the comptroller; and

(viii) any additional records requested by the comptroller to verify a credit or refund claim.

(D) Records required for bad debts acquired by assignment or purchase. In addition to the requirements in subparagraph (C) of this paragraph, an assignee claiming a credit or requesting a refund for sales and use tax paid on a bad debt must maintain and make available to the comptroller the following additional information:

(i) amount of bad debt acquired;

(ii) name and taxpayer number of the original retailer who collected and remitted the sales or use tax;

(iii) name and taxpayer number of the person from whom the assignee acquired the bad debt; and

(iv) a written assignment with specific language transferring the right to a credit or refund of Texas sales or use tax paid on a bad debt executed by the person from whom the assignee acquired the bad debt.

(8) Alternative recordkeeping and tax calculation methods. A person who is otherwise qualified to claim a credit or request a refund under this subsection, and whose volume and character of uncollectible accounts warrants an alternative method of substantiating the refund or credit, may request approval from the comptroller to use an alternative method of maintaining records, or an alternative method of calculating a credit or refund, by submitting a written request to the Audit Division, P.O. Box 13528, Austin, Texas 78711-3528. [~~For purposes of this section, "affiliate" means any entity or entities that would be classified as a member of an affiliated group under 26 U.S.C. §1504.~~]

(A) The comptroller may approve a request to maintain records other than the records specified in paragraph (7)(C) and (D) of this subsection if the records fairly and equitably apportion taxable and nontaxable elements of an uncollectible account or conditional sales contract, and substantiate the amount of Texas sales tax imposed and remitted to the comptroller with respect to the bad debt or unpaid sales price of a taxable item under a conditional sales contract.

(B) The comptroller may approve a request to implement a system to report future sales and use tax responsibilities based on a historical percentage calculated from a sample of transactions if the system utilizes records provided by the person claiming the credit or refund and the person who reported and remitted such tax to the comptroller.

(C) The comptroller may revoke the authorization to report under paragraph (8)(A) or (B) of this subsection if the comptroller determines that the percentage being used is not representative of the taxpayer's business operations or because of a change in law, including a change in the interpretation of an existing law or rule.

(D) A person may submit a new request meeting the requirements of this paragraph after a revocation. The new request should use a method that differs from the alternative method that the comptroller revoked.

(E) Approval of an alternative method is prospective only and may not be used to satisfy the requirements of paragraph (7)(C) and (D) of this subsection, concerning records required, for periods prior to the date specified in the written approval.

(F) The approval of an alternative method applies to only the person who submitted the written request. The approval does not extend to any other person, regardless of whether the requesting person and the other person are affiliates or file a consolidated federal income tax return.

(G) Approval of an alternative recordkeeping method does not apply to any other recordkeeping requirements for any other purpose.

[~~(9) If a retailer or other person later collects all or part of an account for which a bad debt deduction or write-off was claimed, the amount collected must be reported as a taxable sale in the reporting period in which such collection was made.~~]

[~~(10) Credit or installment sales may not be labeled as bad debts merely for the purpose of delaying the payment of the tax.~~]

[~~(e) Repossessions.~~]

[~~(1) When taxable items upon which the retailer or other person has paid tax are repossessed, the retailer or other person is allowed a credit or deduction for that portion of the actual purchase price that remains unpaid. The deduction must not include any nontaxable charges that were a part of the original sales contract. Any payments that the purchaser made prior to repossession must be applied ratably against the various charges in the original sales contract.~~]

[~~(2) A retailer or other person may not deduct from the tax to be reported the expense of collecting an account receivable, or the amount that a third party has retained or that has been paid to a third party for the service of collecting an account or repossessing or selling a repossessed item.~~]

[~~(3) To claim a deduction or credit the person who claims the deduction or credit must be able to provide detailed records that show:~~]

[~~(A) date of original sale and name and Texas sales tax permit number of retailer;~~]

[~~(B) name and address of purchaser;~~]

[~~(C) amount that the purchaser contracted to pay;~~]

[~~(D) taxable and nontaxable charges;~~]

[(E) amount on which retailer reported and paid Texas tax;]

[(F) all payments or other credits applied to the account of the purchaser;]

[(G) city, county, transit authority or special purpose district to which local taxes were reported; and]

[(H) the unpaid portion of the sale price assigned.]

[(4) Sales tax is due on the sale of a repossessed item, irrespective of whether a vendor, mortgagee, secured party, assignee, trustee, sheriff, or an officer of the court has sold the item, unless the sale is otherwise exempt. If the vendor, mortgagee, secured party, assignee, trustee, sheriff, or officer of the court does not collect the tax, the purchaser must remit the tax directly to the comptroller.]

(e) [(f)] Interest on sales and use tax. [This section will refer to the terms "interest" and "time price differential" as interest. The term "credit" includes all deferred payment agreements.]

(1) Cash basis of accounting. Sellers who use [on] a cash basis of accounting and who sell taxable items by means of a credit sale [on credit] and charge interest on the amount of credit extended, including sales and use tax, are required to remit to the comptroller a portion of the interest that has been collected on the state and local sales and use taxes.

(A) [(2)] If the amount of interest charged on the sales and use tax is 18% or less, the seller must remit to the comptroller one-half of the interest charged on the sales and use tax.

(B) [(3)] If the amount of interest charged on the sales and use tax is greater than 18%, the seller must remit the amount of interest charged less 9.0% [9%]. For example, 21% charged less 9.0% [9%] deduction equals 12% interest remitted. A seller will not be allowed the 9.0% [9%] deduction if the interest rate charged on sales and use tax differs from the interest rate charged on the sales price of the taxable item.

(2) [(4)] Determining the amount of interest. In determining the amount of interest to be remitted to the comptroller, a seller does not need to calculate the interest on each individual account. A formula for the calculation may be used if the formula correctly reflects the amount of interest collected. The formula is [will be] subject to verification upon audit of the seller's [taxpayer's] records.

(3) [(5)] Penalty and interest. Except for the provisions of [Texas] Tax Code, §151.423 (Reimbursement to Taxpayer for Tax Collections) and §151.424 (Discount for Prepayments), all reporting, collection, refund, and penalty provisions of [Texas] Tax Code, Chapter 151, including assessment of penalty and interest, apply to interest due.

(f) [(g)] Trade-ins. [In this subsection, a trade-in is considered as a taxable item that is being used to reduce the purchase price of another taxable item.]

(1) Acceptable trade-in. The sales price of a taxable item does not include the value of a trade-in that a seller takes as all or part of the consideration for a sale of a taxable item of the same type that is normally sold in the seller's regular course of business. For example, sales and use tax will be due only on the difference between the amount allowed on an old piano taken in trade and the sales price of a new piano.

(2) Unacceptable trade-in. The sales price of a taxable item does include the value of a trade-in that a seller takes as all or part of the consideration for the sale of a taxable item, if the trade-in is a different type from the type normally sold by the seller in the regular course of business. For example, a seller who sells only [of] pianos who takes a desk in trade as part of the sales price of a piano collects [would collect] sales and use tax on the retail sales price of the piano without any deduction for the value of the desk. In this situation, the seller and buyer are considered to be bartering. However, if the [a] seller of pianos is also a seller of desks, the value of the desk is [would be] allowed as a trade-in.

(3) Tax free items traded-in. Sellers [Persons] who remove items from a tax-free inventory for use as a trade-in owe sales and use tax on their purchase [the cost] price of the items. If both parties to a transaction remove items from a tax-free inventory to trade for other items that each party will use, the transaction is [will be] regarded as bartering [barters] by both parties. Each party to the barter is [will be] required to collect sales and use tax on the retail sales price of the item being transferred. For example, a seller of drill pipe trades pipe to a seller of appliances in exchange for a refrigerator. Both sellers are trading the respective items for use, not resale. The pipe seller must collect sales tax on the retail sales price of the pipe. The appliance seller must collect sales tax on the retail sales price of the refrigerator. See §3.336 of this title (relating to Currency, Certain Coins, and Gold, Silver, and Platinum Bullion) for information on persons who barter for taxable items with gold, silver, diamonds, or precious metals.

[(4) See §3.336 of this title (relating to Sales of Gold, Silver, Coins, and Currency) for information on persons who barter for taxable items with gold, silver, diamonds, or precious metals.]

(g) [(h)] Tax Code, §111.064, provides that interest will be paid on tax amounts found to be erroneously paid and claimed on a request for refund or in an audit. See also §3.325 of this title (relating to Refunds, Interest, and Payments Under Protest). Tax paid on an account that is later determined to be uncollectible and written off as a bad debt for federal tax purposes is not tax paid in error and does not accrue interest.

[(1) Tax paid on an account that is later determined to be uncollectible and written off as a bad debt for federal tax purposes is not tax paid in error and does not accrue interest.]

[(2) A request for refund, or an overpayment of tax in an audit, for a report period due before January 1, 2000, does not accrue interest.]

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 10, 2021.

TRD-202103590
William Hamner
Special Counsel for Tax Administration
Comptroller of Public Accounts
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 475-2220

♦ ♦ ♦

TITLE 40. SOCIAL SERVICES AND ASSISTANCE

PART 19. DEPARTMENT OF FAMILY AND PROTECTIVE SERVICES

CHAPTER 707. CHILD PROTECTIVE INVESTIGATIONS
SUBCHAPTER C. CHILD CARE INVESTIGATIONS

The Department of Family and Protective Services (DFPS) proposes amendments to §§707.745, 707.765, 707.825, and 707.857 in Chapter 707, concerning Child Protective Investigations.

BACKGROUND AND PURPOSE

The purpose of the rule changes is to reflect notification requirements of investigation findings to a residential child care operation after the completion of a child abuse, neglect, or exploitation investigation involving the operation's staff.

The amendments were originally published for public comment in the October 16, 2020, issue of the *Texas Register* (45 TexReg 7404) but were not adopted until June 10, 2021. However, Texas Government Code §2001.027 requires that rule changes be adopted or withdrawn within six months of the date of publication of notice of the proposed rules in the *Texas Register.* As the rules were not adopted within six months of publication of the notice of proposed rule, DFPS has requested the rule amendments be withdrawn and will be re-publishing the rules.

DFPS will be submitting these rules for proposal without any changes from the rules that were originally submitted for adoption. See the June 4, 2021 *Texas Register* issue (45 TexReg 4780).

SECTION-BY-SECTION SUMMARY

The proposed amendments to §707.745 consist of clarifying the notification process to child care operations after the DFPS investigation is complete. Specifically, if DFPS conducts an investigation at: (1) a residential child care operation, DFPS will notify the person in charge of the operation of the investigation findings and name of the alleged or designated perpetrator within five calendar days after the investigation is closed. If the person in charge, administrator, or the director is the perpetrator, DFPS will notify the permit holder or other appropriate person; (2) a child day care operation, the Health and Human Services Child Care Licensing inspector assigned to monitor the operation will notify the operation of the results of the DFPS investigation after the inspector makes determinations about any minimum standard violations.

The proposed amendments to §707.765 include: (1) adding residential child care operations and a state protection and advocacy system, such as Disability Rights Texas, to the list of entities permitted to obtain confidential abuse, neglect, and exploitation information; and (2) clarifying that a child day care operation cited for a deficiency by Health and Human Services Child Care Licensing as a result of the DFPS investigation is permitted to obtain confidential abuse, neglect, and exploitation information.

The proposed amendments to §707.825 specify that if an operation was previously notified of investigation findings when DFPS completed its investigation and the abuse, neglect, or exploitation finding is reversed or altered pursuant to an administrative review of investigation findings, DFPS will notify the child care operation of the change within five calendar days.

The proposed amendments to §707.857 specify that if an operation was previously notified of investigation findings when DFPS completed its investigation and an administrative law judge: (1) reverses or alters the abuse, neglect, or exploitation finding, DFPS will notify the child care operation of the change within five calendar days; and (2) upholds the finding, DFPS will notify the child care operation that the finding was sustained after an appeal has occurred or the timeframe for filing an appeal has expired. In addition, DFPS is updating the current rule language to change "must" to "will" so that the language is consistent with the language used in the other rules in division 3 of subchapter C. This change is non-substantive as the agency construes "will" and "must" as substantively identical, and therefore, despite the language change, DFPS' existing notification requirements are not changing.

FISCAL NOTE

David Kinsey, Chief Financial Officer of DFPS, has determined that 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

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

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

(2) implementation will not affect the number of employee positions;

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

(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 an existing regulation;

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

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

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

Mr. Kinsey 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.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the rules as proposed.

There is no anticipated negative impact on local employment.

COSTS TO REGULATED PERSONS

Pursuant to subsection (c)(7) of Texas Government Code, §2001.0045, the statute does not apply to a rule that is adopted by DFPS.

PUBLIC BENEFIT

Jim Sylvester, former Associate Commissioner for Child Protective Investigations, and Justin Lewis, director of Child Care Investigations, have determined that for each year of the first five years the rules are in effect, the updates will further efforts to

ensure child safety and well-being of children in child care operations.

REGULATORY ANALYSIS

DFPS has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225.

TAKINGS IMPACT ASSESSMENT

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

PUBLIC COMMENT

Comments and questions on this proposal must be submitted within 30 days of publication of the proposal in the *Texas Register.* Electronic comments and questions may be submitted to RULES@dfps.state.tx.us. Hard copy comments may be submitted to the DFPS Rules Coordinator, Legal Services 20R16, Department of Family and Protective Services E-611, P.O. Box 149030, Austin, Texas 78714-9030.

DIVISION 3. NOTIFICATION

40 TAC §707.745

STATUTORY AUTHORITY

The proposed amended section implements the Child Abuse Prevention and Treatment Act and Texas Human Resources Code §40.006.

The amended section is proposed under Human Resources Code (HRC) §40.027, which provides that the DFPS commissioner shall adopt rules for the operation and provision of services by the department.

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

§707.745. Whom will we inform of the abuse, neglect, or exploitation investigation results?

(a) Once the abuse, neglect, or exploitation investigation is complete, we will provide the following written notifications:

(1) - (2) (No change.)

(3) Notification of the investigation findings to the parent of the alleged victim. If the alleged victim is a child in the conservatorship of the Texas Department of Family and Protective Services, we will notify the alleged victim's Child Protective Services' caseworker; [~~and~~]

(4) If the investigation occurred at a residential child care operation, notification of the investigation findings and the name of the person alleged or designated as a perpetrator of abuse, neglect, or exploitation to the person in charge of the operation within five calendar days after the investigation is closed. If the person in charge, the administrator, or the director of the operation is the perpetrator, we will notify the permit holder or other appropriate person; and

(5) Notification to the reporter of the completion of the investigation within five calendar days after the investigation is closed.

(b) If the investigation occurred at a child day care operation, the [~~The~~] Child Care Licensing inspector assigned to monitor the operation will notify the [~~child care~~] operation of the results of our investigation after the inspector makes determinations about any minimum standard violations.

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 13, 2021.

TRD-202103612
Vicki Kozikoujekian
General Counsel
Department of Family and Protective Services
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 929-6862

DIVISION 4. CONFIDENTIALITY

40 TAC §707.765

The proposed amended section implements the Child Abuse Prevention and Treatment Act and Texas Human Resources Code §40.006.

The amended section is proposed under Human Resources Code (HRC) §40.027, which provides that the DFPS commissioner shall adopt rules for the operation and provision of services by the department.

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

§707.765. Who may obtain confidential abuse, neglect, and exploitation investigation information from the Child Care Investigation's file made confidential under the federal Child Abuse Prevention and Treatment Act and Texas Human Resources Code (HRC) §§40.005 and 42.004?

(a) The following may obtain confidential abuse, neglect, and exploitation investigation information from us subject to the limitations described in §707.767 (relating to Are there any portions of the abuse, neglect, or exploitation investigation records that may not be released to anyone?) and §707.769 (relating to Who can review or have a copy of a photograph or an audio or visual recording, depiction, or documentation of a child that is in the abuse, neglect, or exploitation investigation records maintained by us?) in this division:

(1) - (7) (No change.)

(8) A residential child care operation;

(9) [~~(8)~~] A child day care operation cited for a deficiency by CCL as a result of the investigation;

(10) [~~(9)~~] A single-source continuum contractor (SSCC) for community-based care when:

(A) The SSCC subcontracts with the child care operation where the investigation occurred;

(B) The operation has signed a release of information; and

(C) CCL cited the operation for a deficiency as a result of the investigation;

(11) [~~(10)~~] An administrative law judge who conducts a due process hearing related to a finding of abuse, neglect, or exploitation or related to an enforcement action taken by CCL or another state agency as a result of the finding. See division 7 of this subchapter (relating to Due Process Hearings);

(12) [~~(11)~~] A judge of a court of competent jurisdiction in a criminal or civil case arising out of an investigation of child abuse, neglect, or exploitation, if the judge:

(A) provides notice to DFPS and any other interested parties;

(B) after reviewing the information, including audio and/or videotapes, determines that the disclosure is essential to the administration of justice and will not endanger the life or safety of any individual; and

(C) includes in the disclosure order any safeguards that the court finds appropriate to protect the interest of the child involved in the investigation;

(13) [~~(12)~~] According to Texas Family Code (TFC) §162.0062, a prospective adoptive parent of a child who is the subject of the investigation or who is the alleged or designated perpetrator in the investigation;

(14) [~~(13)~~] A child care licensing agency or child welfare agency from another state that requests information on the alleged perpetrator as part of a background check or to assist in its own child abuse, neglect, or exploitation investigation; [~~and~~]

(15) A state protection and advocacy system, such as Disability Rights Texas, that is representing or is authorized by state or federal law to represent a child that is the subject of the investigation; and

(16) [~~(14)~~] Any other person authorized by state or federal law to have a copy.

(b) - (c) (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 13, 2021.

TRD-202103615
Vicki Kozikoujekian
General Counsel
Department of Family and Protective Services
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 929-6862

♦ ♦ ♦

DIVISION 6. ADMINISTRATIVE REVIEWS

40 TAC §707.825

The proposed amended section implements the Child Abuse Prevention and Treatment Act and Texas Human Resources Code §40.006.

The amended section is proposed under Human Resources Code (HRC) §40.027, which provides that the DFPS commissioner shall adopt rules for the operation and provision of services by the department.

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

§707.825. What actions regarding an abuse, neglect, or exploitation finding may we take at the conclusion of the administrative review?

(a) (No change.)

(b) If the finding is reversed or altered, we will:

(1) update our records to reflect the change; and[~~.~~]

(2) inform any operation previously notified of the investigation findings under §707.745(a)(4) of division 2 (relating to Whom will we inform of the abuse, neglect, or exploitation investigation results?) of the reversal or change within five calendar days.

(c) If the finding is reversed, we will also remove your name from the Texas Department of Family and Protective Services Central Registry.

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 13, 2021.

TRD-202103617
Vicki Kozikoujekian
General Counsel
Department of Family and Protective Services
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 929-6862

♦ ♦ ♦

DIVISION 7. DUE PROCESS HEARINGS

40 TAC §707.857

The proposed amended section implements the Child Abuse Prevention and Treatment Act and Texas Human Resources Code §40.006.

The amended section is proposed under Human Resources Code (HRC) §40.027, which provides that the DFPS commissioner shall adopt rules for the operation and provision of services by the department.

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

§707.857. What actions must we take in response to an administrative law judge's action regarding an abuse, neglect, or exploitation finding?

(a) If the administrative law judge (ALJ) alters or reverses the finding, [~~then~~] we will [~~must~~]:

(1) update our records to reflect the change; and [~~.~~]

(2) inform any operation previously notified of investigation findings under §707.745(a)(4) of division 2 (relating to Whom will we inform of the abuse, neglect, or exploitation investigation results?) of the reversal or change within five calendar days.

(b) If the ALJ reverses the finding, we will [~~must~~] also remove your name from the Texas Department of Family and Protective Services (DFPS) Central Registry.

(c) [~~(b)~~] If the ALJ upholds the finding, [~~then~~] we will [~~must~~]:

(1) change your designation from a "designated perpetrator" to a "sustained perpetrator" in the DFPS Central Registry; and[~~.~~]

(2) notify any operation previously notified of investigation findings under §707.745(a)(4) of division 2 (relating to Whom will we inform of the abuse, neglect, or exploitation investigation results?) of the sustained finding after an appeal has occurred or the timeframe for filing an appeal has expired.

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 13, 2021.

TRD-202103619
Vicki Kozikoujekian
General Counsel
Department of Family and Protective Services
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 929-6862

♦ ♦ ♦

PART 21. TEXAS COUNCIL FOR DEVELOPMENTAL DISABILITIES

CHAPTER 876. GENERAL PROVISIONS

40 TAC §876.9

The Texas Council for Developmental Disabilities (Council) proposes amendments to §876.9, concerning Charges for Access to Public Records.

FISCAL NOTE Beth Stalvey, PhD, Council Executive Director, has determined for each year of the first five years that the rule will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the rule as proposed.

GOVERNMENT GROWTH IMPACT STATEMENT TCDD has determined that during the first five years that the rule will be in effect:

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

(2) implementation of the proposed rule will not affect the number of TCDD employee positions;

(3) implementation of the proposed rule will result in no assumed change in future legislative appropriations;

(4) the proposed rule will not affect fees paid to the agency;

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

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

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

(8) the proposed rule 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 rule does 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 rule is 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 October 25, 2021, 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.

§876.9. Charges for Access to Public Records

(a) The charge to any person requesting copies of any public record of the Council will be the charge established by the Texas Government Code, Chapter 552 - Public Information Act [~~Buildings and Procurements Commission at 1 TAC §§111.61-111.70~~].

(b) The Council may reduce or waive these charges at the discretion of the executive director if there is a public benefit.

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 13, 2021.

TRD-202103624
Beth Stalvey
Executive Director
Texas Council for Developmental Disabilities
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 948-2035

♦ ♦ ♦

CHAPTER 877. GRANT AWARDS

40 TAC §§877.1, 877.2, 877.4

The Texas Council for Developmental Disabilities (Council) proposes amendments to §877.1, concerning General Provisions; §877.2, concerning Application and Review Process; and to §877.4, concerning Appeal of Funding Decisions.

The purpose of the amendments to §877.1 and §877.2 is to apply consistent language to all sections regarding the Council Request for Applications process. The purpose of the amendment to §877.4 is to clarify the source material for the agency appeals process.

Beth Stalvey, Council Executive Director, has determined there is no fiscal implications to these amendments.

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 October 25, 2021, 31 days after 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 [~~proposals~~] from state agencies, non-profit organizations, or private for profit organizations that have organizational expertise related to the requirements of the solicitation [~~proposal~~].

(c) The Council may accept unsolicited [~~proposals or unsolicited~~] ideas for future projects consistent with Council policies and procedures.

(d) The Council may develop projects with organizations without competitive applications [~~proposals~~] 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 [~~proposals~~] or by state or federal requirements.

(k) No organization shall receive more than three (3) direct grants from the Council at any time.

§877.2. Application and Review Process.

(a) All requests for applications [~~proposals~~] 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 [~~Proposal~~] information for each request for application [~~proposal~~] shall be available upon request from Council offices and will be made available at the Council's website.

(c) 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 [~~proposals~~].

(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.

§877.4. Appeal of Funding Decisions.

Appeals may be submitted from applicants for grants who did not receive funding, or from grantees whose grants have not been awarded continuation funding. The appeals process adopted by the Council shall be included in the agency grants manual [~~grant application materials~~].

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 13, 2021.

TRD-202103625

Beth Stalvey
Executive Director
Texas Council for Developmental Disabilities
Earliest possible date of adoption: October 24, 2021
For further information, please call: (512) 948-2035

♦ ♦ ♦