ADOPTED RULES

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

TITLE 1. ADMINISTRATION

PART 2. TEXAS ETHICS COMMISSION

CHAPTER 40. FINANCIAL DISCLOSURE FOR PUBLIC OFFICERS

1 TAC §40.11

The Texas Ethics Commission (the commission) adopts new Texas Ethics Commission Rules §40.11, regarding the disclosure of income received from publicly traded corporations on a personal financial statement, without changes as published in the July 1, 2016, issue of the *Texas Register* (41 TexReg 4737) and will not be republished.

Section 572.023(b)(4) of the Government Code requires a personal financial statement (PFS) to include the "identification of each source" of income in excess of $500 derived from interest, dividends, royalties, and rents. The law also requires the category of the amount of income to be disclosed. The form used for the PFS currently requires the source of that income to be disclosed by the source's full name and address.

The basis for the rule is to enhance the potential for individual participation in electoral and governmental processes by easing the burdens of disclosure without reducing the value of disclosure because publicly traded corporations would remain easily identifiable on the PFS. Under the rule, if a filer receives income over $500 from a publicly held corporation in the form of interest, dividends, royalties, or rents, the corporation will be identified only by its full name, and no address will be required.

No comments were received regarding the new rule.

The new rule §40.11 is adopted under Texas Government Code §571.062, which authorizes the commission to adopt rules concerning the laws administered and enforced by the commission.

The new rule §40.11 affects §572.023 of the Government Code.

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

Filed with the Office of the Secretary of State on August 18, 2016.

TRD-201604258
Natalia Luna Ashley
Executive Director
Texas Ethics Commission
Effective date: September 7, 2016
Proposal publication date: July 1, 2016
For further information, please call: (512) 463-5800

♦ ♦ ♦

PART 8. TEXAS JUDICIAL COUNCIL

CHAPTER 175. COLLECTION IMPROVEMENT PROGRAM

The Texas Judicial Council (the Council) adopts the repeal of current Chapter 175 of Title 1 of the Texas Administrative Code (1 TAC §§175.1 - 175.7) and adopts new Chapter 175 consisting of §§175.1 - 175.6 concerning the Collection Improvement Program (the Program). The new rules are adopted with changes to the proposed text as published in the July 1, 2016, issue of the *Texas Register* (41 TexReg 4745). The changes in the adopted chapter respond to public comments and will be republished. The repeals are adopted without changes and will not be republished.

The purpose of the Council's actions is to: 1) revise the current Program components and requirements that the Office of Court Administration is required to develop pursuant to Art. 103.0033 of the Code of Criminal Procedure to ensure that compliance with the Program does not result in an undue hardship on defendants and defendant's dependents, and 2) clarify that the Program is not intended to apply to defendants whose court costs, fees, and fines have been waived by the court. The effective date of the new Chapter 175 is January 1, 2017.

Summary of Comments

The Council received a total of 143 written comments from district and statutory county court judges, justices of the peace, municipal court judges, local collections program staff, and community supervision and corrections departments. The Council also received comments from the Probation Advisory Committee, Texas Municipal Courts Association, Texas Appleseed, Texas Legal Services Center, Texas Fair Defense Project, and American Civil Liberties Union of Texas. No oral comments were received. All of the comments are available on the Council's website at http://www.txcourts.gov/media/1435718/cip-comments.pdf.

Six commenters, including Texas Appleseed, Texas Legal Services Center, Texas Fair Defense Project, and American Civil Liberties Union of Texas, expressed approval of the proposed rules. Several commenters objected to any change to the current rules arguing that change was unnecessary. These commenters did not provide any recommendations or suggested changes to the proposed rules. Most of the comments from those who opposed the proposed rules that listed specific concerns primarily focused on the six key issues discussed below.

1. Workload Increase and Associated Costs

Comments: Many commenters expressed concern that the proposed rules will result in a workload increase for the courts and for local programs that will ultimately require adding staff.

Response: These concerns appear to be based on a misunderstanding of the proposed §175.3(a)(6)(A) requirement that local program staff refer a case back to the court if the payment ability information they collect demonstrates that a defendant is unable to pay any portion of the court costs, fees, and fines without undue hardship to the defendant or the defendant's dependents. This section was intended to codify the local program staff's ability to flag cases when it is evident from the payment ability information a defendant has submitted that the defendant cannot pay any part of the court costs, fees, and fines, or that the defendant can pay some but perhaps not all of them within a reasonable time. This would allow the court the opportunity to consider whether alternative enforcement options are available or whether the amounts should be reduced. In most cases, it would only require the court's review of a proposed payment plan or approval of suggested alternative enforcement options.

The Council has amended §175.3(a)(6)(A) to clarify that when local program staff have received information that a defendant is unable to pay court costs, fees, and fines without undue hardship to the defendant or the defendant's dependents, local program staff are required to inform the court but the defendant is not required to appear before the court.

Comments: Several commenters objected to the new requirement in §175.3(a)(3)(A) that staff obtain statements from defendants who have judge set payment plans stating that the defendant has the ability to pay the court costs, fees, and fines under the payment plan terms ordered by the judge without undue hardship to the defendant or the defendant's dependents. If the defendant is unable to make the statement, the new rules would require local program staff to obtain payment ability information and determine whether the defendant's information needs to be reviewed by the judge.

Response: Under the current rules, local program staff are only required to obtain contact information from defendants who have payment plans set by the judge. Based on the assumption that a court will have considered a defendant's payment ability information prior to referring the defendant to the local program, the Council has eliminated the proposed provision in the adopted rule and the provisions currently in place for judge-set payment plans will remain in place.

2. Presumption of Inability to Pay/Waiver of Court Costs, Fines and Fees

Comments: Many commenters objected to §175.3(a)(6)(B) which lists instances in which a defendant is presumed to be unable to pay court costs, fees, and fines without undue hardship to the defendant or the defendant's dependents. Examples of those instances are if a defendant is required to attend school under the Education Code, if the defendant's household income does not exceed 125% of the federal poverty guidelines, or if the defendant receives assistance under certain federal programs.

Response: Based on the comments, it appears that the commenters believe that the list of instances in which a defendant is presumed to be unable to pay court costs, fees, and fines is an irrebuttable presumption when in fact it is only intended to be a trigger for the purpose of determining whether local program staff need to inform the judge of the defendant's payment ability information. It was not intended to be an irrebuttable presumption nor was it intended to mandate that a court find that the defendant is unable to pay solely because the defendant meets the criteria. Whether a defendant is in fact unable to pay court costs, fees, and fines is a decision to be made by a judge.

To avoid confusion, the Council has changed this provision in the adopted rules to clarify that the criteria are intended to assist local program staff in identifying which cases require additional judicial review and that they do not establish an irrebuttable presumption regarding a defendant's ability to pay.

Comments: Many commenters also objected to §175.3(a)(6)(B) based on a misunderstanding that when a defendant falls under one of the categories that raises the presumption that the defendant is unable to pay court costs, fees, and fines without undue hardship to the defendant or defendant's dependents that this would result in the waiver of all court costs.

Response: The commenters misunderstand the proposed rule. The rule only requires that a defendant's case be brought to the attention of the judge so that the judge can determine if a waiver or reduction of financial obligations or conversion of the financial obligations to a non-monetary option is appropriate.

To avoid confusion, the Council has revised this provision in the proposed rule to clarify that the fact that a person meets the criteria requiring the local program staff to provide the judge information regarding the defendant's ability to pay does not mean that the defendant's court costs, fees, and fines are automatically waived or that they must be waived.

3. Cap on Monthly Payment Amounts, Time Limitations

Comments: Many commenters objected to the language in §175.3(a)(7)(C)(ii) which stated that monthly payments generally should not exceed 20% of a defendant's discretionary income.

Response: The statement that payments generally should not exceed 20% of a defendant's discretionary income was intended as a guideline and best practice; it was not a requirement. The Council has removed this provision from the proposed rules since it is not mandatory. However, the Council is of the opinion that monthly payments at or below 20% of a defendant's discretionary income result in more compliance than payments that exceed this amount because defendants are more likely to comply when the payment terms are reasonable. Payments that exceed 20% of a defendant's discretionary income may result in an increase in non-compliance if they place an undue hardship on defendants and their dependents.

Comments: Several commenters suggested that the rules set time limits so that court involvement does not last indefinitely.

Response: If information is provided to the judge by local program staff regarding the defendant's ability to pay that would indicate the amount needs to be reduced in order to keep the payment plan term within a reasonable time, the judge may make this change. Any attempt to impose this requirement in the rules would interfere with a judge's discretion. For this reason, the Council declines to prescribe time limitations on payment plans in the adopted rules.

4. Definition of Discretionary Income and Household Income

Comments: Many commenters also objected to the definition of discretionary income and household income (§175.2(d) and (e)). Household income is defined as the defendant's income and the defendant's spouse's income. The commenters want the rules to also include as part of household income the income from any other person living in a household.

Response: The term "discretionary income" is only used in the recommended limitation of payment amounts to 20% of a defendant's household income. With the deletion of the 20% of discre-

tionary income limit on payments, the definition of discretionary income is no longer necessary and has been deleted from the adopted rules.

The Council disagrees with commenters' suggestions regarding the definition of household income. Persons other than a spouse who reside in a household are not legally obligated to pay a defendant's courts costs, fines and fees. Even if one were to assume another member of the defendant's household is liable for the defendant's court costs, fines, and fees, local program staff would then be required to collect from all of those individuals' payment ability information including their debt, monthly expenses, etc. For this reason, the Council did not make any changes to the definition of household income in the proposed rules.

5. Applicability of Rule

Comments: Some commenters expressed concern that their jurisdictions are too small to be covered by the rules. Others stated that the rules should apply to every jurisdiction, not only the ones required to participate under Art. 103.0033 of the Code of Criminal Procedure.

Response: In an effort to streamline the rules, the Council removed the language in the current rules that duplicated the statutory language regarding the applicability of the statute and rules. This was a cleanup provision. It was not intended to expand the coverage of the rules to jurisdictions that are not already covered by Art. 103.0033. In order to avoid confusion, the Council has added language to the rule to clarify that the revisions to the rule do not expand the program to jurisdictions not already covered under the rules and Art. 103.0033. The Council cannot expand the coverage of the rules to all jurisdictions as suggested by some of the commenters. This would require a change to Art. 103.0033 of the Code of Criminal Procedure. Such a change is solely within the authority of the Texas Legislature.

Comments: Several commenters expressed concern that the proposed rules would apply to the collection of community supervision (probation) fees assessed when a defendant is placed on community supervision.

Response: Neither the current rules nor the proposed rules apply to probation fees. The Council has added language to the adopted rules that clarifies this.

6. Reduction in Revenue Collected

Comments: Some commenters expressed concern that the new rules would result in the reduction of revenue to the jurisdictions that are subject to the rules.

Response: Most of the concerns raised by the commenters are based on a misunderstanding that the proposed rules automatically require the waiver of costs, fines and fees when a defendant is found to be unable to pay without undue hardship to the defendant and the defendant's dependents. The subsection that provided that monthly payments generally should not exceed 20% of a defendant's monthly discretionary income also contributed to this perception. The removal of the language with the suggested cap on monthly payments of 20% of a defendant's discretionary income and the clarification of the presumption of inability to pay provisions in the proposed rule address these concerns.

The Council disagrees with commenters' assertions that the proposed rules will result in a significant decrease in revenue. The courts' role is to ensure that orders entered by the court are appropriately enforced, including those assessing court costs, fees, and fines. While enforcement of orders assessing court costs, fees and fines will result in increased revenue to state and local governments, the Council is mindful that the courts' role in assessing court costs, fees, and fines, is not to ensure revenue streams for state or local government. As noted by the National Center for State Courts in its clarification regarding CourTools Measure 7:

The responsibility of the courts in general, and individual judges in particular, is to ensure that any fees and fines arising out of a criminal case are reasonable and take into account a defendant's ability to pay. Compliance with legal and financial obligations has two dimensions. First, it requires a court, including its judicial officers and staff, to follow applicable constitutional provisions, statutes, case law and appellate court policies and procedures that apply to collecting monetary penalties, as well as consciously employing recognized best practices in doing so. These best practices include making a determination of an offender's ability to pay, supported by findings of fact. (http://www.courtools.org/~/media/Microsites/Files/CourTools/M7%20Clarification%20v4.ashx)

The proposed rules were drafted to ensure the enforcement of a defendant's compliance with the payment of court costs, fees, and fines while simultaneously ensuring that local programs engage the judiciary in situations in which a defendant may not have the ability to pay the assessed court costs, fees, and fines without undue hardship. They were also drafted to ensure that the procedures used to manage these cases, from the imposition of legal financial obligations, to notice practices, through ultimate disposition, are consistent among all local programs and that the practices of local programs do not inadvertently result in the removal of the courts' role in the determination of a defendant's ability to pay when involvement by the court is necessary.

Other Comments

The Council also received comments regarding the following:

Workgroup Composition

Comments: A few commenters objected to the fact the workgroup that was convened by the Office of Court Administration to discuss revisions to the current rules did not include district and statutory county court judges. The commenters believe that the workgroup focused on concerns related to justice and municipal courts at the expense of the needs and concerns of district and statutory county courts.

Response: Though the workgroup did not include district and statutory county court judges it did include district clerks who are responsible for collecting court costs, fees, and fines for these courts and a district/statutory county court administrator. Additionally, most of the objections raised by these commenters focus on the mistaken belief that the rules will require that the defendant be brought back to court in order to determine inability to pay. As discussed in number 1 above, the adopted rules have been amended to clarify that this will not be necessary.

Lack of Defendants' Accountability for Their Crimes, No Consequences for Poor Defendants' Actions, Separate System for Defendants' Who Are Unable to Pay

Comments: Many commenters expressed concern about the rules establishing a system in which defendants who are unable to pay court costs, fees, and fines would be able to commit crimes without fear of repercussion because there would be no consequences for their actions and that this would lead to an increase in crime. They also expressed concern that the rules

would result in a dual system in which defendants are treated differently based on their income.

Response: The changes to the rules do not provide an automatic waiver of court costs, fees, and fines; further they make explicit that courts should make available alternative options in all cases, as appropriate. As stated above, the proposed changes to the rules are designed to ensure that local programs engage the judiciary in situations in which a defendant may not have the ability to pay the assessed court costs, fees, and fines without undue hardship. They were also amended to help ensure that the procedures used to manage cases, from the imposition of legal financial obligations, to notice practices, through ultimate disposition, are consistent among all local programs and that the practices of local programs do not inadvertently result in the removal of the courts' role in the determination of a defendant's ability to pay when involvement by the court is necessary. In some instances, courts may waive a defendant's obligations or impose alternative compliance options; but this would be because it was necessary under the law and within a court's discretion, not because of the requirements in the proposed rules.

Referral to Court After Court Has Already Reviewed Case

Comments: Several commenters were concerned that if local program staff referred a defendant's case to the court for review and the court did not make any changes to the assessment they would have to return the case to the judge again after they reviewed their payment ability information for the second time.

Response: The adopted rules have been changed to clarify that if a judge has reviewed the case once, the local program staff do not have to refer the defendant's payment ability information to the court for another review unless the defendant provides additional information that has not already been provided to the judge.

Employer Contact Information

Comments: Several commenters objected to the removal of employer contact information from the list of payment ability information that must be collected.

Response: The employer contact information served no purpose other than for local program staff to call and confirm that the defendant was employed. This information is not necessary to set a payment plan and calls could be construed as intimidation. The Council declines to change this provision in the adopted rules.

Payment Ability Information

Comment: One commenter expressed confusion regarding the last sentence in the definition of payment ability information (§175.2(j)). The sentence read as follows: "The payment ability information provided by the defendant to local program staff is presumed to be current unless the defendant notifies the court or local program staff that resources or circumstances have changed and a review is requested."

Response: The Council agrees with commenter and does not see the need for this sentence. A defendant is always able to provide additional information and the information provided originally will be considered to be correct unless other information is provided by defendant. The sentence has been deleted from the adopted rules.

Audit Standards Name Change

Comment: One commenter objected to the proposed change to the title of §175.5, Audit Standards, to Compliance Review Standards.

Response: The proposed change is not substantive, but it does more accurately reflect the audit process described in Art. 103.0033. Therefore, the Council declines to change this provision in the adopted rules.

Judicial Discretion Language

Comment: One commenter provided suggested language that more accurately expresses the judicial discretion exercised by the judge in proposed §175.3(a)(6)(E).

Response: The Council agreed with the suggestion and the adopted rule incorporates this recommendation.

Comment: Several commenters suggested that the language in §175.1(c) of the proposed rule regarding a judge's discretion to waive or to reduce court costs, fees, and fines after the assessment date implied that judges did not have this authority at the time of sentencing.

Response: This was not the intent of the proposed language. The Council agrees with the recommendation and the adopted rule does not include the language "after the assessment date" in §175.1(d).

Definition of Undue Hardship

Comments: Several commenters expressed concern with the fact that "undue hardship" is not defined.

Response: The Council is aware that this is a subjective term and that its definition may depend on the jurisdiction's cost of living and other local factors. For this reason, the Council did not define undue hardship but instead provided guidelines that alert programs to defendants who will likely have an inability to pay without undue hardship to themselves and their defendants so that the judge can review and determine if any changes are necessary.

Availability of Non-Monetary Options

Comments: Several commenters expressed concern about the lack of non-monetary options, such as community service, available in their jurisdictions.

Response: The adopted rules include language that non-monetary option information only has to be collected if any are available.

Additional Reporting to OCA

Comments: Several commenters suggested adding additional reports that local program staff must provide to OCA in addition to those already required and the proposed additional report. One commenter also suggested the reports be submitted quarterly instead of monthly.

Response: The Council does not believe additional reports are necessary at this time and declines to change the reporting due dates or to add additional reports.

No Change Necessary to Current Rule

Comment: A few commenters indicated that they did not believe the rule should be changed.

Response: The Council determined that the Collections Improvement Program rules needed to be amended in order to promote local program practices that fully align with existing

statutes and constitutional provisions relating to a defendant's compliance with legal financial obligations.

Clarification of Cases Subject to the Rules

Comment: Four commenters noted that the language in §175.1(f) listing the types of cases the rules do not apply to is inconsistent with the list of "eligible case" that are subject to review in a compliance review under §175.5. Specifically, cases in which a defendant is incarcerated are not excluded from the CIP rules under §175.1(f) but are not eligible cases for compliance review under §175.5(b).

Response: The Council agrees with commenters and has incorporated the suggestion into the adopted rule.

Additional Information Provided to Defendants Regarding Compliance Options and Review of All Defendants' Payment Ability Information

Comment: Four commenters also suggested that the rules provide that the payment ability information of all defendants be reviewed. They also suggested that local program staff use understandable language on forms so that defendants could understand that they are being asked if they have the ability to pay. They also expressed concern that sometimes defendants' circumstances change and they may be unable to pay at some point after they have agreed to a payment plan. The commenters recommend requiring local program staff to inform defendants how they can seek relief if their circumstances change and to also provide this information in past due notices.

Response: The Council does not believe that payment ability information for all defendants needs to be reviewed by local program staff and it is imperative that judges have the discretion to set the plans that they have determined are appropriate. Based on the assumption that a court will have considered a defendant's payment ability information prior to referring the defendant to the local program, the Council declines to make this change in the adopted rules. Regarding the use of understandable forms, the Council has instructed the Office of Court Administration to provide model forms that can be used by local programs that will be easy to understand. The best practices will also provide that local program staff inform defendants that they should always contact local program staff to discuss changes in circumstances that may require the revision of their payment plans and the rules contemplate that revised payment plans may often result after a defendant has been contacted for failure to pay. The rules provide that the phone contact, written notice, and final notices sent to a defendant after a missed payment provide instructions about what to do if the defendant is unable to make payments.

Additional Item for List of Criteria That Trigger Referral of Defendant's Payment Ability Information to Judge

Comments: Four commenters suggested adding Telephone Lifeline program assistance to the list of criteria that would trigger the requirement that a defendant's payment ability information be referred to the court for review.

Response: The Council believes that the list in the adopted rules covers many who are likely already served by this program. Further, local program staff may still refer others for review even if they do not meet the criteria listed in the rule. The Council has instructed Office of Court Administration staff to provide materials to local program staff informing them of additional types of programs, such as the Telephone Lifeline program, that local programs should be aware may be indicate a need for court review of the defendant's payment ability information.

Comments in Support of Proposed Rules

A few commenters agreed with the elimination of mandatory time payment requirements. One commenter indicated she approved of the proposed changes to the rules.

Texas Appleseed, Texas Legal Services Center, Texas Fair Defense Project, and American Civil Liberties Union of Texas expressed support for the proposed rules and provided additional recommendations that are addressed in the comments discussion.

The Municipal Court Judges Association initially objected to the rules, but after reviewing the suggested changes to the proposed rules that were presented to the Council for final approval, the Association indicated they supported the revised rules.

The Justices of the Peace and Constables Association indicated they also are in favor of the proposed rules.

Other Changes in Adopted Rules

The following changes have been included in the adopted rules based on recommendations and concerns raised by Office of Court Administration staff.

Defendants Whose Costs, Fees, and Fines Have Been Waived

Though the program's provisions have never applied to indigent defendants, this was not specifically mentioned in the rule. The language in the proposed rule stating that the rules do not apply to defendants who are unable to pay any portion of the costs, fees, and fines without undue hardship to the defendant and the defendant's dependents created confusion because many individuals believed this meant that if a person could only pay a portion of the assessed costs, their case was no longer in the program. The adopted rule clarifies that the rules do not apply to defendants whose court costs, fees and fines have been waived.

Standard Payment Plan

In an effort to allow local program staff to focus on defendants who need assistance with payment plans and information regarding possible non-monetary compliance options while also reducing the amount of time and effort needed to complete paperwork in order to obtain a payment plan, the adopted rule adds a new §175.3(a)(7)(A) that allows judges to set standard payment plans that local programs can offer to defendants who have the ability to pay but need additional time to do so. If a defendant chooses one of these options, the defendant does not need to provide payment ability information. These defendants will only need to provide contact information like defendants who have judge-set plans. Before accepting a standard payment plan, the defendant must acknowledge that the defendant: 1) understands the payment plan terms, 2) has the ability to successfully meet the payment plan terms, and 3) declines the opportunity for local program staff to review defendant's payment ability information to consider lower monthly amounts or a longer payment plan term. The Council has instructed the Office of Court Administration to provide a model acknowledgement form that can be used by local programs that will be easy for defendants to understand.

Written Notice

The adopted rule clarifies that written notice is not required if the defendant is successfully contacted by telephone after a missed payment and the defendant has either made a payment or made other payment arrangements.

Postcard Regarding Application and Contact Information

The adopted rule includes a provision for local program staff to send notices to defendants who are ordered to report to the local program, but fail to do so, instructing them to call and make arrangement to submit payment and contact information. The rules currently require that an entire application and contact information sheet be sent. The use of a notice should result in printing and postage savings.

Correct name for reporting web based system

The adopted rule also corrects the name of the reporting system currently in use by OCA.

1 TAC §§175.1 - 175.6

Statutory Authority

New Chapter 175 is adopted under §71.019 of the Texas Government Code, which authorizes the Council to adopt rules expedient for the administration of its functions. The statutory provision for the rules is Article 103.0033 of the Code of Criminal Procedure.

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

§175.1. Purpose and Scope.

(a) The purpose of this chapter is to provide notice to counties and municipalities that are subject to Article 103.0033 of the Code of Criminal Procedure of the scope and components of the Collection Improvement Program (CIP) model developed by the Office of Court Administration pursuant to Article 103.0033 and the standards that will be used to determine whether a county or municipality is complying with the CIP requirements.

(b) Article 103.0033 and this chapter apply to counties with a population of 50,000 or greater and cities with a population of 100,000 or greater based on the last decennial census. Counties that have been granted a waiver under §175.6(b) of this chapter are not required to comply with the requirements in this chapter.

(c) The CIP is designed to improve the enforcement of a defendant's compliance with the payment of costs, fees, and fines that have been ordered by a court, without imposing an undue hardship on the defendant or the defendant's dependents. The CIP components should not be interpreted to conflict with or undermine the provision to defendants of full procedural and substantive rights under the constitution and laws of this state and of the United States.

(d) The CIP does not alter a judge's legal authority or discretion to design payment plans of any amount or length of time; to convert costs, fees, and fines into community service or other non-monetary compliance options as prescribed by law; to waive costs, fees, and fines; or to reduce the total amount a defendant owes at any time; or to adjudicate a case for non-compliance at any time.

(e) The CIP applies to criminal cases in which the defendant is ordered to pay costs, fees, and fines under a payment plan.

(f) The CIP does not apply to cases in which: 1) the court has waived all court costs, fees, and fines; 2) the court authorizes discharge of the costs, fees, and fines through non-monetary compliance options; 3) the defendant has been placed on deferred disposition or has elected to take a driving safety course; or 4) the defendant is incarcerated, unless the defendant is released and payment is requested. The CIP does not apply to the collection of community supervision fees assessed under Sec. 42A.652 of the Code of Criminal Procedure.

(g) Although cases in which the court has ordered a defendant to satisfy his or her obligation regarding costs, fees, and fines through community service or other non-monetary compliance options are not subject to the CIP requirements, a judge may use local program staff to assist the court with monitoring a defendant's compliance with these court orders.

§175.2. Definitions.

(a) "Assessment date" is the date on which a defendant is ordered or otherwise obligated to pay costs, fees, and fines. When a defendant remits partial payment of a citation without appearing in person, the assessment date is the date the partial payment is received.

(b) "Collection Improvement Program" or "CIP" means the program described in this subchapter.

(c) "Contact information" means the defendant's home address and home or primary contact telephone number, and email address, if any; at least two personal contacts and their telephone number, mailing address or email address; and the date the information is obtained.

(d) "Household income" means the defendant's income and the defendant's spouse's income that is available to the defendant.

(e) "Jurisdiction" means a county or municipality that is subject to this chapter.

(f) "Local program" means a program implemented by a jurisdiction pursuant to Art. 103.0033 of the Code of Criminal Procedure.

(g) "Non-monetary compliance option" means an alternative method of satisfying the assessment of costs, fees, and fines other than through the payment of money. This includes those methods provided in Arts. 43.09 and 45.049 of the Code of Criminal Procedure, and any other alternative within the judge's discretion.

(h) "OCA" means the Office of Court Administration of the Texas Judicial System.

(i) "Payment ability information" means the defendant's household income, expenses, account balances in financial institutions, debt balances and payment amounts, number of dependents, and any other information local program staff require to establish a payment plan that the defendant can successfully make without undue hardship to the defendant or the defendant's dependents.

(j) "Payment plan" means a schedule of one or more payment(s) to be made at designated interval(s) by the defendant who does not pay all costs, fees, and fines at the time they are assessed and payment is requested. A judge's order that payment of costs, fees, and fines is due at a future date (an extension) constitutes a payment plan regardless of whether the order requires one payment in full or several payments at designated intervals.

(k) "Spouse" means the person to whom the defendant is married, including a person who is a party to an informal marriage.

§175.3. Collection Improvement Program Components.

(a) Components for Local Program Operations.

(1) Dedicated Local Program Staff. Each program must designate at least one employee whose job description contains an essential job function of CIP program activities. The local program activities may be assigned to one individual employee or distributed among two or more employees. The local program activities need not require 40 hours per week of an employee's time, but must be a priority.

(2) Payment Plan Compliance Monitoring. Local program staff must monitor the defendants' compliance with the terms of their payment plans and document the ongoing monitoring by either an updated payment due list or a manual or electronic tickler system.

(3) Application or Contact Information.

(A) Payment Plans Set by Judge Prior to Referral to the Local Program and Standard Payment Plans Accepted by the Defendant. If the judge has established a payment plan for the defendant prior to referring the case to the local program or the defendant has agreed to a standard payment plan under paragraph (7)(A) of this subsection, local program staff must obtain contact information from the defendant. Contact information documentation must be signed and dated and obtained within one month of the assessment date.

(B) Other Cases. For all other cases, the local program must collect from the defendant a signed and dated application for a payment plan that includes both contact information and payment ability information. The required information must be obtained within one month of the assessment date.

(4) Verification of Contact Information. Within five days of receiving the contact information, local program staff must verify both the home and primary contact telephone number. Verification may be conducted by reviewing written proof of the contact information, by telephoning the personal contacts, or by using a verification service. Verification must be documented by identifying the person conducting it and the date of the verification.

(5) Defendant Interviews.

(A) Within 14 days of receiving an application, local program staff must conduct an in-person or telephone interview with the defendant to review payment ability information. Interviews must be documented by indicating the interviewer and date of the interview.

(B) Within 14 days of receiving a case in which the judge has set a payment plan before referring the case to the program or the defendant has agreed to a standard payment plan under paragraph (7)(A) of this subsection, local program staff must conduct an in-person or telephone interview with the defendant to review the terms of the defendant's payment plan. Interviews must be documented by indicating the interviewer and date of the interview.

(6) Court Review of the Defendant's Ability to Pay Information.

(A) Court Review. Local program staff must provide the court the defendant's payment ability information collected under paragraph (3)(B) of this subsection for the court to review and consider if non-monetary compliance options or waiver or partial waiver of costs, fees or fines are appropriate when the defendant meets one or more of the following criteria:

(i) the defendant is required to attend school pursuant to the compulsory school attendance law in Sec. 25.085 of the Texas Education Code;

(ii) the defendant's household income does not exceed 125 percent of the applicable income level established by the federal poverty guidelines; or

(iii) the defendant receives assistance under the following:

(I) a food stamp program or the financial assistance program established under Chapter 31, Human Resources Code;

(II) the federal special supplemental nutrition program for women, infants, and children authorized by 42 U.S.C. Section 1786;

(III) the medical assistance program under Chapter 32, Human Resources Code; or

(IV) the child health plan program under Chapter 62, Health and Safety Code.

(B) Other Cases. Local program staff must also provide for the court's review the payment ability information of a defendant that does not meet the criteria listed in subparagraph (A) of this paragraph if local program staff receive information that has not already been considered by the court indicating that the payment of the assessed court costs, fees, and fines would cause undue hardship to the defendant or the defendant's dependents. Local program staff may also provide for the court's review the payment ability information of a defendant that local program staff determine should be reviewed by the court..

(C) Information Regarding Non-Monetary Compliance Options. When local program staff provide a defendant's payment ability information for the court's review under subparagraph (A) of this paragraph, local program staff should collect and provide to the court information regarding non-monetary compliance options that may be available, if any, that may enable the defendant to discharge all or part of the defendant's costs, fees, and fines.

(D) Judicial Discretion. Judges retain discretion regarding the determination of whether to waive or reduce costs, fees, and fines for any defendant; to impose non-monetary compliance options to satisfy costs, fees or fines; or the assessment of costs, fees or fines, sentencing, or other disposition decisions. Once a judge reviews a defendant's payment ability information in a case provided for review under subparagraph (A) or (B) of this paragraph, the local program is not required to provide the judge the defendant's payment ability information again unless the defendant provides additional payment ability information that was not previously provided to the judge.

(7) Payment Plans.

(A) Standard Payment Plan. A judge may adopt standard payment plans that include a payment range and time range based on amounts owed that can be made available to defendants when they are referred to the local program. Prior to agreeing to a standard payment plan the defendant must agree in writing that the defendant: 1) understands the payment plan terms, 2) believes that the defendant has the ability to successfully meet the payment plan terms, and 3) declines the opportunity for local program staff to review the defendant's payment ability information to consider lower monthly payments or a longer term than those provided in the standard payment plan.

(B) Other Payment Plans. If a defendant declines a jurisdiction's standard payment plan or the jurisdiction has not adopted a standard payment plan, local program staff must review the payment ability information provided by the defendant and establish appropriate payment terms based on the defendant's ability to pay that will not cause undue hardship to the defendant or the defendant's dependents.

(C) Payment Plan Elements. Payment plans should include the payment amount, the designated interval, and the number of payments that the defendant will make to pay the defendant's court-ordered costs, fees, and fines.

(D) Documentation. Payment plans must be documented by notation in the judgment or court order, on a docket sheet, by written or electronic record, or by other means enabling later review.

(8) Telephone Contact for Past-Due Payments. Within one month of a missed payment, a telephone call must be made to the defendant who has not been in contact with local program staff. In every telephone contact for past due payment, local program staff must provide the defendant with instructions about what to do if the defendant is unable to make payments. This telephone contact must also include information about how the defendant may request a hearing for the

judge to consider the defendant's ability to pay and any non-monetary compliance options available for the defendant to satisfy the judgment. Telephone calls may be made by an automated system, but an electronic report or manual documentation of the telephone contact must be available on request.

(9) Written Notice for Past-Due Payments. Within one month of a missed payment, a written notice must be sent to the defendant who has not been in contact with local program staff. Written notice may be made by regular or certified mail, e-mail, text message or other electronic means. Every written notice for past due payment must provide the defendant with instructions about what to do if the defendant is unable to make payments. The written notice must also include information about how the defendant may request a hearing for the judge to consider the defendant's ability to pay and any non-monetary compliance options available for the defendant to satisfy the judgment. Written notice may be sent by an automated system, but an electronic report or manual documentation of the written notice must be available on request. Notice under this paragraph is not required if local program staff make contact with the defendant under paragraph (8) of this subsection and the defendant makes payment or other payment arrangements.

(10) Final Contact Attempt. Local program staff must send a final written notice by regular or certified mail to the defendant within one month of the written notice described in paragraph (9) of this subsection prior to reporting the case to the court as non-compliant. The written notice must include the same information required in paragraph (9) of this subsection and include reasonable steps the defendant can take to avoid the defendant's case being reported to the court as non-compliant. The written notice must also notify the defendant of the defendant's right to avoid jail time for nonpayment if the defendant is unable to pay the amount owed without undue hardship to the defendant and the defendant's dependents. An electronic report or manual documentation of the written notice must be available on request. The local program should not report the case back to the court as non-compliant until at least one month after the final contact attempt to provide the defendant time to discuss with local program staff new payment plan terms or alternative non-monetary compliance options, if any are available, for the court to consider. This paragraph does not interfere or alter the judge's authority to adjudicate a case for non-compliance at any time.

(11) Delinquent Cases. Each local program must have a component designed to improve collection of balances more than 60 days past due.

(12) Proper Reporting. The local program must report its collection activity data to OCA at least annually in a format approved by OCA, as described in §175.4.

(b) Exceptions to Defendant Communications Rules. Exceptions to the defendant communications rules described in this subsection are limited to those cases in which timely access to the defendant in order to obtain the required application or contact information is not possible, and efforts to obtain an application or contact information are documented, as provided in paragraphs (1) and (2) of this subsection.

(1) Attempt to Obtain Application or Contact Information. An attempt to obtain an application or contact information described in subsection (a)(3) of this section is made by taking one of the following actions within one week of the assessment date: 1) mailing a notice requesting the defendant contact local program staff to make arrangements to complete an application and provide contact information; 2) mailing an application or contact information form; or 3) obtaining the information via the telephone. An electronic report or manual documentation of the attempt must be available on request. Should the defendant fail to contact local program staff or return a completed application or contact information form and the post office not return the notice or application or contact information form as undeliverable, the local program must make a second attempt to contact the defendant with any existing available information within one month of the first attempt. An electronic report or manual documentation of the second attempt must be made available on request.

(2) Application or Contact Information Is Obtained. Should a completed application or contact information form be returned to the local program by the defendant as the result of an attempt described in paragraph (1) of this subsection, it will be considered timely and all other communication timing requirements described in subsection (a)(4) and (5) of this section are based on the date the local program receives the application or contact information form.

(c) Computation of Time. In computing any period of time under these rules, when the last day of the period falls on a Saturday, Sunday, legal holiday, or other day on which the office is not open for business, then the period runs until the end of the next day on which the office is open for business.

§175.4. Content and Form of Local Government Reports.

(a) General Scope. Article 103.0033(i) of the Code of Criminal Procedure requires that each local program submit a written report to OCA at least annually that includes updated information regarding the local program, with the content and form to be determined by OCA. Reporting under Art. 103.0033 of the Code of Criminal Procedure and this subchapter is not the same as reporting of judicial statistics under Sec. 71.035 of the Government Code and different rules for reporting and waiver apply.

(b) Reporting Format and Account Setup. OCA has implemented a web-based online Court Collection Reporting System for local programs or jurisdictions to enter information into the system. For good cause shown by a jurisdiction, OCA may grant a temporary waiver from timely online reporting. Local program participants or jurisdictions must provide OCA with information for the online reporting system to enable OCA to establish the local program reporting system account. The information must include the local program name, program start date, start-up costs, the type of collection and case management software programs used by the local program, the entity to which the local program reports (e.g., judge, district clerk's office, sheriff, etc.), the name and title of the person who manages the daily operations of the local program, the mail and e-mail addresses and telephone and fax numbers of the local program, the courts serviced by the local program, and contact information for the local program staff with access to the system so user identifications and passwords can be assigned.

(c) Content and Timing of Reports.

(1) Annual Report. By the 60th day following the fiscal year end, each local program or jurisdiction must report the following information:

(A) Number of full-time and part-time local program employees;

(B) Total local program expenditures;

(C) Salary expenditures for the local program;

(D) Fringe benefit expenditures for the local program;

(E) Areas other than court collections for which the local program provides services;

(F) Local and contract jail statistics and average cost per day to house a defendant; and

(G) A compilation of 12 months of the monthly reporting information described in paragraph (2) of this subsection, if not reported each month as requested.

(2) Monthly Reports. By the 20th day of the following month, each local program or jurisdiction is requested to provide the following information regarding the previous month's local program activities:

(A) Number of cases in which costs, fees, and fines were assessed;

(B) Number of cases in which local program staff provided the court a defendant's ability to pay information in a case under §175.3(a)(6) for review of the defendant's ability to pay;

(C) For assessed court costs and fees: the dollar amount assessed and collected; the dollar amount of credit given for jail time served; the dollar amount of credit given for community service performed or other non-monetary compliance options; the dollar amount waived because of the defendant's inability to pay, and the dollar amount waived for reasons other than the defendant's inability to pay;

(D) For fines: the dollar amount assessed, collected, or waived; the dollar amount of credit given for jail time served; and the dollar amount of credit given for community service performed or other non-monetary compliance options; and

(E) Aging information consisting of the time span from date of assessment through the date of payment, in 30-day increments up to 120 days, and for more than 120 days.

§175.5. Compliance Review Standards.

(a) Statutory Basis. In accordance with Art. 103.0033(j) of the Code of Criminal Procedure, OCA must periodically review local jurisdictions' compliance with the components described in §175.3(a).

(b) Cases Eligible for Compliance Review. For purposes of this section, "eligible case" means a criminal case in which a judgment has been entered by a trial court. The term does not include cases in which:

(1) the court has waived all court costs, fees, and fines;

(2) the court authorizes discharge of the costs, fees, and fines through non-monetary compliance options;

(3) the defendant has been placed on deferred disposition or has elected to take a driving safety course; or

(4) the defendant is incarcerated, unless the defendant is released and payment is requested.

(c) Compliance Review Methods. OCA must use random selection to generate an adequate sample of eligible cases to be reviewed, and must use the same sampling methodology as used for local programs with similar automation capabilities.

(d) Compliance Review Standards. OCA must use the following standards in the compliance review:

(1) Standards for Components in §175.3(a)(1), (2), (11), and (12). A county is in compliance with these components when either 90% of all courts in the county, or all courts in the county except one court, have satisfied all four requirements. Partial percentages are rounded in favor of the county. A municipality must satisfy all four requirements in order to be in compliance.

(2) Standards for Components in §175.3(a)(3) - (10). A jurisdiction is in substantial compliance with a component when at least 80% of the eligible cases at that stage of collection have satisfied the requirements of the component. A jurisdiction is in partial compliance with a component when at least 50% of the eligible cases at that stage of collection have satisfied the requirements of the component. In order for a jurisdiction to be in compliance with these components, the jurisdiction cannot be in less than partial compliance with any component, may be in partial compliance with a maximum of one component, and must be in substantial compliance with all of the other applicable components.

§175.6. Waivers.

(a) Statutory Basis. Article 103.0033 of the Code of Criminal Procedure provides that OCA may determine that it is not cost-effective to implement a local program in a county or municipality and grant a waiver to the requesting entity.

(b) Criteria for Granting Waivers. OCA will grant a blanket waiver from implementation when the requesting entity demonstrates that:

(1) The estimated costs of implementing the local program are greater than the estimated additional revenue that would be generated by implementing the local program, and a compelling reason exists for submitting the waiver request after the entity's implementation deadline. The requesting jurisdiction and CIP staff must each submit documentation supporting the cost and revenue projections to the Administrative Director of OCA for determination; or

(2) The county contains within its borders a correctional facility operated by or under contract with the Texas Department of Criminal Justice; and has a population of 50,000 or more only because the inmate population of all correctional facilities is included in that population.

(c) Temporary Waivers. OCA will consider a request to grant a temporary waiver for good cause that could not have been reasonably anticipated. Such temporary waivers may be granted after a compliance review to allow a local program to correct deficiencies discovered during the compliance review.

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604292
Maria Elena Ramon
General Counsel
Texas Judicial Council
Effective date: January 1, 2017
Proposal publication date: July 1, 2016
For further information, please call: (512) 463-1682

♦ ♦ ♦

SUBCHAPTER A. GENERAL COLLECTION IMPROVEMENT PROGRAM PROVISIONS

1 TAC §§175.1 - 175.5

Statutory Authority

The repeals are adopted under §71.019 of the Texas Government Code, which authorizes the Council to adopt rules expedient for the administration of its functions. The statutory provision for the repeals is Article 103.0033 of the Code of Criminal Procedure.

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

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604304
Maria Elena Ramon
General Counsel
Texas Judicial Council
Effective date: January 1, 2017
Proposal publication date: July 1, 2016
For further information, please call: (512) 463-1682

♦ ♦ ♦

SUBCHAPTER B. IMPLEMENTATION SCHEDULE AND WAIVERS

1 TAC §175.6, §175.7

Statutory Authority

The repeals are adopted under §71.019 of the Texas Government Code, which authorizes the Council to adopt rules expedient for the administration of its functions. The statutory provision for the repeals is Article 103.0033 of the Code of Criminal Procedure.

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

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604308
Maria Elena Ramon
General Counsel
Texas Judicial Council
Effective date: January 1, 2017
Proposal publication date: July 1, 2016
For further information, please call: (512) 463-1682

♦ ♦ ♦

TITLE 7. BANKING AND SECURITIES

PART 2. TEXAS DEPARTMENT OF BANKING

CHAPTER 11. MISCELLANEOUS SUBCHAPTER A. GENERAL

7 TAC §11.37

The Finance Commission of Texas (the commission), on behalf of the Texas Department of Banking (the department), adopts the amendment to §11.37, concerning the form of consumer complaint notices without changes to the proposed text as published in the June 24, 2016, issue of the *Texas Register* (41 TexReg 4542). The amended rule will not be republished. The amendment allows consumer complaint notices to be in a form that is substantially similar to the current required notice.

Currently, §11.37(b) provides a form consumer complaint notice that must be duplicated exactly when the notice is required to be communicated to consumers. The amendment to §11.37(b) states that this consumer complaint notice must only substantially conform to the form complaint notice that is currently provided by §11.37(b). This allows an entity that is required to communicate the notice to make non-substantive changes to the notice, as might be necessary by the context or formatting in which it is being provided.

Comments supporting the proposed amendment were received from the Independent Bankers Association of Texas (IBAT).

The amendment is adopted pursuant to Finance Code, §11.003 which provides that the commission may adopt rules necessary and reasonable to implement Chapter 11 of the Finance Code.

Finance Code §11.307 is affected by the amended section.

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

Filed with the Office of the Secretary of State on August 19, 2016.

TRD-201604261
Catherine Reyer
General Counsel
Texas Department of Banking
Effective date: September 8, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 475-1301

♦ ♦ ♦

PART 5. OFFICE OF CONSUMER CREDIT COMMISSIONER

CHAPTER 83. REGULATED LENDERS AND CREDIT ACCESS BUSINESSES SUBCHAPTER A. RULES FOR REGULATED LENDERS

The Finance Commission of Texas (commission) adopts amendments to §§83.102, 83.301, 83.302, 83.304, 83.306, 83.310, 83.403, and 83.828; adopts new §83.303 and §83.404; and adopts the repeal of §§83.303, 83.404, and 83.405 in 7 TAC, Chapter 83, Subchapter A, concerning Rules for Regulated Lenders.

The commission adopts the amendments to §§83.102, 83.301, 83.302, 83.304, 83.306, 83.310, 83.403, and 83.828; and the repeals of §§83.303, 83.404, and 83.405 without changes to the proposed text as published in the June 24, 2016, issue of the *Texas Register* (41 TexReg 4543).

The commission adopts new §83.303 and §83.404 with changes to the proposed text as published in the June 24, 2016, issue of the *Texas Register* (41 TexReg 4543). The changes are a result of technical corrections to citations.

The commission received no written comments on the proposal.

In general, the purpose of the rule changes in 7 TAC, Chapter 83, Subchapter A is to update rules regarding the licensing of regulated lenders, and to make technical corrections. The adopted rule changes relate to the following issues: contact information, transfers, criminal history review, definitions, and recordkeeping.

Additionally, certain sections are being repealed in order to replace them with new, reorganized rules.

The agency circulated an early draft of proposed changes to interested stakeholders. The agency then held a stakeholders meeting where attendees provided oral precomments. In addition, the agency received one informal written precomment. Certain concepts recommended by the precommenter were incorporated into the proposal, and the agency appreciates the thoughtful input provided by stakeholders.

The individual purposes of the adopted changes to each section are provided in the following paragraphs.

In §83.102(3), the definition of "amount financed" has been replaced with a reference to Regulation Z, 12 C.F.R. §1026.18(b). The rule previously contained a specific definition of "amount financed" that applies only to rule provisions on computing earnings, deferments, maximum charges, and refunds of unearned interest. The current rules on these issues do not use the term "amount financed," so the specific definition is unnecessary. However, other rules throughout Chapter 83 use the term "amount financed" to refer to the amount calculated under Regulation Z. For this reason, the amendment replaces the former definition with a reference to Regulation Z.

An adopted change to §83.301(2)(A) amends the definition of "principal party" for sole proprietorships. The amendment removes the statement that proprietors include spouses with a community property interest. In addition, an amendment to §83.302(1)(B)(i) removes the requirement to disclose community property interests and documentation regarding separate property status, and replaces it with a requirement to disclose the names of the spouses of principal parties if requested. The agency currently spends considerable time requesting information from license applicants to determine the status of spouses' property interests, and explaining these concepts to applicants. These amendments help streamline the licensing process and reduce regulatory burden. The amendments also make the application process simpler and more straightforward for applicants. In specific cases where the spouse is a principal party, the OCCC would be able to request additional information about the spouse under current §83.302(1)(E) - (F).

Section 83.303 is being repealed and replaced with a new rule, with the intent to clarify the requirements when a licensee transfers ownership. Section 83.303 describes what constitutes a transfer of ownership requiring the filing of a transfer application. The adopted new rule largely maintains the requirements under the current rule, including the requirements for filing a license transfer application. In addition to the license transfer application allowed under the current rule, the new rule allows an alternative method for a transfer of ownership: a new license application on transfer of ownership. The new rule describes what the application has to include, the timing requirements, and which parties are responsible at different points in the transfer process. Subsection (a) describes the purpose of the new section. Subsection (b) defines terms used throughout the subsection. In particular, subsection (b)(3) defines the phrase "transfer of ownership," listing different types of changes in acquisition or control of the licensed entity. The precommenter recommended that this definition specify that a transfer of ownership does not include a relocation of regulated transactions from one licensed location to another. Relocations of regulated transactions are governed by current §83.308(c), which requires licensees to notify debtors that the transactions have been relocated. In response to this recommendation, §83.303(b)(3) as adopted states that a transfer of ownership does not include a relocation of regulated transactions from one licensed location to another licensed location.

Section 83.303(c) specifies that a license may not be sold, transferred, or assigned without the written approval of the OCCC, as provided by Texas Finance Code, §342.163.

Since the proposal, a change has been made to §83.303(c) in order to provide the correct citation to the Texas Finance Code relating to the transfer or assignment of a license.

Section 83.303(d) provides a timing requirement, stating that a complete license transfer application or new license application on transfer of ownership must be filed no later than 30 days after the transfer of ownership. Subsection (e) outlines the requirements for the license transfer application or new license application on transfer of ownership. These requirements include complete documentation of the transfer of ownership, as well as a complete license application for transferees that do not hold an existing regulated lender license. Subsection (e)(5) explains that the application may include a request for permission to operate.

Subsection (f) provides that the OCCC may issue a permission to operate to the transferee. A permission to operate is a temporary authorization from the OCCC allowing a transferee to operate while final approval is pending for an application. Subsection (g) specifies the transferee's authority to engage in business if the transferee has filed a complete application including a request for permission to operate. It also requires the transferee to immediately cease doing business if the OCCC denies the request for permission to operate or denies the application.

Subsection (h) describes the situations where the transferor is responsible for business activity at the licensed location, situations where the transferee is responsible, and situations where both parties are responsible. In this subsection, the precommenter made the following recommendations. First, the precommenter recommended against using the phrase "joint and several responsibility," because the precommenter believes that this phrase could lead to confusion. Second, the precommenter recommended against drafting the subsection's paragraphs so that they overlap with each other. Third, the precommenter recommended that this subsection consist of two paragraphs (one for the transferor's responsibility and one for the transferee's responsibility), for the sake of clarity. In response to these recommendations, the three paragraphs in subsection (h) apply to three distinct periods of time: (1) the period before the transferee begins conducting business (when the transferor is responsible), (2) the period after the transferee begins conducting business and before final approval of the application (when the transferor and transferee are each responsible), and (3) the period after final approval (when the transferee is responsible). For the second period, subsection (h)(2) specifies that the transferor and transferee are each responsible. The agency believes that it is appropriate for the rule to specify that the transferor and transferee are each responsible during this period, which includes any activity performed by the transferee under a permission to operate. In this way, the rule helps ensure that licensees are aware of their responsibilities. The new rule's statement that the transferor is responsible for acts performed during a permission to operate is consistent with the former rule at §83.303(d), which stated: "The transferor must accept full responsibility to any customer and to the OCCC for the licensed business for any acts of the transferee in connection with the operation of the lending business." The permission to operate is a temporary authorization allowing a transferee to operate under a transferor's license while the transferee's application is pending. The OCCC allows

the permission-to-operate procedure in order to accommodate transferees that wish to begin doing business after a routine transfer of ownership but before approval of a license application. The alternative would be to prohibit the transferee from engaging in business until after the license application is approved. If a transferor wishes to protect itself from responsibility for the transferee's acts, then the transferor can delay the transfer of ownership until the transferee's application is approved. Alternatively, the transferor can enter an indemnification agreement with the transferee, under which the transferee must reimburse the transferor for losses resulting from the transferee's acts.

In §83.304, concerning Change in Form or Proportionate Ownership, conforming changes have been made corresponding to adopted new §83.303. Throughout subsections (b) and (c), references have been added to the new license application on transfer of ownership.

Adopted amendments to §83.306 clarify the circumstances in which a licensee must notify the OCCC of changes to information in the original license application. The amendments specify that the requirement to provide updated information within 10 days applies before a license application is approved. New §83.306(b) provides that a licensee must notify the OCCC within 30 days if the information relates to the names of principal parties, criminal history, regulatory actions, or court judgments. New §83.306(c) specifies that each applicant or licensee is responsible for ensuring that all contact information on file with the OCCC is current and correct, and that it is a best practice for licensees to regularly review contact information.

An adopted amendment to §83.310(c) provides that a license applicant must pay a fee to a party designated by the Texas Department of Public Safety (DPS) for processing fingerprints, replacing a statement that the fee will be paid to the OCCC. This amendment conforms the rule to the method by which applicants currently provide fingerprint information through DPS's Fingerprint Applicant Services of Texas (FAST) program. Additional amendments to §83.310(d) conform the rule to new §83.303 and add numbered paragraphs for clarity.

Adopted amendments to §83.403 clarify the agency's procedure for providing delinquency notices to licensees that have failed to pay an annual assessment fee. The amendments specify that notice of delinquency is considered to be given when the OCCC sends the notice by mail to the address on file with the OCCC as a master file address, or by e-mail to the address on file with the OCCC (if the licensee has provided an e-mail address).

Adopted new §83.404 specifies the criminal history information collected by the OCCC, outlines factors the OCCC will consider when reviewing criminal history information, and describes grounds for denial, suspension, and revocation of a regulated lender license. This section replaces former §83.404 and §83.405, which are being repealed. Subsection (a) describes the OCCC's collection of criminal history record information from law enforcement agencies. Subsection (b) identifies the criminal history information that the applicant must disclose. Subsection (c) describes the OCCC's denial, suspension, and revocation based on crimes that are directly related to the licensed occupation of regulated lender. Subsection (c)(1) lists the types of crimes that the OCCC considers to directly relate to the duties and responsibilities of being a regulated lender, including the reasons the crimes relate to the occupation, as provided by Texas Occupations Code, §53.025(a). Subsection (c)(2) contains the factors the OCCC will consider in determining whether a criminal offense directly relates to the duties and responsibilities of a licensee, as provided by Texas Occupations Code, §53.022. Subsection (c)(3) provides the mitigating factors the OCCC will consider to determine whether a conviction renders an applicant or licensee unfit, as provided by Texas Occupations Code, §53.023. Subsection (d) describes the OCCC's authority to deny a license application if it does not find that the financial responsibility, experience, character, and general fitness of the applicant are sufficient to command the confidence of the public and warrant the belief that the business will be operated lawfully and fairly, as provided by Texas Finance Code, §342.104(a). Subsection (e) explains that the OCCC will revoke a license on the licensee's imprisonment following a felony conviction, felony community supervision revocation, revocation of parole, or revocation of mandatory supervision, as provided by Texas Occupations Code, §53.021(b).

§83.404(f) identifies other grounds for denial, suspension, or revocation, including convictions for specific offenses described by statutory provisions cited in the rule.

Since the proposal, a change has been made to §83.404(f)(2) in order to provide a more complete citation to the Texas Code of Criminal Procedure. As the cited provision is being relocated, the revision includes citations for both the current location and the location effective on January 1, 2017.

An adopted amendment to the recordkeeping rule in §83.828(10)(A) lists documentation and disclosures required under the Department of Defense's Military Lending Act Rule, 32 C.F.R. pt. 232. The Department of Defense's recently adopted amendments to the rule have a required compliance date of October 3, 2016. Under the amended Military Lending Act Rule, lenders will generally be required to provide model disclosures to covered military borrowers. 32 C.F.R. §232.6. The amended rule also specifies documentation that lenders can obtain in order to determine whether a consumer is a covered military borrower. 32 C.F.R. §232.5. The adopted amendments to §83.828(10)(A) specify that licensees are required to maintain these documents and disclosures in the individual borrower's loan file. This file must be maintained for four years from the date of the loan, or two years from the date of the final account entry, whichever is later, under current §83.828(14). However, licensees may keep the documents for a longer period of time if they choose. Additionally, an amendments to the recordkeeping rule in §83.828(10)(C) update a reference to the Texas Department of Public Safety "Driver's Crash Report" form and correct a typographical error.

DIVISION 1. GENERAL PROVISIONS

7 TAC §83.102

The rule changes are adopted under Texas Finance Code §11.304, which authorizes the Finance Commission to adopt rules to enforce Title 4 of the Texas Finance Code. Additionally, Texas Finance Code, §342.551 grants the Finance Commission the authority to adopt rules to enforce the consumer loan chapter.

The statutory provisions affected by the adoption are contained in Texas Finance Code, Chapter 342.

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

Filed with the Office of the Secretary of State on August 19, 2016.

TRD-201604267

Leslie L. Pettijohn
Commissioner
Office of Consumer Credit Commissioner
Effective date: September 8, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 936-7621

♦ ♦ ♦

DIVISION 3. APPLICATION PROCEDURES

7 TAC §§83.301 - 83.304, 83.306, 83.310

The rule changes are adopted under Texas Finance Code §11.304, which authorizes the Finance Commission to adopt rules to enforce Title 4 of the Texas Finance Code. Additionally, Texas Finance Code, §342.551 grants the Finance Commission the authority to adopt rules to enforce the consumer loan chapter.

The statutory provisions affected by the adoption are contained in Texas Finance Code, Chapter 342.

§83.303. Transfer of License; New License Application on Transfer of Ownership.

(a) Purpose. This section describes the license application requirements when a licensed entity transfers its license or ownership of the entity. If a transfer of ownership occurs, the transferee must submit either a license transfer application or a new license application on transfer of ownership under this section.

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

(1) License transfer--A sale, assignment, or transfer of a regulated loan license.

(2) Permission to operate--A temporary authorization from the OCCC, allowing a transferee to operate under a transferor's license while final approval is pending for a license transfer application or a new license application on transfer of ownership.

(3) Transfer of ownership--Any purchase or acquisition of control of a licensed entity (including acquisition by gift, devise, or descent), or a substantial portion of a licensed entity's assets, where a substantial change in management or control of the business occurs. The term does not include a change in proportionate ownership as defined in §83.304 of this title (relating to Change in Form or Proportionate Ownership) or a relocation of regulated transactions from one licensed location to another licensed location, as described by §83.308(c) of this title (relating to Relocation). Transfer of ownership includes the following:

(A) an existing owner of a sole proprietorship relinquishes that owner's entire interest in a license or an entirely new entity has obtained an ownership interest in a sole proprietorship license;

(B) any purchase or acquisition of control of a licensed general partnership, in which a partner relinquishes that owner's entire interest or a new general partner obtains an ownership interest;

(C) any change in ownership of a licensed limited partnership interest in which:

(i) a limited partner owning 10% or more relinquishes that owner's entire interest;

(ii) a new limited partner obtains an ownership interest of 10% or more;

(iii) a general partner relinquishes that owner's entire interest; or

(iv) a new general partner obtains an ownership interest (transfer of ownership occurs regardless of the percentage of ownership exchanged of the general partner);

(D) any change in ownership of a licensed corporation in which:

(i) a new stockholder obtains 10% or more of the outstanding voting stock in a privately held corporation;

(ii) an existing stockholder owning 10% or more relinquishes that owner's entire interest in a privately held corporation;

(iii) any purchase or acquisition of control of 51% or more of a company that is the parent or controlling stockholder of a licensed privately held corporation occurs; or

(iv) any stock ownership changes that result in a change of control (i.e., 51% or more) for a licensed publicly held corporation occur;

(E) any change in the membership interest of a licensed limited liability company:

(i) in which a new member obtains an ownership interest of 10% or more;

(ii) in which an existing member owning 10% or more relinquishes that member's entire interest; or

(iii) in which a purchase or acquisition of control of 51% or more of any company that is the parent or controlling member of a licensed limited liability company occurs;

(F) any transfer of a substantial portion of the assets of a licensed entity under which a new entity controls business at a licensed location; and

(G) any other purchase or acquisition of control of a licensed entity, or a substantial portion of a licensed entity's assets, where a substantial change in management or control of the business occurs.

(4) Transferee--The entity that controls business at a licensed location after a transfer of ownership.

(5) Transferor--The licensed entity that controls business at a licensed location before a transfer of ownership.

(c) License transfer approval. No regulated loan license may be sold, transferred, or assigned without the written approval of the OCCC, as provided by Texas Finance Code, §342.163. A license transfer is approved when the OCCC issues its final written approval of a license transfer application.

(d) Timing. No later than 30 days after the event of a transfer of ownership, the transferee must file a complete license transfer application or new license application on transfer of ownership in accordance with subsection (e). A transferee may file an application before this date.

(e) Application requirements.

(1) Generally. This subsection describes the application requirements for a license transfer application or a new license application on transfer of ownership. A transferee must submit the application in a format prescribed by the OCCC. The OCCC may accept prescribed alternative formats to facilitate multistate uniformity of applications or in order to accept approved electronic submissions. The transferee must pay appropriate fees in connection with the application.

(2) Documentation of transfer of ownership. The application must include documentation evidencing the transfer of ownership. The documentation should include one or more of the following:

(A) a copy of the asset purchase agreement when only the assets have been purchased;

(B) a copy of the purchase agreement or other evidence relating to the acquisition of the equity interest of a licensee that has been purchased or otherwise acquired;

(C) any document that transferred ownership by gift, devise, or descent, such as a probated will or a court order; or

(D) any other documentation evidencing the transfer event.

(3) Application information for new licensee. If the transferee does not hold a regulated loan license at the time of the application, then the application must include the information required for new license applications under §83.302 of this title (relating to Filing of New Application). The instructions in §83.302 of this title apply to these filings.

(4) Application information for transferee that holds a license. If the transferee holds a regulated loan license at the time of the application, then the application must include amendments to the transferee's original license application describing the information that is unique to the transfer event, including disclosure questions, owners and principal parties, and a new financial statement, as provided in §83.302 of this title. The instructions in §83.302 of this title apply to these filings. The responsible person at the new location must file a personal affidavit, personal questionnaire, and employment history, if not previously filed. Other information required by §83.302 of this title need not be filed if the information on file with the OCCC is current and valid.

(5) Request for permission to operate. The application may include a request for permission to operate. The request must be in writing and signed by the transferor and transferee. The request must include all of the following:

(A) a statement by the transferor granting authority to the transferee to operate under the transferor's license while final approval of the application is pending;

(B) an acknowledgement that the transferor and transferee each accept responsibility to any consumer and to the OCCC for any acts performed under the license while the permission to operate is in effect; and

(C) if the application is a new license application on transfer of ownership, an acknowledgement that the transferor will immediately surrender or inactivate its license if the OCCC approves the application.

(f) Permission to operate. If the application described by subsection (e) includes a request for permission to operate and all required information, and the transferee has paid all fees required for the application, then the OCCC may issue a permission to operate to the transferee. A request for permission to operate may be denied even if the application contains all of the required information. The denial of a request for permission to operate does not create a right to a hearing. If the OCCC grants a permission to operate, the transferor must cease operating under the authority of the license. Two companies may not simultaneously operate under a single license. A permission to operate terminates if the OCCC denies an application described by subsection (e).

(g) Transferee's authority to engage in business. If a transferee has filed a complete application including a request for permission to operate as described by subsection (e), by the deadline described by subsection (d), then the transferee may engage in business as a regulated lender. However, the transferee must immediately cease doing business if the OCCC denies the request for permission to operate or denies the application. If the OCCC denies the application, then the transferee has a right to a hearing on the denial, as provided by §83.307(d) of this title (relating to Processing of Application).

(h) Responsibility.

(1) Responsibility of transferor. Before the transferee begins performing regulated lender activity under a license, the transferor is responsible to any consumer and to the OCCC for all regulated lender activity performed under the license.

(2) Responsibility of transferor and transferee. If a transferee begins performing regulated lender activity under a license before the OCCC's final approval of an application described by subsection (e), then the transferor and transferee are each responsible to any consumer and to the OCCC for activity performed under the license during this period.

(3) Responsibility of transferee. After the OCCC's final approval of an application described by subsection (e), the transferee is responsible to any consumer and to the OCCC for all regulated lender activity performed under the license. The transferee is responsible for any transactions that it purchases from the transferor. In addition, if the transferee receives a license transfer, then the transferee's responsibility includes all activity performed under the license before the license transfer.

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

Filed with the Office of the Secretary of State on August 19, 2016.

TRD-201604268
Leslie L. Pettijohn
Commissioner
Office of Consumer Credit Commissioner
Effective date: September 8, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 936-7621

7 TAC §83.303

The repeal is adopted under Texas Finance Code §11.304, which authorizes the Finance Commission to adopt rules to enforce Title 4 of the Texas Finance Code. Additionally, Texas Finance Code, §342.551 grants the Finance Commission the authority to adopt rules to enforce the consumer loan chapter.

The statutory provisions affected by the adopted repeal are contained in Texas Finance Code, Chapter 342.

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

Filed with the Office of the Secretary of State on August 19, 2016.

TRD-201604271

Leslie L. Pettijohn
Commissioner
Office of Consumer Credit Commissioner
Effective date: September 8, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 936-7621

♦ ♦ ♦

DIVISION 4. LICENSE

7 TAC §83.403, §83.404

The rule changes are adopted under Texas Finance Code §11.304, which authorizes the Finance Commission to adopt rules to enforce Title 4 of the Texas Finance Code. Additionally, Texas Finance Code, §342.551 grants the Finance Commission the authority to adopt rules to enforce the consumer loan chapter.

The statutory provisions affected by the adoption are contained in Texas Finance Code, Chapter 342.

§83.404. Denial, Suspension, or Revocation Based on Criminal History.

(a) Criminal history record information. After an applicant submits a complete license application, including all required fingerprints, and pays the fees required by §83.310 of this title (relating to Fees), the OCCC will investigate the applicant and its principal parties. The OCCC will obtain criminal history record information from the Texas Department of Public Safety and the Federal Bureau of Investigation based on the applicant's fingerprint submission. The OCCC will continue to receive information on new criminal activity reported after the fingerprints have been initially processed.

(b) Disclosure of criminal history. The applicant must disclose all criminal history information required to file a complete application with the OCCC. Failure to provide any information required as part of the application or requested by the OCCC reflects negatively on the belief that the business will be operated lawfully and fairly. The OCCC may request additional criminal history information from the applicant, including the following:

(1) information about arrests, charges, indictments, and convictions of the applicant and its principal parties;

(2) reliable documents or testimony necessary to make a determination under subsection (c), including letters of recommendation from prosecution, law enforcement, and correctional authorities;

(3) proof that the applicant has maintained a record of steady employment, has supported the applicant's dependents, and has otherwise maintained a record of good conduct; and

(4) proof that all outstanding court costs, supervision fees, fines, and restitution as may have been ordered have been paid or are current.

(c) Crimes directly related to licensed occupation. The OCCC may deny a license application, or suspend or revoke a license, if the applicant or licensee has been convicted of an offense that directly relates to the duties and responsibilities of a licensee under Texas Finance Code, Chapter 342, as provided by Texas Occupations Code, §53.021(a)(1).

(1) Originating, acquiring, or servicing loans under Texas Finance Code, Chapter 342 involves or may involve making representations to consumers regarding the terms of the loan, receiving money from consumers, remitting money to third parties, maintaining accounts, repossessing property without a breach of the peace, maintaining goods that have been repossessed, collecting due amounts in a legal manner, and foreclosing on real property in compliance with state and federal law. Consequently, the following crimes are directly related to the duties and responsibilities of a licensee and may be grounds for denial, suspension, or revocation:

(A) theft;

(B) assault;

(C) any offense that involves misrepresentation, deceptive practices, or making a false or misleading statement (including fraud or forgery);

(D) any offense that involves breach of trust or other fiduciary duty;

(E) any criminal violation of a statute governing credit transactions or debt collection;

(F) failure to file a government report, filing a false government report, or tampering with a government record;

(G) any greater offense that includes an offense described in subparagraphs (A) - (F) of this paragraph as a lesser included offense;

(H) any offense that involves intent, attempt, aiding, solicitation, or conspiracy to commit an offense described in subparagraphs (A) - (G) of this paragraph.

(2) In determining whether a criminal offense directly relates to the duties and responsibilities of holding a license, the OCCC will consider the following factors, as specified in Texas Occupations Code, §53.022:

(A) the nature and seriousness of the crime;

(B) the relationship of the crime to the purposes for requiring a license to engage in the occupation;

(C) the extent to which a license might offer an opportunity to engage in further criminal activity of the same type as that in which the person previously had been involved; and

(D) the relationship of the crime to the ability, capacity, or fitness required to perform the duties and discharge the responsibilities of a licensee.

(3) In determining whether a conviction for a crime renders an applicant or a licensee unfit to be a licensee, the OCCC will consider the following factors, as specified in Texas Occupations Code, §53.023:

(A) the extent and nature of the person's past criminal activity;

(B) the age of the person when the crime was committed;

(C) the amount of time that has elapsed since the person's last criminal activity;

(D) the conduct and work activity of the person before and after the criminal activity;

(E) evidence of the person's rehabilitation or rehabilitative effort while incarcerated or after release, or following the criminal activity if no time was served; and

(F) evidence of the person's current circumstances relating to fitness to hold a license, which may include letters of recommendation from one or more of the following:

(i) prosecution, law enforcement, and correctional officers who prosecuted, arrested, or had custodial responsibility for the person;

(ii) the sheriff or chief of police in the community where the person resides; and

(iii) other persons in contact with the convicted person.

(d) Crimes related to character and fitness. The OCCC may deny a license application if the OCCC does not find that the financial responsibility, experience, character, and general fitness of the applicant are sufficient to command the confidence of the public and warrant the belief that the business will be operated lawfully and fairly, as provided by Texas Finance Code, §342.104(a)(1). In conducting its review of character and fitness, the OCCC will consider the criminal history of the applicant and its principal parties. If the applicant or a principal party has been convicted of an offense described by subsections (c)(1) or (f)(2) of this section, this reflects negatively on an applicant's character and fitness. The OCCC may deny a license application based on other criminal history of the applicant or its principal parties if, when the application is considered as a whole, the agency does not find that the financial responsibility, experience, character, and general fitness of the applicant are sufficient to command the confidence of the public and warrant the belief that the business will be operated lawfully and fairly. The OCCC will, however, consider the factors identified in subsection (c)(2) - (3) of this section in its review of character and fitness.

(e) Revocation on imprisonment. A license will be revoked on the licensee's imprisonment following a felony conviction, felony community supervision revocation, revocation of parole, or revocation of mandatory supervision, as provided by Texas Occupations Code, §53.021(b).

(f) Other grounds for denial, suspension, or revocation. The OCCC may deny a license application, or suspend or revoke a license, based on any other ground authorized by statute, including the following:

(1) a conviction for an offense that does not directly relate to the duties and responsibilities of the occupation and that was committed less than five years before the date of application, as provided by Texas Occupations Code, §53.021(a)(2);

(2) a conviction for an offense listed in Texas Code of Criminal Procedure, art. 42.12, §3g (effective through December 31, 2016), art. 42A.054 (effective January 1, 2017), or art. 62.001(6), as provided by Texas Occupations Code, §53.021(a)(3)-(4);

(3) errors or incomplete information in the license application;

(4) a fact or condition that would have been grounds for denying the license application, and that either did not exist at the time of the application or the OCCC was unaware of at the time of application, as provided by Texas Finance Code, §342.156(3); and

(5) any other information warranting the belief that the business will not be operated lawfully and fairly, as provided by Texas Finance Code, §342.104(a)(1) and §342.156.

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

Filed with the Office of the Secretary of State on August 19, 2016.

TRD-201604269

Leslie L. Pettijohn
Commissioner
Office of Consumer Credit Commissioner
Effective date: September 8, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 936-7621

♦ ♦ ♦

7 TAC §83.404, §83.405

The repeals are adopted under Texas Finance Code §11.304, which authorizes the Finance Commission to adopt rules to enforce Title 4 of the Texas Finance Code. Additionally, Texas Finance Code, §342.551 grants the Finance Commission the authority to adopt rules to enforce the consumer loan chapter.

The statutory provisions affected by the adopted repeals are contained in Texas Finance Code, Chapter 342.

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

Filed with the Office of the Secretary of State on August 19, 2016.

TRD-201604272
Leslie L. Pettijohn
Commissioner
Office of Consumer Credit Commissioner
Effective date: September 8, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 936-7621

♦ ♦ ♦

DIVISION 10. DUTIES AND AUTHORITY OF AUTHORIZED LENDERS

7 TAC §83.828

The rule changes are adopted under Texas Finance Code §11.304, which authorizes the Finance Commission to adopt rules to enforce Title 4 of the Texas Finance Code. Additionally, Texas Finance Code, §342.551 grants the Finance Commission the authority to adopt rules to enforce the consumer loan chapter.

The statutory provisions affected by the adoption are contained in Texas Finance Code, Chapter 342.

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

Filed with the Office of the Secretary of State on August 19, 2016.

TRD-201604270
Leslie L. Pettijohn
Commissioner
Office of Consumer Credit Commissioner
Effective date: September 8, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 936-7621

♦ ♦ ♦

CHAPTER 87. TAX REFUND ANTICIPATION LOANS

The Finance Commission of Texas (commission) adopts amendments and a new rule in 7 TAC Chapter 87, concerning Tax Refund Anticipation Loans. The commission adopts amendments to §§87.102 - 87.105 and 87.107; and adopts new §87.201.

The commission adopts the amendments and new rule without changes to the proposed text as published in the June 24, 2016, issue of the *Texas Register* (41 TexReg 4551).

The commission received no written comments on the proposal.

In general, the purpose of the revisions to these rules for tax refund anticipation loan facilitators is to implement changes resulting from the commission's review of Chapter 87 under Texas Government Code, §2001.039. The notice of intention to review 7 TAC Chapter 87 was published in the *Texas Register* on May 6, 2016 (41 TexReg 3317). The agency did not receive any comments on the notice of intention to review.

The agency circulated an early draft of proposed changes to interested stakeholders and then held a stakeholders meeting, including online participation. The agency believes that early participation by stakeholders in the rulemaking process results in more informed and balanced proposals.

The rule changes clarify the term of registration, require that registrants maintain current contact information, implement a statutory late filing fee, and add a required notice that registrants must provide to consumers explaining how they can file a complaint with the agency.

The individual purposes of the amendments to each rule and of the new rule are provided in the following paragraphs.

Adopted amendments to §87.102(a) remove unnecessary language and add a reference to the agency's name and acronym, Office of Consumer Credit Commissioner (OCCC). The agency believes that the use of "OCCC" provides better clarity to the rules when the context calls for action by the agency, as opposed to the commissioner specifically.

Corresponding changes to further the use of this terminology are included throughout Chapter 87. The following provisions contain adopted amendments to replace the use of "commissioner" or "commissioner's" with a reference to the OCCC: §87.103(a)(1) and §87.104.

Adopted new §87.103(b) explains that an applicant may apply for a registration for the current year or a registration for the following year. Subsection (b) also specifies the effective period of a registration. Although the existing rules in Chapter 87 specify requirements for renewing a registration, they did not specify when the registration is effective or when it expires. Subsection (b) conforms to the agency's current practices and is intended to provide clarity on the effective period of registration.

Adopted new §87.103(c) explains that applicants and registrants must keep their contact information up-to-date. This provision is intended to ensure that the agency can contact registrants, so that the agency can carry out its responsibility to monitor facilitators and ensure compliance, as provided by Texas Finance Code, §352.005.

Adopted amendments to §87.105(a) - (c) amend the text to provide clarity and consistency. In particular, an amendment to subsection (c) replaces the term "Annual Assessments" with "Renewals," to ensure consistency with other rules in Chapter 87.

Adopted new §87.105(d) specifies that a facilitator must pay a $250 late filing fee if the facilitator: 1) obtains a new registration after engaging in business as a facilitator (i.e., engages in unregistered activity), or 2) renews a registration for the current year after January 30. This requirement is based on Texas Finance Code, §349.302, which provides a late filing fee of $250 for obtaining a late registration with the OCCC. Subsection (d) is intended to provide clarity regarding the amount of the late filing fee and the situations where it is required.

Adopted amendments to §87.107(a) conform to other amendments in the adoption. The former December 1 renewal deadline is replaced with a requirement to pay any late filing fee required by §87.105(d). This means that if a facilitator renews a registration for the current year after January 30, the facilitator must pay a $250 late filing fee in order to renew. The amendments to subsection (a) are intended to clarify renewal requirements and ensure consistency with Texas Finance Code, §349.302.

Adopted new §87.107(b) specifies that a facilitator may not renew a registration that has been expired for more than one year, and that if a registration has been expired for more than one year, the facilitator must apply for a new registration. This provision is intended to clarify renewal requirements and ensure consistency with other amendments to the rules.

Adopted new §87.201 requires facilitators to provide a notice explaining how consumers can file a complaint with the OCCC. Subsection (a) describes the content of the OCCC notice, which includes the facilitator's contact information and the OCCC's contact information. Subsection (b) explains that the OCCC notice must be provided on either the privacy notice or the written disclosure of fees required under Texas Finance Code, §352.004. This requirement is based on Texas Finance Code, §11.307(b), which provides that the commission shall adopt rules requiring regulated entities to include complaint notices on legally required privacy notices. Because refund anticipation loan facilitators perform tax preparation services, they are required to provide privacy notices to consumers under federal law, as provided by Regulation P, 12 C.F.R. §§1016.3(l)(3)(ii)(H), 1016.3(s)(1), 1016.4(a).

The OCCC believes that new §87.201 is necessary so that consumers and creditors will have the most current contact information for the OCCC, as well as readily available information for consumers explaining how they can file a complaint with the OCCC. Registrants are afforded multiple ways to comply with the new rule: 1) add the OCCC notice to the current federal privacy notice in the box for "Other important information"; 2) add the OCCC notice to the registrant's existing disclosure form under Texas Finance Code, §352.004; or 3) provide the OCCC notice on a new page that is part of one of these two forms.

As stated in the proposal, the OCCC wishes to help registrants minimize potential costs with a delayed implementation date of January 1, 2017, for new §87.201. Accordingly, the agency will allow registrants to continue the use of current forms through December 31, 2016. Starting January 1, 2017, registrants must comply with new §87.201 by adding the OCCC notice to either their existing privacy notice or existing written disclosure provided to consumers.

The delayed implementation date applies only to new §87.201. Thus, the amendments to §§87.102 - 87.105 and 87.107 will be implemented immediately upon the effective date of these rules, which is anticipated to be on or around September 8, 2016.

SUBCHAPTER A. REGISTRATION PROCEDURES

7 TAC §§87.102 - 87.105, 87.107

The rule changes are adopted under Texas Finance Code, §11.304, which authorizes the commission to adopt rules to enforce Chapter 14 and Title 4 of the Texas Finance Code. The rule changes are also adopted under Texas Finance Code, §352.003, which authorizes the commission to prescribe procedures for the registration of tax refund anticipation loan facilitators. New §87.201 is adopted under Texas Finance Code, §11.307(b), which provides that the commission shall adopt rules requiring regulated entities to include complaint notices on legally required privacy notices.

The statutory provisions affected by the adoption are contained in Texas Finance Code, Chapters 11 and 352.

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

Filed with the Office of the Secretary of State on August 19, 2016.

TRD-201604273
Leslie L. Pettijohn
Commissioner
Office of Consumer Credit Commissioner
Effective date: September 8, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 936-7621

♦ ♦ ♦

SUBCHAPTER B. DISCLOSURES

7 TAC §87.201

The rule changes are adopted under Texas Finance Code, §11.304, which authorizes the commission to adopt rules to enforce Chapter 14 and Title 4 of the Texas Finance Code. The rule changes are also adopted under Texas Finance Code, §352.003, which authorizes the commission to prescribe procedures for the registration of tax refund anticipation loan facilitators. New §87.201 is adopted under Texas Finance Code, §11.307(b), which provides that the commission shall adopt rules requiring regulated entities to include complaint notices on legally required privacy notices.

The statutory provisions affected by the adoption are contained in Texas Finance Code, Chapters 11 and 352.

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

Filed with the Office of the Secretary of State on August 19, 2016.

TRD-201604274
Leslie L. Pettijohn
Commissioner
Office of Consumer Credit Commissioner
Effective date: September 8, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 936-7621

♦ ♦ ♦

TITLE 19. EDUCATION

PART 2. TEXAS EDUCATION AGENCY

CHAPTER 102. EDUCATIONAL PROGRAMS

SUBCHAPTER KK. COMMISSIONER'S RULES CONCERNING COMPLIANCE INVESTIGATIONS IN CONNECTION WITH STATE-FUNDED EDUCATION PROGRAM GRANTS

19 TAC §102.1401

The Texas Education Agency (TEA) adopts new §102.1401, concerning educational programs. The new section is adopted without changes to the proposed text as published in the July 1, 2016 issue of the *Texas Register* (41 TexReg 4754) and will not be republished. The adopted new section establishes provisions for TEA compliance investigations in connection with state education grant programs.

REASONED JUSTIFICATION. TEA currently lacks an explicit rule framework for state education grant compliance investigations, corrective actions, and sanctions. Given sufficient statutory authority to adopt rules in this area and in order to ensure fiscal responsibility in connection with state grant funds and appropriate implementation of state grant program requirements, the TEA adopts new 19 TAC §102.1401, Compliance Investigations. The new section outlines the framework for compliance investigations, corrective actions, and sanctions the TEA may initiate for recipients of state education program grant funds to ensure taxpayer dollars are being spent appropriately and prevent fraud, waste, and abuse.

SUMMARY OF COMMENTS AND AGENCY RESPONSES. The public comment period on the proposal began July 1, 2016, and ended August 1, 2016. Following is a summary of public comments received and corresponding agency responses regarding the proposed new 19 TAC Chapter 102, Educational Programs, Subchapter KK, Commissioner's Rules Concerning Compliance Investigations in Connection with State-Funded Education Program Grants, §102.1401, Compliance Investigations.

Comment. Disability Rights Texas (DRTx) commented that students with disabilities, their parents, and educators will benefit from the adopted rule provision that permits a person or entity to file a complaint seeking to initiate a compliance investigation.

Agency Response. The agency agrees.

Comment. DRTx commented in connection with the potential benefit to students with disabilities, their parents, and educators that (1) the rule should clarify that a final compliance investigation report must be made available to the public by the state education grant recipient in the interests of transparency and public accountability; and (2) an explicit provision of the rule that requires notice and posting of the final report would assist in deterring noncompliance and promoting the satisfaction of corrective action plans.

Agency Response. The agency disagrees that the rule should explicitly require that a state education grant recipient must make a final compliance investigation report publicly available, as the Public Information Act already requires the same. The agency disagrees that an explicit provision should be added to the rule that would require notice and posting a final report by state edu-

cation grant recipients. The agency has determined that the rule provisions are sufficient to deter noncompliance and encourage satisfaction of corrective action plans.

Comment. DRTx commented that the commissioner should only be able to waive an Out-of-Compliance Status in writing with a stated basis for the waiver.

Agency Response. The agency disagrees that the commissioner's waiver authority should be constrained by rule in such a manner because it is unnecessary to effectuate the purpose of the rule and is contrary to the general proposition that the commissioner may waive provisions of the Texas Education Code (TEC).

Comment. DRTx sought clarification on whether the definition of a state education program would include programs in TEC, Title 2, Subchapter F, Chapter 29, Subchapter A, including §29.013 (Noneducational Community-Based Support Services for Certain Students with Disabilities); §29.018 (Special Education Grant); and §29.022 (Video Surveillance of Special Education Settings), per TEC, §42.2528 (Excess Funds for Video Surveillance of Special Education Settings).

Agency Response. The comment falls outside the scope of the rule comment process due to the fact that the comment seeks a legal interpretation of the scope of the rule.

STATUTORY AUTHORITY. The new section is adopted under the Texas Education Code (TEC), §7.028(a)(2), which authorizes the agency to monitor compliance with state grant requirements, and §39.056(a), which authorizes the commissioner to direct the agency to conduct monitoring reviews and random on-site visits of a school district or charter school as authorized by TEC, §7.028.

CROSS REFERENCE TO STATUTE. The new section implements the Texas Education Code, §7.028(a)(2) and §39.056(a).

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604316
Cristina De La Fuente-Valadez
Director, Rulemaking
Texas Education Agency
Effective date: September 11, 2016
Proposal publication date: July 1, 2016
For further information, please call: (512) 475-1497

♦ ♦ ♦

CHAPTER 109. BUDGETING, ACCOUNTING, AND AUDITING

SUBCHAPTER AA. COMMISSIONER'S RULES CONCERNING FINANCIAL ACCOUNTABILITY

19 TAC §109.1001

The Texas Education Agency adopts an amendment to §109.1001, concerning the financial accountability rating system. The amendment is adopted with changes to the proposed text as published in the June 24, 2016 issue of the *Texas Register* (41 TexReg 4580). The section establishes provisions that detail the purpose, ratings, types of ratings, criteria, reporting, and sanctions for the financial accountability rating system. The adopted amendment clarifies the financial accountability rating indicators used to determine each school district's rating for the 2015-2016 rating year and subsequent years and describes a new "No Rating" category for certain school districts that receive territory from an annexation order under the Texas Education Code (TEC), §13.054, or consolidation under the TEC, Chapter 41, Subchapter H.

REASONED JUSTIFICATION. Chapter 109, Budgeting, Accounting, and Auditing, Subchapter AA, Commissioner's Rules Concerning Financial Accountability, establishes provisions that detail the purpose, ratings, types of ratings, criteria, reporting, and sanctions for the financial accountability rating system, in accordance with Senate Bill 218, 77th Texas Legislature, 2001, and House Bill (HB) 3, 81st Texas Legislature, 2009. HB 5, Section 49, 83rd Texas Legislature, Regular Session, 2013, amended the TEC, §39.082, requiring that the commissioner of education include in the financial accountability rating system processes for anticipating the future financial solvency of each school district and open-enrollment charter school, including analysis of district and school revenues and expenditures for preceding school years. The TEC, §39.082, also requires the commissioner to adopt rules by which to measure the financial management performance and future financial solvency of a district or an open-enrollment charter school and sets forth specific requirements relating to indicators adopted by the commissioner and the assignment of ratings.

Section 109.1001 includes the financial accountability rating system and rating worksheets that explain the indicators that the Texas Education Agency will analyze to assign financial accountability ratings for school districts and open-enrollment charter schools. The rule also specifies the minimum financial accountability rating information that a school district and an open-enrollment charter school is to report to parents and taxpayers in the district.

The adopted amendment clarifies the financial accountability rating indicators used to determine each school district's rating for the 2015-2016 rating year and subsequent years by revising the ratings worksheet calculations in Figure: 19 TAC §109.1001(e)(2) and Figure: 19 TAC §109.1001(e)(3). The adopted worksheets, dated August 2016, differ from the current worksheets, dated August 2015, as follows.

Indicator 5 was revised to show the operation of adding variable F for pension expense and net pension liability (NPL) instead of subtracting the variable from the calculation.

Indicators 6, 9, and 10 were revised to remove the pension expense and NPL variables from the calculation since the amounts for pension expense and NPL are not applicable to the indicator calculations.

Indicator 10 was revised to add variable E (function code 81 - capital outlay) in order to make the indicator more uniform for all districts.

Both figures, as well as subsection (h), were modified to include a new category for "No Rating" for the 2016-2017 rating year and subsequent years. The rating allows a school district that receives territory from an annexation or consolidation order by the commissioner due to closure or action under the TEC, Chapter 41, to not receive a financial accountability rating for two consec-

utive rating years after the annexation/consolidation with another school district.

The figures were modified at adoption to correct a typographical error in Indicator 5. The worksheets as proposed inadvertently showed variable F being subtracted rather than added.

SUMMARY OF COMMENTS AND AGENCY RESPONSES. The public comment period on the proposal began June 24, 2016, and ended July 25, 2016. Following is a summary of public comments received and corresponding agency responses regarding the proposed amendment to 19 TAC Chapter 109, Budgeting, Accounting, and Auditing, Subchapter AA, Commissioner's Rules Concerning Financial Accountability, §109.1001, Financial Accountability Ratings.

Comment. An administrator from Texas City Independent School District asked how long a district would receive "No Rating" under TEC, §13.054.

Agency Response. The agency provides the following clarification. A school district that is receiving territory due to an annexation order by the commissioner under the TEC, §13.054, or consolidation under the TEC, Chapter 41, Subchapter H, will not receive a rating for two consecutive years beginning with the rating year that is based on financial data from the fiscal year in which the order of annexation becomes effective.

STATUTORY AUTHORITY. The amendment is adopted under the Texas Education Code (TEC), §39.082, which requires the commissioner to develop and implement a financial accountability rating system for school districts and open-enrollment charter schools. The section establishes certain requirements, including procedures, to enable the commissioner and administrators to provide meaningful financial oversight and improvement along with transparency to the public. The section provides additional requirements and rulemaking authority for the commissioner. The amendment is also proposed under the TEC, §39.085, which provides the commissioner rulemaking authority for the implementation and administration of the financial accountability subchapter of the TEC, Chapter 39.

CROSS REFERENCE TO STATUTE. The amendment implements the Texas Education Code, §39.082 and §39.085.

§109.1001. Financial Accountability Ratings.

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

(1) Annual Financial Report (AFR)--The audited annual report required by the Texas Education Code (TEC), §44.008, that is due to the Texas Education Agency (TEA) by no later than 150 days after the close of a school district's or an open-enrollment charter school's fiscal year.

(2) Debt--An amount of money owed to a person, bank, company, or other organization.

(3) Electronic submission--The TEA electronic data feed format required for use by school districts, open-enrollment charter schools, and regional education service centers (ESCs).

(4) Financial Integrity Rating System of Texas (FIRST)--The financial accountability rating system administered by the TEA in accordance with the TEC, §39.082 and §39.085. The system provides additional transparency to public education finance and meaningful financial oversight and improvement for school districts (School FIRST) and open-enrollment charter schools (Charter FIRST).

(5) Fiscal year--The fiscal year of a school district or an open-enrollment charter school, which begins on July 1 or September 1 of each year, as determined by the board of trustees of the district or the governing body of the charter holder in accordance with the TEC, §44.0011.

(6) Foundation School Program (FSP)--The program established under the TEC, Chapters 41, 42, and 46, or any successor program of state-appropriated funding for school districts in this state.

(7) Public Education Information Management System (PEIMS)--The system that school districts and open-enrollment charter schools use to load, validate, and submit their data to the TEA.

(8) Summary of Finances (SOF) report--The document of record for FSP allocations. An SOF report is produced for each school district and open-enrollment charter school by the TEA division responsible for state funding that describes the school district's or open-enrollment charter school's funding elements and FSP state aid.

(9) Warrant hold--The process by which state payments issued to payees indebted to the state, or payees with a tax delinquency, are held by the Texas Comptroller of Public Accounts until the debt is satisfied in accordance with the Texas Government Code, §403.055.

(b) The TEA will assign a financial accountability rating to each school district and open-enrollment charter school as required by the TEC, §39.082.

(c) The commissioner of education will evaluate the rating system every three years as required by the TEC, §39.082, and may modify the system in order to improve the effectiveness of the rating system. If the rating system has been modified, the TEA will communicate changes to ratings criteria and their effective dates to school districts and open-enrollment charter schools.

(d) The TEA will use the following sources of data in calculating the financial accountability indicators for school districts and open-enrollment charter schools:

(1) AFR. For each school district and open-enrollment charter school, the TEA will use audited financial data in the district's or charter's AFR. The AFR, submitted as an electronic submission through the TEA website, must include data required in the Financial Accountability System Resource Guide (FASRG) adopted under §109.41 of this title (relating to Financial Accountability System Resource Guide);

(2) PEIMS. The TEA will use PEIMS data submitted by the school district or open-enrollment charter school in the calculation of the financial accountability indicators.

(3) Warrant holds. The TEA will use warrant holds as reported by the Texas Comptroller of Public Accounts in the calculation of the financial accountability indicators.

(4) FSP. The TEA will use the average daily attendance (ADA) information used for FSP funding purposes for the school district or open-enrollment charter school in the calculation of the financial accountability indicators.

(e) The TEA will base the financial accountability rating of a school district on its overall performance on the financial measurements, ratios, and other indicators established by the commissioner, as shown in the figures provided in this subsection. Financial accountability ratings for a rating year are based on the data from the immediate prior fiscal year.

(1) The financial accountability rating indicators for rating year 2014-2015 are based on fiscal year 2014 financial data and are

provided in the figure in this paragraph entitled "School FIRST - Rating Worksheet Dated August 2015 for rating year 2014-2015."
Figure: 19 TAC §109.1001(e)(1) (No change.)

(2) The financial accountability rating indicators for rating year 2015-2016 are based on fiscal year 2015 financial data and are provided in the figure in this paragraph entitled "School FIRST - Rating Worksheet Dated August 2015 for rating year 2015-2016."
Figure: 19 TAC §109.1001(e)(2)

(3) The financial accountability rating indicators for rating year 2016-2017 are based on fiscal year 2016 financial data and are provided in the figure in this paragraph entitled "School FIRST - Rating Worksheet Dated August 2015 for rating year 2016-2017." The financial accountability rating indicators for rating years after 2016-2017 will use the same calculation and scoring method provided in the figure in this paragraph.
Figure: 19 TAC §109.1001(e)(3)

(4) The specific calculations and scoring methods used in the financial accountability rating worksheets for school districts for rating years prior to 2014-2015 remain in effect for all purposes with respect to those rating years.

(f) The TEA will base the financial accountability rating of an open-enrollment charter school on its overall performance on the financial measurements, ratios, and other indicators established by the commissioner, as shown in the figures provided in this subsection. Financial accountability ratings for a rating year are based on the data from the immediate prior fiscal year.

(1) The financial accountability rating indicators for rating year 2014-2015 are based on fiscal year 2014 financial data and are provided in the figure in this paragraph entitled "Charter FIRST - Rating Worksheet Dated August 2015 for rating year 2014-2015."
Figure: 19 TAC §109.1001(f)(1) (No change.)

(2) The financial accountability rating indicators for rating year 2015-2016 are based on fiscal year 2015 financial data and are provided in the figure in this paragraph entitled "Charter FIRST - Rating Worksheet Dated August 2015 for rating year 2015-2016."
Figure: 19 TAC §109.1001(f)(2) (No change.)

(3) The financial accountability rating indicators for rating year 2016-2017 are based on fiscal year 2016 financial data and are provided in the figure in this paragraph entitled "Charter FIRST - Rating Worksheet Dated August 2015 for rating year 2016-2017." The financial accountability rating indicators for rating years after 2016-2017 will use the same calculation and scoring method provided in the figure in this paragraph.
Figure: 19 TAC §109.1001(f)(3) (No change.)

(4) The specific calculations and scoring methods used in the financial accountability rating worksheets for open-enrollment charter schools for rating years prior to 2014-2015 remain in effect for all purposes with respect to those rating years.

(g) The types of financial accountability ratings that school districts or open-enrollment charter schools may receive for the rating year 2014-2015 are as follows.

(1) P for pass. This rating applies only to the financial accountability rating for rating year 2014-2015 based on fiscal year 2014 financial data. In accordance with the procedures established in this section, a school district or an open-enrollment charter school will receive a P rating if it scores within the applicable range established by the commissioner for a P rating.

(2) F for substandard achievement. This rating applies to the financial accountability rating for rating year 2014-2015 based on fiscal year 2014 financial data. In accordance with the procedures established in this section, a school district or an open-enrollment charter school will receive an F rating if it scores within the applicable range established by the commissioner for an F rating.

(h) The types of financial accountability ratings that school districts or open-enrollment charter schools may receive for the rating year 2015-2016 and all subsequent rating years are as follows.

(1) A for superior achievement. Beginning with the financial accountability rating for rating year 2015-2016 and all subsequent rating years, in accordance with the procedures established in this section, a school district or an open-enrollment charter school will receive an A rating if it scores within the applicable range established by the commissioner for an A rating.

(2) B for above standard achievement. Beginning with the financial accountability rating for rating year 2015-2016 and all subsequent rating years, in accordance with the procedures established in this section, a school district or an open-enrollment charter school will receive a B rating if it scores within the applicable range established by the commissioner for a B rating.

(3) C for standard achievement. Beginning with the financial accountability rating for rating year 2015-2016 and all subsequent rating years, in accordance with the procedures established in this section, a school district or an open-enrollment charter school will receive a C rating if it scores within the applicable range established by the commissioner for a C rating.

(4) F for substandard achievement. Beginning with the financial accountability rating for rating year 2015-2016 and all subsequent rating years, in accordance with the procedures established in this section, a school district or an open-enrollment charter school will receive an F rating if it scores within the applicable range established by the commissioner for an F rating.

(5) No Rating. Beginning with the financial accountability rating for rating year 2016-2017 and all subsequent rating years, in accordance with the procedures established in this section, a school district receiving territory due to an annexation order by the commissioner under the TEC, §13.054, or consolidation under the TEC, Chapter 41, Subchapter H, will not receive a rating for two consecutive rating years beginning with the rating year that is based on financial data from the fiscal year in which the order of annexation becomes effective. After the second rating year, the receiving district will be subject to the financial accountability rating system established by the commissioner in this section.

(i) The commissioner may lower a financial accountability rating based on the findings of an action conducted under the TEC, Chapter 39.

(j) A financial accountability rating remains in effect until replaced by a subsequent financial accountability rating.

(k) The TEA will issue a preliminary financial accountability rating to a school district or an open-enrollment charter school on or before August 8 of each year. The TEA will base the financial accountability rating for a rating year on the data from the fiscal year preceding the rating year.

(1) The TEA will not delay the issuance of the preliminary or final rating if a school district or an open-enrollment charter school fails to meet the statutory deadline under the TEC, §44.008, for submitting the AFR. Instead, the school district or open-enrollment charter school will receive an F rating for substandard achievement.

(2) If the TEA receives an appeal of a preliminary rating, described by subsection (l) of this section, the TEA will issue a final

rating to the school district or open-enrollment charter school no later than 60 days after receiving the appeal.

(3) If the TEA does not receive an appeal of a preliminary rating, described by subsection (l) of this section, the preliminary rating automatically becomes a final rating 31 days after issuance of the preliminary rating.

(l) A school district or an open-enrollment charter school may appeal its preliminary financial accountability rating through the following appeals process.

(1) The TEA division responsible for financial accountability must receive a written appeal no later than 30 days after the TEA's release of the preliminary rating. The appeal must include adequate evidence and additional information that supports the school district's or open-enrollment charter school's position. Appeals received 31 days or more after TEA issues a preliminary rating will not be considered.

(2) A data error attributable to the TEA is a basis for an appeal. If a preliminary rating contains a data error attributable to the TEA, a school district or an open-enrollment charter school may submit a written appeal requesting a review of the preliminary rating.

(3) A school district or an open-enrollment charter school may appeal any adverse issue it identifies in the preliminary rating. However, the financial accountability rating system is required to apply the rules uniformly. Therefore, an error by a school district or an open-enrollment charter school in recording data or submitting data through the TEA data collection and reporting system is not a valid basis for appealing a preliminary rating and unlikely to negate concerns raised by the indicator. The appeals process is not a permissible method to correct data that were inaccurately reported by the school district or open-enrollment charter school after those data were certified as accurate. A request for exception to the rules for a school district or an open-enrollment charter school is disfavored and likely to be denied.

(4) The TEA will only consider appeals that would result in a change of the preliminary rating.

(5) The TEA division responsible for financial accountability will select an external review panel to independently oversee the appeals process.

(6) The TEA division responsible for financial accountability will submit the information provided by the school district or open-enrollment charter school to the external review panel members for review.

(7) Each external review panel member will examine the appeal and supporting documentation and will submit his or her recommendation to the TEA division responsible for financial accountability.

(8) The TEA division responsible for financial accountability will compile the recommendations and forward them to the commissioner.

(9) The commissioner will make a final ratings decision.

(m) A final rating issued by the TEA under this section may not be appealed under the TEC, §7.057, or any other law or rule.

(n) A financial accountability rating by a voluntary association is a local option of the school district or open-enrollment charter school, but it does not substitute for a financial accountability rating by the TEA.

(o) Each school district and open-enrollment charter school is required to report information and financial accountability ratings to parents, taxpayers, and other stakeholders by implementing the following reporting procedures.

(1) Each school district and open-enrollment charter school must prepare and distribute an annual financial management report in accordance with this subsection.

(2) Each school district and open-enrollment charter school must provide the public with an opportunity to comment on the report at a public hearing.

(3) The school district's or open-enrollment charter school's annual financial management report must include:

(A) a description of its financial management performance based on a comparison, provided by the TEA, of its performance on the indicators established by the commissioner and reflected in this section. The report will contain information that discloses:

(i) state-established standards; and

(ii) the school district's or open-enrollment charter school's financial management performance under each indicator for the current and previous year's financial accountability ratings;

(B) any descriptive information required by the commissioner, including:

(i) a copy of the superintendent's current employment contract or other written documentation of employment if no contract exists. This must disclose all compensation and benefits paid to the superintendent. The school district or open-enrollment charter school may publish the superintendent's employment contract on its website instead of publishing it in the annual financial management report;

(ii) a summary schedule for the fiscal year (12-month period) of expenditures paid on behalf of the superintendent and each board member and total reimbursements received by the superintendent and each board member. This includes transactions on the school district's or open-enrollment charter school's credit card(s), debit card(s), stored-value card(s), and any other similar instrument(s) to cover expenses incurred by the superintendent and each board member. The summary schedule must separately report reimbursements for meals, lodging, transportation, motor fuel, and other items. The summary schedule of total reimbursements should not include reimbursements for supplies and materials that were purchased for the operation of the school district or open-enrollment charter school;

(iii) a summary schedule for the fiscal year of the dollar amount of compensation and fees received by the superintendent from an outside school district or open-enrollment charter school or any other outside entity in exchange for professional consulting or other personal services. The schedule must separately report the amount received from each entity;

(iv) a summary schedule for the fiscal year of the total dollar amount of gifts that had a total economic value of $250 or more received by the executive officers and board members. This reporting requirement applies only to gifts received by the school district's or open-enrollment charter school's (or charter holder's) executive officers and board members (and their immediate family as described by Government Code, Chapter 573, Subchapter B, Relationships by Consanguinity or by Affinity) from an outside entity that received payments from the school district or open-enrollment charter school (or charter holder) in the prior fiscal year and to gifts from competing vendors that were not awarded contracts in the prior fiscal year. This reporting requirement does not apply to reimbursement by an outside entity for travel-related expenses when the purpose of the travel was to investigate matters directly related to an executive officer's or board member's duties or to investigate matters related to attendance at education-related conferences and seminars with the primary pur-

pose of providing continuing education (this exclusion does not apply to trips for entertainment purposes or pleasure trips). This reporting requirement excludes an individual gift or a series of gifts from a single outside entity that had a total economic value of less than $250 per executive officer or board member; and

(v) a summary schedule for the fiscal year of the dollar amount received by board members for the total amount of business transactions with the school district or open-enrollment charter school (or charter holder). This reporting requirement is not to duplicate the items disclosed in the summary schedule of reimbursements received by board members; and

(C) any other information the board of trustees of the school district or open-enrollment charter school determines to be useful.

(4) The board of trustees of each school district or open-enrollment charter school must hold a public hearing on the annual financial management report within two months after receiving a final financial accountability rating. The public hearing must be held at a location in the district's or open-enrollment charter school's facilities. The board must give notice of the hearing to owners of real estate property in the geographic boundaries of the school district or open-enrollment charter school and to parents of school district or open-enrollment charter school students. In addition to other notice required by law, the board must provide notice of the hearing:

(A) to a newspaper of general circulation in the geographic boundaries of the school district or each campus of an open-enrollment charter school once a week for two weeks prior to holding the public meeting, providing the time and place of the hearing. The first notice in the newspaper may not be more than 30 days prior to the public meeting or less than 14 days prior to the public meeting. If no newspaper is published in the county in which the district's central administration office is located or within the geographic boundaries of an open-enrollment charter school's campus, then the board must publish the notice in the county nearest to the county seat of the county in which the district's central administration office is located or in which the campus of the open-enrollment charter school is located; and

(B) through electronic mail to the mass communication media serving the school district or open-enrollment charter school, including, but not limited to, radio and television.

(5) At the hearing, the school district or open-enrollment charter school must provide the annual financial management report to the attending parents and taxpayers.

(6) The school district or open-enrollment charter school must retain the annual financial management report for at least three years after the public hearing and make it available to parents and taxpayers upon request.

(7) Each school district or open-enrollment charter school that received an F rating must file a corrective action plan with the TEA, prepared in accordance with instructions from the commissioner, within one month after the school district's or open-enrollment charter school's public hearing. The commissioner may require certain information in the corrective action plan to address the factor(s) that may have contributed to a school district's or an open-enrollment charter school's F rating.

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604314
Cristina De La Fuente-Valadez
Director, Rulemaking
Texas Education Agency
Effective date: September 11, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 475-1497

♦ ♦ ♦

PART 8. WINDHAM SCHOOL DISTRICT

CHAPTER 300. GENERAL PROVISIONS

19 TAC §300.1

The Windham School District Board of Trustees adopts amendments to §300.1, concerning Public Presentations and Comments to the Windham School District Board of Trustees, without changes to the proposed text as published in the July 8, 2016, issue of the *Texas Register* (41 TexReg 4918).

The adopted amendments are necessary to conform the rule to legislation from the 84th legislative session that prohibits the possession of firearms by anyone other than law enforcement at an open meeting.

No comments were received regarding the amendments.

The amendments are adopted under Texas Government Code §492.007, §492.013, Chapter 551; Texas Penal Code §30.06, §30.07.

Cross Reference to Statutes: None.

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604286
Michael Mondville
General Counsel
Windham School District
Effective date: September 11, 2016
Proposal publication date: July 8, 2016
For further information, please call: (936) 291-5300

♦ ♦ ♦

TITLE 22. EXAMINING BOARDS

PART 1. TEXAS BOARD OF ARCHITECTURAL EXAMINERS

CHAPTER 1. ARCHITECTS

Introduction. The Texas Board of Architectural Examiners (Board) adopts amendments to §1.174, concerning Complaint Process; §1.177, concerning Administrative Penalty Schedule; and §1.232, concerning Board Responsibilities. The amendments are adopted without changes to the proposed text published in the July 8, 2016, issue of the *Texas Register* (41 TexReg 4920).

Reasoned Justification. The amendments to §1.174 update the Board's requirements relating to the issuance of warnings in disciplinary matters. The adopted rule clarifies that a warning is available only if the violation in question is the sole violation of the Board's laws and rules, and the Respondent has not previously been subject to a Board warning or order. The purpose of these amendments is to provide greater clarity of the longstanding practice of the Board, and to give the executive director more definite guidance in the issuance of warnings.

Additionally, adopted subsection (j)(4) identifies the specific violations of the Board's laws and rules that may be resolved with a warning. Previously, the rule stated that a warning could be issued if the guidelines in §1.232 recommended an administrative penalty or reprimand as an appropriate sanction. This language created some confusion about whether the rule could be interpreted to mean that a warning was available if the guidelines recommended an administrative penalty but not a reprimand, or the guidelines recommended other penalties in addition to an administrative penalty or reprimand. This was not the interpretation of the Board, and the rule change will eliminate this issue by specifically identifying violations of the Board's rules that are appropriate for the issuance of a warning. The adopted rule will provide more definite guidance for the executive director and aligns with current Board practices in issuing warnings.

Additionally, the adopted rule clarifies that the issuance of a warning is at the sole discretion of the executive director and is not an available sanction following a contested case under the Administrative Procedure Act. This is consistent with current Board practice and the Board's interpretation of the previous rule.

Additionally, former §1.174(j)(1) has been repealed. This subsection required the Board, prior to approval of a proposed settlement agreement, to notify a complainant of the terms of any agreement, and the date, time, and location of the meeting during which the Board would consider the agreement. The previous rule implemented procedures that were more strenuous than the statutory requirement under Tex. Occ. Code §1051.253, which requires the Board to provide all complainants with a quarterly status update of the Board's investigation until disposition of the complaint. The repealed rule is unnecessary to protect the complainant's role in the investigative process, in that, in addition to quarterly status updates, each complainant is given an opportunity to provide documentary evidence and testimony regarding any alleged violation, and under §1.174(m), any complainant may file a request for reconsideration of any dismissed complaint. Furthermore, in situations where a complainant sought to provide testimony on a proposed settlement, application of the repealed rule could have led to the Board's inappropriate consideration of evidence outside of the administrative record, if the settlement was rejected by the Board and the case referred to SOAH for formal adjudication. The determination of the appropriate sanction in a disciplinary action is a matter of law that is wholly within the purview of the Board, and any marginal benefit of complainant testimony during the consideration of a proposed settlement is outweighed by the danger presented by potential violations of the Administrative Procedure Act, as described.

The adopted amendments to §1.177 revise the Board's rule relating to the imposition of administrative penalties. First, the adopted rule alters the Board's process for imposing a minor, moderate, or major penalty. Previously, the rule directed the Board to identify a given violation as minor, moderate, or major based upon an analysis of three factors: seriousness of misconduct, economic harm, and sanction history. The consideration of "seriousness of misconduct" under the previous rule was heavily dependent on proving the state of mind of the Respondent. The determination of negligence, gross negligence, or recklessness is subjective, and could result in an unpredictable battle of experts at hearing. Uncertainty regarding penalty recommendations following a hearing inhibits informed consideration of proposed settlement by staff, the Board, and Respondents. Furthermore, the precedence placed on disciplinary history and economic harm in recommending a sanction level under the previous rule could have resulted in an otherwise serious violation being considered minor if the Respondent did not have disciplinary history or the Board lacked evidence on economic harm, which is often the case. In light of these concerns, paragraph (1) of the adopted rule repeals the three-factor analysis, and instead specifically states that particular violations of the Board's laws and rules are appropriate for minor, moderate, or major penalties, as identified. The Board has determined that the adopted rule will result in more predictable determinations of penalty amounts, and that these determinations will be more consistent with the Board's understanding of the severity of any given violation.

Additionally, the adopted rule increases the maximum penalties for minor and moderate penalties from $500 to $1,000, and $2,000 to $3,000, respectively. This allows the Board greater flexibility in determining the appropriate administrative penalty, and, along with the maximum penalty of $5,000 for major violations, results in a more even distribution of minor, moderate, and major penalties within the $0 -$5,000 administrative penalty range established under Tex. Occ. Code §1051.452(a).

Additionally, the adopted rule directs the Board to consider the factors in Board Rules 1.141(c) and/or 1.165(f) in determining the specific amount of an administrative penalty within the minor, moderate, or major penalty range, or in determining the appropriate administrative penalty for a violation of the Board's laws or rules that has not been specifically defined as a minor, moderate, or major violation. The adopted rule enables the Board to impose an increased administrative penalty if the Respondent has previously been found to have violated the Board's laws or rules, or if the Respondent has committed multiple violations of the Board's laws or rules, and to consider each sheet of architectural plans issued in violation of the Board's laws as a separate violation. Finally, the adopted rule clarifies the Board's authority to impose administrative penalties in addition to other sanctions, such as revocation, suspension, or a refusal to renew a registration. These amendments provide greater notice to the public of the Board's processes in determining administrative penalties, allows case-by-case analysis of relevant facts to determine appropriate administrative penalties in disciplinary matters, and provides greater guidance to the Board that will promote more predictable and consistent determinations of administrative penalty amounts.

The adopted amendments to §1.232 revise the Board's guidelines that are used to identify the range of sanctions, in addition to administrative penalties, that are appropriate for certain violations of the Board's laws and rules. These sanctions include suspension, probated suspension, revocation, denial of registration, denial of reapplication, and probationary initial registration. The adopted amendments eliminate a reprimand as a potential ground for discipline. This amendment updates the Board rules to become more consistent with current Board practices, given that a reprimand has not been imposed since 2004.

Additionally, the adopted amendments include the addition of statutory and rule violations that were not previously included in the guidelines. This will allow the guidelines to be more comprehensive, and result in greater predictability in the imposition of disciplinary action.

Additionally, the adopted amendments delete procedural information relating to filing of exceptions and replies to exceptions. The former rule provided twenty days to file exceptions and fifteen days to file replies. This differs from the rule at the State Office of Administrative Hearings (1 TAC §155.507), which allows 15 days for each. In order to simplify the Board's regulations and procedures, the rule has been deleted, and the Board will rely upon SOAH's rule.

Additionally, the adopted rule implements Government Code §2001.141, which requires a final decision or order to include a ruling on each proposed finding of fact or conclusion of law submitted by a party under an agency rule. This rule change will allow the Board or Respondent to submit particular issues to a SOAH judge, thereby providing focus on matters that are most relevant to any given case.

Finally, the adopted amendment clarifies the Board's authority to impose administrative penalties in addition to other sanctions, such as revocation, suspension, or a refusal to renew a registration, and to impose a more severe sanction for a Respondent who has previous disciplinary history with the Board.This allows the Board greater flexibility in making determinations relating to sanctions, and is consistent with historical Board practices.

Summary of Comments and Agency Response. The Board did not receive any comments on the proposed rule.

SUBCHAPTER I. DISCIPLINARY ACTION

22 TAC §1.174, §1.177

Statutory Authority.

The amendments are adopteded under the Occupations Code §§1051.202, 1051.252, 1051.401, 1051.451, 1051.452, 1051.501, 1051.751, and 1051.752.

Section 1051.202 provides the Texas Board of Architectural Examiners with authority to promulgate rules to implement Chapters 1051, 1052, and 1053 of the Texas Occupations Code.

Section 1051.252 requires the board to adopt rules to establish a comprehensive procedure for receiving and adjudicating complaints from consumers and service recipients, including procedures regarding sanctions.

Section 1051.401 requires the Board to establish procedures by which a decision to suspend or revoke or a refusal to renew a certificate of registration is made by the board.

Section 1051.451 authorizes the Board to impose an administrative penalty on a person who engages in conduct for which the person is subject to disciplinary action under Chapters 1051, 1052, or 1053, regardless of whether the person holds a certificate of registration.

Section 1051.452 requires the Board to adopt an administrative penalty schedule for violations of Board laws and rules to ensure that the amounts of penalties imposed are appropriate to the violation.

Section 1051.501 grants the board general enforcement authority to ensure that enforcement action is taken against a person who violates Chapters 1051, 1052, or 1053.

Section 1051.751, authorizes the Board to revoke, suspend, or refuse to renew a certificate of registration; reprimand a certificate holder; or impose an administrative penalty on a person following a determination that a ground for discipline exists under §1051.752. Additionally, the Board is authorized to place a registrant on probated suspension, which could include regular reports to the Board, practice limitations, or remedial education until the person attains a degree of skill satisfactory to the board in those areas that are the basis of the probation.

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604296
Lance Brenton
General Counsel
Texas Board of Architectural Examiners
Effective date: September 11, 2016
Proposal publication date: July 8, 2016
For further information, please call: (512) 305-8519

SUBCHAPTER L. HEARINGS--CONTESTED CASES

22 TAC §1.232

Statutory Authority.

The amendments are adopted under the Occupations Code §§1051.202, 1051.252, 1051.401, 1051.451, 1051.452, 1051.501, 1051.751, and 1051.752.

Section 1051.202 provides the Texas Board of Architectural Examiners with authority to promulgate rules to implement Chapters 1051, 1052, and 1053 of the Texas Occupations Code.

Section 1051.252 requires the board to adopt rules to establish a comprehensive procedure for receiving and adjudicating complaints from consumers and service recipients, including procedures regarding sanctions.

Section 1051.401 requires the Board to establish procedures by which a decision to suspend or revoke or a refusal to renew a certificate of registration is made by the board.

Section 1051.451 authorizes the Board to impose an administrative penalty on a person who engages in conduct for which the person is subject to disciplinary action under Chapters 1051, 1052, or 1053, regardless of whether the person holds a certificate of registration.

Section 1051.452 requires the Board to adopt an administrative penalty schedule for violations of Board laws and rules to ensure that the amounts of penalties imposed are appropriate to the violation.

Section 1051.501 grants the board general enforcement authority to ensure that enforcement action is taken against a person who violates Chapters 1051, 1052, or 1053.

Section 1051.751, authorizes the Board to revoke, suspend, or refuse to renew a certificate of registration; reprimand a certificate holder; or impose an administrative penalty on a person following a determination that a ground for discipline exists under §1051.752. Additionally, the Board is authorized to place a

registrant on probated suspension, which could include regular reports to the Board, practice limitations, or remedial education until the person attains a degree of skill satisfactory to the board in those areas that are the basis of the probation.

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604298
Lance Brenton
General Counsel
Texas Board of Architectural Examiners
Effective date: September 11, 2016
Proposal publication date: July 8, 2016
For further information, please call: (512) 305-8519

♦ ♦ ♦

PART 5. STATE BOARD OF DENTAL EXAMINERS

CHAPTER 100. GENERAL PROVISIONS

22 TAC §100.6

The State Board of Dental Examiners (Board) adopts new rule §100.6, relating to executive committees. The rule is adopted without changes to the proposed text as published in the July 8, 2016, issue of the *Texas Register* (41 TexReg 4935).

This rule explains the processes and procedures for the establishment of executive committees of the board.

The board received no written comments regarding this rule.

The new rule is adopted under Texas Occupations Code §254.001(a), which gives the Board authority to adopt rules necessary to perform its duties and ensure compliance with state laws relating to the practice of dentistry to protect the public health and safety.

No statutes are affected by this new rule.

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

Filed with the Office of the Secretary of State on August 17, 2016.

TRD-201604219
Kelly Parker
Executive Director
State Board of Dental Examiners
Effective date: September 6, 2016
Proposal publication date: July 8, 2016
For further information, please call: (512) 475-0977

♦ ♦ ♦

22 TAC §100.7

The State Board of Dental Examiners (Board) adopts new rule §100.7, relating to standing committees. The rule is adopted without changes to the proposed text as published in the July 8, 2016, issue of the *Texas Register* (41 TexReg 4936).

This rule explains the processes and procedures for the establishment of standing committees of the board.

The board received no written comments regarding this rule.

The new rule is adopted under Texas Occupations Code §254.001(a), which gives the Board authority to adopt rules necessary to perform its duties and ensure compliance with state laws relating to the practice of dentistry to protect the public health and safety.

No statutes are affected by this new rule.

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

Filed with the Office of the Secretary of State on August 17, 2016.

TRD-201604220
Kelly Parker
Executive Director
State Board of Dental Examiners
Effective date: September 6, 2016
Proposal publication date: July 8, 2016
For further information, please call: (512) 475-0977

♦ ♦ ♦

22 TAC §100.8

The State Board of Dental Examiners (Board) adopts new rule §100.8, relating to ad hoc committees. The rule is adopted without changes to the proposed text as published in the July 8, 2016, issue of the *Texas Register* (41 TexReg 4936).

This rule explains the processes and procedures for the establishment of ad hoc committees of the board.

The board received no written comments regarding this rule.

The new rule is adopted under Texas Occupations Code §254.001(a), which gives the Board authority to adopt rules necessary to perform its duties and ensure compliance with state laws relating to the practice of dentistry to protect the public health and safety.

No statutes are affected by this new rule.

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

Filed with the Office of the Secretary of State on August 17, 2016.

TRD-201604221
Kelly Parker
Executive Director
State Board of Dental Examiners
Effective date: September 6, 2016
Proposal publication date: July 8, 2016
For further information, please call: (512) 475-0977

♦ ♦ ♦

22 TAC §100.9

The State Board of Dental Examiners (Board) adopts new rule §100.9 relating to advisory committees and workgroups established by the board. The rule is adopted with nonsubstantive changes to the proposed text as published in the July 8, 2016,

issue of the *Texas Register* (41 TexReg 4936). The section title was reworded from "Advisory Committees and Workgroups Established the Board" to "Advisory Committees and Workgroups Established by the Board." The section is republished below.

This rule explains the processes and procedures for the establishment of advisory committees and workgroups established by the board

The board received no written comments regarding this rule.

The new rules is adopted under Texas Occupations Code §254.001(a), which gives the Board authority to adopt rules necessary to perform its duties and ensure compliance with state laws relating to the practice of dentistry to protect the public health and safety.

No statutes are affected by this new rule.

§100.9. Advisory Committees and Workgroups Established by the Board.

(a) In addition to any specific statutory authority to establish particular advisory committees, the board may authorize advisory committees from outside the board's membership to advise the board on rulemaking, pursuant to §2001.031 of the Texas Government Code and subject to chapter 2110 of the Texas Government Code, State Agency Advisory Committees.

(b) Creation and dissolution. The board, in a regularly scheduled meeting, may vote to establish advisory committees and workgroups from outside the board's membership to address specific subjects, purposes, or ends. Unless continued by a vote of the board, advisory committees and workgroups outside the board's membership are abolished the sooner of one year from the date of creation or when the specific subject, purpose, or end for which the advisory committee or workgroup was established, have been served.

(c) Chair. Each advisory committee or workgroup shall select from among its members a chairperson who shall preside over the advisory committee or workgroup and shall report to the board or agency as needed.

(d) Membership. The presiding officer shall determine the method by which members are designated to the advisory committee or workgroup. The membership of an advisory committee must provide a balanced representation between members of the dental industry and consumers of the dental industry. Advisory committee and workgroup members shall serve terms as determined by the board.

(e) Board member liaisons. The presiding officer may appoint board member or board members to serve as a liaison(s) to an advisory committee or workgroup and report to the board the recommendations of the advisory committee or workgroup for consideration by the board. The role of a board member liaison is limited to clarifying the board's charge and intent to the advisory committee or workgroup.

(f) Agency staff liaisons. The executive director of the agency may assign agency staff to assist the advisory committee and workgroup.

(g) Meetings and participation. All meetings shall be open to the public and noticed on the Secretary of State's website to allow the public an opportunity to participate.

(h) Purpose. The board rule establishing the advisory committee or workgroup shall state the purpose and tasks of the committee and describe the manner in which the committee will report to the board.

(i) Committee actions. The actions of advisory committees are recommendations only.

(j) The following is an advisory committee and workgroup established by the board or established by statute: Dental Hygiene Advisory Committee, established by Subchapter B of Chapter 262 of the Texas Occupations Code.

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

Filed with the Office of the Secretary of State on August 17, 2016.

TRD-201604222
Kelly Parker
Executive Director
State Board of Dental Examiners
Effective date: September 6, 2016
Proposal publication date: July 8, 2016
For further information, please call: (512) 475-0977

♦ ♦ ♦

22 TAC §100.11

The State Board of Dental Examiners (Board) adopts new rule §100.11, relating to stakeholder meetings convened by the staff. The rule is adopted without changes to the proposed text as published in the July 8, 2016, issue of the *Texas Register* (41 TexReg 4939).

This rule explains the processes and procedures for stakeholder meetings convened by staff.

The board received no written comments regarding this rule.

This new rule is adopted under Texas Occupations Code §254.001(a), which gives the Board authority to adopt rules necessary to perform its duties and ensure compliance with state laws relating to the practice of dentistry to protect the public health and safety.

No statutes are affected by this new rule.

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

Filed with the Office of the Secretary of State on August 17, 2016.

TRD-201604223
Kelly Parker
Executive Director
State Board of Dental Examiners
Effective date: September 6, 2016
Proposal publication date: July 8, 2016
For further information, please call: (512) 475-0977

♦ ♦ ♦

CHAPTER 107. DENTAL BOARD PROCEDURES

SUBCHAPTER B. PROCEDURES FOR INVESTIGATING COMPLAINTS

22 TAC §§107.100 - 107.108, 107.110

The Texas State Board of Dental Examiners adopts the repeal of rules §§107.100 - 108 and 107.110, relating to complaint procedures. The repeal of this rule is adopted without changes to

the proposed text as published in the July 8, 2016, issue of the *Texas Register* (41 TexReg 4939).

The repeal of §§107.100 - 108 and 107.110 is necessary because the Board proposed re-organization of the chapter. The rules will be replaced with new rules that seek to better explain the board's process for receiving and investigating complaints.

The Board received no written comments regarding the proposed repeal.

The repeal of §§107.100 - 108 and 107.110 is adopted under Texas Occupations Code §254.001(a). The Board interprets §254.001(a) to give the Board authority to adopt rules necessary to perform its duties and ensure compliance with state law relating to the practice of dentistry to protect the public health and safety. No other statutes, articles, or codes are affected by the repeal of this rule.

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

Filed with the Office of the Secretary of State on August 17, 2016.

TRD-201604216
Kelly Parker
Executive Director
State Board of Dental Examiners
Effective date: September 6, 2016
Proposal publication date: July 8, 2016
For further information, please call: (512) 475-0977

♦ ♦ ♦

22 TAC §§107.100 - 107.109

The State Board of Dental Examiners (Board) adopts new §§107.100 - 107.109, relating to complaint procedures. The rules are adopted without changes to the proposed text as published in the July 8, 2016, issue of the *Texas Register* (41 TexReg 4940).

These rules explain the processes and procedures for investigating complaints.

The board received one written comment regarding adopted new rule §107.102:

The Texas Dental Association (TDA) submitted a written comment relating to the closure of a complaint that is submitted to the board without the name and contact information of the complainant. TDA noted that it supports the board's acceptance and investigation of anonymous complaints where there is sufficient information to investigate the complaint.

The board agrees with TDA's position that all jurisdictional anonymous complaints should be investigated but disagrees that the rule should explicitly mention anonymous complaints. The board anticipates no change to the agency's investigation of anonymous complaints as a result of the adoption of this rule. Currently, a complaint is closed in the preliminary inquiry period if the agency cannot identify probable cause to proceed with the investigation. The rule change merely provides notice to the public that a lack of information in a complaint may result in an inability for the agency to identify probable cause to proceed from a preliminary inquiry/investigation to the commencement of an official complaint/official investigation. This reflects the current process, and the rule change introduces no additional discretion on the part of agency staff to dispose of anonymous complaints.

The board received one written comment regarding adopted new rule §107.103:

The Texas Dental Association (TDA) submitted a written comment expressing two concerns regarding the proposed rule: whether the agency would continue to investigate and prosecute allegations related to the unlicensed practice of dentistry, and whether the preliminary investigation would be conducted by a license dentist or a licensed dental hygienist.

In response to the first inquiry, the board believes that the proposed rule more adequately expresses the board's authority to investigate and prosecute allegations of the unlicensed practice of dentistry, as well as other violations of the Dental Practice Act committed by non-dentists. The new rule captures the fact that the board should investigation any violation of the subtitle or board rules. Unlicensed practice of dentistry is a violation of the Dental Practice Act and the board intends no change to its investigation and prosecution of unlicensed practice of dentistry.

In response to the second inquiry, the board disagrees with TDA's recommended language. The new rule contemplates no change from the current rules and practices of the agency.

These new rules are adopted under Texas Occupations Code §254.001(a), which gives the Board authority to adopt rules necessary to perform its duties and ensure compliance with state laws relating to the practice of dentistry to protect the public health and safety. Texas Occupations Code §255 requires the board to adopt rules related to complaint investigation and disposition.

No statutes are affected by these new rules.

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

Filed with the Office of the Secretary of State on August 17, 2016.

TRD-201604218
Kelly Parker
Executive Director
State Board of Dental Examiners
Effective date: September 6, 2016
Proposal publication date: July 8, 2016
For further information, please call: (512) 475-0977

♦ ♦ ♦

PART 6. TEXAS BOARD OF PROFESSIONAL ENGINEERS

CHAPTER 133. LICENSING

The Texas Board of Professional Engineers (Board) adopts amendments to §133.27, concerning Application for Temporary License for Engineers Currently Licensed Outside the United States; §133.41, concerning Supplementary Experience Record; and §133.43, concerning Experience Evaluation, without changes to the proposed text as published in the June 17, 2016, issue of the *Texas Register* (41 TexReg 4378) and will not be republished.

The adopted rule changes to §133.27 implement a licensing agreement between the Texas Board of Professional Engineers

and the Republic of Korea. South Korea (The Republic of Korea) has been added to the existing rule for Temporary Licenses that currently addresses Australia, Canada and Mexico. The agreement was signed on March 10, 2016.

The adopted rule changes to §133.41 and §133.43 implement process changes related to enhancing engagement of Engineers in Training. These changes allow a person to demonstrate enhanced competence and readiness for licensure on the license application by including information on the Supplementary Experience Record regarding additional training and participation in professional organizations.

The Board received no comments for or against the proposed rule changes. No changes were made to the rules as proposed.

SUBCHAPTER C. PROFESSIONAL ENGINEER LICENSE APPLICATION REQUIREMENTS

22 TAC §133.27

The amendment is adopted pursuant to Texas Occupations Code §1001.202, which authorizes the Board to make and enforce all rules and regulations and bylaws consistent with the Act as necessary for the performance of its duties, the governance of its own proceedings, and the regulation of the practice of engineering in this state.

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604312
Lance Kinney, P.E.
Executive Director
Texas Board of Professional Engineers
Effective date: September 11, 2016
Proposal publication date: June 17, 2016
For further information, please call: (512) 440-7723

♦ ♦ ♦

SUBCHAPTER E. EXPERIENCE

22 TAC §133.41, §133.43

The amendments are adopted pursuant to Texas Occupations Code §1001.202, which authorizes the Board to make and enforce all rules and regulations and bylaws consistent with the Act as necessary for the performance of its duties, the governance of its own proceedings, and the regulation of the practice of engineering in this state.

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604313
Lance Kinney, P.E.
Executive Director
Texas Board of Professional Engineers
Effective date: September 11, 2016
Proposal publication date: June 17, 2016
For further information, please call: (512) 440-7723

♦ ♦ ♦

PART 14. TEXAS OPTOMETRY BOARD

CHAPTER 273. GENERAL RULES

22 TAC §273.4

The Texas Optometry Board adopts amendments to §273.4 without changes to the proposed section as published in the June 17, 2016, issue of the *Texas Register* (41 TexReg 4380).

The amendments set fees for license renewal of active Optometric Glaucoma Specialists. The addition to the fee will fund the agency's contribution to the costs of the Prescription Monitoring Program as set out in Senate Bill 195, Regular Session, 84th Legislature.

No comments were received.

The amendment is adopted under the Texas Optometry Act, Texas Occupations Code, §§351.151, 351.152, and Senate Bill 195, Regular Session, 84th Legislature. No other sections are affected by the amendments.

The Texas Optometry Board interprets §351.151 as authorizing the adoption of procedural and substantive rules for the regulation of the optometric profession. The agency interprets §351.152 as authorizing the agency to set license renewal fees, and Senate Bill 195, Regular Session, 84th Legislature, as authorizing the agency to increase renewal fees to fund the Prescription Monitoring Program.

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

Filed with the Office of the Secretary of State on August 17, 2016.

TRD-201604199
Chris Kloeris
Executive Director
Texas Optometry Board
Effective date: September 6, 2016
Proposal publication date: June 17, 2016
For further information, please call: (512) 305-8500

♦ ♦ ♦

PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 281. ADMINISTRATIVE PRACTICE AND PROCEDURES

SUBCHAPTER A. GENERAL PROVISIONS

22 TAC §281.8

The Texas State Board of Pharmacy adopts amendments to §281.8, concerning Grounds for Discipline for a Pharmacy

License. The amendments are adopted without changes to the proposed text as published in the June 24, 2016, issue of the *Texas Register* (41 TexReg 4588).

The amendments implement provisions of SB 460 which amends the Texas Pharmacy Act to include waiving, discounting, reducing, or offering to waive, discount, or reduce a patient copayment or deductible for a compounded drug.

The Alliance of Independent Pharmacists of Texas (AIP) expressed concern about pharmacies complying with the subjective nature of the rule. AIP suggested that the board provide additional guidance for documenting financial hardships. The Board disagrees with the comment and the amendments comply with what is already in law. Richie Ray commented in support of the rule.

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

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

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604293
Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
Effective date: September 11, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 305-8028

♦ ♦ ♦

SUBCHAPTER B. GENERAL PROCEDURES IN A CONTESTED CASE

22 TAC §281.31

The Texas State Board of Pharmacy adopts amendments to §281.31, concerning Burden of Proof. The amendments are adopted without changes to the proposed text as published in the June 24, 2016, issue of the *Texas Register* (41 TexReg 4590).

The amendments clarify the rules for show cause order hearings.

Richie Ray commented in support of the rule.

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

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

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604295
Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
Effective date: September 11, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 305-8028

♦ ♦ ♦

SUBCHAPTER C. DISCIPLINARY GUIDELINES

22 TAC §281.66

The Texas State Board of Pharmacy adopts amendments to §281.66, concerning Application for Reissuance or Removal of Restrictions of a License or Registration. The amendments are adopted without changes to the proposed text as published in the June 24, 2016, issue of the *Texas Register* (41 TexReg 4590).

The amendments correct grammar in the rule.

No comments were received.

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

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

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604297
Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
Effective date: September 11, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 305-8028

♦ ♦ ♦

CHAPTER 283. LICENSING REQUIREMENTS FOR PHARMACISTS

22 TAC §283.12

The Texas State Board of Pharmacy adopts amendments to §283.12, concerning Licenses for Military Service Members, Military Veterans, and Military Spouses. The amendments are adopted without changes to the proposed text as published in

the June 24, 2016, issue of the *Texas Register* (41 TexReg 4591).

The amendments eliminate the provisions allowing individuals who are unable to obtain a social security number, to provide an individual taxpayer identification number in lieu of a social security number because a social security number is required in order to process criminal background checks.

Richie Ray commented in support of the rule.

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

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

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604299
Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
Effective date: September 11, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 305-8028

♦ ♦ ♦

CHAPTER 291. PHARMACIES

SUBCHAPTER A. ALL CLASSES OF PHARMACIES

22 TAC §291.1

The Texas State Board of Pharmacy adopts amendments to §291.1, concerning Pharmacy License Application. The amendments are adopted without changes to the proposed text as published in the June 24, 2016, issue of the *Texas Register* (41 TexReg 4593).

The amendments eliminate the provisions allowing individuals who are unable to obtain a social security number to provide an individual taxpayer identification number in lieu of a social security number, because a social security number is required in order to process criminal background checks.

Richie Ray commented in support of the rule.

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

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

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604307
Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
Effective date: September 11, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 305-8028

♦ ♦ ♦

SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

22 TAC §291.33

The Texas State Board of Pharmacy adopts amendments to §291.33, concerning Operational Standards. The amendments are adopted with changes to the proposed text as published in the June 24, 2016, issue of the *Texas Register* (41 TexReg 4596).

The amendments require pharmacies that ship prescription medications to ensure the medication is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

The Coalition for Nurses in Advanced Practice provided grammatical corrections. The Board agrees with the changes and made the changes suggested.

Richie Ray suggested that since the time frame for filing a change of name application was eliminated in §291.33, the time frame should be updated in §291.3. The Board agrees with the suggestion and will update §291.3 at a future time.

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

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

§291.33. Operational Standards.

(a) Licensing requirements.

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

(2) A Class A pharmacy which changes ownership shall notify the board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

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

(4) A Class A pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writ-

ing of the names of the new managing officers within ten days of the change, following the procedures as specified in §291.3 of this title.

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

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

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

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

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

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

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

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

(b) Environment.

(1) General requirements.

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

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

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

(i) Such counseling area shall be:

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

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

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

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

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

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

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

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

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

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

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

(2) Security.

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

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

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

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

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

(C) Prior to authorizing individuals to enter the prescription department, the pharmacist-in-charge or owner may des-

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

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

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

(3) Temporary absence of pharmacist.

(A) On-site supervision by pharmacist.

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

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

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

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

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

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

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

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

(I) initiating and receiving refill authorization requests;

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

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

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

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

(VI) prepackaging and labeling prepackaged drugs.

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

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

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

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

(I) date of the delivery;

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

(III) patient's name;

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

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

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

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

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

(B) Pharmacist is off-site.

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

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

(iii) A pharmacy may use an automated storage and distribution device as specified in subsection (i) of this section for

pick-up of a previously verified prescription by a patient or patient's agent, provided the following conditions are met:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(I) date and time of the delivery;

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

(III) patient's name;

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

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

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

(c) Prescription dispensing and delivery.

(1) Patient counseling and provision of drug information.

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

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

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

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

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

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

(vi) proper storage;

(vii) refill information; and

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

(B) Such communication shall be:

(i) provided to new and existing patients of a pharmacy with each new prescription drug order. A new prescription drug order is one that has not been dispensed by the pharmacy to the patient in the same dosage and strength within the last year;

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

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

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

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

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

(III) in an electronic logbook; or

(IV) in a hard-copy log; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Pharmaceutical care services.

(A) Drug regimen review.

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

(I) known allergies;

(II) rational therapy-contraindications;

(III) reasonable dose and route of administration;

(IV) reasonable directions for use;

(V) duplication of therapy;

(VI) drug-drug interactions;

(VII) drug-food interactions;

(VIII) drug-disease interactions;

(IX) adverse drug reactions; and

(X) proper utilization, including overutilization or underutilization.

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

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

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

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

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

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

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

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

(iii) managing patient compliance programs;

(iv) providing preventative health care services; and

(v) providing case management of patients who are being treated with high-risk or high-cost drugs, or who are considered

"high risk" due to their age, medical condition, family history, or related concern.

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

(i) date the prescriber was consulted;

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

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

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

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

(4) Substitution of dosage form.

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

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

(ii) the dosage form so dispensed:

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

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

(III) does not alter desired clinical outcomes;

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

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

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

(i) a description of the change;

(ii) the reason for the change;

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

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

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

(i) the date of the notification;

(ii) the method of notification;

(iii) a description of the change; and

(iv) the reason for the change.

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

(6) Prescription containers.

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

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

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

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

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

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

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

(iii) the container is cleaned; and

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

(7) Labeling.

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

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

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

(iii) date the prescription is dispensed;

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

(v) name of the prescribing practitioner;

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

(vii) name of the patient or if such drug was prescribed for an animal, the species of the animal and the name of the

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

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

(ix) quantity dispensed;

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

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

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

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

(I) The name shall be either:

(-a-) the brand name; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(I) identifies the:

(-a-) pharmacy by name and address;

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

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

(-d-) name of the patient; and

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

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

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

(8) Returning Undelivered Medication to Stock.

(A) As specified in §431.021(w), Health and Safety Code, a pharmacist may not accept an unused prescription or drug,

in whole or in part, for the purpose of resale or re-dispensing to any person after the prescription or drug has been originally dispensed, or sold except as provided in §291.8 of this title (relating to Return of Prescription Drugs). Prescriptions that have not been picked up by or delivered to the patient or patient's agent may be returned to the pharmacy's stock for dispensing.

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

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

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

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

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

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

(2) refrigerator;

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

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

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

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

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

(1) current copies of the following:

(A) Texas Pharmacy Act and rules;

(B) Texas Dangerous Drug Act and rules;

(C) Texas Controlled Substances Act and rules; and

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

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

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

(B) a reference text on drug interactions. A separate reference is not required if other references maintained by the pharmacy contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken;

(C) a general information reference text, such as:

(i) Facts and Comparisons with current supplements;

(ii) Clinical Pharmacology;

(iii) American Hospital Formulary Service with current supplements; or

(iv) Remington's Pharmaceutical Sciences; and

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

(f) Drugs.

(1) Procurement and storage.

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

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

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

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

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

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

(3) Nonprescription Schedule V controlled substances.

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

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

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

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

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

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

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

(i) true name of the purchaser;

(ii) current address of the purchaser;

(iii) name and quantity of controlled substance purchased;

(iv) date of each purchase; and

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

(4) Class A Pharmacies may not sell, purchase, trade or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).

(g) Prepackaging of drugs.

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

(2) The label of a prepackaged unit shall indicate:

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

(B) facility's lot number;

(C) facility's beyond use date; and

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

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

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

(B) facility's lot number;

(C) manufacturer or distributor;

(D) manufacturer's lot number;

(E) manufacturer's expiration date;

(F) quantity per prepackaged unit;

(G) number of prepackaged units;

(H) date packaged;

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

(J) signature, or electronic signature of the responsible pharmacist.

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

(h) Customized patient medication packages.

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

(2) Label.

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

(i) the name of the patient;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(I) identifies the:

(-a-) pharmacy by name and address;

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

(-c-) name of the patient; and

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

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

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

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

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

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

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

(A) the name and address of the patient;

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

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

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

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

(F) any special labeling instructions; and

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

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

(i) Automated devices and systems.

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

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

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

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

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

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

(ii) manufacturer or distributor;

(iii) manufacturer's lot number;

(iv) manufacturer's expiration date;

(v) date of loading;

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

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

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

(2) Automated pharmacy dispensing systems.

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

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

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

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

(B) Quality assurance program. A pharmacy which uses an automated pharmacy dispensing system to fill prescription

drug orders shall operate according to a written program for quality assurance of the automated pharmacy dispensing system which:

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

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

(C) Policies and procedures of operation.

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

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

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

(III) require prior to use, that a pharmacist checks, verifies, and documents that the automated pharmacy dispensing system has been accurately filled each time the system is stocked;

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

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

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

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

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

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

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

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

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

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

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

(II) the following checks are conducted by a pharmacist:

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

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

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

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

(II) The pharmacy has conducted initial testing and has a continuous quality assurance program which documents that the automated pharmacy dispensing system dispenses accurately as specified in subparagraphs (A) and (B) of this paragraph.

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

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

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

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

(3) Automated checking device.

(A) For the purpose of §291.32(c)(2)(D) of this title, the final check of a dispensed prescription shall be considered accomplished using an automated checking device provided:

(i) a check of the final product is conducted by a pharmacist prior to delivery to the patient or the following checks are performed by a pharmacist:

(I) the prepackaged drug used to fill the order is checked by a pharmacist who verifies that the drug is labeled and packaged accurately; and

(II) a pharmacist checks the accuracy of each original or new prescription drug order.

(ii) the prescription is dispensed, labeled, and made ready for delivery to the patient in compliance with Class A (Community) Pharmacy rules; and

(iii) prior to delivery to the patient:

(I) the automated checking device confirms that the correct drug and strength has been labeled with the correct label for the correct patient; and

(II) a pharmacist performs all other duties required to ensure that the prescription has been dispensed safely and accurately as prescribed.

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

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

(ii) The pharmacy documents and maintains:

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

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

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

(4) Automated storage and distribution device. A pharmacy may use an automated storage and distribution device to deliver a previously verified prescription to a patient or patient's agent when the pharmacy is open or when the pharmacy is closed as specified in subsection (b)(3)(B)(iii) of this section, provided:

(A) the device is used to deliver refills of prescription drug orders and shall not be used to deliver new prescriptions as defined by §291.31(28) of this title (relating to Definitions);

(B) the automated storage and distribution device may not be used to deliver a controlled substance;

(C) drugs stored in the automated storage and distribution device are stored at proper temperatures;

(D) the patient or patient's agent is given the option to use the system;

(E) the patient or patient's agent has access to a pharmacist for questions regarding the prescription at the pharmacy where the automated storage and distribution device is located, by a telephone available at the pharmacy that connects directly to another pharmacy, or by a telephone available at the pharmacy and a posted telephone number to reach another pharmacy;

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

(G) the automated storage and distribution device has been tested by the pharmacy and found to dispense prescriptions accurately. The pharmacy shall make the results of such testing available to the board upon request;

(H) the automated storage and distribution device may be loaded with previously verified prescriptions only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist;

(I) the pharmacy will make the automated storage and distribution device available for inspection by the board;

(J) the automated storage and distribution device is located within the pharmacy building whereby pharmacy staff has access to the device from within the prescription department and patients have access to the device from outside the prescription department. The device may not be located on an outside wall of the pharmacy and may not be accessible from a drive-thru;

(K) the automated storage and distribution device is secure from access and removal of prescription drug orders by unauthorized individuals;

(L) the automated storage and distribution device has adequate security system to prevent unauthorized access and to maintain patient confidentiality; and

(M) the automated storage and distribution device records a digital image of the individual accessing the device to pick-up a prescription and such record is maintained by the pharmacy for two years.

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604300
Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
Effective date: September 11, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 305-8028

♦ ♦ ♦

SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)

22 TAC §291.76

The Texas State Board of Pharmacy adopts amendments to §291.76, concerning Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center. The amendments are adopted with changes to the proposed text as published in the June 24, 2016, issue of the *Texas Register* (41 TexReg 4603).

The amendments allow pharmacists to record certain information in the patient's chart in lieu of keeping a separate log.

The Coalition for Nurses in Advanced Practice provided grammatical corrections. The Board agrees with the changes and made the changes suggested.

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

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

§291.76. Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center.

(a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities, and operation of a pharmacy located in a freestanding ambulatory surgical center that is licensed by the Texas Department of State Health Services. Class C pharmacies located in a freestanding ambulatory surgical center shall comply with

this section, in lieu of §§291.71 - 291.75 of this title (relating to Purpose; Definitions; Personnel; Operational Standards; and Records).

(b) Definitions. The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.

(2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

(B) the patient at the direction of a practitioner.

(3) Ambulatory surgical center (ASC)--A freestanding facility that is licensed by the Texas Department of State Health Services that primarily provides surgical services to patients who do not require overnight hospitalization or extensive recovery, convalescent time or observation. The planned total length of stay for an ASC patient shall not exceed 23 hours. Patient stays of greater than 23 hours shall be the result of an unanticipated medical condition and shall occur infrequently. The 23-hour period begins with the induction of anesthesia.

(4) Automated medication supply system--A mechanical system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(5) Board--The Texas State Board of Pharmacy.

(6) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the ASC in areas that pertain to the practice of pharmacy.

(7) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug immediate precursor, or other substance included in Schedule I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(8) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(9) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(10) Downtime--Period of time during which a data processing system is not operable.

(11) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(12) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other ASC department (excluding the pharmacy) for the purpose of administration to a patient of the ASC.

(13) Formulary--List of drugs approved for use in the ASC by an appropriate committee of the ambulatory surgical center.

(14) Hard copy--A physical document that is readable without the use of a special device (i.e., data processing system, computer, etc.).

(15) Investigational new drug--New drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the federal Food and Drug Administration.

(16) Medication order--An order from a practitioner or his authorized agent for administration of a drug or device.

(17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other areas or departments of the ASC, or dispensed to an ultimate user or his or her agent.

(19) Prescription drug--

(A) A substance for which federal or state law requires a prescription before it may be legally dispensed to the public;

(B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend that complies with federal law; or

(ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or

(C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

(20) Prescription drug order--

(A) An order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) An order pursuant to Subtitle B, Chapter 157, Occupations Code.

(21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(22) Part-time pharmacist--A pharmacist who works less than full-time.

(23) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.

(24) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

(25) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and Safety Code, Chapter 481, as amended.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. Each ambulatory surgical center shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis.

(B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following:

(i) establishing specifications for procurement and storage of all materials, including drugs, chemicals, and biologicals;

(ii) participating in the development of a formulary for the ASC, subject to approval of the appropriate committee of the ASC;

(iii) distributing drugs to be administered to patients pursuant to the practitioner's medication order;

(iv) filling and labeling all containers from which drugs are to be distributed or dispensed;

(v) maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and patient care areas, as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the ASC;

(vi) maintaining records of all transactions of the ASC pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials;

(vii) participating in those aspects of the ASC's patient care evaluation program which relate to pharmaceutical material utilization and effectiveness;

(viii) participating in teaching and/or research programs in the ASC;

(ix) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the ASC;

(x) providing effective and efficient messenger and delivery service to connect the ASC pharmacy with appropriate areas of the ASC on a regular basis throughout the normal workday of the ASC;

(xi) labeling, storing, and distributing investigational new drugs, including maintaining information in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of investigational new drugs;

(xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this subsection; and

(xiii) maintaining records in a data processing system such that the data processing system is in compliance with the requirements for a Class C (institutional) pharmacy located in a free-standing ASC.

(2) Consultant pharmacist.

(A) The consultant pharmacist may be the pharmacist-in-charge.

(B) A written contract shall exist between the ASC and any consultant pharmacist, and a copy of the written contract shall be made available to the board upon request.

(3) Pharmacists.

(A) General.

(i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the ASC pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.

(ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for pharmaceutical materials.

(iii) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or pharmacy technician trainees under his or her supervision.

(iv) All pharmacists while on duty shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be limited to, the following:

(i) receiving and interpreting prescription drug orders and oral medication orders and reducing these orders to writing either manually or electronically;

(ii) selecting prescription drugs and/or devices and/or suppliers; and

(iii) interpreting patient profiles.

(C) Special requirements for compounding non-sterile preparations. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(4) Pharmacy technicians and pharmacy technician trainees.

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

(B) Duties. Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (3)(B) of this subsection. Duties may include, but need not be limited to, the following functions, under the direct supervision of a pharmacist:

(i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials, electronic signature to the appropriate quality control records prior to distribution;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy

technician trainees have completed the training specified in §291.131 of this title;

(iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(v) distributing routine orders for stock supplies to patient care areas;

(vi) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section;

(vii) maintaining inventories of drug supplies;

(viii) maintaining pharmacy records; and

(ix) loading drugs into an automated medication supply system. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist.

(C) Procedures.

(i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard written procedures and guidelines.

(ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as pharmacy technicians or pharmacy technician trainees working in a Class A pharmacy.

(D) Special requirements for compounding non-sterile preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title.

(5) Owner. The owner of an ASC pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(A) establishing policies for procurement of prescription drugs and devices and other products dispensed from the ASC pharmacy;

(B) establishing and maintaining effective controls against the theft or diversion of prescription drugs;

(C) if the pharmacy uses an automated medication supply system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(D) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(E) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows:

(A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician.

(B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

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

(D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist.

(d) Operational standards.

(1) Licensing requirements.

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

(B) An ASC pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(C) An ASC pharmacy which changes location and/or name shall notify the board of the change within 10 days and file for an amended license as specified in §291.3 of this title.

(D) An ASC pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change, following the procedures in §291.3 of this title.

(E) An ASC pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

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

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

(H) An ASC pharmacy, licensed under the Act, §560.051(a)(3), concerning institutional pharmacy (Class C), 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 other type of pharmacy; provided, however, such license is required to comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Records), 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.

(I) An ASC pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title.

(J) ASC pharmacy personnel shall not compound sterile preparations unless the pharmacy has applied for and obtained a Class C-S pharmacy license.

(K) An ASC 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).

(L) An ASC 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).

(2) Environment.

(A) General requirements.

(i) Each ambulatory surgical center shall have a designated work area separate from patient areas, and which shall have space adequate for the size and scope of pharmaceutical services and shall have adequate space and security for the storage of drugs.

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

(B) Special requirements.

(i) The ASC pharmacy shall have locked storage for Schedule II controlled substances and other controlled drugs requiring additional security.

(ii) The ASC pharmacy shall have a designated area for the storage of poisons and externals separate from drug storage areas.

(C) Security.

(i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed and capable of being locked by key, combination, or other mechanical or electronic means, so as to prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-charge may enter the pharmacy or have access to storage areas for prescription drugs and/or devices.

(ii) The pharmacist-in-charge shall consult with ASC personnel with respect to security of the drug storage areas, including provisions for adequate safeguards against theft or diversion of dangerous drugs and controlled substances, and to security of records for such drugs.

(iii) The pharmacy shall have locked storage for Schedule II controlled substances and other drugs requiring additional security.

(3) Equipment and supplies. Ambulatory surgical centers supplying drugs for postoperative use shall have the following equipment and supplies:

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

(B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and

(C) adequate supply of prescription labels and other applicable identification labels.

(4) Library. A reference library shall be maintained that includes the following in hard-copy or electronic format and that pharmacy personnel shall be capable of accessing at all times:

(A) current copies of the following:

(i) Texas Pharmacy Act and rules;

(ii) Texas Dangerous Drug Act and rules;

(iii) Texas Controlled Substances Act and rules;

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

(B) at least one current or updated general drug information reference which is required to contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken; and

(C) basic antidote information and the telephone number of the nearest regional poison control center.

(5) Drugs.

(A) Procurement, preparation, and storage.

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

(ii) The pharmacist-in-charge shall have the responsibility for determining specifications of all drugs procured by the facility.

(iii) ASC pharmacies may not sell, purchase, trade, or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).

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

(v) Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug.

(vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined together until such drugs are disposed of.

(B) Formulary.

(i) A formulary may be developed by an appropriate committee of the ASC.

(ii) The pharmacist-in-charge or consultant pharmacist shall be a full voting member of any committee which involves pharmaceutical services.

(iii) A practitioner may grant approval for pharmacists at the ASC to interchange, in accordance with the facility's formulary, for the drugs on the practitioner's medication orders provided:

(I) a formulary has been developed;

(II) the formulary has been approved by the medical staff of the ASC;

(III) there is a reasonable method for the practitioner to override any interchange; and

(IV) the practitioner authorizes pharmacist in the ASC to interchange on his/her medication orders in accordance with the facility's formulary through his/her written agreement to abide by the policies and procedures of the medical staff and facility.

(C) Prepackaging and loading drugs into automated medication supply system.

(i) Prepackaging of drugs.

(I) Drugs may be prepackaged in quantities suitable for distribution to other Class C pharmacies under common ownership or for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(II) The label of a prepackaged unit shall indicate:

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

(-b-) facility's lot number;

(-c-) expiration date;

(-d-) quantity of the drug, if quantity is greater than one; and

(-e-) if the drug is distributed to another Class C pharmacy, name of the facility responsible for prepackaging the drug.

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

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

(-b-) facility's lot number;

(-c-) manufacturer or distributor;

(-d-) manufacturer's lot number;

(-e-) expiration date;

(-f-) quantity per prepackaged unit;

(-g-) number of prepackaged units;

(-h-) date packaged;

(-i-) name, initials, or electronic signature of the prepacker;

(-j-) signature or electronic signature of the responsible pharmacist; and

(-k-) if the drug is distributed to another Class C pharmacy, name of the facility receiving the prepackaged drug.

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

(ii) Loading bulk unit of use drugs into automated medication supply systems. Automated medication supply systems may be loaded with bulk unit of use drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist. In order for the pharmacist to electronically monitor, the medication supply system must allow for bar code scanning to verify the loading of drugs, and a record of the loading must be maintained by the system and accessible for electronic review by the pharmacist.

(6) Medication orders.

(A) Drugs may be administered to patients in ASCs only on the order of a practitioner. No change in the order for drugs may be made without the approval of a practitioner except as authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.

(B) Drugs may be distributed only pursuant to the practitioner's medication order.

(C) ASC pharmacies shall be exempt from the labeling provisions and patient notification requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication orders.

(D) In ASCs with a full-time pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the facility when the pharmacy is closed, the following is applicable.

(i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of a patient may be removed from the ASC pharmacy.

(ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

(iii) A record shall be made at the time of withdrawal by the authorized person removing the drugs and devices. The record shall contain the following information:

(I) name of the patient;

(II) name of device or drug, strength, and dosage form;

(III) dose prescribed;

(IV) quantity taken;

(V) time and date; and

(VI) signature or electronic signature of person making withdrawal.

(iv) The medication order in the patient's chart may substitute for such record, provided the medication order meets all the requirements of clause (iii) of this subparagraph.

(v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more than 72 hours from the time of such withdrawal.

(E) In ASCs with a part-time or consultant pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the ASC when the pharmacist is not on duty, or when the pharmacy is closed, the following is applicable.

(i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be removed from the ASC pharmacy.

(ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

(iii) A record shall be made at the time of withdrawal by the authorized person removing the drugs and devices; the record shall meet the same requirements as specified in subparagraph (D) of this paragraph.

(iv) The pharmacist shall conduct an audit of patient's medical record according to the schedule set out in the policy and procedures at a reasonable interval, but such interval must occur at least once in every calendar week that the pharmacy is open.

(7) Floor stock. In facilities using a floor stock method of drug distribution, the following is applicable for removing drugs or devices in the absence of a pharmacist.

(A) Prescription drugs and devices may be removed from the pharmacy only in the original manufacturer's container or prepackaged container.

(B) Only a designated licensed nurse or practitioner may remove such drugs and devices.

(C) A record shall be made at the time of withdrawal by the authorized person removing the drug or device; the record shall contain the following information:

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

(ii) quantity removed;

(iii) location of floor stock;

(iv) date and time; and

(v) signature or electronic signature of person making the withdrawal.

(D) A pharmacist shall verify the withdrawal according to the following schedule.

(i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as practical, but in no event more than 72 hours from the time of such withdrawal.

(ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after a reasonable interval, but such interval must occur at least once in every calendar week that the pharmacy is open.

(iii) The medication order in the patient's chart may substitute for the record required in subparagraph (C) of this paragraph, provided the medication order meets all the requirements of subparagraph (C) of this paragraph.

(8) Policies and procedures. Written policies and procedures for a drug distribution system, appropriate for the ambulatory surgical center, shall be developed and implemented by the pharmacist-in-charge with the advice of the appropriate committee. The written policies and procedures for the drug distribution system shall include, but not be limited to, procedures regarding the following:

(A) controlled substances;

(B) investigational drugs;

(C) prepackaging and manufacturing;

(D) medication errors;

(E) orders of physician or other practitioner;

(F) floor stocks;

(G) adverse drug reactions;

(H) drugs brought into the facility by the patient;

(I) self-administration;

(J) emergency drug tray;

(K) formulary, if applicable;

(L) drug storage areas;

(M) drug samples;

(N) drug product defect reports;

(O) drug recalls;

(P) outdated drugs;

(Q) preparation and distribution of IV admixtures;

(R) procedures for supplying drugs for postoperative use, if applicable;

(S) use of automated medication supply systems;

(T) use of data processing systems; and

(U) drug regimen review.

(9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall be supplied according to the following procedures.

(A) Drugs may only be supplied to patients who have been admitted to the ASC.

(B) Drugs may only be supplied in accordance with the system of control and accountability established for drugs supplied from the ambulatory surgical center; such system shall be developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.

(C) Only drugs listed on the approved postoperative drug list may be supplied; such list shall be developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the nature and type to meet the immediate postoperative needs of the ambulatory surgical center patient.

(D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including name, address, and phone number of the facility, and necessary auxiliary labels) by the pharmacy, provided, however that topicals and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-hour supply.

(E) At the time of delivery of the drug, the practitioner shall complete the label, such that the prescription container bears a label with at least the following information:

(i) date supplied;

(ii) name of practitioner;

(iii) name of patient;

(iv) directions for use;

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

(vi) unique identification number.

(F) After the drug has been labeled, the practitioner or a licensed nurse under the supervision of the practitioner shall give the appropriately labeled, prepackaged medication to the patient.

(G) A perpetual record of drugs which are supplied from the ASC shall be maintained which includes:

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

(ii) date supplied;

(iii) name of practitioner;

(iv) name of patient;

(v) directions for use;

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

(vii) unique identification number.

(H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall review the records at least once in every calendar week that the pharmacy is open.

(10) Drug regimen review.

(A) A pharmacist shall evaluate medication orders and patient medication records for:

(i) known allergies;

(ii) rational therapy--contraindications;

(iii) reasonable dose and route of administration;

(iv) reasonable directions for use;

(v) duplication of therapy;

(vi) drug-drug interactions;

(vii) drug-food interactions;

(viii) drug-disease interactions;

(ix) adverse drug reactions;

(x) proper utilization, including overutilization or underutilization; and

(xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of the drug in its current regimen.

(B) A retrospective, random drug regimen review as specified in the pharmacy's policies and procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed 31 days between such reviews.

(C) Any questions regarding the order must be resolved with the prescriber and a written notation of these discussions made and maintained.

(e) Records.

(1) Maintenance of records.

(A) Every inventory or other record required to be kept under the provisions of this section (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center) shall be:

(i) kept by the pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative, and other authorized local, state, or federal law enforcement agencies; and

(ii) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the 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 subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(B) Records of controlled substances listed in Schedule II shall be maintained separately and readily retrievable from all other records of the pharmacy.

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

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

(i) the records in the alternative data retention system contain all of the information required on the manual record; and

(ii) the alternative data retention system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(E) Controlled substance records shall be maintained in a manner to establish receipt and distribution of all controlled substances.

(F) An ASC pharmacy shall maintain a perpetual inventory of controlled substances listed in Schedule II - V which shall be verified for completeness and reconciled at least once in every calendar week that the pharmacy is open.

(G) Distribution records for controlled substances, listed in Schedule II - V, shall include the following information:

(i) patient's name;

(ii) practitioner's name who order the drug;

(iii) name of drug, dosage form, and strength;

(iv) time and date of administration to patient and quantity administered;

(v) signature or electronic signature of individual administering the controlled substance;

(vi) returns to the pharmacy; and

(vii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(H) The record required by subparagraph (G) of this paragraph shall be maintained separately from patient records.

(I) A pharmacist shall conduct an audit by randomly comparing the distribution records required by subparagraph (G) with the medication orders in the patient record on a periodic basis to verify proper administration of drugs not to exceed 30 days between such reviews.

(2) Patient records.

(A) Each medication order or set of orders issued together shall bear the following information:

(i) patient name;

(ii) drug name, strength, and dosage form;

(iii) directions for use;

(iv) date; and

(v) signature or electronic signature of the practitioner or that of his or her authorized agent, defined as a employee or consultant/full or part-time pharmacist of the ASC.

(B) Medication orders shall be maintained with the medication administration record in the medical records of the patient.

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

(A) If an ASC pharmacy's data processing system is not in compliance with the board's requirements, the pharmacy must maintain a manual recordkeeping system.

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

(C) A pharmacy that changes or discontinues use of a data processing system must:

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

(ii) purge the records to a printout which contains:

(I) all of the information required on the original document; or

(II) for records of distribution and return for all controlled substances, the same information as required on the audit trail printout as specified in subparagraph (F) of this paragraph. The information on the printout shall be sorted and printed by drug name and list all distributions and returns chronologically.

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

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

(F) The data processing system shall have the capacity to produce a hard-copy printout of an audit trail of drug distribution and return for any strength and dosage form of a drug (by either brand or generic name or both) during a specified time period. This printout shall contain the following information:

(i) patient's name and room number or patient's facility identification number;

(ii) prescribing or attending practitioner's name;

(iii) name, strength, and dosage form of the drug product actually distributed;

(iv) total quantity distributed from and returned to the pharmacy;

(v) if not immediately retrievable via electronic image, the following shall also be included on the printout:

(I) prescribing or attending practitioner's address; and

(II) practitioner's DEA registration number, if the medication order is for a controlled substance.

(G) An audit trail printout for each strength and dosage form of these drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the facility. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

(H) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law enforcement or regulatory agencies.

(I) In the event that an ASC pharmacy which uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for on-line data entry as soon as the system is available for use again.

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

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

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

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

(i) the actual date of distribution;

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

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

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

(D) If the distribution is for a Schedule II controlled substance, the following is applicable.

(i) The pharmacy, practitioner, or other registrant who is receiving the controlled substances shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222) to the distributing pharmacy.

(ii) The distributing pharmacy shall:

(I) complete the area on the DEA order form (DEA 222) titled "To Be Filled in by Supplier";

(II) maintain Copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and

(III) forward Copy 2 of the DEA order form (DEA 222) to the divisional office of the Drug Enforcement Administration.

(5) Other records. Other records to be maintained by the pharmacy include:

(A) a permanent log of the initials or identification codes which will identify each pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified, i.e., identical initials or identification codes cannot be used;

(B) Copy 3 of DEA order form (DEA 222), which has been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents and/or for each order filled using the DEA Controlled Substance Ordering System (CSOS), the original signed order and all linked records for that order;

(C) a copy of the power of attorney to sign DEA 222 order forms (if applicable);

(D) suppliers' invoices of dangerous drugs and controlled substances dated and initialed or signed by the person receiving

the drugs; a pharmacist shall verify that the controlled drugs listed on the invoices were added to the pharmacy's perpetual inventory by clearly recording his/her initials and the date of review of the perpetual inventory;

(E) supplier's credit memos for controlled substances and dangerous drugs;

(F) a copy of inventories required by §291.17 of this title (relating to Inventory Requirements) except that a perpetual inventory of controlled substances listed in Schedule II may be kept in a data processing system if the data processing system is capable of producing a copy of the perpetual inventory on-site;

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

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

(I) a copy of any notification required by the Texas Pharmacy Act or these rules, including, but not limited to, the following:

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

(ii) notification of a change in pharmacist-in-charge of a pharmacy; and

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

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

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

(i) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of the Drug Enforcement Administration as required by the Code of Federal Regulations, Title 21, §1304(a), and submits a copy of this written notification to the Texas State Board of Pharmacy. 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.

(ii) The pharmacy maintains a copy of the notification required in this subparagraph.

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

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

(C) Access to records. If the records are kept in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records.

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

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604301
Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
Effective date: September 11, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 305-8028

♦ ♦ ♦

SUBCHAPTER F. NON-RESIDENT PHARMACY (CLASS E)

22 TAC §291.104

The Texas State Board of Pharmacy adopts amendments to §291.104, concerning Operational Standards. The amendments are adopted without changes to the proposed text as published in the June 24, 2016, issue of the *Texas Register* (41 TexReg 4608).

The amendments update the requirements for Class E pharmacies to submit prescription to the Texas State Board of Pharmacy instead of the Texas Department of Public Safety.

Richie Ray suggested that since the time frame for filing a change of name application was eliminated in §291.104, the time frame should be updated in §291.3. The Board agrees with the suggestion and will update §291.3 at a future time.

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

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

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604302
Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
Effective date: September 11, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 305-8028

♦ ♦ ♦

SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES

22 TAC §291.133

The Texas State Board of Pharmacy adopts amendments to §291.133, concerning Pharmacies Compounding Sterile Preparations. The amendments are adopted with changes to the proposed text as published in the June 24, 2016, issue of the *Texas Register* (41 TexReg 4611).

The amendments update the rules with regard to USP <797>.

The Texas Society of Health-System Pharmacists supported the amendments and suggested correcting the reference to ISA to ISO. Richie Ray suggested adding the word "testing" in subsection (c)(4)(G). The board agrees with the comments and made the recommended changes.

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

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

§291.133. Pharmacies Compounding Sterile Preparations.

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

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

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

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

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

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

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

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

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

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

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

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

(4) Ante-area--An ISO Class 8 or better area where personnel may perform hand hygiene and garbing procedures, staging of components, order entry, labeling, and other high-particulate generating activities. It is also a transition area that:

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

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

(5) Aseptic Processing--A mode of processing pharmaceutical and medical preparations that involves the separate sterilization of the preparation and of the package (containers-closures or packaging material for medical devices) and the transfer of the preparation into the container and its closure under at least ISO Class 5 conditions.

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

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

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

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

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

(11) Buffer Area--An ISO Class 7 or, if a Class B pharmacy, ISO Class 8 or better, area where the primary engineering control area is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.

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

(13) Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.

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

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

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

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

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

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

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

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

(18) Critical Area--An ISO Class 5 environment.

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

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

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

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

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

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

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

(26) HVAC--Heating, ventilation, and air conditioning.

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

(28) IPA--Isopropyl alcohol (2-propanol).

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

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

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

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

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

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

(35) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original container into unit dose packaging or a multiple dose container for distribution

within a facility licensed as a Class C pharmacy or to other pharmacies under common ownership for distribution within those facilities. The term as defined does not prohibit the prepackaging of drug products for use within other pharmacy classes.

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

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

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

(39) Positive Control--A quality assurance sample prepared to test positive for microbial growth.

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

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

(42) Reasonable quantity--An amount of a compounded drug that:

(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office or facility before the beyond use 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.

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

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

(45) SOPs--Standard operating procedures.

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

(47) Sterilization by Filtration--Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

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

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

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

(c) Personnel.

(1) Pharmacist-in-charge.

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

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

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

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

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

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

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

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

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

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

(2) Pharmacists.

(A) General.

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

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

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

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

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

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

(B) Initial training and continuing education.

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

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

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

(III) possess knowledge about:

(-a-) aseptic processing;

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

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

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

(-e-) sterilization techniques.

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

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

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

(II) four hours of ACPE-accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacist is engaged in compounding high risk sterile preparations.

(3) Pharmacy technicians and pharmacy technician trainees.

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

(B) Initial training and continuing education.

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

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

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

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

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

(II) and

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

(-b-) possess knowledge about:

(-1-) aseptic processing;

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

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

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

(-5-) sterilization techniques.

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

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

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

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

(IV) supervising pharmacist conducts a final check.

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

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

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

(II) four hours of ACPE accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if pharmacy technician is engaged in compounding high risk sterile preparations.

(4) Evaluation and testing requirements.

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

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

(i) every 12 months for low- and medium-risk level compounding; and

(ii) every six months for high-risk level compounding.

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

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

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

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

(i) aseptic technique;

(ii) critical area contamination factors;

(iii) environmental monitoring;

(iv) structure and engineering controls related to facilities;

(v) equipment and supplies;

(vi) sterile preparation calculations and terminology;

(vii) sterile preparation compounding documentation;

(viii) quality assurance procedures;

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

(x) handling of hazardous drugs, if applicable;

(xi) cleaning procedures; and

(xii) general conduct in the clean room.

(E) The aseptic technique of each person compounding or responsible for the direct supervision of personnel compounding sterile preparations shall be observed and evaluated by expert personnel as satisfactory through written and practical tests, and challenge testing, and such evaluation documented. Compounding personnel shall not evaluate their own aseptic technique or results of their own media-fill challenge testing.

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

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

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

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

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

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

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

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

(iii) whenever unacceptable techniques are observed; and

(iv) at least on an annual basis for low- and medium-risk level compounding, and every six months for high-risk level compounding.

(L) The pharmacist-in-charge shall ensure that proper hand hygiene and garbing practices of compounding personnel are evaluated prior to compounding, supervising, or verifying sterile preparations intended for patient use and whenever an aseptic media fill is performed.

(i) Sampling of compounding personnel glove fingertips shall be performed for all risk level compounding.

(ii) All compounding personnel shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands).

(iii) Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing in order to assess garbing competency and after completing the media-fill preparation (without applying sterile 70% IPA).

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

(v) All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure no less than three times before initially being allowed to compound sterile preparations for patient use. Immediately after the compounding personnel completes the hand hygiene and garbing procedure (i.e., after donning of sterile gloves and before any disinfecting with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands of the compounding personnel onto agar plates or media test paddles by having the individual lightly touching each fingertip onto the agar. The test plates or test paddles will be incubated for the appropriate incubation period and at the appropriate temperature. Results of the initial gloved fingertip evaluations shall indicate zero colony-forming units (0 CFU) growth on the agar plates or media test paddles, or the test shall be considered a failure. In the event of a failed gloved fingertip test, the evaluation shall be repeated until the individual can successfully don sterile gloves and pass the gloved fingertip evaluation, defined as zero CFUs growth. No preparation intended for patient use shall be compounded by an individual until the results of the initial gloved fingertip evaluation indicate that the individual can competently perform aseptic procedures except that a pharmacist may temporarily supervise pharmacy technicians compounding sterile preparations while waiting for the results of the evaluation for no more than three days.

(vi) Re-evaluation of all compounding personnel shall occur at least annually for compounding personnel who compound low and medium risk level preparations and every six months for compounding personnel who compound high risk level preparations. Results of gloved fingertip tests conducted immediately after compounding personnel complete a compounding procedure shall indicate no more than 3 CFUs growth, or the test shall be considered a failure, in which case, the evaluation shall be repeated until an acceptable test can be achieved (i.e., the results indicated no more than 3 CFUs growth).

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

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

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

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

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

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

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

(d) Operational Standards.

(1) General Requirements.

(A) Sterile preparations may be compounded:

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

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

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

(B) Sterile compounding in anticipation of future prescription drug or medication orders 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 (6)(G) 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) facility's lot number;

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

(IV) quantity or amount in the container;

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

(VI) device-specific instructions, where appropriate.

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

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

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

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

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

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

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

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

(A) Low-risk level compounded sterile preparations.

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

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

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

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

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

(ii) Examples of Low-Risk Compounding. Examples of low-risk compounding include the following.

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

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

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

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

(ii) The primary engineering control device shall be certified and maintain ISO Class 5 for exposure of critical sites and

shall be located in a segregated compounding area restricted to sterile compounding activities that minimizes the risk of contamination of the compounded sterile preparation.

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

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

(C) Medium-risk level compounded sterile preparations.

(i) Medium-Risk Conditions. Medium-risk level compounded sterile preparations, are those compounded aseptically under low-risk conditions and one or more of the following conditions exists.

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

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

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

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

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

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

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

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

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

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

(D) High-risk level compounded sterile preparations.

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

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

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

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

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

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

(III) Compounding personnel are improperly garbed and gloved.

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

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

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

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

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

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

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

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

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

(3) Immediate Use Compounded Sterile Preparations. For the purpose of emergency or immediate patient care, such situations may include cardiopulmonary resuscitation, emergency room treat-

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

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

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

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

(D) Administration begins not later than one hour following the completion of preparing the compounded sterile preparation.

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

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

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

(4) Single-dose and multiple dose containers.

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

(B) Single-dose containers, including single-dose large volume parenteral solutions and single-dose vials, exposed to ISO Class 5 or cleaner air may be used up to six hours after initial needle puncture.

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

(D) Multiple-dose containers may be used up to 28 days after initial needle puncture unless otherwise specified by the manufacturer.

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

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

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

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

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

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

(A) Low and Medium Risk Preparations. A pharmacy that prepares low- and medium-risk preparations shall have a clean room for the compounding of sterile preparations that is constructed to minimize the opportunities for particulate and microbial contamination. The clean room shall:

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

(ii) be maintained at a temperature of 20 degrees Celsius or cooler and at a humidity below 60%;

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

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

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

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

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

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

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

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

(xi) contain an ante-area that contains a sink with hot and cold running water that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination. A Class B pharmacy may have a sink with hot and cold running water that enables hands-free use with a closed system of soap dispensing

immediately outside the ante-area if antiseptic hand cleansing is performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations once inside the ante-area; and

(xii) contain a buffer area. The following is applicable for the buffer area.

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

(II) The buffer area shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation should be continuously monitored.

(III) A buffer area that is not physically separated from the ante-area shall employ the principle of displacement airflow as defined in Chapter 797, Pharmaceutical Compounding--Sterile Preparations, of the USP/NF, with limited access to personnel.

(IV) The buffer area shall not contain sources of water (i.e., sinks) or floor drains other than distilled or sterile water introduced for facilitating the use of heat block wells for radiopharmaceuticals.

(B) High-risk Preparations.

(i) In addition to the requirements in subparagraph (A) of this paragraph, when high-risk preparations are compounded, the primary engineering control shall be located in a buffer area that provides a physical separation, through the use of walls, doors and pass-throughs and has a minimum differential positive pressure of 0.02 to 0.05 inches water column.

(ii) Presterilization procedures for high-risk level compounded sterile preparations, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.

(C) Automated compounding device.

(i) General. If automated compounding devices are used, the pharmacy shall have a method to calibrate and verify the accuracy of automated compounding devices used in aseptic processing and document the calibration and verification on a daily basis, based on the manufacturer's recommendations, and review the results at least weekly.

(ii) Loading bulk drugs into automated compounding devices.

(I) Automated compounding device may be loaded with bulk drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(II) The label of an automated compounding device container shall indicate the brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor.

(III) Records of loading bulk drugs into an automated compounding device shall be maintained to show:

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

(-b-) manufacturer or distributor;

(-c-) manufacturer's lot number;

(-d-) manufacturer's expiration date;

(-e-) quantity added to the automated compounding device;

(-f-) date of loading;

(-g-) name, initials, or electronic signature of the person loading the automated compounding device; and

(-h-) name, initials, or electronic signature of the responsible pharmacist.

(IV) The automated compounding device shall not be used until a pharmacist verifies that the system is properly loaded and affixes his or her signature or electronic signature to the record specified in subclause (III) of this clause.

(D) Hazardous drugs. If the preparation is hazardous, the following is also applicable.

(i) Hazardous drugs shall be prepared only under conditions that protect personnel during preparation and storage.

(ii) Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure.

(iii) All personnel involved in the compounding of hazardous drugs shall wear appropriate protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and appropriate gloving at all times when handling hazardous drugs, including receiving, distribution, stocking, inventorying, preparation, for administration and disposal.

(iv) Appropriate safety and containment techniques for compounding hazardous drugs shall be used in conjunction with aseptic techniques required for preparing sterile preparations.

(v) Disposal of hazardous waste shall comply with all applicable local, state, and federal requirements.

(vi) Prepared doses of hazardous drugs must be dispensed, labeled with proper precautions inside and outside, and distributed in a manner to minimize patient contact with hazardous agents.

(E) Blood-labeling procedures. When compounding activities require the manipulation of a patient's blood-derived material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be performed in a ISO Class 5 biological safety cabinet located in a buffer area and shall be clearly separated from routine material-handling procedures and equipment used in preparation activities to avoid any cross-contamination. The preparations shall not require sterilization.

(F) Cleaning and disinfecting the sterile compounding areas. The following cleaning and disinfecting practices and frequencies apply to direct and contiguous compounding areas, which include ISO Class 5 compounding areas for exposure of critical sites as well as buffer areas, ante-areas, and segregated compounding areas.

(i) The pharmacist-in-charge is responsible for developing written procedures for cleaning and disinfecting the direct and contiguous compounding areas and assuring the procedures are followed.

(ii) These procedures shall be conducted at the beginning of each work shift, before each batch preparation is started, when there are spills, and when surface contamination is known or suspected resulting from procedural breaches, and every 30 minutes during continuous compounding of individual compounded sterile preparations, unless a particular compounding procedure requires more than 30 minutes to complete, in which case, the direct compounding area is to be cleaned immediately after the compounding activity is completed.

(iii) Before compounding is performed, all items shall be removed from the direct and contiguous compounding areas and all surfaces are cleaned by removing loose material and residue from spills, followed by an application of a residue-free disinfecting agent (e.g., IPA), which is allowed to dry before compounding begins. In a Class B pharmacy, objects used in preparing sterile radiopharmaceuticals (e.g., dose calibrator) which cannot be reasonably removed from the compounding area shall be sterilized with an application of a residue-free disinfection agent.

(iv) Work surfaces in the buffer areas and ante-areas, as well as segregated compounding areas, shall be cleaned and disinfected at least daily. Dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 air quality.

(v) Floors in the buffer area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent at least once daily when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs. It is incumbent on compounding personnel to ensure that such cleaning is performed properly.

(vi) In the buffer area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly. Cleaning and disinfecting agents shall be used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues.

(vii) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer area and ante-area, but only in that order. If cleaning materials are reused, procedures shall be developed that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bio-burden of the area being cleaned.

(viii) Supplies and equipment removed from shipping cartons must be wiped with a disinfecting agent, such as sterile IPA. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes. However, if sterile supplies are received in sealed pouches, the pouches may be removed as the supplies are introduced into the ISO Class 5 area without the need to disinfect the individual sterile supply items. No shipping or other external cartons may be taken into the buffer area or segregated compounding area.

(ix) Storage shelving emptied of all supplies, walls, and ceilings are cleaned and disinfected at planned intervals, monthly, if not more frequently.

(x) Cleaning must be done by personnel trained in appropriate cleaning techniques.

(xi) Proper documentation and frequency of cleaning must be maintained and shall contain the following:

(I) date and time of cleaning;

(II) type of cleaning performed; and

(III) name of individual who performed the cleaning.

(G) Security requirements. The pharmacist-in-charge may authorize personnel to gain access to that area of the pharmacy containing dispensed sterile preparations, in the absence of the pharmacist, for the purpose of retrieving dispensed prescriptions to deliver to patients. If the pharmacy allows such after-hours access, the area containing the dispensed sterile preparations shall be an enclosed and lockable area separate from the area containing undispensed prescription drugs. A list of the authorized personnel having such access shall be in the pharmacy's policy and procedure manual.

(H) Storage requirements and beyond-use dating.

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

(ii) Beyond-use dating.

(I) Beyond-use dates for compounded sterile preparations shall be assigned based on professional experience, which shall include careful interpretation of appropriate information sources for the same or similar formulations.

(II) Beyond-use dates for compounded sterile preparations that are prepared strictly in accordance with manufacturers' product labeling must be those specified in that labeling, or from appropriate literature sources or direct testing.

(III) When assigning a beyond-use date, compounding personnel shall consult and apply drug-specific and general stability documentation and literature where available, and they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy.

(IV) The sterility and storage and stability beyond-use date for attached and activated container pairs of drug products for intravascular administration shall be applied as indicated by the manufacturer.

(7) Primary engineering control device. The pharmacy shall prepare sterile preparations in a primary engineering control device (PEC), such as a laminar air flow hood, biological safety cabinet, compounding aseptic isolator (CAI), or compounding aseptic containment isolator (CACI) which is capable of maintaining at least ISO Class 5 conditions for 0.5 micrometer particles while compounding sterile preparations.

(A) Laminar air flow hood. If the pharmacy is using a laminar air flow hood as its PEC, the laminar air flow hood shall:

(i) be located in the buffer area and placed in the buffer area in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system;

(ii) be certified by a qualified independent contractor according to the appropriate Controlled Environment Testing Association (CETA) standard (CAG-003-2006) for operational efficiency at least every six months and whenever the device or room is relocated or altered or major service to the facility is performed;

(iii) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specification, and the inspection and/or replacement date documented; and

(iv) be located in a buffer area that has a minimum differential positive pressure of 0.02 to 0.05 inches water column. A buffer area that is not physically separated from the ante-area shall employ the principle of displacement airflow as defined in Chapter 797, Pharmaceutical Compounding--Sterile Preparations, of the USP/NF, with limited access to personnel.

(B) Biological safety cabinet.

(i) If the pharmacy is using a biological safety cabinet as its PEC for the preparation of hazardous sterile compounded preparations, the biological safety cabinet shall be a Class II or III vertical flow biological safety cabinet located in an ISO Class 7 area that is physically separated from other preparation areas. The area for preparation of sterile chemotherapeutic preparations shall:

(I) have not less than 0.01 inches water column negative pressure to the adjacent positive pressure ISO Class 7 or better ante-area; and

(II) have a pressure indicator that can be readily monitored for correct room pressurization.

(ii) Pharmacies that prepare a low volume of hazardous drugs, are not required to comply with the provisions of clause (i) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., closed-system vial transfer device within a BSC).

(iii) If the pharmacy is using a biological safety cabinet as its PEC for the preparation of non-hazardous sterile compounded preparations, the biological safety cabinet shall:

(I) be located in the buffer area and placed in the buffer area in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system;

(II) be certified by a qualified independent contractor according to the International Organization of Standardization (ISO) Classification of Particulate Matter in Room Air (ISO 14644-1) for operational efficiency at least every six months and whenever the device or room is relocated or altered or major service to the facility is performed, in accordance with the manufacturer's specifications and test procedures specified in the Institute of Environmental Sciences and Technology (IEST) document IEST-RP-CC002.3;

(III) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specification, and the inspection and/or replacement date documented; and

(IV) be located in a buffer area that has a minimum differential positive pressure of 0.02 to 0.05 inches water column.

(C) Compounding aseptic isolator.

(i) If the pharmacy is using a compounding aseptic isolator (CAI) as its PEC, the CAI shall provide unidirectional airflow within the main processing and antechambers, and be placed in an ISO Class 7 buffer area unless the isolator meets all of the following conditions:

(I) The isolator must provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations.

(II) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site must maintain ISO Class 5 levels during compounding operations.

(III) The CAI must be validated according to CETA CAG-002-2006 standards.

(IV) The pharmacy shall maintain documentation from the manufacturer that the isolator meets this standard when located in worse than ISO Class 7 environments.

(ii) If the isolator meets the requirements in clause (i) of this subparagraph, the CAI may be placed in a non-ISO classified area of the pharmacy; however, the area shall be segregated from other areas of the pharmacy and shall:

(I) be clean, well lit, and of sufficient size;

(II) be used only for the compounding of low- and medium-risk, non-hazardous sterile preparations;

(III) be located in an area of the pharmacy with non-porous and washable floors or floor covering to enable regular disinfection; and

(IV) be an area in which the CAI is placed in a manner as to avoid conditions that could adversely affect its operation.

(iii) In addition to the requirements specified in clauses (i) and (ii) of this subparagraph, if the CAI is used in the compounding of high-risk non-hazardous preparations, the CAI shall be placed in an area or room with at least ISO 8 quality air so that high-risk powders weighed in at least ISO-8 air quality conditions, compounding utensils for measuring and other compounding equipment are not exposed to lesser air quality prior to the completion of compounding and packaging of the high-risk preparation.

(D) Compounding aseptic containment isolator.

(i) If the pharmacy is using a compounding aseptic containment isolator as its PEC for the preparation of low- and medium-risk hazardous drugs, the CACI shall be located in a separate room away from other areas of the pharmacy and shall:

(I) provide at least 0.01 inches water column negative pressure compared to the other areas of the pharmacy;

(II) provide unidirectional airflow within the main processing and antechambers, and be placed in an ISO Class 7 buffer area, unless the CACI meets all of the following conditions.

(-a-) The isolator must provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations.

(-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site must maintain ISO Class 5 levels during compounding operations.

(-c-) The CACI must be validated according to CETA CAG-002-2006 standards.

(-d-) The pharmacy shall maintain documentation from the manufacturer that the isolator meets this standard when located in worse than ISO Class 7 environments.

(ii) If the CACI meets all conditions specified in clause (i) of this subparagraph, the CACI shall not be located in the same room as a CAI, but shall be located in a separate room in the pharmacy, that is not required to maintain ISO classified air. The room in which the CACI is located shall provide a minimum of 0.01 inches water column negative pressure compared with the other areas of the pharmacy and shall meet the following requirements:

(I) be clean, well lit, and of sufficient size;

(II) be maintained at a temperature of 20 degrees Celsius or cooler and a humidity below 60%;

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

(IV) be located in an area of the pharmacy with walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices, non-shedding and resistant to damage by disinfectant agents; and

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

(iii) If the CACI is used in the compounding of high-risk hazardous preparations, the CACI shall be placed in an area or room with at least ISO 8 quality air so that high-risk powders, weighed in at least ISO-8 air quality conditions, are not exposed to lesser air quality prior to the completion of compounding and packaging of the high-risk preparation.

(iv) Pharmacies that prepare a low volume of hazardous drugs, are not required to comply with the provisions of clauses (i) and (iii) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., CACI that is located in a non-negative pressure room).

(8) Additional Equipment and Supplies. Pharmacies compounding sterile preparations shall have the following equipment and supplies:

(A) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure that proper storage requirements are met, if sterile preparations are stored in the refrigerator;

(B) a calibrated system or device to monitor the temperature where bulk chemicals are stored;

(C) a temperature-sensing mechanism suitably placed in the controlled temperature storage space to reflect accurately the true temperature;

(D) if applicable, a Class A prescription balance, or analytical balance and weights. Such balance shall be properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy;

(E) equipment and utensils necessary for the proper compounding of sterile preparations. Such equipment and utensils used in the compounding process shall be:

(i) of appropriate design, appropriate capacity, and be operated within designed operational limits;

(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug preparation beyond the desired result;

(iii) cleaned and sanitized immediately prior to and after each use; and

(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;

(F) appropriate disposal containers for used needles, syringes, etc., and if applicable, hazardous waste from the preparation of hazardous drugs and/or biohazardous waste;

(G) appropriate packaging or delivery containers to maintain proper storage conditions for sterile preparations;

(H) infusion devices, if applicable; and

(I) all necessary supplies, including:

(i) disposable needles, syringes, and other supplies for aseptic mixing;

(ii) disinfectant cleaning solutions;

(iii) sterile 70% isopropyl alcohol;

(iv) sterile gloves, both for hazardous and non-hazardous drug compounding;

(v) sterile alcohol-based or water-less alcohol based surgical scrub;

(vi) hand washing agents with bactericidal action;

(vii) disposable, lint free towels or wipes;

(viii) appropriate filters and filtration equipment;

(ix) hazardous spill kits, if applicable; and

(x) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.

(9) Labeling.

(A) Prescription drug or medication orders. In addition to the labeling requirements for the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following:

(i) the generic name(s) or the official name(s) of the principal active ingredient(s) of the compounded sterile preparation;

(ii) for outpatient prescription orders other than sterile radiopharmaceuticals, a statement that the compounded sterile preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement);

(iii) a beyond-use date. The beyond-use date shall be determined as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF, and paragraph (7)(G) of this subsection;

(B) Batch. If the sterile preparation is compounded in a batch, the following shall also be included on the batch label:

(i) unique lot number assigned to the batch;

(ii) quantity;

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

(iv) device-specific instructions, where appropriate.

(C) Pharmacy bulk package. The label of a pharmacy bulk package shall:

(i) state prominently "Pharmacy Bulk Package--Not for Direct Infusion;"

(ii) contain or refer to information on proper techniques to help ensure safe use of the preparation; and

(iii) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.

(10) Written drug information for prescription drug orders only. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing a prescription drug order. A statement which indicates that the preparation was compounded by the pharmacy must be included in this written information. If there is no written information available, the pa-

tient shall be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate, the prescriber, concerning the drug. This paragraph does not apply to the preparation of radiopharmaceuticals.

(11) Pharmaceutical Care Services. In addition to the pharmaceutical care requirements for the pharmacy's specific license classification, the following requirements for sterile preparations compounded pursuant to prescription drug orders must be met. This paragraph does not apply to the preparation of radiopharmaceuticals.

(A) Primary provider. There shall be a designated physician primarily responsible for the patient's medical care. There shall be a clear understanding between the physician, the patient, and the pharmacy of the responsibilities of each in the areas of the delivery of care, and the monitoring of the patient. This shall be documented in the patient medication record (PMR).

(B) Patient training. The pharmacist-in-charge shall develop policies to ensure that the patient and/or patient's caregiver receives information regarding drugs and their safe and appropriate use, including instruction when applicable, regarding:

(i) appropriate disposition of hazardous solutions and ancillary supplies;

(ii) proper disposition of controlled substances in the home;

(iii) self-administration of drugs, where appropriate;

(iv) emergency procedures, including how to contact an appropriate individual in the event of problems or emergencies related to drug therapy; and

(v) if the patient or patient's caregiver prepares sterile preparations in the home, the following additional information shall be provided:

(I) safeguards against microbial contamination, including aseptic techniques for compounding intravenous admixtures and aseptic techniques for injecting additives to premixed intravenous solutions;

(II) appropriate storage methods, including storage durations for sterile pharmaceuticals and expirations of self-mixed solutions;

(III) handling and disposition of premixed and self-mixed intravenous admixtures; and

(IV) proper disposition of intravenous admixture compounding supplies such as syringes, vials, ampules, and intravenous solution containers.

(C) Pharmacist-patient relationship. It is imperative that a pharmacist-patient relationship be established and maintained throughout the patient's course of therapy. This shall be documented in the patient's medication record (PMR).

(D) Patient monitoring. The pharmacist-in-charge shall develop policies to ensure that:

(i) the patient's response to drug therapy is monitored and conveyed to the appropriate health care provider;

(ii) the first dose of any new drug therapy is administered in the presence of an individual qualified to monitor for and respond to adverse drug reactions; and

(iii) reports of adverse events with a compounded sterile preparation are reviewed promptly and thoroughly to correct and prevent future occurrences.

(12) Drugs, components, and materials used in sterile compounding.

(A) Drugs used in sterile compounding shall be a USP/NF grade substances manufactured in an FDA-registered facility.

(B) If USP/NF grade substances are not available shall be of a chemical grade in one of the following categories:

(i) Chemically Pure (CP);

(ii) Analytical Reagent (AR);

(iii) American Chemical Society (ACS); or

(iv) Food Chemical Codex.

(C) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.

(D) All components shall:

(i) be manufactured in an FDA-registered facility; or

(ii) in the professional judgment of the pharmacist, be of high quality and obtained from acceptable and reliable alternative sources; and

(iii) stored in properly labeled containers in a clean, dry area, under proper temperatures.

(E) Drug preparation containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug preparation beyond the desired result.

(F) Components, drug preparation containers, and closures shall be rotated so that the oldest stock is used first.

(G) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug preparation.

(H) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.

(13) Compounding process.

(A) Standard operating procedures (SOPs). All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed and implemented for:

(i) the facility;

(ii) equipment;

(iii) personnel;

(iv) preparation evaluation;

(v) quality assurance;

(vi) preparation recall;

(vii) packaging; and

(viii) storage of compounded sterile preparations.

(B) USP/NF. Any compounded formulation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

(C) Personnel Cleansing and Garbing.

(i) Any person with an apparent illness or open lesion, including rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infection, that may adversely affect the safety or quality of a drug preparation being compounded shall be excluded from working in ISO Class 5, ISO Class 7, and ISO Class 8 compounding areas until the condition is remedied.

(ii) Before entering the buffer area, compounding personnel must remove the following:

(I) personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests);

(II) all cosmetics, because they shed flakes and particles; and

(III) all hand, wrist, and other body jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of personal protective equipment (e.g., fit of gloves and cuffs of sleeves).

(iii) The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed.

(iv) Personnel shall don personal protective equipment and perform hand hygiene in an order that proceeds from the dirtiest to the cleanest activities as follows:

(I) Activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye shield. Eye shields are optional unless working with irritants like germicidal disinfecting agents or when preparing hazardous drugs.

(II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, personnel shall perform a hand hygiene procedure by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Personnel shall begin washing arms at the hands and continue washing to elbows for at least 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in the ante-area. Hands and forearms to the elbows shall be completely dried using lint-free disposable towels, an electronic hands-free hand dryer, or a HEPA filtered hand dryer.

(III) After completion of hand washing, personnel shall don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclosed at the neck.

(IV) Once inside the buffer area or segregated compounding area, and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations. Hands shall be allowed to dry thoroughly before donning sterile gloves.

(V) Sterile gloves that form a continuous barrier with the gown shall be the last item donned before compounding begins. Sterile gloves shall be donned using proper technique to ensure the sterility of the glove is not compromised while donning. The cuff of the sterile glove shall cover the cuff of the gown at the wrist. When preparing hazardous preparations, the compounder shall double glove or shall use single gloves ensuring that the gloves are sterile powder-free chemotherapy-rated gloves. Routine application of sterile 70% IPA shall occur throughout the compounding day and whenever non-sterile surfaces are touched.

(v) When compounding personnel shall temporarily exit the buffer area during a work shift, the exterior gown, if not visibly soiled, may be removed and retained in the ante-area, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face mask/eye shield, and gloves shall be replaced with new ones before re-entering the buffer area along with performing proper hand hygiene.

(vi) During high-risk compounding activities that precede terminal sterilization, such as weighing and mixing of non-sterile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 environment. Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 shall re-garb personal protective equipment along with washing their hands properly, performing antiseptic hand cleansing with a sterile 70% IPA-based or another suitable sterile alcohol-based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7 buffer area.

(vii) When compounding aseptic isolators or compounding aseptic containment isolators are the source of the ISO Class 5 environment, at the start of each new compounding procedure, a new pair of sterile gloves shall be donned within the CAI or CACI. In addition, the compounding personnel should follow the requirements as specified in this subparagraph, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any components of personal protective equipment or cleansing are not required.

(14) Quality Assurance.

(A) Initial Formula Validation. Prior to routine compounding of a sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a preparation that is sterile and that contains the stated amount of active ingredient(s).

(i) Low risk preparations.

(I) Quality assurance practices include, but are not limited to the following:

(-a-) Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality.

(-b-) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments and goggles.

(-c-) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.

(-d-) Visual inspection of compounded sterile preparations, except for sterile radiopharmaceuticals, to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually by each person authorized to compound in a low-risk level under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low-risk level sterile preparations. Once begun, this test is completed without interruption within an ISO Class 5 air quality environment. Three sets of four 5-milliliter aliquots of sterile Soybean-Casein Digest Medium are transferred with the same sterile 10-milliliter syringe and vented needle combination

into separate sealed, empty, sterile 30-milliliter clear vials (i.e., four 5-milliliter aliquots into each of three 30-milliliter vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.

(ii) Medium risk preparations.

(I) Quality assurance procedures for medium-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations, as well as a more challenging media-fill test passed annually, or more frequently.

(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. This test is completed without interruption within an ISO Class 5 air quality environment. Six 100-milliliter aliquots of sterile Soybean-Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-milliliter syringe and 18-gauge needle combination is used to exchange two 5-milliliter aliquots of medium from one container to the other container in the pair. For example, after a 5-milliliter aliquot from the first container is added to the second container in the pair, the second container is agitated for 10 seconds, then a 5-milliliter aliquot is removed and returned to the first container in the pair. The first container is then agitated for 10 seconds, and the next 5-milliliter aliquot is transferred from it back to the second container in the pair. Following the two 5-milliliter aliquot exchanges in each pair of containers, a 5-milliliter aliquot of medium from each container is aseptically injected into a sealed, empty, sterile 10-milliliter clear vial, using a sterile 10-milliliter syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.

(iii) High risk preparations.

(I) Procedures for high-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations. In addition, a media-fill test that represents high-risk level compounding is performed twice a year by each person authorized to compound high-risk level compounded sterile preparations.

(II) Example of a Media-Fill Test Procedure Compounded Sterile Preparations Sterilized by Filtration. This test, or an equivalent test, is performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level compounded sterile preparations. Note: Sterility tests for autoclaved compounded sterile preparations are not required unless they are prepared in batches of more than 25 units. This test is completed without interruption in the following sequence:

(-a-) Dissolve 3 grams of non-sterile commercially available Soybean-Casein Digest Medium in 100 milliliters of non-bacteriostatic water to make a 3% non-sterile solution.

(-b-) Draw 25 milliliters of the medium into each of three 30-milliliter sterile syringes. Transfer 5 milliliters from each syringe into separate sterile 10-milliliter vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.

(-c-) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron porosity filter unit and a 20-gauge needle to each syringe. Inject the next 10 milliliters from each syringe into three separate 10-milliliter sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20 to 35 degrees Celsius for a minimum of 14 days. Inspect for microbial growth over 14 days as described in Chapter 797 Pharmaceutical Compounding--Sterile Preparations, of the USP/NF.

(III) Filter Integrity Testing. Filters need to undergo testing to evaluate the integrity of filters used to sterilize high-risk preparations, such as Bubble Point Testing or comparable filter integrity testing. Such testing is not a replacement for sterility testing and shall not be interpreted as such. Such test shall be performed after a sterilization procedure on all filters used to sterilize each high-risk preparation or batch preparation and the results documented. The results should be compared with the filter manufacturer's specification for the specific filter used. If a filter fails the integrity test, the preparation or batch must be sterilized again using new unused filters.

(B) Finished preparation release checks and tests.

(i) All high-risk level compounded sterile preparations that are prepared in groups of more than 25 identical individual single-dose packages (such as ampuls, bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than 12 hours at 2 - 8 degrees Celsius and longer than six hours at warmer than 8 degrees Celsius before they are sterilized shall be tested to ensure they are sterile and do not contain excessive bacterial endotoxins as specified in Chapter 71, Sterility Tests of the USP/NF before being dispensed or administered.

(ii) All compounded sterile preparations, except for sterile radiopharmaceuticals, that are intended to be solutions must be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed.

(iii) The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded sterile preparations at all contamination risk levels shall be inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are dispensed or administered.

(iv) Written procedures for checking compounding accuracy shall be followed for every compounded sterile preparation during preparation, in accordance with pharmacy's policies and procedures, and immediately prior to release, including label accuracy and the accuracy of the addition of all drug products or ingredients used to prepare the finished preparation and their volumes or quantities. A pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(C) Environmental Testing.

(i) Viable and nonviable environmental sampling testing. Environmental sampling shall occur, at a minimum, every six months as part of a comprehensive quality management program and under any of the following conditions:

(I) as part of the commissioning and certification of new facilities and equipment;

(II) following any servicing of facilities and equipment;

(III) as part of the re-certification of facilities and equipment;

(IV) in response to identified problems with end products or staff technique; or

(V) in response to issues with compounded sterile preparations, observed compounding personnel work practices, or patient-related infections (where the compounded sterile preparation is being considered as a potential source of the infection).

(ii) Total particle counts. Certification that each ISO classified area (e.g., ISO Class 5, 7, and 8), is within established guidelines shall be performed no less than every six months and whenever the equipment is relocated or the physical structure of the buffer area or ante-area has been altered. All certification records shall be maintained and reviewed to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and air changes per hour. Testing shall be performed by qualified operators using current, state-of-the-art equipment, with results of the following:

(I) ISO Class 5 - not more than 3520 particles 0.5 micrometer and larger size per cubic meter of air;

(II) ISO Class 7 - not more than 352,000 particles of 0.5 micrometer and larger size per cubic meter of air for any buffer area; and

(III) ISO Class 8 - not more than 3,520,000 particles of 0.5 micrometer and larger size per cubic meter of air for any ante-area.

(iii) Pressure differential monitoring. A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 or ISO Class 8 and the general pharmacy area shall not be less than 0.02 inch water column.

(iv) Sampling plan. An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas and in the segregated compounding areas at greatest risk of contamination. The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.

(v) Viable air sampling. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments shall be performed by properly trained individuals for all compounding risk levels. For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning. Locations shall include zones of air backwash turbulence within the laminar airflow workbench and other areas where air backwash turbulence may enter the compounding area. For low-risk level compounded sterile preparations within 12-hour or less beyond-use-date prepared in a primary engineering control that maintains an ISO Class 5, air sampling shall be performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class 5 environment during the certification of the primary engineering control.

(vi) Air sampling frequency and process. Air sampling shall be performed at least every 6 months as a part of the re-certification of facilities and equipment. A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed. At the end of the designated sampling or exposure period for air sampling activities, the microbial growth media plates are recovered and their covers secured and they are inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology or infection control personnel shall be consulted. A colony forming unit (cfu) count greater than 1 cfu per cubic meter of air for ISO Class 5, greater than 10 cfu per cubic meter of air for ISO Class 7, and greater than 100 cfu per cubic meter of air for ISO Class 8 or worse should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed. Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time. Regardless of the number of cfu identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler. Highly pathogenic microorganisms (e.g., gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patient receiving compounded sterile preparations and must be immediately remedied, regardless of colony forming unit count, with the assistance, if needed, of a competent microbiologist, infection control professional, or industrial hygienist.

(vii) Compounding accuracy checks. Written procedures for checking compounding accuracy shall be followed for every compounded sterile preparation during preparation and immediately prior to release, including label accuracy and the accuracy of the addition of all drug products or ingredients used to prepare the finished preparation and their volumes or quantities. At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(15) Quality control.

(A) Quality control procedures. The pharmacy shall follow established quality control procedures to monitor the compounding environment and quality of compounded drug preparations for conformity with the quality indicators established for the preparation. When developing these procedures, pharmacy personnel shall consider the provisions of USP Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding-Non-sterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations, USP Chapter 800, Hazardous Drugs--Handling in Healthcare Settings, USP Chapter 823, Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses, USP Chapter 1160, Pharmaceutical Calculations in Prescription Compounding, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding of the current USP/NF. Such procedures shall be documented and be available for inspection.

(B) Verification of compounding accuracy and sterility.

(i) The accuracy of identities, concentrations, amounts, and purities of ingredients in compounded sterile preparations shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.

(ii) If the correct identity, purity, strength, and sterility of ingredients and components of compounded sterile preparations cannot be confirmed such ingredients and components shall be discarded immediately. Any compounded sterile preparation that fails sterility testing following sterilization by one method (e.g., filtration) is to be discarded and not subjected to a second method of sterilization.

(iii) If individual ingredients, such as bulk drug substances, are not labeled with expiration dates, when the drug substances are stable indefinitely in their commercial packages under labeled storage conditions, such ingredients may gain or lose moisture during storage and use and shall require testing to determine the correct amount to weigh for accurate content of active chemical moieties in compounded sterile preparations.

(e) Records. Any testing, cleaning, procedures, or other activities required in this subsection shall be documented and such documentation shall be maintained by the pharmacy.

(1) Maintenance of records. Every record required under this section must be:

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

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

(2) Compounding records.

(A) Compounding pursuant to patient specific prescription drug orders or medication orders. Compounding records for all compounded preparations shall be maintained by the pharmacy and shall include:

(i) the date and time of preparation;

(ii) a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of each; however, if the sterile preparation is compounded according to the manufacturer's labeling instructions, then documentation of the formula is not required;

(iii) written or electronic signature or initials of the pharmacist or pharmacy technician or pharmacy technician trainee performing the compounding;

(iv) written or electronic signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting finals checks of compounded pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the compounding function;

(v) the container used and the number of units of finished preparation prepared; and

(vi) a reference to the location of the following documentation which may be maintained with other records, such as quality control records:

(I) the criteria used to determine the beyond-use date; and

(II) documentation of performance of quality control procedures.

(B) Compounding records 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 for each component;

(III) component manufacturer/distributor or suitable identifying number;

(IV) container specifications (e.g., syringe, pump cassette);

(V) unique lot or control number assigned to batch;

(VI) expiration date of batch-prepared preparations;

(VII) date of preparation;

(VIII) name, initials, or electronic signature of the person(s) involved in the preparation;

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

(X) finished preparation evaluation and testing specifications, if applicable; and

(XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.

(f) Office Use Compounding and Distribution of Sterile Compounded Preparations

(1) General.

(A) A pharmacy may compound, dispense, deliver, and distribute a compounded sterile preparation as specified in Subchapter D, Texas Pharmacy Act Chapter 562.

(B) A Class A-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations to a Class C or Class C-S pharmacy.

(C) A Class C-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations that the Class C-S pharmacy has compounded for other Class C or Class C-S pharmacies under common ownership.

(D) To compound and deliver a compounded preparation under this subsection, a pharmacy 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.

(E) This subsection does not apply to Class B pharmacies compounding sterile radiopharmaceuticals that are furnished for departmental or physicians' use if such authorized users maintain a Texas radioactive materials license.

(2) Written Agreement. A pharmacy that provides sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:

(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded drugs may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except to a veterinarian as authorized by §563.054 of the Act;

(B) require the practitioner or receiving pharmacy to include on a patient's chart, medication order or medication administration record the lot number and beyond-use date of a compounded preparation administered to a patient;

(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:

(i) a patient to report an adverse reaction or submit a complaint; and

(ii) the pharmacy to recall batches of compounded preparations.

(3) Recordkeeping.

(A) Maintenance of Records.

(i) Records of orders and distribution of sterile compounded preparations to a practitioner for office use or to an institutional pharmacy for administration to a patient shall:

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

(II) maintained separately from the records of preparations 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 sterile compounded preparations ordered by a practitioner for office use or by an institutional pharmacy for administration to a patient. The record shall include the following information:

(i) date of the order;

(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the institutional pharmacy ordering the preparation; and

(iii) name, strength, and quantity of the preparation ordered.

(C) Distributions. The pharmacy shall maintain a record of all sterile compounded preparations distributed pursuant to an order to a practitioner for office use or by an institutional pharmacy for administration to a patient. The record shall include the following information:

(i) date the preparation was compounded;

(ii) date the preparation was distributed;

(iii) name, strength and quantity in each container of the preparation;

(iv) pharmacy's lot number;

(v) quantity of containers shipped; and

(vi) name, address, and phone number of the practitioner or institutional pharmacy to whom the preparation is distributed.

(D) Audit Trail.

(i) The pharmacy shall store the order and distribution records of preparations for all sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a pharmacy licensed to compound sterile preparations for administration to a patient in such a manner as to be able to provide an audit trail for all orders and distributions of any of the following during a specified time period:

(I) any strength and dosage form of a preparation (by either brand or generic name or both);

(II) any ingredient;

(III) any lot number;

(IV) any practitioner;

(V) any facility; and

(VI) any pharmacy, if applicable.

(ii) The audit trail shall contain the following information:

(I) date of order and date of the distribution;

(II) practitioner's name, address, and name of the institutional pharmacy, if applicable;

(III) name, strength and quantity of the preparation in each container of the preparation;

(IV) name and quantity of each active ingredient;

(V) quantity of containers distributed; and

(VI) pharmacy's lot number.

(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:

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

(B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";

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

(D) pharmacy's lot number;

(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;

(F) quantity or amount in the container;

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

(H) device-specific instructions, where appropriate.

(g) Recall Procedures.

(1) The pharmacy shall have written procedures for the recall of any compounded sterile preparation provided to a patient, to a practitioner for office use, or a pharmacy for administration. Written procedures shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.

(2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.

(3) In the event of a recall, the pharmacist-in-charge shall ensure that:

(A) 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) the board is notified of the recall, in writing, not later than 24 hours after the recall is issued;

(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.

(5) A pharmacy that compounds sterile preparations shall notify the board immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy.

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604303
Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
Effective date: September 11, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 305-8028

♦ ♦ ♦

SUBCHAPTER H. OTHER CLASSES OF PHARMACY

22 TAC §291.151

The Texas State Board of Pharmacy adopts amendments to §291.151, concerning Pharmacies Located in a Freestanding Emergency Medical Care Facility (Class F). The amendments are adopted without changes to the proposed text as published in the June 24, 2016, issue of the *Texas Register* at (41 TexReg 4617), and will not be republished.

The amendments clarify recordkeeping requirements and allow pharmacists to record certain information in the patient's chart in lieu of keeping a separate log.

No comments were received.

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

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

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604306

Gay Dodson, R. Ph.
Executive Director
Texas State Board of Pharmacy
Effective date: September 11, 2016
Proposal publication date: June 24, 2016
For further information, please call: (512) 305-8028

♦ ♦ ♦

PART 23. TEXAS REAL ESTATE COMMISSION

CHAPTER 535. GENERAL PROVISIONS
SUBCHAPTER E. REQUIREMENTS FOR LICENSURE

22 TAC §535.53

The Texas Real Estate Commission (TREC) adopts amendments to 22 TAC §535.53, Business Entity; Designated Broker, in Chapter 535, General Provisions, without changes, as published in the May 20, 2016, issue of the *Texas Register* (41 TexReg 3598).

The amendments are adopted to clarify that a business entity must be qualified to transact business in Texas at all times to maintain an active license and that the business entity must notify TREC when it is no longer qualified to transact business in Texas. In addition, the amendments more fully set out the scope of required errors and omissions insurance coverage.

The reasoned justification for the amendments is greater clarity in the rule.

No comments were received on the amendments as published.

The amendments are adopted under Texas Occupations Code, §1101.151, which authorizes the Texas Real Estate Commission to adopt and enforce rules necessary to administer Chapters 1101 and 1102; and to establish standards of conduct and ethics for its license holders to fulfill the purposes of Chapters 1101 and 1102 and ensure compliance with Chapters 1101 and 1102.

The statutes affected by this amendment are Texas Occupations Code, Chapter 1101. No other statute, code or article is affected by the amendments.

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

Filed with the Office of the Secretary of State on August 18, 2016.

TRD-201604228
Kerri Lewis
General Counsel
Texas Real Estate Commission
Effective date: September 7, 2016
Proposal publication date: May 20, 2016
For further information, please call: (512) 936-3092

♦ ♦ ♦

22 TAC §535.55

The Texas Real Estate Commission (TREC) adopts amendments to 22 TAC §535.55, Education and Sponsorship Requirements for a Salesperson, in Chapter 535, General Provisions, without changes, as published in the May 20, 2016, issue of the *Texas Register* (41 TexReg 3599).

The amendments are adopted to align the rule with statutory changes in SB 699, enacted by the 84th Legislature regarding the number of hours required for continuing education and changing term "salesperson" to "sales agent."

The reasoned justification is greater clarity and consistency in the rules.

No comments were received on the amendments as published.

The amendments are adopted under Texas Occupations Code, §1101.151, which authorizes the Texas Real Estate Commission to adopt and enforce rules necessary to administer Chapters 1101 and 1102; and to establish standards of conduct and ethics for its license holders to fulfill the purposes of Chapters 1101 and 1102 and ensure compliance with Chapters 1101 and 1102.

The statutes affected by this amendment are Texas Occupations Code, Chapter 1101. No other statute, code or article is affected by the amendments.

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

Filed with the Office of the Secretary of State on August 18, 2016.

TRD-201604229
Kerri Lewis
General Counsel
Texas Real Estate Commission
Effective date: September 7, 2016
Proposal publication date: May 20, 2016
For further information, please call: (512) 936-3092

♦ ♦ ♦

SUBCHAPTER F. REQUIREMENTS FOR EDUCATION PROVIDERS, COURSES AND INSTRUCTORS FOR QUALIFYING EDUCATION

22 TAC §535.64

The Texas Real Estate Commission (TREC) adopts amendments to 22 TAC §535.64, Content Requirements for Qualifying Real Estate Courses, in Chapter 535, General Provisions, with changes, as published in the June 10, 2016, issue of the *Texas Register* (41 TexReg 4151).

The amendments are adopted to provide consistency and better quality in Real Estate Marketing qualifying courses and are recommended by the Commission's Education Standards Advisory Committee.

One comment was received on the amendments as published. The commenter suggested several edits to the Real Estate Marketing Course Approval form adopted by reference in the rule. The Education Standards Advisory Committee discussed the suggestions and made several clarifying revisions to the form in response to the comments. A typographical error in the rule was also corrected. The Education Standards Advisory Committee recommended adoption of the rule and form with the clarifying edits. The Commission agreed.

The revisions to the form adopted by reference in the rule as adopted do not change the nature or scope so much that the rule and form as adopted could be deemed a different rule or form. The rule and form as adopted do not affect individuals other than those contemplated by the rules as proposed. The rule and form as adopted do not impose more onerous requirements than the proposed rule and form.

The reasoned justification is greater quality and consistency in this qualifying education course resulting in better educated license holders and therefore greater consumer protection.

The amendments are adopted under Texas Occupations Code, §1101.151, which authorizes the Texas Real Estate Commission to adopt and enforce rules necessary to administer Chapters 1101 and 1102; and to establish standards of conduct and ethics for its license holders to fulfill the purposes of Chapters 1101 and 1102 and ensure compliance with Chapters 1101 and 1102.

The statutes affected by this amendment are Texas Occupations Code, Chapter 1101. No other statute, code or article is affected by the amendments.

§535.64. Content Requirements for Qualifying Real Estate Courses.

(a) Mandatory qualifying courses. To be approved by the Commission, the following mandatory qualifying courses must contain the content outlined below:

(1) Principles of Real Estate I, which shall contain the following topics, the units of which are outlined in the PRINS 1-0, Qualifying Real Estate Course Approval Form, Principles of Real Estate I, hereby adopted by reference:

(A) Introduction to Modern Real Estate Practice - 200 minutes;

(B) Real Property - 60 minutes;

(C) Concepts and Responsibilities of Home Ownership - 95 minutes;

(D) Real Estate Brokerage and the Law of Agency - 180 minutes;

(E) Fair Housing Laws - 150 minutes;

(F) Ethics of Practice as a License Holder - 30 minutes;

(G) Texas Real Estate License Act - 180 minutes;

(H) Legal Descriptions - 100 minutes;

(I) Real Estate Contracts - 135 minutes;

(J) Interests in Real Estate - 180 minutes;

(K) How Home Ownership is Held - 70 minutes; and

(L) Listing Agreements - 120 minutes.

(2) Principles of Real Estate II, which shall contain the following topics, the units of which are outlined in the PRINS 2-0, Qualifying Real Estate Course Approval Form, Principles of Real Estate II, hereby adopted by reference:

(A) Real Estate Math - 200 minutes;

(B) Real Estate Appraisal - 200 minutes;

(C) Real Estate Financing Principles - 210 minutes;

(D) Control of Land Use - 115 minutes;

(E) Specializations - 50 minutes;

(F) Real Estate Investments - 110 minutes;

(G) Leases - 95 minutes;

(H) Property Management - 120 minutes;

(I) Estates, Transfers, and Titles - 200 minutes; and

(J) Closing Procedures/Closing the Real Estate Transaction - 200 minutes.

(3) Law of Agency, which shall contain the following topics, the units of which are outlined in the LOA-0, Qualifying Real Estate Course Approval Form, Law of, hereby adopted by reference:

(A) Agency Concepts - 130 minutes;

(B) Basic Agency Relationships, Disclosure & Duties to Client - 125 minutes;

(C) Duties and Disclosures to Third Parties - 125 minutes;

(D) Seller Agency - 120 minutes;

(E) Buyer Agency - 150 minutes;

(F) Representing More than one Party in a Transaction: Intermediary Brokerage - 165 minutes;

(G) Creation and Termination of Agency - 85 minutes;

(H) Clarifying Agency Relationships - 45 minutes;

(I) Employment Issues - 120 minutes;

(J) Agency, Ethics and the Law - 155 minutes;

(K) Deceptive Trade Practices & Consumer Protection Act - 140 minutes; and

(L) Implementation and Presentation - 140 minutes.

(4) Law of Contracts, which shall contain the following topics, the units of which are outlined in the LOC-0, Qualifying Real Estate Course Approval Form, Law of Contracts, hereby adopted by reference:

(A) Texas Contract Law - 155 minutes;

(B) Basics of Real Estate Law - 115 minutes;

(C) Introduction to Contracts - 75 minutes;

(D) Ownership Rights and Limitations - 120 minutes;

(E) Contracts Used in Real Estate - 275 minutes;

(F) The Sales Contract - 135 minutes;

(G) Contingencies, Addenda and Amendments - 105 minutes;

(H) Financing Real Estate - 235 minutes;

(I) Conveyance of Title - 90 minutes;

(J) Transaction Process and Closing - 135 minutes; and

(K) Common Contract Mistakes - 60 minutes.

(5) Promulgated Contract Forms, which shall contain the following topics, the units of which are outlined in the PCF-0, Qualifying Real Estate Course Approval Form, Promulgated Contract Forms, hereby adopted by reference:

(A) Contract Law Overview - 155 minutes;

(B) Laws, Rules and Regulations - 150 minutes;

(C) Parties, Properties and Financing - 155 minutes;

(D) Covenants, Commitments and Notices - 160 minutes;

(E) Closing, Possession and More - 220 minutes;

(F) The Remaining Promulgated Forms - 205 minutes;

(G) Promulgated Addenda, Notices and Other Forms - 205 minutes;

(H) Other Real Estate Matters - 115 minutes; and

(I) Practice Makes Perfect - 135 minutes.

(6) Real Estate Finance, which shall contain the following topics, the units of which are outlined in the REF-0, Qualifying Real Estate Course Approval Form, Real Estate Finance, hereby adopted by reference:

(A) The Nature & Cycle of Real Estate Finance - 105 minutes;

(B) Money & the Monetary System - 100 minutes;

(C) Additional Government Influence - 200 minutes;

(D) The Secondary Mortgage Market - 95 minutes;

(E) Sources of Funds - 110 minutes;

(F) Instruments of Real Estate Finance - 170 minutes;

(G) Loan Types, Terms & Issues - 200 minutes;

(H) Government Loans - 215 minutes;

(I) Lender Loan Processes - 220 minutes;

(J) Defaults & Foreclosures - 85 minutes.

(7) Real Estate Brokerage (mandatory for a broker's license) which shall contain the following topics, the units of which are outlined in the REB-0, Qualifying Real Estate Course Approval Form, Real Estate Brokerage, hereby adopted by reference:

(A) The Real Estate Industry - 30 minutes;

(B) Starting a Brokerage Business - 110 minutes;

(C) Ethical & Legal Business Practices - 300 minutes

(D) Analyzing the Market & the Competition - 110 minutes

(E) Managing Risk - 110 minutes;

(F) Financing Your Business - 110 minutes;

(G) Negotiating a Commercial Lease - 100 minutes;

(H) The Marketing Plan - 150 minutes;

(I) Management Style & Structure - 100 minutes;

(J) Recruiting & Hiring - 100 minutes;

(K) Professional Brokerage Competency & Associate License Holder Productivity - 180 minutes;

(L) Evaluating the Business - 50 minutes;

(M) Growth Opportunities - 50 minutes.

(b) Elective qualifying courses. To be approved by the Commission, the following elective qualifying courses must contain the content outlined below:

(1) Property Management, which shall contain the following topics, the units of which are outlined in the PROPM-0, Qualifying Real Estate Course Approval Form, Property Management, hereby adopted by reference:

(A) Professional Property Management - 120 minutes;

(B) Feasibility of Property Management - 90 minutes

(C) Marketing Plan - 60 minutes;

(D) Management Operations - 130 minutes;

(E) Owner Relations - 120 minutes;

(F) Market Analysis and Management of Housing - 95 minutes;

(G) Leases - 100 minutes;

(H) Tenant Relations - 115 minutes;

(I) Federal, State and Local Laws - 230 minutes;

(J) Maintenance and Construction - 90 minutes;

(K) Commercial Property Management - 150 minutes;

(L) Risk and Environmental Issues - 110 minutes; and

(M) Safety and Security Issues for Property Managers and Staff - 90 minutes;

(2) Real Estate Marketing, which shall contain the following topics, the units of which are outlined in the REM-0, Qualifying Real Estate Course Approval Form, Real Estate Marketing, hereby adopted by reference:

(A) Real Estate Marketing - 80 minutes;

(B) The Marketing Concept - 80 minutes

(C) Marketing Research and Data Analysis - 150 minutes;

(D) Prospecting and Target Marketing - 80 minutes;

(E) Technology and Online Marketing - 100 minutes;

(F) Social Media Marketing - 120 minutes;

(G) Product and Pricing Strategies -180 minutes;

(H) Compensation Models - 60 minutes;

(I) Characteristics of a Successful Sales Agent - 150 minutes;

(J) Understanding Clients - 90 minutes;

(K) Negotiating and Selling Skills - 120 minutes;

(L) Steps to Executing Agreements - 50 minutes; and

(M) State and Federal Laws - 90 minutes;

(N) Ethics and Real Estate Professionalism - 150 minutes;

(3) other than Property Management, and Real Estate Marketing, meet the requirements of §1101.003 of the Act; or

(4) Residential Inspection for Real Estate Agents (or equivalent), which shall include but is not limited to:

(A) repair-related contract forms and addenda;

(B) inspector and client agreements;

(C) inspection standards of practice and standard inspection report form;

(D) tools and procedures;

(E) electromechanical systems (plumbing, heating, air conditioning, appliances, energy-saving considerations); and

(F) structures (lot and landscape, roofs, chimney, gutters, paved areas, walls, windows and doors, insect damage and storage areas).

(c) Related qualifying course. Acceptable related qualifying courses are those courses taken for credit from an accredited college or university, or course approved by the Commission for continuing education credit, that a broker is required to take to fulfill licensing requirements, in any one of the following areas:

(1) accounting;

(2) advertising;

(3) architecture;

(4) business or management;

(5) construction;

(6) finance;

(7) investments;

(8) law;

(9) marketing; and

(10) real estate.

(d) Course Approval forms. All forms adopted by this section are available from the Texas Real Estate Commission, P.O. Box 12188, Austin, Texas 78711-2188, www.trec.texas.gov.

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

Filed with the Office of the Secretary of State on August 18, 2016.

TRD-201604230
Kerri Lewis
General Counsel
Texas Real Estate Commission
Effective date: September 7, 2016
Proposal publication date: June 10, 2016
For further information, please call: (512) 936-3092

♦ ♦ ♦

SUBCHAPTER H. RECOVERY FUND

22 TAC §535.83

The Texas Real Estate Commission (TREC) adopts new §535.83, Association of Designated Broker on Claim, in Chapter 535, General Provisions, without changes, as published in the May 20, 2106, issue of the *Texas Register* (41 TexReg 3601).

The new rule is adopted to clarify which designated broker is to be associated with a licensed business entity when a Real Estate Recovery Trust Account claim is filed or paid on behalf of that licensed business entity.

The reasoned justification is greater clarity of statutory provisions.

No comments were received on the new rule as published.

The new rule is adopted under Texas Occupations Code, §1101.151, which authorizes the Texas Real Estate Commission to adopt and enforce rules necessary to administer Chapters 1101 and 1102; and to establish standards of conduct and ethics for its license holders to fulfill the purposes of Chapters 1101 and 1102 and ensure compliance with Chapters 1101 and 1102.

The statutes affected by the new rule are Texas Occupations Code, Chapter 1101. No other statute, code or article is affected by the new rule.

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

Filed with the Office of the Secretary of State on August 18, 2016.

TRD-201604232
Kerri Lewis
General Counsel
Texas Real Estate Commission
Effective date: September 7, 2016
Proposal publication date: May 20, 2016
For further information, please call: (512) 936-3092

♦ ♦ ♦

SUBCHAPTER L. INACTIVE LICENSE STATUS

22 TAC §535.123

The Texas Real Estate Commission (TREC) adopts amendments to 22 TAC §535.123, Inactive Broker Status, in Chapter 535, General Provisions, with changes, as published in the May 20, 2016, issue of the *Texas Register* (41 TexReg 3602).

The amendments are adopted to clarify that a licensed business entity becomes inactive when it is no longer qualified to transact business in Texas or it's designated broker's license is suspended, or revoked, including probated suspension or revocation.

No comments were received on the amendments as published. However, language was inserted to clarify that the revocation included probated revocation for internal consistency within the rule and for consistency with the definition of good standing in 22 TAC §535.53, Business Entity, Designated Broker.

The revisions to the rule as adopted do not change the nature or scope so much that the rule as adopted could be deemed a different rule. The rule as adopted do not affect individuals other than those contemplated by the rule as proposed. The rule as adopted do not impose more onerous requirements than the proposed rule in conjunction with existing 22 TAC §535.53, Business Entity, Designated Broker.

The reasoned justification is greater clarity and consistency in the rules.

The amendments are adopted under Texas Occupations Code, §1101.151, which authorizes the Texas Real Estate Commission to adopt and enforce rules necessary to administer Chapters 1101 and 1102; and to establish standards of conduct and ethics for its license holders to fulfill the purposes of Chapters 1101 and 1102 and ensure compliance with Chapters 1101 and 1102.

The statutes affected by this amendment are Texas Occupations Code, Chapter 1101. No other statute, code or article is affected by the amendments.

§535.123. Inactive Broker Status.

(a) The license of an individual broker immediately becomes inactive when:

(1) the Commission receives an application for inactive status from the broker; or

(2) the broker is placed on inactive status by the Commission for failure to comply with a requirement of the Act or this chapter.

(b) The license of a business entity broker immediately becomes inactive when:

(1) the Commission receives an application for inactive status from the broker;

(2) the entity is not qualified to transact business in Texas;

(3) the designated broker's license:

(A) expires;

(B) is suspended, including a probated suspension; or

(C) is revoked, including a probated revocation; or

(4) the designated broker dies or resigns as designated broker.

(c) The broker must confirm to the Commission in writing that the broker has given all sales agents sponsored by the broker written notice of termination of sponsorship at least 30 days before filing the application for inactive status.

(d) It is the responsibility of the broker on inactive status to pay all required license renewal fees timely to prevent the inactive license from expiring.

(e) To return to active status, a broker on inactive status must apply to the Commission for return to active status on a form approved by the Commission, pay the appropriate fee, and satisfy any continuing education requirements under the Act and this chapter.

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

Filed with the Office of the Secretary of State on August 18, 2016.

TRD-201604233
Kerri Lewis
General Counsel
Texas Real Estate Commission
Effective date: September 7, 2016
Proposal publication date: May 20, 2016
For further information, please call: (512) 936-3092

♦ ♦ ♦

SUBCHAPTER Q. ADMINISTRATIVE PENALTIES

22 TAC §535.191

The Texas Real Estate Commission (TREC) adopts amendments to 22 TAC §535.191, Schedule of Administrative Penalties, in Chapter 535, General Provisions, without changes, as published in the May 20, 2016, issue of the *Texas Register* (41 TexReg 3602).

The amendments are adopted to lower the administrative penalty for bad check violations and include a penalty for violations of 22 TAC §535.53.

No comments were received on the amendments as published.

The reasoned justification is greater clarity in the rules.

The amendments are adopted under Texas Occupations Code, §1101.151, which authorizes the Texas Real Estate Commission to adopt and enforce rules necessary to administer Chapters 1101 and 1102; and to establish standards of conduct and ethics for its license holders to fulfill the purposes of Chapters 1101 and 1102 and ensure compliance with Chapters 1101 and 1102.

The statutes affected by this amendment are Texas Occupations Code, Chapter 1101. No other statute, code or article is affected by the amendments.

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

Filed with the Office of the Secretary of State on August 18, 2016.

TRD-201604234
Kerri Lewis
General Counsel
Texas Real Estate Commission
Effective date: September 7, 2016
Proposal publication date: May 20, 2016
For further information, please call: (512) 936-3092

♦ ♦ ♦

SUBCHAPTER R. REAL ESTATE INSPECTORS

22 TAC §§535.227 - 535.233

The Texas Real Estate Commission (TREC) adopts amendments to 22 TAC §§535.227, Standards of Practice: General Provisions, 535.228, Standards of Practice: Minimum Inspection Requirements for Structural Systems; 535.229, Standards of Practice: Minimum Inspection Requirements for Electrical Systems; 535.230, Standards of Practice: Minimum Inspection Requirements for Heating, Ventilation, and Air Conditioning Systems; 535.231, Standards of Practice: Minimum Inspection Requirements for Plumbing Systems; 535.232, Standards of Practice: Minimum Inspection Requirements for Appliances; and 535.233, Standards of Practice: Minimum Inspection Requirements for Optional Systems in Subchapter R, Real Estate Inspectors, in Chapter 535, General Provisions. The rules are adopted with changes to the text as published in the May 20, 2016, issue of the *Texas Register* (41 TexReg 3603).

The adopted amendments to §535.227, Standards of Practice: General Provisions provide clarity and consistency by restructuring and renumbering this section, streamlining wording, and removing redundant language. These amendments move §535.227(b) to subsection (a), and renumber the other subsections accordingly. Language was added to subsection (a) clarifying when the SOPs apply, and the definitions for "specialized equipment," "specialized procedures," "substantially completed," and "technically exhaustive" were incorporated into the body of subsection (a) because those definitions are not used elsewhere in the rules.

The adopted amendments to §535.228, Standards of Practice: Minimum Inspection Requirements for Structural Systems, and §535.233, Standards of Practice: Minimum Inspection Requirements for Optional Systems renumber and restructure those pro-

visions, streamline wording, and remove redundant language to provide clarity and consistency.

The adopted amendments to §535.229, Standards of practice: Minimum Inspection Requirements for Electrical Systems; §535.230, Standards of Practice: Minimum Inspection Requirements for Heating, Ventilation, and Air Conditioning Systems; §535.231, Standards of Practice: Minimum Inspection Requirements for Plumbing Systems; and §535.232, Standards of Practice: Minimum Inspection Requirements for Appliances renumber and restructure those provisions for clarity and consistency.

One comment was received. The commenter recommended defining "performing" or otherwise modifying the term when used. The Commenter also recommended changes to §535.229 Standards of practice: Minimum Inspection Requirements for Electrical Systems to update that rule to correspond with changes to the International Residential Code and National Electric Code. This comment would require substantive changes to the rules as published. These amendments to the rules are meant to be a non-substantive reorganization of the rules and not intended to implement any substantive changes. The Inspector Committee will consider this comment at a future date when it considers substantive changes to the Standards of Practice.

The commenter recommended subdividing a subsection of §535.227 for consistency with the other rules. The Inspector Committee agreed and the change was made.

The commenter recommended changing the term "bibbs" to "bibs" in §535.231. The inspector disagrees with this comment because "bibbs" is the standard industry term. The commenter recommended changes regarding the numbering and structuring of §535.230 and §535.231. Staff disagrees with this recommendation because it does not follow the acceptable Rule construction guidelines. The commenter also pointed out several typographical errors, which have been corrected.

The revisions to the rules as adopted do not change the nature or scope so much that they could be deemed different rules. The rules as adopted do not affect individuals other than those contemplated by the rules as proposed. The rules as adopted do not impose more onerous requirements than the proposed rules.

The reasoned justification is greater clarity and consistency in the rules.

The amendments are adopted under Texas Occupations Code §1101.151, which authorizes the Texas Real Estate Commission to adopt and enforce rules necessary to administer Chapters 1101 and 1102; and Texas Occupations Code §1102.058, which authorizes the Commission to adopt rules related to the standards of practice of real estate inspection.

The statute affected by this amendment is Chapter 1102, Texas Occupations Code. No other statute, code or article is affected by the amendments.

§535.227. Standards of Practice: General Provisions.

(a) Scope.

(1) These standards of practice apply when a professional inspector or real estate inspector who is licensed under this chapter accepts employment to perform a real estate inspection for a prospective buyer or seller of real property.

(2) These standards of practice define the minimum requirements for a real estate inspection conducted on a one to four family unit that is substantially completed. Substantially completed means the stage of construction when a new building, addition, improvement, or alteration to an existing building can be occupied or used for its intended purpose.

(3) For the purposes of these standards of practice a real estate inspection:

(A) is a limited visual survey and basic performance evaluation of the systems and components of a building using normal controls that provides information regarding the general condition of a residence at the time of inspection.

(B) is not intended to be a comprehensive investigation or exploratory probe to determine the cause or effect of deficiencies noted by the inspector; and

(C) does not require the use of:

(i) specialized equipment, including but not limited to:

(I) thermal imaging equipment;

(II) moisture meters;

(III) gas or carbon monoxide detection equipment;

(IV) environmental testing equipment and devices;

(V) elevation determination devices; or

(VI) ladders capable of reaching surfaces over one story above ground surfaces; or

(ii) specialized procedures, including but not limited to:

(I) environmental testing;

(II) elevation measurement;

(III) calculations; or

(IV) any method employing destructive testing that damages otherwise sound materials or finishes.

(4) These standards of practice do not prohibit an inspector from providing a higher level of inspection performance than required by these standards of practice or from inspecting components and systems in addition to those listed under the standards of practice.

(b) Definitions.

(1) Accessible--In the reasonable judgment of the inspector, capable of being approached, entered, or viewed without:

(A) hazard to the inspector;

(B) having to climb over obstacles, moving furnishings or large, heavy, or fragile objects;

(C) using specialized equipment or procedures;

(D) disassembling items other than covers or panels intended to be removed for inspection;

(E) damaging property, permanent construction or building finish; or

(F) using a ladder for portions of the inspection other than the roof or attic space.

(2) Chapter 1102--Texas Occupations Code, Chapter 1102.

(3) Component--A part of a system.

(4) Cosmetic--Related only to appearance or aesthetics, and not related to performance, operability, or water penetration.

(5) Deficiency--In the reasonable judgment of the inspector, a condition that:

(A) adversely and materially affects the performance of a system, or component; or

(B) constitutes a hazard to life, limb, or property as specified by these standards of practice.

(6) Deficient--Reported as having one or more deficiencies.

(7) Inspect--To operate in normal ranges using ordinary controls at typical settings, look at and examine accessible systems or components and report observed deficiencies as specified by these standards of practice.

(8) Performance--Achievement of an operation, function or configuration relative to accepted industry standard practices with consideration of age and normal wear and tear from ordinary use.

(9) Report--To provide the inspector's opinions and findings on the standard inspection report form as required by §535.222 and §535.223 of this title.

(10) Standards of practice--§§535.227 - 535.233 of this title.

(c) General Requirements. The inspector shall:

(1) operate fixed or installed equipment and appliances listed herein in at least one mode with ordinary controls at typical settings;

(2) visually inspect accessible systems or components from near proximity to the systems and components, and from the interior of the attic and crawl spaces; and

(3) complete the standard inspection report form as required by §535.222 and §535.223 of this title.

(d) General limitations. The inspector is not required to:

(1) inspect:

(A) items other than those listed within these standards of practice;

(B) elevators;

(C) detached buildings, decks, docks, fences, waterfront structures, or related equipment;

(D) anything buried, hidden, latent, or concealed;

(E) sub-surface drainage systems;

(F) automated or programmable control systems, automatic shut-off, photoelectric sensors, timers, clocks, metering devices, signal lights, lightning arrestor system, remote controls, security or data distribution systems, solar panels or smart home automation components; or

(G) concrete flatwork such as driveways, sidewalks, walkways, paving stones or patios;

(2) report:

(A) past repairs that appear to be effective and workmanlike except as specifically required by these standards;

(B) cosmetic or aesthetic conditions; or

(C) wear and tear from ordinary use;

(3) determine:

(A) the presence or absence of pests, termites, or other wood-destroying insects or organisms;

(B) the presence, absence, or risk of:

(i) asbestos;

(ii) lead-based paint;

(iii) mold, mildew;

(iv) corrosive or contaminated drywall "Chinese Drywall"; or

(v) any other environmental hazard, environmental pathogen, carcinogen, toxin, mycotoxin, pollutant, fungal presence or activity, or poison;

(C) types of wood or preservative treatment and fastener compatibility; or

(D) the cause or source of a condition;

(E) the cause or effect of deficiencies;

(F) any of the following issues concerning a system or component:

(i) insurability or warrantability;

(ii) suitability, adequacy, compatibility, capacity, reliability, marketability, or operating costs;

(iii) recalls, counterfeit products, or product lawsuits;

(iv) life expectancy or age;

(v) energy efficiency, vapor barriers, or thermostatic performance;

(vi) compliance with any code, listing, testing or protocol authority;

(vii) utility sources; or

(viii) manufacturer or regulatory requirements, except as specifically required by these standards;

(4) anticipate future events or conditions, including but not limited to:

(A) decay, deterioration, or damage that may occur after the inspection;

(B) deficiencies from abuse, misuse or lack of use;

(C) changes in performance of any component or system due to changes in use or occupancy;

(D) the consequences of the inspection or its effects on current or future buyers and sellers;

(E) common household accidents, personal injury, or death;

(F) the presence of water penetrations; or

(G) future performance of any item;

(5) operate shut-off, safety, stop, pressure or pressure-regulating valves or items requiring the use of codes, keys, combinations, or similar devices;

(6) designate conditions as safe;

(7) recommend or provide engineering, architectural, appraisal, mitigation, physical surveying, realty, or other specialist services;

(8) review historical records, installation instructions, repair plans, cost estimates, disclosure documents, or other reports;

(9) verify sizing, efficiency, or adequacy of the ground surface drainage system;

(10) verify sizing, efficiency, or adequacy of the gutter and downspout system;

(11) operate recirculation or sump pumps;

(12) remedy conditions preventing inspection of any item;

(13) apply open flame or light a pilot to operate any appliance;

(14) turn on decommissioned equipment, systems or utility services; or

(15) provide repair cost estimates, recommendations, or re-inspection services.

(e) In the event of a conflict between the general provisions set out in this section, and the specific provisions specified elsewhere in the standards of practice, specific provisions shall take precedence.

(f) Departure provision.

(1) An inspector may depart from the inspection of a component or system required by the standards of practice only if:

(A) the inspector and client agree the item is not to be inspected;

(B) the inspector is not qualified to inspect the item;

(C) in the reasonable judgment of the inspector, the inspector determines that:

(i) conditions exist that prevent inspection of an item;

(ii) conditions or materials are hazardous to the health or safety of the inspector; or

(iii) the actions of the inspector may cause damage to the property;

(D) the item is a common element of a multi-family development and is not in physical contact with the unit being inspected, such as the foundation under another building or a part of the foundation under another unit in the same building;

(2) If an inspector departs from the inspection of a component or system required by the standards of practice, the inspector shall:

(A) notify the client at the earliest practical opportunity that the component or system will not be inspected; and

(B) make an appropriate notation on the inspection report form, stating the reason the component or system was not inspected.

(3) If the inspector routinely departs from inspection of a component or system required by the standards of practice, and the inspector has reason to believe that the property being inspected includes that component or system, the earliest practical opportunity for the notice required by this subsection is the first contact the inspector makes with the prospective client.

(g) Enforcement. Failure to comply with the standards of practice is grounds for disciplinary action as prescribed by Chapter 1102.

§535.228. Standards of Practice: Minimum Inspection Requirements for Structural Systems

(a) Foundations.

(1) The inspector shall:

(A) render a written opinion as to the performance of the foundation; and

(B) report:

(i) the type of foundations;

(ii) the vantage point from which the crawl space was inspected;

(C) generally report present and visible indications used to render the opinion of adverse performance, such as:

(i) binding, out-of-square, non-latching doors;

(ii) framing or frieze board separations;

(iii) sloping floors;

(iv) window, wall, floor, or ceiling cracks or separations; and

(v) rotating, buckling, cracking, or deflecting masonry cladding.

(D) report as Deficient:

(i) deteriorated materials;

(ii) deficiencies in foundation components such as; beams, joists, bridging, blocking, piers, posts, pilings, columns, sills or subfloor;

(iii) deficiencies in retaining walls related to foundation performance;

(iv) exposed or damaged reinforcement;

(v) crawl space ventilation that is not performing; and

(vi) crawl space drainage that is not performing.

(2) The inspector is not required to:

(A) enter a crawl space or any area where headroom is less than 18 inches or the access opening is less than 24 inches wide and 18 inches high;

(B) provide an exhaustive list of indicators of possible adverse performance; or

(C) inspect retaining walls not related to foundation performance.

(b) Grading and drainage.

(1) The inspector shall report as Deficient:

(A) drainage around the foundation that is not performing;

(B) deficiencies in grade levels around the foundation; and

(C) deficiencies in installed gutter and downspout systems.

(2) The inspector is not required to:

(A) inspect flatwork or detention/retention ponds (except as related to slope and drainage);

(B) determine area hydrology or the presence of underground water; or

(C) determine the efficiency or performance of underground or surface drainage systems.

(c) Roof covering materials.

(1) The inspector shall:

(A) inspect the roof covering materials from the surface of the roof;

(B) report:

(i) type of roof coverings;

(ii) vantage point from where the roof was inspected;

(iii) evidence of water penetration;

(iv) evidence of previous repairs to the roof covering material, flashing details, skylights and other roof penetrations; and

(C) report as Deficient deficiencies in:

(i) fasteners;

(ii) adhesion;

(iii) roof covering materials;

(iv) flashing details;

(v) skylights; and

(vi) other roof penetrations.

(2) The inspector is not required to:

(A) inspect the roof from the roof level if, in the inspector's reasonable judgment:

(i) the inspector cannot safely reach or stay on the roof; or

(ii) significant damage to the roof covering materials may result from walking on the roof;

(B) determine:

(i) the remaining life expectancy of the roof covering; or

(ii) the number of layers of roof covering material;

(C) identify latent hail damage;

(D) exhaustively examine all fasteners and adhesion, or

(E) provide an exhaustive list of locations of deficiencies and water penetrations.

(d) Roof structures and attics.

(1) The inspector shall:

(A) report:

(i) the vantage point from which the attic space was inspected;

(ii) approximate average depth of attic insulation;

(iii) evidence of water penetration;

(B) report as Deficient:

(i) attic space ventilation that is not performing;

(ii) deflections or depressions in the roof surface as related to adverse performance of the framing and decking;

(iii) missing insulation;

(iv) deficiencies in:

(I) installed framing members and decking;

(II) attic access ladders and access openings; and

(III) attic ventilators.

(2) The inspector is not required to:

(A) enter attics or unfinished spaces where openings are less than 22 inches by 30 inches or headroom is less than 30 inches;

(B) operate powered ventilators; or

(C) provide an exhaustive list of locations of deficiencies and water penetrations.

(e) Interior walls, ceilings, floors, and doors.

(1) The inspector shall:

(A) report evidence of water penetration;

(B) report as Deficient:

(i) deficiencies in the condition and performance of doors and hardware;

(ii) deficiencies related to structural performance or water penetration; and

(iii) the absence of or deficiencies in fire separation between the garage and the living space and between the garage and its attic.

(2) The inspector is not required to:

(A) report cosmetic damage or the condition of floor, wall, or ceiling coverings; paints, stains, or other surface coatings; cabinets; or countertops, or

(B) provide an exhaustive list of locations of deficiencies and water penetrations.

(f) Exterior walls, doors, and windows.

(1) The inspector shall:

(A) report evidence of water penetration;

(B) report as Deficient:

(i) the absence of performing emergency escape and rescue openings in all sleeping rooms;

(ii) a solid wood door less than 1-3/8 inches in thickness, a solid or honeycomb core steel door less than 1-3/8 inches thick, or a 20-minute fire-rated door between the residence and an attached garage;

(iii) missing or damaged screens;

(iv) deficiencies related to structural performance or water penetration;

(v) deficiencies in:

(I) weather stripping, gaskets or other air barrier materials;

(II) claddings;

(III) water resistant materials and coatings;

(IV) flashing details and terminations;

(V) the condition and performance of exterior doors, garage doors and hardware; and

(VI) the condition and performance of windows and components.

(2) The inspector is not required to:

(A) report the condition of awnings, blinds, shutters, security devices, or other non-structural systems;

(B) determine the cosmetic condition of paints, stains, or other surface coatings; or

(C) operate a lock if the key is not available.

(D) provide an exhaustive list of locations of deficiencies and water penetrations.

(g) Exterior and interior glazing.

(1) The inspector shall report as Deficient:

(A) insulated windows that are obviously fogged or display other evidence of broken seals;

(B) deficiencies in glazing, weather stripping and glazing compound in windows and doors; and

(C) the absence of safety glass in hazardous locations.

(2) The inspector is not required to:

(A) exhaustively inspect insulated windows for evidence of broken seals;

(B) exhaustively inspect glazing for identifying labels; or

(C) identify specific locations of damage.

(h) Interior and exterior stairways.

(1) The inspector shall report as Deficient:

(A) spacing between intermediate balusters, spindles, or rails for steps, stairways, guards, and railings that permit passage of an object greater than 4 inches in diameter, except that on the open side of the staircase treads, spheres less than 4-3/8 inches in diameter may pass through the guard rail balusters or spindles; and

(B) deficiencies in steps, stairways, landings, guardrails, and handrails.

(2) The inspector is not required to exhaustively measure every stairway component.

(i) Fireplaces and chimneys.

(1) The inspector shall report as Deficient:

(A) built-up creosote in accessible areas of the firebox and flue;

(B) the presence of combustible materials in near proximity to the firebox opening;

(C) the absence of fireblocking at the attic penetration of the chimney flue, where accessible; and

(D) deficiencies in the:

(i) damper;

(ii) lintel, hearth, hearth extension, and firebox;

(iii) gas valve and location;

(iv) circulating fan;

(v) combustion air vents; and

(vi) chimney structure, termination, coping, crown, caps, and spark arrestor.

(2) The inspector is not required to:

(A) verify the integrity of the flue;

(B) perform a chimney smoke test; or

(C) determine the adequacy of the draft.

(j) Porches, Balconies, Decks, and Carports.

(1) The inspector shall:

(A) inspect:

(i) attached balconies, carports, and porches;

(ii) abutting porches, decks, and balconies that are used for ingress and egress; and

(B) report as Deficient:

(i) on decks 30 inches or higher above the adjacent grade, spacings between intermediate balusters, spindles, or rails that permit passage of an object greater than four inches in diameter; and

(ii) deficiencies in accessible components.

(2) The inspector is not required to:

(A) exhaustively measure every porch, balcony, deck, or attached carport components; or

(B) enter any area where headroom is less than 18 inches or the access opening is less than 24 inches wide and 18 inches high.

§535.229. Standards of Practice: Minimum Inspection Requirements for Electrical Systems

(a) Service entrance and panels.

(1) The inspector shall report as Deficient:

(A) a drop, weatherhead or mast that is not securely fastened to the building;

(B) the absence of or deficiencies in the grounding electrode system;

(C) missing or damaged dead fronts or covers plates;

(D) conductors not protected from the edges of electrical cabinets, gutters, or cutout boxes;

(E) electrical cabinets and panel boards not appropriate for their location; such as a clothes closet, bathrooms or where they are exposed to physical damage;

(F) electrical cabinets and panel boards that are not accessible or do not have a minimum of 36-inches of clearance in front of them;

(G) deficiencies in:

(i) electrical cabinets, gutters, cutout boxes, and panel boards;

(ii) the insulation of the service entrance conductors, drip loop, separation of conductors at weatherheads, and clearances;

(iii) the compatibility of overcurrent devices and conductors;

(iv) the overcurrent device and circuit for labeled and listed 240 volt appliances;

(v) bonding and grounding;

(vi) conductors;

(vii) the operation of installed ground-fault or arc-fault circuit interrupter devices; and

(H) the absence of:

(i) trip ties on 240 volt overcurrent devices or multi-wire branch circuit;

(ii) appropriate connections;

(iii) anti-oxidants on aluminum conductor terminations;

(iv) a main disconnecting means.

(2) The inspector is not required to:

(A) determine present or future sufficiency of service capacity amperage, voltage, or the capacity of the electrical system;

(B) test arc-fault circuit interrupter devices when the property is occupied or damage to personal property may result, in the inspector's reasonable judgment;

(C) conduct voltage drop calculations;

(D) determine the accuracy of overcurrent device labeling;

(E) remove covers where hazardous as judged by the inspector;

(F) verify the effectiveness of overcurrent devices; or

(G) operate overcurrent devices.

(b) Branch circuits, connected devices, and fixtures.

(1) The inspector shall:

(A) manually test the installed and accessible smoke and carbon monoxide alarms;

(B) report the type of branch circuit conductors;

(C) report as Deficient:

(i) the absence of ground-fault circuit interrupter protection in all:

(I) bathroom receptacles;

(II) garage receptacles;

(III) outdoor receptacles;

(IV) crawl space receptacles;

(V) unfinished basement receptacles;

(VI) kitchen countertop receptacles; and

(VII) receptacles that are located within six feet of the outside edge of a sink;

(ii) the failure of operation of ground-fault circuit interrupter protection devices;

(iii) missing or damaged receptacle, switch or junction box covers;

(iv) the absence of:

(I) equipment disconnects;

(II) appropriate connections, such as copper/aluminum approved devices, if branch circuit aluminum conductors are discovered in the main or sub-panel based on a random sampling of accessible receptacles and switches;

(v) deficiencies in:

(I) receptacles;

(II) switches;

(III) bonding or grounding;

(IV) wiring, wiring terminations, junction boxes, devices, and fixtures, including improper location;

(V) doorbell and chime components;

(VI) smoke and carbon monoxide alarms;

(vi) improper use of extension cords;

(vii) deficiencies in or absences of conduit, where applicable; and

(vii) the absence of smoke alarms:

(I) in each sleeping room;

(II) outside each separate sleeping area in the immediate vicinity of the sleeping rooms; and

(III) in the living space of each story of the dwelling.

(2) The inspector is not required to:

(A) inspect low voltage wiring;

(B) disassemble mechanical appliances;

(C) verify the effectiveness of smoke alarms;

(D) verify interconnectivity of smoke alarms;

(E) activate smoke or carbon monoxide alarms that are or may be monitored or require the use of codes;

(F) verify that smoke alarms are suitable for the hearing-impaired; or

(G) remove the covers of junction, fixture, receptacle or switch boxes unless specifically required by these standards.

§535.230. Standards of Practice: Minimum Inspection Requirements for Heating, Ventilation, and Air Conditioning Systems.

(a) Heating equipment.

(1) General requirements.

(A) The inspector shall report:

(i) the type of heating systems; and

(ii) the energy sources; and

(B) report as Deficient:

(i) inoperative units;

(ii) deficiencies in the thermostats;

(iii) inappropriate location;

(iv) the lack of protection from physical damage;

(v) burners, burner ignition devices or heating elements, switches, and thermostats that are not a minimum of 18 inches above the lowest garage floor elevation, unless the unit is listed for garage floor installation;

(vi) the absence of an opening that would allow access to equipment for inspection, service, repair or replacement without removing permanent construction or building finish;

(vii) when applicable; a floored passageway and service platform that would allow access for equipment inspection, service, repair or replacement; and

(viii) deficiencies in mounting and performance of window and wall units;

(2) Requirements for electric units. The inspector shall report deficiencies in:

(A) performance of heat pumps;

(B) performance of heating elements; and

(C) condition of conductors; and

(3) Requirements for gas units. The inspector shall report as Deficient:

(A) gas leaks;

(B) flame impingement, uplifting flame, improper flame color, or excessive scale buildup;

(C) the absence of a gas shut-off valve within six feet of the appliance;

(D) the absence of a gas appliance connector or one that exceeds six feet in length;

(E) gas appliance connectors that are concealed within or extended through walls, floors, partitions, ceilings or appliance housings; and

(F) deficiencies in:

(i) combustion, and dilution air;

(ii) gas shut-off valves;

(iii) access to a gas shutoff valves that prohibits full operation;

(iv) gas appliance connector materials; and

(v) the vent pipe, draft hood, draft, proximity to combustibles, and vent termination point and clearances; and

(b) Cooling equipment

(1) Requirements for cooling units other than evaporative coolers.

(A) the inspector shall report the type of systems;

(B) the inspector shall report as Deficient:

(i) inoperative units;

(ii) inadequate cooling as demonstrated by its performance;

(iii) the absence of an opening that would allow access to equipment for inspection, service, repair or replacement without removing permanent construction or building finish;

(iv) when applicable; a floored passageway and service platform that would allow access for equipment inspection, service, repair or replacement;

(v) noticeable vibration of blowers or fans;

(vi) water in the auxiliary/secondary drain pan;

(vii) a primary drain pipe that discharges in a sewer vent;

(viii) missing or deficient refrigerant pipe insulation;

(ix) dirty coils, where accessible;

(x) condensing units lacking adequate clearances or air circulation or that has deficiencies in the fins, location, levelness, or elevation above grade surfaces;

(xi) deficiencies in:

(I) the condensate drain and auxiliary/secondary pan and drain system;

(II) mounting and performance of window or wall units; and

(III) thermostats.

(2) Requirements for evaporative coolers.

(A) The inspector shall report:

(i) type of systems;

(ii) the type of water supply line;

(B) The inspector shall report as Deficient:

(i) inoperative units;

(ii) inadequate access and clearances;

(iii) deficiencies in performance or mounting;

(iv) missing or damaged components;

(v) the presence of active water leaks; and

(vi) the absence of backflow prevention.

(c) Duct systems, chases, and vents.

(1) The inspector shall report as Deficient:

(A) damaged duct systems or improper material;

(B) damaged or missing duct insulation;

(C) the absence of air flow at accessible supply registers;

(D) the presence of gas piping and sewer vents concealed in ducts, plenums and chases;

(E) ducts or plenums in contact with earth; and

(2) The inspector shall report as Deficient deficiencies in:

(A) filters;

(B) grills or registers; and

(C) the location of return air openings.

(d) For heating, ventilation, and air conditioning systems inspected under this section, the inspector is not required to perform the following actions:

(1) program digital thermostats or controls;

(2) inspect:

(A) for pressure of the system refrigerant, type of refrigerant, or refrigerant leaks;

(B) winterized or decommissioned equipment; or

(C) duct fans, humidifiers, dehumidifiers, air purifiers, motorized dampers, electronic air filters, multi-stage controllers, sequencers, heat reclaimers, wood burning stoves, boilers, oil-fired units, supplemental heating appliances, de-icing provisions, or reversing valves;

(3) operate:

(A) setback features on thermostats or controls;

(B) cooling equipment when the outdoor temperature is less than 60 degrees Fahrenheit;

(C) radiant heaters, steam heat systems, or unvented gas-fired heating appliances; or

(D) heat pumps, in the heat pump mode, when the outdoor temperature is above 70 degrees;

(4) verify:

(A) compatibility of components;

(B) tonnage match of indoor coils and outside coils or condensing units;

(C) the accuracy of thermostats; or

(D) the integrity of the heat exchanger; or

(5) determine:

(A) sizing, efficiency, or adequacy of the system;

(B) balanced air flow of the conditioned air to the various parts of the building; or

(C) types of materials contained in insulation.

§535.231. Standards of Practice: Minimum Inspection Requirements for Plumbing Systems.

(a) Plumbing systems.

(1) The inspector shall:

(A) report:

(i) location of water meter;

(ii) location of homeowners main water supply shut-off valve; and

(iii) static water pressure;

(B) report as Deficient:

(i) the presence of active leaks;

(ii) the lack of a pressure reducing valve when the water pressure exceeds 80 PSI;

(iii) the lack of an expansion tank at the water heater(s) when a pressure reducing valve is in place at the water supply line/system;

(iv) the absence of:

(I) fixture shut-off valves;

(II) dielectric unions, when applicable;

(III) back-flow devices, anti-siphon devices, or air gaps at the flow end of fixtures; and

(v) deficiencies in:

(I) water supply pipes and waste pipes;

(II) the installation and termination of the vent system;

(III) the performance of fixtures and faucets not connected to an appliance;

(IV) water supply, as determined by viewing functional flow in two fixtures operated simultaneously;

(V) fixture drain performance;

(VI) orientation of hot and cold faucets;

(VII) installed mechanical drain stops;

(VIII) commodes, fixtures, showers, tubs, and enclosures; and

(IX) the condition of the gas distribution system.

(2) The inspector is not required to:

(A) operate any main, branch, or shut-off valves;

(B) operate or inspect sump pumps or waste ejector pumps;

(C) verify the performance of:

(i) the bathtub overflow;

(ii) clothes washing machine drains or hose bibbs; or

(iii) floor drains;

(D) inspect:

(i) any system that has been winterized, shut down or otherwise secured;

(ii) circulating pumps, free-standing appliances, solar water heating systems, water-conditioning equipment, filter systems, water mains, private water supply systems, water wells, pressure tanks, sprinkler systems, swimming pools, or fire sprinkler systems;

(iii) inaccessible gas supply system components for leaks;

(iv) for sewer clean-outs; or

(v) for the presence or performance of private sewage disposal systems; or

(E) determine:

(i) quality, potability, or volume of the water supply; or

(ii) effectiveness of backflow or anti-siphon devices.

(b) Water heaters.

(1) General Requirements.

(A) The inspector shall:

(i) report:

(I) the energy source;

(II) the capacity of the units;

(ii) report as Deficient:

(I) inoperative units;

(II) leaking or corroded fittings or tanks;

(III) damaged or missing components;

(IV) the absence of a cold water shut-off valve;

(V) if applicable, the absence of a pan or a pan drain system that does not terminate over a waste receptor or to the exterior of the building above the ground surface;

(VI) inappropriate locations;

(VII) the lack of protection from physical damage;

(VIII) burners, burner ignition devices or heating elements, switches, or thermostats that are not a minimum of 18 inches above the lowest garage floor elevation, unless the unit is listed for garage floor installation;

(IX) the absence of an opening that would allow access to equipment for inspection, service, repair or replacement without removing permanent construction or building finish;

(X) when applicable; a floored passageway and service platform that would allow access for equipment inspection, service, repair or replacement;

(XI) the absence of or deficiencies in the temperature and pressure relief valve and discharge piping;

(XII) a temperature and pressure relief valve that failed to operate, when tested manually;

(B) The inspector is not required to:

(i) verify the effectiveness of the temperature and pressure relief valve, discharge piping, or pan drain pipes;

(ii) operate the temperature and pressure relief valve if the operation of the valve may, in the inspector's reasonable judgment, cause damage to persons or property; or

(iii) determine the efficiency or adequacy of the unit.

(2) Requirements for electric units. The inspector shall report as Deficient deficiencies in:

(A) performance of heating elements; and

(B) condition of conductors; and

(3) Requirements for gas units. The inspector shall report as Deficient:

(A) gas leaks;

(B) flame impingement, uplifting flame, improper flame color, or excessive scale build-up;

(C) the absence of a gas shut-off valve within six feet of the appliance;

(D) the absence of a gas appliance connector or one that exceeds six feet in length;

(E) gas appliance connectors that are concealed within or extended through walls, floors, partitions, ceilings or appliance housings;

(F) deficiencies in:

(i) combustion and dilution air;

(ii) gas shut-off valves;

(iii) access to a gas shutoff valves that prohibit full operation;

(iv) gas appliance connector materials; and

(v) vent pipe, draft hood, draft, proximity to combustibles, and vent termination point and clearances.

(c) Hydro-massage therapy equipment.

(1) The inspector shall report as Deficient:

(A) inoperative units;

(B) the presence of active leaks;

(C) deficiencies in components and performance;

(D) missing and damaged components;

(E) the absence of an opening that would allow access to equipment for inspection, service, repair or replacement without removing permanent construction or building finish; and

(F) the absence or failure of operation of ground-fault circuit interrupter protection devices; and

(2) The inspector is not required to determine the adequacy of self-draining features of circulation systems.

§535.232. Standards of Practice: Minimum Inspection Requirements for Appliances.

(a) General provisions. The inspector is not required to:

(1) operate or determine the condition of other auxiliary components of inspected items;

(2) test for microwave oven radiation leaks;

(3) inspect self-cleaning functions;

(4) disassemble appliances;

(5) determine the adequacy of venting systems; or

(6) determine proper routing and lengths of duct systems.

(b) Dishwashers. The inspector shall report as Deficient:

(1) inoperative units;

(2) deficiencies in performance or mounting;

(3) rusted, missing or damaged components;

(4) the presence of active water leaks; and

(5) the absence of backflow prevention.

(c) Food waste disposers. The inspector shall report as Deficient:

(1) inoperative units;

(2) deficiencies in performance or mounting;

(3) missing or damaged components; and

(4) the presence of active water leaks.

(d) Range hoods and exhaust systems. The inspector shall report as Deficient:

(1) inoperative units;

(2) deficiencies in performance or mounting;

(3) missing or damaged components;

(4) ducts that do not terminate outside the building, if the unit is not of a re-circulating type or configuration; and

(5) improper duct material.

(e) Electric or gas ranges, cooktops, and ovens. The inspector shall report as Deficient:

(1) inoperative units;

(2) missing or damaged components;

(3) combustible material within thirty inches above the cook top burners;

(4) absence of an anti-tip device, if applicable;

(5) gas leaks;

(6) the absence of a gas shutoff valve within six feet of the appliance;

(7) the absence of a gas appliance connector or one that exceeds six feet in length;

(8) gas appliance connectors that are concealed within or extended through walls, floors, partitions, ceilings or appliance housings; and

(9) deficiencies in:

(A) thermostat accuracy (within 25 degrees at a setting of 350° F);

(B) mounting and performance;

(C) gas shut-off valves;

(D) access to a gas shutoff valves that prohibits full operation; and

(E) gas appliance connector materials.

(f) Microwave ovens. The inspector shall inspect built-in units and report as Deficient:

(1) inoperative units;

(2) deficiencies in performance or mounting; and

(3) missing or damaged components.

(g) Mechanical exhaust systems and bathroom heaters. The inspector shall report as Deficient:

(1) inoperative units;

(2) deficiencies in performance or mounting;

(3) missing or damaged components;

(4) ducts that do not terminate outside the building; and

(5) a gas heater that is not vented to the exterior of the building unless the unit is listed as an unvented type.

(h) Garage door operators. The inspector shall report as Deficient:

(1) inoperative units;

(2) deficiencies in performance or mounting;

(3) missing or damaged components;

(4) installed photoelectric sensors located more than six inches above the garage floor; and

(5) door locks or side ropes that have not been removed or disabled.

(i) Dryer exhaust systems. The inspector shall report as Deficient:

(1) missing or damaged components;

(2) the absence of a dryer exhaust system when provisions are present for a dryer;

(3) ducts that do not terminate to the outside of the building;

(4) screened terminations; and

(5) ducts that are not made of metal with a smooth interior finish.

§535.233. Standards of Practice: Minimum Inspection Requirements for Optional Systems.

(a) An inspector is not required to inspect the components or systems described under this section.

(b) If an inspector agrees to inspect a component or system described under this section, the general provisions under §535.227 of this title and the provisions and requirements of this section applicable to that component or system apply.

(c) Landscape irrigation (sprinkler) systems.

(1) The inspector shall:

(A) manually operate all zones or stations on the system through the controller;

(B) report as Deficient:

(i) the absence of a rain or moisture sensor,

(ii) inoperative zone valves;

(iii) surface water leaks;

(iv) the absence of a backflow prevention device;

(v) the absence of shut-off valves between the water meter and backflow device;

(vi) deficiencies in the performance and mounting of the controller;

(vii) missing or damaged components; and

(viii) deficiencies in the performance of the water emission devices; such as, sprayer heads, rotary sprinkler heads, bubblers or drip lines.

(2) The inspector is not required to inspect:

(A) for effective coverage of the irrigation system;

(B) the automatic function of the controller;

(C) the effectiveness of the sensors; such as, rain, moisture, wind, flow or freeze sensors; or

(D) sizing and effectiveness of backflow prevention device.

(d) Swimming pools, spas, hot tubs, and equipment.

(1) The inspector shall:

(A) report the type of construction;

(B) report as Deficient:

(i) the presence of a single blockable main drain (potential entrapment hazard);

(ii) a pump motor, blower, or other electrical equipment that lacks bonding;

(iii) the absence of or deficiencies in safety barriers;

(iv) water leaks in above-ground pipes and equipment;

(v) the absence or failure in performance of ground-fault circuit interrupter protection devices; and

(vi) deficiencies in:

(I) surfaces;

(II) tiles, coping, and decks;

(III) slides, steps, diving boards, handrails, and other equipment;

(IV) drains, skimmers, and valves;

(V) filters, gauges, pumps, motors, controls, and sweeps;

(VI) lighting fixtures; and

(VII) the pool heater that these standards of practice require to be reported for the heating system.

(2) The inspector is not required to:

(A) disassemble filters or dismantle or otherwise open any components or lines;

(B) operate valves;

(C) uncover or excavate any lines or concealed components of the system;

(D) fill the pool, spa, or hot tub with water;

(E) inspect any system that has been winterized, shut down, or otherwise secured;

(F) determine the presence of sub-surface water tables;

(G) determine the effectiveness of entrapment covers;

(H) determine the presence of pool shell or sub-surface leaks; or

(I) inspect ancillary equipment such as computer controls, covers, chlorinators or other chemical dispensers, or water ionization devices or conditioners other than required by this section.

(e) Outbuildings.

(1) The inspector shall report as Deficient the absence or failure in performance of ground-fault circuit interrupter protection devices in grade-level portions of unfinished accessory buildings used for storage or work areas, boathouses, and boat hoists; and

(2) The inspector shall report as Deficient deficiencies in the structural, electrical, plumbing, heating, ventilation, and cooling systems that these standards of practice require to be reported for the principal building.

(f) Private water wells.

(1) The inspector shall:

(A) operate at least two fixtures simultaneously;

(B) recommend or arrange to have performed coliform testing;

(C) report:

(i) the type of pump and storage equipment;

(ii) the proximity of any known septic system;

(D) report as Deficient deficiencies in:

(i) water pressure and flow and performance of pressure switches;

(ii) the condition of accessible equipment and components; and

(iii) the well head, including improper site drainage and clearances.

(2) The inspector is not required to:

(A) open, uncover, or remove the pump, heads, screens, lines, or other components of the system;

(B) determine the reliability of the water supply or source; or

(C) locate or verify underground water leaks.

(g) Private sewage disposal (septic) systems.

(1) The inspector shall:

(A) report:

(i) the type of system;

(ii) the location of the drain or distribution field;

(iii) the proximity of any known water wells, underground cisterns, water supply lines, bodies of water, sharp slopes or breaks, easement lines, property lines, soil absorption systems, swimming pools, or sprinkler systems;

(B) report as Deficient:

(i) visual or olfactory evidence of effluent seepage or flow at the surface of the ground;

(ii) inoperative aerators or dosing pumps; and

(iii) deficiencies in:

(I) accessible components;

(II) functional flow;

(III) site drainage and clearances around or adjacent to the system; and

(IV) the aerobic discharge system.

(2) The inspector is not required to:

(A) excavate or uncover the system or its components;

(B) determine the size, adequacy, or efficiency of the system; or

(C) determine the type of construction used.

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

Filed with the Office of the Secretary of State on August 18, 2016.

TRD-201604237
Kristen Worman
Deputy General Counsel
Texas Real Estate Commission
Effective date: September 7, 2016
Proposal publication date: May 20, 2016
For further information, please call: (512) 936-3093

♦ ♦ ♦

TITLE 25. HEALTH SERVICES

PART 4. ANATOMICAL BOARD OF THE STATE OF TEXAS

CHAPTER 477. DISTRIBUTION OF BODIES

25 TAC §§477.1, 477.2, 477.4, 477.5, 477.7

The Anatomical Board of the State of Texas (Board) adopts amendments to §§477.1, 477.2, 477.4, 477.5, and 477.7 concerning the rules and procedures for the distribution of cadavers and/or anatomical specimens to recognized search organizations. The Board adopts amendments to §§477.1, 477.2, 477.4, 477.5, and 477.7 without changes to the proposed text as published in the July 1, 2016, issue of the *Texas Register* (41 TexReg 4779).

The Board's adopted amendments are to implement Health and Safety Code §691.030 and §692A.011 as amended by Senate Bill 1214 in the 84th Legislative Session. The amendments to §691.030 and §692A.011 provide that the use of cadavers and/or anatomical specimens by recognized search organizations must be coordinated through the Anatomical Board of the State of Texas.

The amendment to §477.1 defines the term "search organizations" to be organizations described in §691.030(a)(3) of the Health and Safety Code.

Amendments to §477.2 necessitate that search organizations meet the requirements described in §691.030(a)(3) of the Health and Safety Code.

Amendments to §477.4 set forth the circumstances under which a cadaver or anatomical specimen may be transferred to a recognized search organization.

Amendments to §477.5 relate to the procedure for a recognized search organization to request transfer of cadavers and/or anatomical specimens, the procedure for approval of the transfer, availability of cadavers and/or anatomical specimens, and the procedure for return of cadavers and/or anatomical specimens.

The amendment to §477.7 requires a recognized search organization receiving cadavers and/or anatomical specimens to file a yearly cadaver procurement and use report.

No comments were received regarding the adoption of the amendments.

The adopted amendments to §§477.1, 477.2, 477.4, 477.5, and 477.7 are also authorized by the Board's general rulemaking power under Health and Safety Code §691.022(b).

The adopted amendments affect Texas Administrative Code, Title 25, Chapter 477.

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604290
Stephen Luk
Secretary - Treasurer
Anatomical Board of the State of Texas
Effective date: September 11, 2016
Proposal publication date: July 1, 2016
For further information, please call: (214) 648-2267

♦ ♦ ♦

CHAPTER 479. FACILITIES: STANDARDS AND INSPECTIONS

25 TAC §§479.1 - 479.3, 479.5

The Anatomical Board of the State of Texas (Board) adopts amendments to §§479.1 - 479.3, and 479.5 concerning the rules and procedures for the distribution of cadavers and/or anatomical specimens to recognized search organizations. The Board adopts amendments to §§479.1 - 479.3, and 479.5 without changes to the proposed text as published in the July 1, 2016, issue of the *Texas Register* (41 TexReg 4781).

The Board's adopted amendments are to implement Health and Safety Code §691.030 and §692A.011 as amended by Senate Bill 1214 in the 84th Legislative Session. The amendments to §691.030 and §692A.011 provide that the use of cadavers and/or anatomical specimens by recognized search organizations must be coordinated through the Anatomical Board of the State of Texas.

Amendments to §479.1 allow recognized search organizations and forensic science programs to receive and hold cadavers and/or anatomical specimens.

Amendments to §479.2 relate to the procedure for a search organization to apply to receive and hold cadavers and/or anatomical specimens. This section also relates to the inspection of the facilities of a search organization.

Amendments to §479.3 allow recognized search organizations and forensic science programs to use anatomical specimens in specific field locations provided that certain conditions are met.

Amendments to §479.5 provide a limited exception to Texas Penal Code §42.10 for recognized search organizations and forensic science programs to use human cadaveric materials for training purposes under strict circumstances.

No comments were received regarding the adoption of the amendments.

The adopted amendments to §§479.1, 479.2, 479.3, and 479.5 are authorized by the Board's general rulemaking power under Health and Safety Code §691.022(b).

The adopted amendments affect the Texas Administrative Code, Title 25, Chapter 479.

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604291
Stephen Luk
Secretary - Treasurer
Anatomical Board of the State of Texas
Effective date: September 11, 2016
Proposal publication date: July 1, 2016
For further information, please call: (214) 648-2267

♦ ♦ ♦

TITLE 34. PUBLIC FINANCE

PART 4. EMPLOYEES RETIREMENT SYSTEM OF TEXAS

CHAPTER 81. INSURANCE

34 TAC §§81.1, 81.3, 81.5, 81.7 - 81.9, 81.11

The Employees Retirement System of Texas (ERS) adopts amendments to 34 Texas Administrative Code (TAC), Chapter 81, concerning Insurance, §§81.1 (Definitions), 81.3 (Health Maintenance Organizations), 81.5 (Eligibility), 81.8 (Waiver of Health Coverage), 81.9 (Grievance Procedures), and 81.11 (Cancellation of Coverage and Sanctions) without changes to the proposed text as published in the July 8, 2016, issue of the *Texas Register* (41 TexReg 4960), and these sections will not be republished. ERS adopts amendments to 34 TAC §81.7 (Enrollment and Participation) with changes to the proposed text as published, and this section will be republished. The change from the proposed text allows a certified nurse-midwife to be considered a practitioner who can certify the date of birth for a newborn natural child for purposes of eligibility for life and AD&D coverage in the Group Benefits Program (GBP). The amendments were approved by the ERS Board of Trustees at its August 16, 2016, meeting.

ERS adopts amendments to Chapter 81 to comply with recent legislation which added Subchapter J to Chapter 1551, Insurance Code, in connection with a state consumer-directed health plan and to comply with provisions of the Affordable Care Act (ACA). In addition, the amendments simplify plan administration and provide clarification to GBP plan participants, including consolidation of the available GBP optional coverages into one subsection.

Section 81.1, concerning Definitions, is amended to update the rule to use more current terminology, provide clarity to existing definitions, provide definitions to terms that previously existed within the rule, and to eliminate definitions that are no longer necessary. A definition for "Consumer Directed HealthSelect℠" was added for the new GBP high deductible health plan, in connection with the new Insurance Code Chapter 1551, Subchapter J. "GBP health coverage" was also included to describe all of the health plans that are offered through the GBP. The definition of a "spouse" as a dependent in the GBP was reformatted to add additional clarity and guidance to GBP participants that a member's spouse must be formally married or informally married with a filed Declaration of Informal Marriage prior to the effective date of the dependent spouse's enrollment in the GBP. The amendment also creates a narrow exception to the requirement based on clear and compelling evidence that the marriage existed prior to enrollment in the GBP. The definition regarding dependents is also amended to specify the requirements for continued health insurance eligibility for children over age 26 who are mentally or physically incapacitated in accordance with Texas Insurance Code §1551.004(a)(3).

The term "insurance required contribution" replaces "premium" throughout Chapter 81 to more clearly reflect that plans within the GBP are governmental insurance programs that include self-funded benefit plans that do not have traditional premiums like non-governmental plans subject to state insurance laws. GBP benefits are governed by Chapter 1551, Insurance Code, and have statutory eligibility and enrollment requirements that are different from other insurance benefits offered outside of the GBP.

Section 81.3, concerning Administration, is amended to be titled "Health Maintenance Organizations." The amendments provide additional clarity regarding the requirements of health maintenance organizations (HMOs) in the GBP, and there are no substantive changes to the HMO provisions. The rules regarding administration of the insurance required contributions and state contributions in the GBP, currently in §81.3(b) and (c), are moved to §81.7, in order to aggregate the information within a rule that is relevant to that subject and make it easier for users to find applicable rules for a particular subject.

Section 81.5, concerning Eligibility, is amended to clarify that a former COBRA unmarried child is eligible to enroll a newly acquired dependent child within 30 days of the child's date of birth or placement for adoption. Otherwise, these particular GBP participants cannot add dependents to their coverage. Additionally, subsections of §81.5 were moved within the section to provide better organization of the rule.

Section 81.5 (Eligibility) and §81.7 (Enrollment and Participation), are amended to comply with provisions of the ACA by decreasing the waiting period for coverage to the first day of the month following 60 days of employment, deleting references to a preexisting conditions limitation or exclusion, and to provide that married dependents under age 26, who are otherwise eligible dependents, may continue to be enrolled as dependents and are not required to apply for COBRA coverage until they reach age 26.

Section 81.7, concerning Enrollment and Participation, is amended to include subsections moved from §81.3, addressing payment of insurance required contributions and state contributions, in order to aggregate the information within a rule that is relevant to that subject and to clarify the payment of insurance required contributions by the type of participant. The amendments add language to clarify that a Medicare-eligible surviving dependent, eligible for health coverage under the GBP, may be automatically enrolled in the Medicare Advantage Plan unless the surviving dependent opts out and enrolls in other coverage. The amendments also add requirements related to the new optional coverage for a vision plan and the new health benefits plan, Consumer Directed HealthSelect, offered through the GBP, and reflect that the Consumer Directed HealthSelect, commuter spending accounts, vision plan, limited purpose flexible spending accounts, and health savings accounts are additional coverages and plans available to certain eligible members and participants. The amendments also allow participants enrolled in an HMO, whose contract is not renewed, to enroll in another approved HMO for which they are eligible. Such participants may also enroll in HealthSelect or Consumer Directed HealthSelect instead of another HMO. The amendments also clarify qualifying life events that may permit a change in coverage for participants, including dropping or adding eligible dependents, if the requested change is consistent with the qualifying life event. In addition, amendments clarify that annual enrollment opportunities are at times announced by ERS in order to specify that there are different annual enrollment opportunities for members who are not Medicare-eligible and for those members who are not active employees and are eligible for Medicare. Section 81.7 is also amended to repeal §81.7(j), the provision reflecting the preexisting conditions exclusion for the GBP disability income insurance plan, because the rule is not necessary since the Master Benefit Plan Document for the long- and short-term disability plan already includes such requirements.

Section 81.8, concerning Waiver of Health Coverage, is amended to provide better organization and additional clarity regarding incentive credits.

Section 81.9, concerning Grievance Procedure, is amended by changing the title of the section to "Grievance Procedures" to reflect that there is more than one type of grievance procedure, depending on the particular GBP plan, to clarify the grievance procedures applicable for the different types of plans in the GBP and to provide more details regarding the grievance procedures. The amendments provide additional clarity regarding available grievance rights for participants whose claims are denied by administering firms or carriers in the GBP, clarify that participants with a denied claim in certain plans must request reconsideration from the carrier or administering firm prior to seeking grievance review by ERS, and reflect that the applicable plan documents set forth grievance procedures for denied claims.

Section 81.11, concerning Termination of Coverage, is amended by changing the title of the section to "Cancellation of Coverage and Sanctions," to make a distinction between sanctions and cancellation of coverage, which can be unrelated to sanctions. The amendments reorganize the rule for better clarity regarding the conditions and timeframes for cancellation of GBP coverage for participants.

One comment was received on the proposed rule amendments.

Comment. The Coalition for Nurses in Advanced Practice (CNAP) suggested adding certified nurse-midwife as practitioners who can certify the date of birth for a newborn natural child for purposes of eligibility for life and AD&D coverage in the GBP.

Agency Response: The agency agrees that the suggested change is acceptable because certified nurse-midwives are authorized by Texas law to certify the dates of birth for newborn natural children as long as the birth is within the scope of the certified nurse-midwife's practice.

The amendments are adopted under the Texas Insurance Code, §1551.052, which provides authorization for the ERS Board of Trustees to adopt rules necessary to carry out its statutory duties and responsibilities and under §1551.068, Texas Insurance Code, which authorizes the ERS Board of Trustees to modify, amend, or interpret rules to the extent necessary to comply with any applicable federal law.

§81.7. Enrollment and Participation.

(a) Enrollment Categories.

(1) Full-time employees and their dependents.

(A) A new employee:

(i) who is not subject to the health insurance waiting period and is eligible under the Act and as provided for in §81.5(a)(1) of this chapter (relating to Eligibility) for automatic insurance coverage, shall be enrolled in the basic plan unless the employee completes an enrollment form to elect other coverage or to waive GBP health coverage as provided in §81.8 of this chapter (relating to Waiver of Health Coverage). Coverage of an employee under the basic plan, and other coverage selected as provided in this paragraph, becomes effective on the date on which the employee begins active duty.

(ii) who is subject to the health insurance waiting period and is eligible under the Act and as provided for in §81.5(a)(1) of this chapter for automatic insurance coverage, shall be enrolled in the basic plan beginning on the first day of the calendar month following 60 days of employment unless, before this date, the employee completes an enrollment form to elect other coverage or to waive GBP health coverage as provided in §81.8 of this chapter.

(iii) who has existing, current, and continuous GBP health coverage as of the date the employee begins active duty is not subject to the health insurance waiting period and is eligible to enroll as a new employee in health insurance and additional coverage and plans which include optional coverage by completing an enrollment form before the first day of the calendar month after the date the employee begins active duty. Health and additional coverage selected before the first day of the calendar month after the date the employee begins active duty are effective the first day of the following month.

(B) Dependent enrollment and optional coverage:

(i) To enroll eligible dependents, to elect to enroll in an approved HMO, and to elect additional coverage and plans which include optional coverage, an employee not subject to the health insurance waiting period shall complete an enrollment form within 30 days after the date on which the employee begins active duty. Coverage selected within 30 days after the date on which the employee begins active duty becomes effective on the first day of the month following the date on which the enrollment form is completed. An enrollment form completed after the initial period for enrollment as provided in this paragraph is subject to the provisions of subsection (d) of this section.

(ii) To enroll eligible dependents or to elect to enroll in an approved HMO, an employee subject to the health insurance waiting period shall complete an enrollment form before the first day of the month following 60 days of employment. Coverage selected before the first day of the month following 60 days of employment becomes effective on the first day of the month following 60 days of employment. An employee completing an enrollment form after the initial period for enrollment as provided in this paragraph is subject to the provisions of subsection (d) of this section. The provisions of subparagraph (A)(ii) of this paragraph apply to the election of additional coverage and plans, which include optional coverage, for an employee subject to the health insurance waiting period.

(C) Except as otherwise provided in this section, an employee may not change coverage.

(D) An eligible employee who enrolls in the GBP is eligible to participate in premium conversion and shall be automatically enrolled in the premium conversion plan. The employee shall be automatically enrolled in the plan for subsequent plan years as long as the employee remains on active duty.

(E) Coverage for a newly eligible dependent, other than a dependent referred to in subparagraph (F) or (H) of this paragraph, will be effective on the first day of the month following the date the person becomes a dependent if an enrollment form is completed on or within 30 days after the date the person first becomes a dependent. If the enrollment form is completed and signed after the initial period for enrollment as provided in this paragraph, the enrollment form will be governed by the rules in subsection (d) of this section.

(F) A member's newborn natural child will be covered immediately and automatically for 30 days from the date of birth in the health plan in effect for the employee/retiree. A member's newly adopted child will be covered immediately and automatically from the date of placement for adoption for 30 days in the health plan in effect for the employee/retiree. To continue coverage for more than 30 days after the date of birth or placement for adoption, an enrollment form for GBP health coverage must be submitted by the member within 30 days after the date of birth or placement for adoption.

(G) The effective date of a newborn natural child's life and AD&D coverage will be the date of birth, if the child is born alive, as certified by an attending physician or a certified nurse-midwife. The effective date of a newly adopted child's life and AD&D coverage will be the date of placement for adoption. The effective date of all other

eligible dependents' life and AD&D coverage will be as stated in subparagraph (E) of this paragraph.

(H) GBP health coverage of a member's eligible child for whom a covered employee/retiree is court-ordered to provide medical support becomes effective on the date on which the member's benefits coordinator receives a valid copy of the qualified medical child support order.

(I) The effective date of GBP health coverage for an employee's/retiree's dependent, other than a newborn natural child or newly adopted child, will be as stated in subparagraph (E) of this paragraph.

(J) For purposes of this section, an enrollment form is completed when all information necessary to effect an enrollment has been transmitted to ERS in the form and manner prescribed by ERS.

(2) Part-time employees. A part-time employee or other employee who is not automatically covered must complete an application/enrollment form provided by ERS authorizing necessary deductions for insurance required contributions for elected coverage. All other rules for enrollment stated in paragraph (1) of this subsection, other than the rule as to automatic coverage, apply to such employee:

(A) If the employee is not subject to a health insurance waiting period, this form must be submitted to ERS either through ERS Online or through his/her benefits coordinator on, or within 30 days after, the date on which the employee begins active duty.

(B) If the employee is subject to a health insurance waiting period, this form must be submitted to ERS either through ERS Online or through his/her benefits coordinator before the first day of the month following 60 days of employment.

(C) If the employee has existing, current, and continuous GBP health coverage as of the date the employee begins active duty, the employee is not subject to the health insurance waiting period and is eligible to enroll as a new employee in health insurance and additional coverage and plans which include optional coverage by completing an enrollment form before the first day of the calendar month after the date the employee begins active duty. Health and additional coverage selected before the first day of the calendar month after the date the employee begins active duty are effective the first day of the following month.

(3) Retirees and their dependents.

(A) Provided the insurance required contributions are paid or deducted, an employee's GBP health, dental, vision and term life insurance coverage (including eligible dependent coverage) may be continued upon retirement as provided in §81.5(b) of this chapter. The life insurance will be reduced to the maximum amount which the retiree is permitted to retain under the insurance plan as a retiree. All other coverage in force for an active employee, but not available to a retiree, will automatically be discontinued concurrently with the commencement of retirement status. Except as provided in subparagraph (E) of this paragraph, if a retiree retires directly from active duty and is not covered as an active employee on the day before becoming an annuitant, the retiree may enroll in the basic plan.

(B) A retiree may enroll in GBP health, dental, vision and life insurance coverage for which the retiree is eligible as provided in §81.5(b) of this chapter, including dependent coverage, by completing an enrollment form as specified in clauses (i) - (iii) of this subparagraph. For the purposes of this subparagraph, the effective date of retirement of a retiree who is eligible to receive, but who has not yet received, an annuity is the date on which ERS receives written notice of the retirement. An application/enrollment form received after the initial period for enrollment as provided in this subparagraph, is subject to the provisions of subsection (d) of this section.

(i) A retiree who is not subject to the health insurance waiting period on the effective date of retirement as provided in §81.5(b) of this chapter, may enroll in GBP health, dental, vision and life insurance coverage or waive GBP health coverage as provided in §81.8 of this chapter for which the retiree is eligible, including dependent coverage, by completing an enrollment form or waiver of coverage as applicable before, on, or within 30 days after, the retiree's effective date of retirement.

(ii) A retiree who is subject to the health insurance waiting period on the effective date of retirement as provided in §81.5(b) of this chapter, may enroll in GBP health coverage or waive GBP health coverage as provided in §81.8 of this chapter for which the retiree is eligible, including dependent coverage, by completing an enrollment form or waiver of coverage as applicable, before the first day of the calendar month following 60 days after the date of retirement or before the first day of the calendar month after the retiree's 65th birthday, whichever is later as appropriate. The effective date for such coverage shall be the first day of the calendar month following 60 days after the date of retirement or the first day of the calendar month following the retiree's 65th birthday, whichever is later as appropriate.

(iii) A retiree who is ineligible for health insurance on the effective date of retirement as provided in §81.5(b) of this chapter, may enroll in GBP health coverage or waive GBP health coverage as provided in §81.8 of this chapter for which the retiree is eligible, including dependent coverage, by completing an enrollment form or waiver of coverage as applicable, before the first day of the calendar month after the retiree's 65th birthday. The effective date for such coverage shall be the first day of the calendar month following 60 days after the date of retirement or the first day of the calendar month following the retiree's 65th birthday, whichever is later.

(C) A retiree who becomes eligible for minimum retiree optional life insurance coverage or dependent life insurance coverage as provided in §81.5(b)(6) of this chapter, may apply for approval of such coverage by providing evidence of insurability acceptable to ERS.

(D) Enrollments in and applications to change coverage become effective as provided in subparagraph (B) of this paragraph unless other coverage is in effect at that time. If other coverage is in effect at that time, coverage or waiver of coverage becomes effective on the first day of the month following the date of approval of retirement by ERS; or, if cancellation of the other coverage preceded the date of approval of retirement, the first day of the month following the date the other coverage was canceled.

(E) A retiree who seeks enrollment in GBP health coverage after turning age 65 or is retired and enrolled in a health plan and turns age 65 will be automatically enrolled in the Medicare Advantage Plan unless the retiree opts out of the Medicare Advantage Plan and enrolls in other coverage by completing an enrollment form as specified in subparagraph (B)(i) - (iii) of this paragraph. If the retiree is determined to be ineligible for Medicare coverage, then he/she will be returned to the coverage in place immediately before turning 65.

(F) A Medicare-eligible retiree who seeks enrollment in GBP health coverage or is retired and enrolled in a health plan and becomes eligible for Medicare will be automatically enrolled in HealthSelect Medicare Rx. A retiree who declines HealthSelect Medicare Rx loses all GBP prescription drug coverage. If the retiree is determined to be ineligible for Medicare coverage, then he/she will be returned to the coverage in place immediately before turning 65.

(4) Medicare-eligible Dependents.

(A) A dependent as defined in §81.1 of this chapter (relating to Definitions) who becomes eligible for Medicare-primary coverage as specified in §81.1 of this chapter, either through disability, age, or other requirements as set forth by CMS, will be automatically enrolled in the Medicare Advantage Plan unless the retiree and his/her dependents opt out of the Medicare Advantage Plan and enroll in other coverage by completing an enrollment form as specified in paragraph (3)(B)(i) - (iii) of this subsection. If the dependent is determined to be ineligible for Medicare coverage, then he/she will be returned to the coverage in place immediately before turning 65.

(B) A Medicare-eligible dependent eligible for GBP health coverage will be automatically enrolled in HealthSelect Medicare Rx. A Medicare-eligible dependent who declines HealthSelect Medicare Rx loses all GBP prescription drug coverage. If the dependent is determined to be ineligible for Medicare coverage, then he/she will be returned to the coverage in place immediately before turning 65.

(5) Surviving dependents.

(A) Provided that the insurance required contributions are paid or deducted, the health, dental, and vision insurance coverage of a surviving dependent may be continued on the death of the deceased employee/retiree if the dependent is eligible for such coverage as provided by §81.5(e) of this chapter.

(B) A surviving spouse who is receiving an annuity shall make insurance required contribution payments by deductions from the annuity as provided in subsection (h)(7) of this section. A surviving spouse who is not receiving an annuity may make payments as provided in subsection (h)(7) of this section.

(C) A Medicare-eligible surviving dependent eligible for GBP health coverage will be automatically enrolled in the Medicare Advantage Plan unless the surviving dependent opts out of the Medicare Advantage Plan and enrolls in other coverage.

(D) A Medicare-eligible surviving dependent eligible for GBP health coverage will be automatically enrolled in HealthSelect Medicare Rx. A Medicare-eligible surviving dependent who declines HealthSelect Medicare Rx loses all GBP prescription drug coverage.

(6) Former COBRA unmarried children. A former COBRA unmarried child must provide an application to continue GBP health, dental and vision insurance coverage within 30 days after the date the notice of eligibility is mailed by ERS. Coverage becomes effective on the first day of the month following the month in which continuation coverage ends. Insurance required contribution payments must be made as provided in subsection (h)(1)(A) of this section.

(b) Premium conversion plans.

(1) An eligible employee participating in the GBP is deemed to have elected to participate in the premium conversion plan and to pay insurance required contributions with pre-tax dollars as long as the employee remains on active duty. The plan is intended to be qualified under the Internal Revenue Code, §79 and §106.

(2) Maximum benefit available. Subject to the limitations set forth in these rules and in the plan, to avoid discrimination, the maximum amount of flexible benefit dollars which a participant may receive in any plan year for insurance required contributions under this section shall be the amount required to pay the participant's portion of the insurance required contributions for coverage under each type of insurance included in the plan.

(c) Special rules for additional coverage and plans which include optional coverage.

(1) Only an employee/retiree or a former officer or employee specifically authorized to join the GBP may apply for additional coverage and plans. An employee/retiree may apply for or elect additional coverage and plans for which he/she is eligible without concurrent enrollment in GBP health coverage provided by the GBP. Additional coverage and plans, as determined by the Board of Trustees, may include:

(A) dental coverage;

(B) optional term life;

(C) dependent term life;

(D) short- and long-term disability;

(E) voluntary accidental death and dismemberment;

(F) long-term care;

(G) health care and dependent care reimbursement;

(H) commuter spending account;

(I) vision;

(J) limited purpose flexible spending account; or

(K) health savings account.

(2) An eligible member in the GBP and eligible dependents may participate in an approved HMO if they reside in the approved service area of the HMO and are otherwise eligible under the terms of the contract with the HMO.

(3) An eligible member in the GBP electing additional coverage and plans and/or Consumer Directed HealthSelect, HMO or Medicare Advantage coverage in lieu of the basic plan is obligated for the full payment of insurance required contributions. If the insurance required contributions are not paid, all coverage not fully funded by the state contribution will be canceled. A person eligible for the state contribution will retain member-only GBP health coverage as a member provided the state contribution is sufficient to cover the insurance required contribution for such coverage. If the state contribution is not sufficient for member-only coverage in the health plan selected by the member employee/retiree, the member employee/retiree will be enrolled in the basic plan or the Medicare Advantage Plan, as applicable, except as provided for in subsection (g)(2)(B) of this section.

(4) An eligible member in the GBP enrolled in an HMO and the HMO's contract is not renewed for the next fiscal year will be eligible to make one of the following elections:

(A) change to another approved HMO for which the member is eligible by completing an enrollment form during the annual enrollment period. The effective date of the change in coverage will be September 1;

(B) enroll in HealthSelect of Texas, Consumer Directed HealthSelect, or a Medicare Advantage Plan (if eligible) by completing an enrollment form during the annual enrollment period. The effective date of the change in coverage will be September 1; or

(C) if the member does not make one of the elections, as defined in subparagraphs (A) or (B) of this paragraph, the member and covered eligible dependents will automatically be enrolled in the basic plan or the Medicare Advantage Plan, as applicable.

(5) A member enrolled in an HMO whose contract with ERS is terminated during the fiscal year or that fails to maintain compliance with the terms of its contract, as determined by ERS, will be eligible to make one of the following elections:

(A) change to another approved HMO for which the member is eligible. The effective date of the change in coverage will be determined by ERS; or

(B) enroll in HealthSelect of Texas, Consumer Directed HealthSelect, or a Medicare Advantage Plan (if eligible). The effective date of the change in coverage will be determined by ERS.

(d) Changes in coverage after the initial period for enrollment.

(1) Changes for a qualifying life event.

(A) Subject to the provisions of paragraphs (3) and (4) of this subsection, a member shall be allowed to change coverage during a plan year within thirty (30) days of a qualifying life event that occurs as provided in this paragraph if the change in coverage is consistent with the qualifying life event.

(B) A qualifying life event occurs when a participant experiences one of the following changes:

(i) change in marital status;

(ii) change in dependent status;

(iii) change in employment status;

(iv) change of address that results in loss of benefits eligibility;

(v) change in Medicare or Medicaid status, or CHIP status;

(vi) significant cost of benefit or coverage change imposed by a third party provider; or

(vii) change in coverage ordered by a court.

(C) A member who loses benefits eligibility as a result of a change of address shall change coverage as provided in paragraphs (6) - (9) of this subsection.

(D) A member may apply to change coverage on, or within 30 days after, the date of the qualifying life event, provided, however, a change in election due to CHIP or Medicaid status under subparagraph (B) of this paragraph may be submitted on, or within 60 days after, the change in CHIP or Medicaid status.

(E) Except as otherwise provided in subsection (a)(1)(F) and (H) of this section, the change in coverage is effective on the first day of the month following the date on which the enrollment form is completed.

(F) Documentation may be required in support of the qualifying life event.

(G) Following a qualifying life event, a member may change applicable coverage, drop or add an eligible dependent if the change is consistent with the qualifying life event.

(2) Effects of change in cost of benefits to the premium conversion plan. There shall be an automatic adjustment in the amount of premium conversion plan dollars used to purchase optional benefits in the event of a change, for whatever reason, during an applicable period of coverage, of the cost of providing such optional benefit to the extent permitted by applicable law and regulation. The automatic adjustment shall be equal to the increase or decrease in such cost. A participant shall be deemed by virtue of participation in the plan to have consented to the automatic adjustment.

(3) An eligible member who wishes to add or increase optional coverage after the initial period for enrollment must make application for approval by providing evidence of insurability acceptable to ERS, if required. Unless not in compliance with paragraph (1) of this subsection, coverage will become effective on the first day of the month following the date approval is received by ERS, if the applicant is a retiree or an individual in a direct pay status. If the applicant is an employee whose coverage was canceled while the employee was on LWOP, the approved change in coverage will become effective on the date the employee returns to active duty if the employee returns to active duty within 30 days of the approval letter. If the date the employee returns to active duty is more than 30 days after the date on the approval letter, the approval is null and void; and a new application shall be required. An employee/retiree may withdraw the application at any time prior to the effective date of coverage by submitting a written notice of withdrawal.

(4) The evidence of insurability provision applies only to:

(A) employees who wish to enroll in Elections III or IV optional term life insurance, except as otherwise provided in subsection (f) of this section;

(B) employees who wish to enroll in or increase optional term life insurance, dependent life insurance, or disability income insurance after the initial period for enrollment;

(C) employees enrolled in the GBP whose coverage was waived, dropped or canceled, except as otherwise provided in subsection (f) of this section; and

(D) retirees who wish to enroll in minimum optional life insurance or dependent life insurance as provided in subsection (a)(3)(C) of this section.

(5) An employee/retiree who wishes to add eligible dependents to the employee's/retiree's HMO coverage may do so:

(A) during the annual enrollment period; or

(B) upon the occurrence of a qualifying life event as provided in paragraph (1) of this subsection.

(6) A member who is enrolled in an approved HMO and who permanently moves out of the HMO service area shall make one of the following elections, to become effective on the first day of the month following the date on which the member moves out of the HMO service area:

(A) enroll in another approved HMO for which the member and all covered dependents are eligible; or

(B) if the member and all covered dependents are not eligible to enroll in an approved HMO; either:

(i) enroll in HealthSelect of Texas or Consumer Directed HealthSelect; or

(ii) enroll in an approved HMO if the member is eligible, and drop any ineligible covered dependent, unless not in compliance with §81.11(c)(3) of this chapter (relating to Cancellation of Coverage and Sanctions).

(7) When a covered dependent of a member permanently moves out of the member's HMO service area, the member shall make one of the following elections, to become effective on the first day of the month following the date on which the dependent moves out of the HMO service area:

(A) drop the ineligible dependent, unless not in compliance with §81.11(c)(3) of this chapter;

(B) enroll in an approved HMO if the member and all covered dependents are eligible; or

(C) enroll in HealthSelect of Texas or Consumer Directed HealthSelect, provided the eligible member and all dependents enroll in the same health plan at that time.

(8) An eligible member will be allowed an annual opportunity to make changes in coverage.

(A) Subject to other requirements of this section, a member will be allowed to:

(i) change or enroll themselves and any eligible dependents in an eligible health, dental or vision plan;

(ii) enroll themselves and their eligible dependents in an eligible health, dental or vision plan from a waived or canceled status;

(iii) add, decrease or cancel eligible coverage, unless prohibited by §81.11(c)(3) of this chapter;

(iv) apply for coverage as provided in paragraph (3) of this subsection; and

(v) waive any or all GBP coverage including health as provided in §81.8 of this chapter.

(B) Surviving dependents and former COBRA unmarried children are not eligible to add dependents to coverage through annual enrollment. A surviving dependent or former COBRA unmarried child may enroll an eligible dependent in dental or vision insurance coverage if the dependent is enrolled in health insurance coverage.

(C) Annual enrollment opportunities will be scheduled each year at times announced by ERS.

(9) A participant who is a retiree or a surviving dependent, or who is in a direct pay status, may decrease or cancel any coverage at any time unless such coverage is health insurance coverage ordered by a court as provided in §81.5(c) of this chapter.

(10) A member and his/her dependents who are enrolled in the Medicare Advantage Plan may collectively enroll in HealthSelect of Texas, Consumer Directed HealthSelect or an HMO.

(A) Such opportunity will be scheduled on at least an annual basis each year, at times announced by ERS.

(B) Additional opportunities will occur each month prior to an annual enrollment period. Coverage selected during these opportunities will be effective on the first of the month following processing by CMS.

(11) If a member drops coverage for his/her dependent because the dependent gained other coverage effective the first day of a month, then the effective date of the qualifying life event can be either the last day of the month preceding the gained coverage or on the first day of the month in which the gained coverage is effective.

(e) Special provisions relating to term life benefits

(1) An employee or annuitant who is enrolled in the group term life insurance plan may file a claim for an accelerated life benefit for himself or his covered dependent in accordance with the terms of the plan in effect at that time. An accelerated life benefit paid will be deducted from the amount that would otherwise be payable under the plan.

(2) An employee or annuitant who is enrolled in the group term life insurance plan may make, in conjunction with receipt of a viatical settlement, an irrevocable beneficiary designation in accordance with the terms of the plan in effect at that time.

(f) Re-enrollment in the GBP.

(1) The provisions of subsection (a)(1) of this section shall apply to the enrollment of an employee who terminates employment and returns to active duty within the same fiscal year, who transfers from one employer to another, or who returns to active duty after a period of LWOP during which coverage is canceled.

(2) An employee to whom paragraph (1) of this subsection applies shall be subject to the same requirements as a newly hired employee to re-enroll in the coverage in which the employee was previously enrolled. Provided that all applicable preexisting conditions exclusions were satisfied on the date of termination, transfer, or cancellation, no new preexisting conditions exclusions will apply. If not, any remaining period of preexisting conditions exclusions must be satisfied upon re-enrollment.

(3) If an employee is a member of the Texas National Guard or any of the reserve components of the United States armed forces, and the employee's coverage is canceled during a period of LWOP or upon termination of employment as the result of an assignment to active military duty, the period of active military duty shall be applied toward satisfaction of any period of preexisting conditions exclusions remaining upon the employee's return to active employment.

(g) Continuing coverage in special circumstances.

(1) Continuation of coverage for terminating employees. A terminating employee is eligible to continue all coverage through the last day of the month in which employment is terminated.

(2) Continuation of coverage for employees on LWOP status.

(A) An employee in LWOP status may continue the coverage in effect on the date the employee entered that status for the period of leave, but not more than 12 months. The employee must pay insurance required contributions directly as provided in subsection (h)(1)(A) of this section.

(B) An employee whose LWOP is a result of the Family and Medical Leave Act of 1993 will continue to receive the state contribution during such period of LWOP. The employee must pay insurance required contributions directly as defined in subsection (h)(1)(A) of this section. Failure to make the payment of insurance required contributions by the due date will result in the cancellation of all coverage except for member-only health and basic life coverage. The employee will continue in the health plan in which he/she was enrolled immediately prior to the cancellation of all other coverage.

(3) Continuation of coverage for a former member or employee of the Legislature. Provided that the insurance required contributions are paid, the GBP health, dental, vision and life insurance coverage of a former member or employee of the Legislature may be continued on conclusion of the term of office or employment.

(4) Continuation coverage for a former board member. Provided that the insurance required contributions are paid, the GBP health, dental, vision and life insurance coverage of a former member of a board or commission, or of the governing body of an institution of higher education, as both are described in §1551.109 of the Act, may be continued on conclusion of service if no lapse in coverage occurs after the term of office. Life insurance will be reduced to the maximum amount for which the former board member is eligible.

(5) Continuation of coverage for a former judge. A former state of Texas judge, who is eligible for judicial assignments and who does not serve on judicial assignments during a period of one calendar month or longer, may continue the coverage that was in effect during the calendar month immediately prior to the month in which the for-

mer judge did not serve on judicial assignments. This coverage may continue for no more than 12 continuous months during which the former judge does not serve on judicial assignments as long as, during the period, the former judge continues to be eligible for assignment.

(6) Continuation of coverage for a surviving spouse and/or dependent child/children of a deceased employee/retiree. The surviving spouse and/or dependent child/children of a deceased employee/retiree, who, in accordance with §81.5(j)(1) of this chapter, elects to continue coverage may do so by submitting the required election notification and enrollment forms to ERS. The enrollment form, including all insurance required contributions due for the election/enrollment period, must be postmarked or received by ERS on or before the date indicated on the continuation of coverage enrollment form. Continuing coverage will begin on the first day of the month following the month in which the employee/retiree dies, provided all insurance required contributions due for the month in which the employee/retiree died and for the election/enrollment period have been paid in full.

(7) Continuation of coverage for a covered employee whose employment has been terminated, voluntarily or involuntarily (other than for gross misconduct), whose work hours have been reduced such that the employee is no longer eligible for the GBP as an employee, or whose coverage has ended following the maximum period of LWOP as provided in paragraph (2)(A) of this subsection. An employee, his/her spouse and/or dependent child/children, who, in accordance with §81.5(j)(2) of this chapter, elect to continue GBP health, dental and vision coverage may do so by submitting the required election notification and enrollment forms to ERS. The enrollment form, including all insurance required contributions due for the election/enrollment period, must be postmarked or received by ERS on or before the date indicated on the continuation of coverage enrollment form. Continuing coverage will begin on the first day of the month following the month in which the employee's coverage ends, provided all insurance required contributions due for the month in which the coverage ends and for the election/enrollment period have been paid in full.

(8) Continuation of coverage for a spouse who is divorced from a member and/or the spouse's dependent child/children. The divorced spouse and/or the spouse's dependent child/children of an employee/retiree who, in accordance with §81.5(j)(4) of this chapter, elect to continue coverage may do so by submitting the required election notification and enrollment forms to ERS. The enrollment form, including all insurance required contributions due for the election/enrollment period, must be postmarked or received by ERS on or before the date indicated on the continuation of coverage enrollment form. Continuing coverage will begin on the first day of the month following the month in which the divorce decree is signed, provided all insurance required contributions due for the month in which the divorce decree is signed and for the election/enrollment period have been paid in full.

(9) Continuation of coverage for a dependent child who has attained 26 years of age. A 26-year-old dependent child (not provided for by §81.5(c) of this chapter) of a member who, in accordance with §81.5(j)(5) of this chapter, elects to continue coverage may do so by submitting the required election notification and enrollment forms to ERS. The enrollment form, including all insurance required contributions due for the election/enrollment period, must be postmarked or received by ERS on or before the date indicated on the continuation of coverage enrollment form. Continuing coverage will begin on the first day of the month following the month in which the dependent child of the member attains 26 years of age, provided all insurance required contributions due for the month in which the dependent child attained age 26 and for the election/enrollment period have been paid in full.

(10) Extension of continuation of coverage for certain dependents of former employees who are continuing coverage under the provisions of paragraph (6) of this subsection.

(A) The surviving dependent of a deceased former employee, who, in accordance with §81.5(j)(6)(A) of this chapter, elects to extend continuation coverage may do so by submitting the required election notification and enrollment forms to ERS. The enrollment form, including all insurance required contributions due for the election/enrollment period, must be postmarked or received by ERS on or before the date indicated on the continuation enrollment form. The election/enrollment period begins on the first day of the month following the month in which the former employee died.

(B) A spouse who is divorced from a former employee and/or the divorced spouse's dependent child/children, who, in accordance with §81.5(j)(6)(B) of this chapter, elects to extend continuation coverage may do so by submitting the required election notification and enrollment forms to ERS. The enrollment form, including all insurance required contributions due for the election/enrollment period, must be postmarked or received by ERS on or before the date indicated on the continuation enrollment form. The election/enrollment period begins on the first day of the month following the month in which the divorce decree was signed.

(C) A dependent child who has attained 26 years of age, who, in accordance with §81.5(j)(6)(C) of this chapter, elects to extend continuation coverage may do so by submitting the required election notification and enrollment forms to ERS. The enrollment form, including all insurance required contributions due for the election/enrollment period, must be postmarked or received by ERS on or before the date indicated on the continuation enrollment form. The election/enrollment period begins on the first day of the month following the month in which the dependent child attained age 26.

(11) Continuation coverage defined. Continuation coverage as provided for in paragraphs (6) - (10) of this subsection means the continuation of only GBP health, dental and vision coverage which meets the following requirements.

(A) Type of benefit coverage. The coverage shall consist of only the GBP health, dental and vision coverage, which, as of the time the coverage is being provided, are identical to the GBP health, dental and vision coverage provided for a similarly situated person for whom a cessation of coverage event has not occurred.

(B) Period of coverage. The coverage shall extend for at least the period beginning on the first day of the month following the date of the cessation of coverage event and ending not earlier than the earliest of the following:

(i) in the case of loss of coverage due to termination of an employee's employment for other than gross misconduct, reduction in work hours, or end of maximum period of LWOP, the last day of the 18th calendar month of the continuation period;

(ii) in the case of loss of coverage due to termination of an employee's employment for other than gross misconduct, reduction in work hours, or end of maximum period of LWOP, if the employee, spouse, or dependent child has been certified by the Social Security Administration as being disabled as provided in §81.5(j)(3) of this chapter, up to the last day of the 29th calendar month of the continuation period;

(iii) in any case other than loss of coverage due to termination of an employee's employment for other than gross misconduct, reduction in work hours, or end of maximum period of LWOP, the last day of the 36th calendar month of the continuation period;

(iv) the date on which the employer ceases to provide any group health plan to any employee/retiree;

(v) the date on which coverage ceases under the plan due to failure to make timely payment of any insurance required contribution as provided in subsection (h) of this section;

(vi) the date on which the participant, after the date of election, becomes covered under any other group health plan under which the participant is not subject to a preexisting conditions limitation or exclusion; or

(vii) the date on which the participant, after the date of election, becomes entitled to benefits under the Social Security Act, Title XVIII.

(C) Insurance required contribution costs. The insurance required contribution for a participant during the continuation coverage period will be 102% of the employee's/retiree's GBP health, dental and vision coverage rate and is payable as provided in subsection (h) of this section.

(i) The insurance required contribution for a participant eligible for 36 months of coverage will be 102% of the employee's/retiree's GBP health, dental and vision coverage rate and is payable as provided in subsection (h)(1)(A) of this section.

(ii) The insurance required contribution for a participant eligible for 29 months of coverage will increase to 150% of the employee's/retiree's GBP health, dental and vision coverage rate for the 19th through 29th months of coverage and is payable as provided in subsection (h)(1)(A) of this section.

(D) No requirement of insurability. No evidence of insurability is required for a participant who elects to continue GBP health coverage under the provisions of §81.5(j)(1) - (6) of this chapter.

(E) Conversion option. An option to enroll under the conversion plan available to employees/retirees is also available to a participant who continues GBP coverage for the maximum period as provided in subparagraph (B)(i) - (iii) of this paragraph. The conversion notice will be provided to a participant during the 180-day period immediately preceding the end of the continuation period.

(h) Payment of Insurance Required Contributions.

(1) A member whose monthly cost of coverage is greater than the combined amount contributed by the state or employer for the member's coverage must pay a monthly contribution in an amount that exceeds the combined monthly contributions of the state or the employer. A member shall pay his/her monthly insurance required contributions through deductions from monthly compensation or annuity payments or by direct payment, as provided in this paragraph.

(A) A member who is not receiving a monthly compensation or an annuity payment, or is receiving a monthly compensation or annuity payment that is less than the member's monthly insurance required contribution, shall pay his/her monthly insurance required contribution under this subparagraph.

(i) An employee whose monthly compensation is less than the employee's monthly insurance required contribution shall pay his/her monthly insurance required contribution through his/her employer. A non-salaried board member of an employer shall pay his/her monthly insurance required contributions through the employer for which he/she sits as a board member.

(ii) A retiree whose monthly annuity payment is less than the retiree's monthly insurance required contribution shall pay his/her monthly insurance required contributions directly to ERS.

(B) If the member does not comply with subparagraph (A) of this subsection by the due date required, ERS will cancel all coverage not fully funded by the state contribution. If the state contribution is sufficient to cover the required insurance contribution for such coverage, the member will retain member-only health and basic life coverage. If the state contribution is not sufficient to cover the member-only coverage in the health plan selected, the member will be enrolled in the basic plan except as provided for in paragraph (2)(B) of this subsection.

(2) An institution of higher education may contribute a portion or all of the insurance required contribution for its part-time employees described by §1551.101(e)(2) of the Act, if:

(A) the institution of higher education pays the contribution with funds that are not appropriated from the general revenue fund;

(B) the institution of higher education electing to pay the contribution for its part-time employees does so for all similarly situated eligible part-time employees; and

(C) the contribution paid as provided in this paragraph is paid beginning on the first day of the month following the part-time employee's completion of any applicable waiting period.

(3) A participant who continues GBP health, dental and vision coverage under COBRA as provided in §81.5(j) of this chapter (relating to Eligibility) must pay his/her monthly insurance contributions on the first day of each month covered.

(A) A participant's monthly insurance required contribution is 102% of the monthly amount charged for other participants in the same coverage category and in the same plan. All insurance required contributions due for the election/enrollment period must be postmarked or received by ERS on or before the date indicated on the continuation of coverage enrollment form. Subsequent insurance required contributions are due on the first day of each month of the participant's coverage and must be postmarked or received by ERS within 30 days of the due date to avoid cancellation of coverage.

(B) A participant's monthly insurance required contribution for continuing coverage as provided in §81.5(j))(3) of this chapter is increased after the 18th month of coverage to 150% of the monthly amount charged for other participants in the same coverage category and in the same plan. The participant's monthly insurance required contribution is due on the first day of each month covered, and must be postmarked or received by ERS within 30 days of the due date.

(4) The full cost for GBP health, dental and vision coverage is required to be paid for a member's unmarried child who is over 26 years of age, whose coverage under COBRA expired, and who has reinstated coverage in the GBP pursuant to §1551.158 of the Act. No state contribution is paid for this coverage.

(5) Survivors of a paid law enforcement officer employed by the state or a custodial employee of the institutional division of the Texas Department of Criminal Justice who suffers a death in the line of duty as provided by Chapter 615, Government Code, are eligible for GBP coverage as provided in subparagraphs (A) - (C) of this paragraph.

(A) The insurance required contribution due under this paragraph for a surviving spouse's GBP coverage is the same amount as a member-only contribution. The state contribution applicable to member-only coverage is applied to the surviving spouse's contribution for the coverage.

(B) The insurance required contribution due under this paragraph for GBP coverage for a surviving spouse with dependent children is the same amount as the member-with-children contribution.

The state contribution applicable to member-with-children coverage is applied to the contribution of the surviving spouse with dependent children for the coverage.

(C) The insurance required contribution due under this paragraph for a surviving dependent child's GBP coverage, when there is no surviving spouse, is the same amount as member-only contribution. The state contribution applicable to member-only coverage is applied to the surviving dependent child's contribution for the coverage.

(D) The surviving spouse or surviving dependent child must timely pay his/her insurance required contributions for the GBP coverage. The survivor's contribution must be either deducted by ERS from the survivor's annuity payment, if any, or submitted to ERS via direct payment. Any applicable state contribution will be paid directly to ERS by the employer that employed the deceased law enforcement officer or custodial employee.

(6) If a retiree whose eligibility for health insurance is based on §§1551.102(i), 1551.111(e) or 1551.112(c) of the Act, obtains interim health insurance as provided in §1551.323 of the Act, the retiree must pay the total contribution for such coverage for as long as the retiree wants the coverage or until the first day of the month following the retiree's 65th birthday. The amount of contribution shall be determined by the Board of Trustees based on an actuarial determination, as recommended by ERS' consulting actuary for insurance, of the estimated total claims costs for individuals eligible for such coverage. If a retiree who is eligible for coverage under this paragraph is also eligible for COBRA coverage, then COBRA coverage should be exhausted, if possible, before applying for the coverage under this paragraph.

(7) A member's surviving spouse or surviving dependent who is receiving an annuity shall authorize deductions for insurance required contributions from the annuity as provided in paragraph (1) of this subsection. A member's surviving spouse or surviving dependent who is not receiving an annuity may make payments as provided in paragraph (1)(A) of this subsection.

(i) The amount of state contribution for certain retirees is determined in accordance with §1551.3196 of the Act.

(1) An individual is grandfathered at the time of retirement and not subject to §1551.3196 of the Act, if on or before September 1, 2014, the individual has served in one or more positions for at least five years for which the individual was eligible to participate in the GBP as an employee.

(2) Records of ERS shall be used to determine whether or not an individual meets the grandfathering requirements specified in paragraph (1) of this subsection. ERS may, in its sole discretion, require an individual to provide additional documentation satisfactory to ERS that the individual meets the grandfathering requirements specified in paragraph (1) of this subsection.

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

Filed with the Office of the Secretary of State on August 16, 2016.

TRD-201604195
Paula A. Jones
Deputy Executive Director and General Counsel
Employees Retirement System of Texas
Effective date: September 5, 2016
Proposal publication date: July 8, 2016
For further information, please call: (877) 275-4377

♦ ♦ ♦

CHAPTER 85. FLEXIBLE BENEFITS

34 TAC §85.4

The Employees Retirement System of Texas (ERS) adopts an amendment to 34 Texas Administrative Code (TAC) Chapter 85, concerning Flexible Benefits, §85.4 (Separate Plans), without changes to the proposed text as published in the July 8, 2016, issue of the *Texas Register* (41 TexReg 4982). The amendment was approved by the ERS Board of Trustees at its August 16, 2016, meeting. This section will not be republished.

Section 85.4(c) is amended to update a numerical reference to the subsection regarding the Insurance Premium Conversion Plan described in Chapter 81. The reference needs to be updated to conform with proposed amendments to Chapter 81.

No comments were received on the proposed rule amendment.

The amendment is adopted under the Texas Insurance Code, §1551.052, which provides authorization for the ERS Board of Trustees to adopt rules necessary to carry out its statutory duties and responsibilities and under §1551.068, Texas Insurance Code, which authorizes the ERS Board of Trustees to modify, amend, or interpret rules to the extent necessary to comply with any applicable federal law.

No other statutes are affected by the proposed amendment.

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

Filed with the Office of the Secretary of State on August 16, 2016.

TRD-201604196
Paula A. Jones
Deputy Executive Director and General Counsel
Employees Retirement System of Texas
Effective date: September 5, 2016
Proposal publication date: July 8, 2016
For further information, please call: (877) 275-4377

♦ ♦ ♦

TITLE 37. PUBLIC SAFETY AND CORRECTIONS

PART 6. TEXAS DEPARTMENT OF CRIMINAL JUSTICE

CHAPTER 163. COMMUNITY JUSTICE ASSISTANCE DIVISION STANDARDS

37 TAC §163.39

The Texas Board of Criminal Justice adopts amendments to §163.39, concerning Residential Services, with non-substantive grammatical changes to the proposed text as published in the July 8, 2016, issue of the *Texas Register* (41 TexReg 4986).

The adopted amendments are necessary to conform the rule to updated health care regulations and standards.

No comments were received regarding the amendments.

The amendments are adopted under Texas Government Code §492.013, §509.003.

Cross Reference to Statutes: None.

§163.39. Residential Services.

(a) General Administration.

(1) Purpose. Residential facilities and contract residential beds funded by the Texas Department of Criminal Justice Community Justice Assistance Division (TDCJ CJAD) shall provide the courts with a sentencing alternative for the purpose of:

(A) Providing residential placement of offenders on community supervision and others who are eligible in accordance with statutes;

(B) Providing sanctions, services, and programs to modify criminal behavior, deter criminal activity, protect the public, restore victims of crime, and provide offenders with resources to lead productive lives;

(C) Strengthening and expanding the options available to judges to impose alternatives other than imprisonment for offenders; and

(D) Reducing the offender's likelihood of a technical violation or subsequent arrest, and recidivism.

(2) Feasibility Studies. A judicial district interested in establishing a residential community corrections facility (CCF) shall first conduct and prepare a feasibility study in accordance with the TDCJ CJAD Feasibility Study Guidelines-Community Corrections Facility. The product and results of such feasibility study shall be submitted to the TDCJ CJAD. After receipt by the TDCJ CJAD of the initial feasibility study related to a proposed CCF, the community supervision and corrections department (CSCD) may be required to provide supplemental information or additional materials for further review and consideration.

(3) Notice of Construction or Operation of a CCF.

(A) If a CSCD or private vendor operating under a contract with a CSCD or judicial district proposes to construct or operate a CCF within 1,000 feet of a residential area, a primary or secondary school, property designated as a public park or public recreation area by the state or a political subdivision of the state, or a church, synagogue, or other place of worship, the CSCD shall prominently post an outdoor sign at the proposed location of the facility. The sign shall be at least 24 by 36 inches in size written in lettering at least two inches in size. The sign shall state that a correctional or rehabilitation facility is intended to be located on the premises, and provide the name and business address of the CSCD. The municipality or county in which the CCF is to be located may require the sign to be both in English and a language other than English, if it is likely that a substantial number of the residents in the area speak a language other than English as their familiar language.

(B) The CSCD shall provide notice of the proposed location of the facility to the commissioners court of the county or governing body of the municipality where the facility is intended to be located no later than 60 days before the CSCD begins construction or operation of the facility. The notice shall contain the following:

(i) A statement of the entity's intent to construct or operate a correctional or rehabilitation facility in an area;

(ii) A description of the proposed location of the facility; and

(iii) A statement that Texas Local Government Code §§244.001 - .026 governs the procedure for notice of and consent to the facility.

(4) Public Meetings. A CSCD or private vendor having a contract with a CSCD or judicial district shall not establish a CCF unless the CSCD has held a public meeting before the action is taken. In addition, a CSCD may not expend funds provided by the TDCJ CJAD to lease or purchase real property, construct buildings, or use a facility or real property acquired or improved with state funds for a CCF unless the CSCD has held a public meeting before the action is taken. The public meeting shall be held at a site as close as practicable to the location at which the proposed action is to be taken. The meeting shall not be held on a Saturday, Sunday, or legal holiday. The meeting shall begin after 6:00 p.m. More than 30 days before the date of the meeting, the department that the facility is to serve, or a vendor proposing to operate a facility, at a minimum shall:

(A) Publish by advertisement a notice that is no less than three and one-half inches by five inches of the date, hour, place, and subject of the hearing as required in subsection (a)(4) of this rule in three consecutive issues of a newspaper of, or in newspapers that collectively have, general circulation in the county in which the proposed facility is to be located. The notice shall specifically state the address of the facility or property on which a proposed action is to be taken and provide a description of the proposed action.

(B) Mail a copy of the notice to each police chief, sheriff, city council member, mayor, county commissioner, county judge, school board member, state representative, and state senator who serves or represents the area.

(5) Maximum Resident Capacity and Facility Utilization. The maximum resident capacity of a CCF shall be defined as the total number of residents who can be housed at the facility at any given time as delineated by the operating agency in the most current community justice plan and approved by the TDCJ CJAD director. CCFs funded through TDCJ CJAD shall reach 90% capacity within the first six months of operation and maintain a minimum of 90% thereafter, using appropriate and eligible placements only. Any revisions to the maximum and minimum resident capacities for the CCF shall be subject to approval by the TDCJ CJAD through the community justice plan amendment process.

(6) Contract Residential Services. Business entities, agencies, or persons contracting with CSCDs or judicial districts for residential services shall comply with all applicable competitive bidding and other laws and regulations. CSCDs or judicial districts contracting with business entities, agencies, or persons for residential services shall comply with any applicable competitive bidding and other laws and regulations. The CSCD director shall monitor, audit, and inspect the performance and compliance of the service provider and vendor with the terms and conditions of the contract with the CSCD and with applicable laws and regulations.

(7) Mission Statement. The CSCD director and facility director shall prepare and maintain a mission statement that describes the general purposes and overall goals of the facility's programs.

(b) Personnel.

(1) Screening for Tuberculosis (TB) Infection. The CSCD director or facility director shall ensure that as soon as practicable but no later than seven calendar days of assuming any duties within a CCF, all staff undergo a screening for TB infection. Follow-up screening for TB infection shall be conducted on all staff, at a minimum, once every year from the anniversary date of the initial screening. The results of all screenings shall be maintained on file.

(2) Required Personnel.

(A) Each facility with an employment component shall have a designated employment coordinator whose duties and responsibilities include assisting residents in obtaining and maintaining employment. The employment coordinator shall be responsible for addressing other employment issues for residents such as résumé development, interviewing skills and techniques, and appropriate dress for job interviews.

(B) Every facility shall have a designated staff member whose duties and responsibilities include facilitating or ensuring the required cognitive and other facility programs are accomplished.

(3) Criminal Histories and Arrest Records. Prior to employment and on at least an annual or more frequent basis thereafter, criminal histories and arrest records shall be obtained from both the Texas Department of Public Safety (DPS) and National Crime Information Center on each of the CCF's employees, contract vendor staff, if applicable, and volunteers. This requirement shall apply to both vendor contracts and the CSCD operated CCFs. Upon verification that no new conviction(s) have occurred, an entry documenting such shall be made in the personnel file. The criminal history document and other arrest record documentation shall then be destroyed. Employees who have access to criminal histories must meet DPS criteria for accessing the Texas Law Enforcement Telecommunication System operated by the DPS or files containing a copy of an employee's or resident's criminal history.

(4) Residential Officer Certification. Governed by §163.33(f) of this title.

(5) Residential Personnel Training. Initial Training Requirements and Defensive Driving are governed by §163.33(j) of this title. Training Requirements for Monitoring Self-Administration of Medications are set forth in subsection (n)(10) of this rule.

(c) Building, Safety, Sanitation, and Health Codes.

(1) Compliance. The CSCD director and facility director shall ensure that the facility's construction, maintenance, and operations complies with all applicable state, federal, and local laws, building codes, and regulations related to safety, sanitation, and health. Records of compliance inspections, audits, or written reports by internal and external sources shall be kept on file for examination and review by the TDCJ CJAD and other governmental agencies and authorities from program inception forward. The CSCD director and facility director shall promptly notify the TDCJ CJAD in writing of any circumstances wherein the facility or its operations do not maintain such compliance.

(2) Water Supply. The CSCD director or designee shall ensure that the facility's potable water source and supply is sanitary and approved by an independent, qualified agency or individual in compliance with the applicable governmental laws and regulations.

(3) Sanitation. The facility shall conform to the applicable sanitation and health regulations and codes.

(4) Waste. The liquid and solid wastes related to the facility shall be collected, stored, and disposed of in accordance with a plan approved by the regulatory authority, agency, or department.

(5) Physical Plant. The facility's buildings, including the improvements, fixtures, electric and heating, and air conditioning, shall conform to all applicable building codes of federal, state, and local laws, ordinances, regulations, and minimum guidelines established by the TDCJ CJAD for physical plants and facilities housing residents.

(6) Fires. The facility, its furnishings, fire protection equipment, and alarm system shall comply with the regulations of the fire authority having jurisdiction. Fire drills are to be conducted at least quarterly. There shall be a written evacuation plan to be used in the event of a fire. The plan is to be certified by an independent qualified governmental agency or department or individual trained in the application of national and state fire safety codes. Such plan shall be reviewed annually, updated if necessary, and reissued to the local fire jurisdiction. The facility shall conduct fire inspections at least quarterly or at intervals approved by the fire authority having jurisdiction. Fire safety equipment located at the facility shall be tested as specified by the manufacturer or the fire authority, whichever is more frequent. An annual inspection of the facility shall be conducted by the fire authority having jurisdiction or other qualified person(s).

(7) Emergency Plan. There shall be a written emergency plan for the facility and its operations, which includes an evacuation plan, to be used in the event of a major flood, storm, or other emergencies. This plan shall be reviewed annually and updated, if necessary. Evacuation drills shall be conducted at least three times yearly. Each shift at least yearly shall conduct an evacuation drill when the majority of residents are present. All facility personnel shall be trained in the implementation of the written emergency plan. The evacuation plan shall specify preferred evacuation routes, subsequent dispositions, temporary housing of residents, and provisions for access to medical care or hospital transportation for injured residents and staff. The facility's emergency plan shall be distributed to local authorities such as law enforcement, state police, and civil defense to keep them informed of their roles in the event of an emergency. The emergency plan shall include the following:

(A) Location of buildings and room floor plans;

(B) Use of exit signs and directional arrows that are easily seen and read; and

(C) Location(s) of publicly posted plan.

(d) Separate Offender Housing. The CSCD director and facility director shall ensure that a facility that is part of or attached to a detention facility or a correctional institution shall house CCF residents separately from the offenders incarcerated in the detention facility. At no time shall the CCF residents be co-mingled with these incarcerated offenders.

(e) Program and Service Areas.

(1) Space and Furnishings. The facility shall have space and furnishings to accommodate activities such as group meetings, private counseling, classroom activities, visitation, and recreation.

(2) Housekeeping and Maintenance. The CSCD director and facility director shall ensure the facility is clean and in good repair, and housekeeping and maintenance plan is in effect.

(3) Other Physical Environment and Facilities Issues. In each facility:

(A) Space shall be provided for janitor closets which are equipped with cleaning implements;

(B) There shall be storage areas in the facility for clothing, bedding, and cleaning supplies;

(C) There shall be clean, usable bedding, linens, and towels for new residents with provision for exchange or laundering on at least a weekly basis;

(D) On an emergency or indigent basis, the facility shall provide personal hygiene articles;

(E) There shall be adequate control of vermin and pests;

(F) There shall be timely trash and garbage removal; and

(G) Sanitation and safety inspections of all internal and external areas and equipment shall be performed and documented on a routine basis to protect the health and safety of all residents, staff, and visitors.

(f) Supervision.

(1) Operations Manual. An operations manual shall be prepared for and used by each CCF which shall contain information and specify procedures and policies for resident census, contraband, supervision, physical plant inspection, and emergency procedures, including detailed implementation instructions. The operations manual shall be accessible to all employees and volunteers. The operations manual shall include, at a minimum, the matters set forth in the Guidelines for the Policies and Procedures of the TDCJ CJAD Funded Residential Facilities. The operations manual shall be submitted to the TDCJ CJAD director for review and approval. The manual shall be approved by the TDCJ CJAD director at least 60 days prior to the acceptance of any residents into the facility. The CSCD director and facility director shall ensure that the operations manual is reviewed at least every two years, and new or revised policies and procedures are made available, including all changes, to designated staff and volunteers prior to implementation. This manual shall be submitted to the TDCJ CJAD upon request or for auditing purposes.

(2) Staffing Availability. The CSCD director and facility director shall ensure that the facility has the staff needed to provide coverage of designated security posts, surveillance of residents, and to perform ancillary functions. The facility shall have at least one staff member on duty that is the same gender as the resident population.

(3) Activity Log. The CSCD director and facility director shall ensure that CCF staff maintain an activity log and prepare shift reports that record, at a minimum, emergency situations, unusual situations and incidents, and all absences of residents from a facility.

(4) Use of Force. The CSCD director and facility director shall ensure that a CCF has written policies, procedures, and practices that restrict the use of physical force to instances of self-protection, protection of residents or others, or prevention of property damage. In no event shall the use of physical force against a resident be justifiable as punishment. A written report shall be prepared following all uses of force, and promptly submitted to the CSCD director and facility director for review and follow-up. The application of restraining devices, aerosol sprays, and chemical agents shall only be accomplished by an individual who is properly trained in the use of such devices and only in an emergency situation for self-protection, protection of others, or other circumstances as described previously.

(5) Use of Firearms. The CSCD director and facility director shall ensure that the possession of firearms by staff is banned and the use of firearms is prohibited in or on facility property except in the execution of official duties by certified peace officers or other duly licensed law enforcement personnel.

(6) Access to Facility. The facility shall be secured to prevent unrestricted access by the general public or others without proper authorization.

(7) Control of Contraband and Searches. All facilities shall incorporate into the facility operations manual a list of authorized items offenders are allowed to possess while a resident of the facility. All incoming residents shall receive a copy of this list during the intake or orientation process, along with a written explanation of the provisions of Texas Penal Code §38.114, which states that any resident found to possess any item not provided by, or authorized by the facility director, or any item authorized or provided by the facility that has been altered to accommodate a use other than the originally intended use, may be charged with a Class C misdemeanor. Any employee or volunteer who provides contraband to a resident of a CCF may be charged with a Class B misdemeanor. There shall also be policies defining facility shakedowns, strip searches, and pat searches of residents to control contraband and provide for its disposal.

(8) Levels of Security. The CSCD director and facility director shall ensure that appropriate levels of security are maintained for the population served by the facility at all times. These levels of security shall create, at a minimum, a monitored and structured environment in which a resident's interior and exterior movements and activities can be supervised by specific destination and time. At the discretion of the facility director or designee, residents may be granted exterior movements. Exterior movements include, but are not limited to, employment programs, community service restitution, support and treatment programs, and programmatic incentives. The following minimum requirements shall be met for all exterior movements:

(A) The facility director or designee approves the exterior movement;

(B) A staff member orally advises the resident of the conditions and limitations of the exterior movement;

(C) The resident acknowledges in writing an understanding of the conditions and limitations of the exterior movement; and

(D) Exterior movements involving programmatic incentives may only be granted if the following additional requirements are met:

(i) The resident meets all established requirements for the programmatic incentive, as determined by the supervisor of the program, and submits a written request for the exterior movement;

(ii) The requested absence will not exceed 72 hours unless there are unusual circumstances;

(iii) The resident provides an itinerary for the absence including method of travel, departure and arrival times, and locations during the exterior movement;

(iv) The facility director or designee approves the itinerary and establishes the conditions of the exterior movement involving programmatic incentives; and

(v) A staff member shall make random announced or unannounced personal or telephone contacts with the resident to verify the location of the resident during the exterior movement.

(9) Emergency Furloughs. At the discretion of the facility director or designee, a resident may be granted an emergency furlough for the purpose of allowing a resident to attend a funeral, visit a critically ill person, obtain medical treatment, or attend to other exceptional business. Emergency furloughs may only be granted if the following conditions are met:

(A) The resident submits a written request for the emergency furlough;

(B) The facility director or designee verifies through an independent source including, but not limited to a physician, Red Cross representative, minister, rabbi, priest, or other spiritual leader that the presence of the resident is appropriate;

(C) The resident provides a proposed itinerary including method of travel, departure and arrival times, and locations during the emergency furlough;

(D) The requested absence shall not exceed 72 hours unless there are unusual circumstances;

(E) The court of original jurisdiction approves the travel if the resident will depart the state of Texas;

(F) The facility director or designee approves the itinerary and establishes the conditions of the emergency furlough; and

(G) The facility director or designee provides by email or fax the approved itinerary to the CSCD director and the court of the original or sending jurisdiction prior to the date that the emergency furlough is approved to begin.

(10) Supervision Process. Governed by §163.5(c) of this title.

(11) The CCF shall ensure that Spanish language assistance and the translation of selected documents are provided for Spanish-speaking residents who cannot speak or read English.

(g) Resident Abuse, Neglect, and Exploitation. The facility shall protect the residents from abuse, neglect, and exploitation. In accordance with the Prison Rape Elimination Act, 28 C.F.R. §115.31, all CCFs shall establish a zero tolerance standard for the incidence of sexual abuse and sexual harassment. Each facility shall make prevention of offender sexual abuse and sexual harassment a top priority. The CCFs shall have policies and procedures in accordance with national standards published by the attorney general of the United States. These policies and procedures shall include, but not be limited to the following:

(1) Detection, prevention, reduction, and punishment of offender sexual assault;

(2) Standardized definitions to record accurate data regarding the incidence of offender sexual assault; and

(3) A disciplinary process for facility staff who fail to take appropriate action to detect, prevent, and reduce sexual assaults, to punish residents guilty of sexual assault, and to protect the Eighth Amendment rights of all facility residents.

(h) Rules and Discipline. There shall be documentation of program rule violations and the disciplinary process.

(1) Rules of Conduct. All incoming residents and staff shall receive written rules of conduct which specify acts prohibited within the facility and penalties that can be imposed for various degrees of violation.

(2) Limitations of Corrective Actions. Specific limits on corrective actions and summary punishment shall be established and strictly adhered to in an effort to reduce the potential of staff participating in abusive behavior towards participants. Limits shall include:

(A) No physical contact by staff shall be made on a resident;

(B) No profane, sexual, or racial comments shall be directed at residents by staff;

(C) Residents shall not be used to impose corrective actions on other residents;

(D) The severity of the corrective action shall be commensurate with the severity of the infraction; and

(E) The duration of corrective action shall be limited to the minimum time necessary to achieve effectiveness.

(3) Grievance Procedure. A grievance procedure shall be available to all residents in a CCF. The grievance procedure shall include at least one level of appeal and shall be evaluated at least annually to determine its efficiency and effectiveness.

(4) Spanish translations of the disciplinary rules and procedures shall be provided for Spanish-speaking residents who cannot speak or read English.

(i) Incident Notification. Within 24 hours of occurrence, the CSCD director and facility director shall notify and report by telephone or fax all serious or unusual events pertaining to the facility's operations and staff to the district judge, or if applicable, the judge designated to perform administrative duties for the district courts trying criminal cases, the TDCJ Emergency Action Center (EAC) in Huntsville, Texas (phone number (936) 437-6600; fax number (936) 437-8996), and if applicable, the CSCD director of the original or sending jurisdiction if the incident involves a resident from that sending jurisdiction. The TDCJ EAC shall notify the TDCJ CJAD director and appropriate CJAD management staff. Such serious and unusual events for this purpose shall include, but are not limited to, the following:

(1) The death of a resident or staff member while at the facility;

(2) Any incident which results in life threatening or serious bodily injury to a resident or staff member while at the facility or on assignment, including emergency furloughs or programmatic incentives, away from the facility;

(3) Major disturbance or riot at the facility or in its vicinity; and

(4) Any incident involving serious misconduct by facility staff, which may result in the filing of criminal charges or civil action;

(5) Any incidence of absconding by a resident convicted of an offense as identified in Title 5 of the Texas Penal Code (Title 5) and placed in the facility for such offense; and

(6) Any incidence of absconding by a resident who is suspected of committing a felony offense during the course of absconding from the facility or within 24 hours after leaving the facility.

(j) Residents' Rights. Residents shall be granted access to courts and any attorney licensed in the United States or a legal aid society (an organization providing legal services to residents or other persons) contacting the resident in order to provide legal services. Such contacts include, but are not limited to: confidential telephone communications, uncensored correspondence, and confidential visits.

(k) Resident Eligibility. A CSCD or other governmental entity that operates a residential facility, contracts for the operation of a residential facility, or contracts for beds or services shall define a specific target population of medium to high risk/needs offenders to be served. Placement of offenders in a CCF shall only be by an order of the court, which may include a pretrial agreement signed by the judge presiding over an established drug court. Applicable screening shall be conducted to include screening for substance abuse, medical and mental health issues, and minimum eligibility criteria as outlined in this rule.

(1) CCFs shall accept only those offenders who meet the target population criteria as defined by the facility and are physically and mentally capable of participating in any program offered at the facility, if participation in the program is required of all residents in the facility. Exceptions to this requirement:

(A) Placement is prohibited by statute;

(B) The offender matches the profile of offenders historically committed to county jail or prison from the jurisdiction; or the offender has high risk/needs, who, if supervised at a lower supervision level would have an increased likelihood of violating the conditions of community supervision;

(C) The local jurisdiction may house offenders convicted under Title 5 and in accordance with statute, in the CCF if Title 5 offenders are included in the facility's program proposal within the community justice plan approved by the local judiciary. In currently operating facilities where the jurisdiction desires to add Title 5 offenders to the target population, a public meeting shall be held, in accordance with the law and TDCJ CJAD standards and policy, to advise the public of the types of offenders and offenses who will potentially be placed in the facility. Public support shall be considered by the TDCJ CJAD for final approval of the change in offender population to be targeted. If a jurisdiction has documentation that this requirement was previously met, it can provide that documentation to the TDCJ CJAD for review and possible exemption from having an additional public meeting. If a facility is approved to house Title 5 offenders, the CSCD director and the facility director shall comply with all applicable provisions contained in Texas Government Code §76.016, Victim Notification; Texas Code of Criminal Procedure art. 56.01 - .93, Rights of Crime Victims; and Texas Code of Criminal Procedure art. 42.21, Notice of Release of Family Violence Offenders; and

(D) Prior to or within 30 days after admission to the facility, the offender shall undergo a screening process to include a substance abuse screening instrument to determine the offender's appropriateness for placement. The process shall be documented and maintained in the supervision case file. Should the offender not meet the facility defined eligibility criteria, the offender may be referred back to the court of original jurisdiction.

(2) Courtesy Supervision. CCFs shall, on a space available basis, accept eligible adult offenders needing residential services on courtesy supervision from other jurisdictions. CSCDs that manage CCFs are responsible for the direct supervision of all residents in the CCF while in residential placement.

(l) Denying Admission or Continued Placement. If an offender is placed into a CCF, and by statute or standard is an inappropriate placement, or does not meet eligibility criteria of the TDCJ CJAD approved facility, the CSCD or facility director shall notify, in writing, the court of original jurisdiction. If a CCF facility has reached capacity at the time of the eligible offender's placement to that facility, such offender may be placed on a waiting list for that facility and returned to the court of original jurisdiction for further instructions or an alternative sanction.

(m) Food Service. The food preparation and dining area shall provide space for meal service based on the population size and need.

(1) Dietary Allowances. Meals shall be approved and reviewed annually by a registered dietician, licensed nutritionist, registered nurse with a minimum of a Bachelor of Science degree in nursing, physician assistant, or physician to ensure that the meals meet the nationally recommended allowances for basic nutrition.

(2) Special Diets. Each facility shall provide special diets as prescribed by appropriate medical or dental personnel.

(3) Food Service Management. Food service operations shall be supervised by a staff member who is experienced in institutional food preparation or mass food management. Food services staff, including residents assigned to work in the facility kitchen, shall meet all requirements established by local health authorities.

(4) Exclusion as Discipline. The use of food as a disciplinary measure is prohibited.

(5) Meal Requirements. The CSCD director or facility director shall ensure that at least three meals, including two hot meals, are provided during each 24-hour period. Variations may be allowed based on weekend and holiday food service demands, or in the event of emergency or security situations, provided basic nutritional goals are met.

(n) Health Care.

(1) Access to Care.

(A) Residents shall have unimpeded access to health care and to a system for processing complaints regarding health care.

(B) The facility shall have a designated health authority with responsibility for health care pursuant to a written agreement, contract, or job description. The health authority may be a physician, health administrator, or health agency. In the event that the designated health authority is a free community health clinic, one which provides services to everyone in the community regardless of ability to pay, then the CCF is not required to enter into a written contract or agreement. A copy of the mission statement of the free community health clinic and a copy of the criteria for admission shall be on file in lieu of a contract between the two agencies.

(C) Each CCF shall have a policy defining the level, if any, of financial responsibility to be incurred by the resident who receives the medical or dental services.

(2) Emergency Health Care.

(A) Twenty-four hour emergency health care shall be provided for residents, to include arrangements for the following:

(i) On site emergency first aid and crisis intervention;

(ii) Emergency evacuation of the resident from the facility;

(iii) Use of an emergency vehicle;

(iv) Use of one or more designated hospital emergency rooms or other appropriate health facilities;

(v) Emergency on-call services from a physician, advanced practice nurse, physician assistant, dentist, and a mental health professional when the emergency health facility is not located in a nearby community; and

(vi) Security procedures providing for the immediate transfer of residents, when appropriate.

(B) A training program for direct care personnel shall be established by a recognized health authority in cooperation with the facility director that includes the following:

(i) Signs, symptoms, and action required in potential emergency situations;

(ii) Administration of first aid and cardiopulmonary resuscitation;

(iii) Methods of obtaining assistance;

(iv) Signs and symptoms of mental illness, retardation, and chemical dependency; and

(v) Procedures for patient transfers to appropriate medical facilities or health care providers.

(C) First aid kits shall be available in designated areas of the facility. Contents and locations shall be approved by the health authority.

(3) Health Screening and Medical Examinations. Medical, dental, and mental health screening shall be performed by qualified health care personnel on all offenders within 10 working days prior to or after admission to the facility. The purpose of the screening is to determine if the offender has any disease, illness, or condition that precludes admission. The health screening shall include the following:

(A) Questionnaires for health screening shall be established to document inquiries into and observations of the following:

(i) Current illness and health problems, including sexually transmitted and other infectious diseases;

(ii) Dental problems;

(iii) Mental health problems, including suicide attempts or ideation;

(iv) Use of alcohol and other drugs, which includes types of drugs used, mode of use, amounts used, frequency of use, date or time of last use, and a history of problems that may have occurred after ceasing use, for example, convulsions; and

(v) Other health problems designated by the responsible health authority.

(B) Observation by qualified health care personnel of:

(i) Behavior, which includes state of consciousness, mental status, appearance, conduct, tremor, and sweating;

(ii) Body deformities, ease of movement, and so forth; and

(iii) Conditions of skin, including trauma markings, bruises, lesions, jaundice, rashes, infestations, and needle marks or other indications of drug abuse.

(C) Medical Examinations.

(i) A new resident admitted to the facility who was not transferred from a jail or other correctional facility shall have a medical history and physical examination completed within 10 working days prior to or after admission to the facility.

(ii) TB screening of residents shall be completed within seven calendar days of admission into the residential facility and repeated annually thereafter. If a resident was confined in a jail or other correctional facility immediately prior to admission to a CCF, a TB screening test that was completed no more than 30 days prior to transfer to a residential facility may be accepted, provided that a TB questionnaire is completed and filed with the TB screening test results.

(iii) Medical examinations shall be conducted for any employee or resident suspected of having a communicable disease.

(4) Serious and Infectious Diseases.

(A) The facility shall provide for the management of serious and infectious diseases.

(B) The CCFs shall have policies and procedures to direct actions to be taken by employees concerning residents who have been diagnosed with human immunodeficiency virus (HIV), including, at a minimum, the following:

(i) When and where residents shall be tested;

(ii) Appropriate safeguards for staff and residents;

(iii) Staff and resident training;

(iv) Issues of confidentiality; and

(v) Counseling and support services.

(5) Dental Care. Access to dental care shall be made available to each resident.

(6) Medications--General Guidelines.

(A) Staff who dispense medication shall have the proper training and credentials. Staff who supervise self-administration of medication shall be appropriately trained to perform the task.

(B) Policy and procedure shall direct the possession and use of controlled substances, prescribed medications, supplies, and over-the-counter (OTC) drugs. Prescribed medications shall be dispensed according to the directions of the prescribing physician, advanced practice nurse, or physician assistant.

(C) Each residential facility shall have a written policy in place that sets forth required procedural guidelines for the administration, documentation, storage, management, accountability of all resident medication, inventory, disposal of medications, handling medication errors, and adverse reactions.

(D) If medications are distributed by facility staff, records shall be maintained and audited monthly and shall include, but not be limited to the date, time, name of the resident receiving the medication, and the name of the staff distributing the medication.

(E) Each facility shall ensure that the phone number of a pharmacy and a comprehensive drug reference source is readily available to the staff.

(7) Medication Storage.

(A) Prescription and OTC medications shall be kept in locked storage and accessible only by staff who are authorized to provide medication. Syringes, needles, and other medical supplies shall also be kept in locked storage.

(B) All controlled/scheduled medications shall be stored under double lock and key.

(C) Each facility shall ensure that all medications, syringes, and needles are stored in the original container.

(D) Medications labeled as internal and external use only shall not be stored together in the same medication box or medication drawer.

(E) Sample prescription medications provided by physicians shall be stored with proper labeling information that includes the name of the medication; name of the prescribing physician, advanced practice nurse, or physician assistant; date prescribed; and dosage instructions.

(F) Medications that require refrigeration shall be stored in a refrigerator designated for medications only. A thermometer shall be maintained inside the refrigerator with the temperature checked and recorded daily on a temperature log.

(G) The facility shall have a written policy approved by the local medical authority that states the acceptable temperature range for the medication refrigerator, and a written policy for what actions shall be taken by staff in the event the refrigerator temperature is above or below the approved temperature range.

(H) Medications that are discontinued, have expired dates, or are no longer in use shall be stored in a separate locked container or drawer until destroyed.

(I) Facilities that allow residents to keep medications in the resident's possession shall have written guidelines specific for keep-on-person medications. Staff shall ensure that authorized residents keep medication on their person or safely stored and inaccessible to other residents.

(8) Medication Inventory and Disposal.

(A) Facility staff shall conduct an inventory count of all controlled/scheduled medications daily, at a minimum, once per 24-hour period. The count shall be conducted and witnessed by one other staff member. Documentation of inventory counts shall be maintained for a minimum of three years.

(B) The facility shall conduct a monthly inventory of all prescription and OTC drugs provided to or purchased by the resident. The monthly audit shall be conducted by a staff member who is not responsible for conducting the daily inventory counts.

(C) A monthly audit shall be conducted of all medication administration records to verify the accuracy of recorded information. The monthly audit of medication administration records shall be conducted by a staff member who is not responsible for the documentation of medication administration records.

(D) When a discrepancy is noted between the medication administration record and the monthly inventory count, documentation explaining the reason for the discrepancy and action taken to correct it shall be recorded. In the event an inventory count reveals unaccounted for controlled/scheduled medication, an investigation shall be conducted and a summary report written detailing the steps taken to resolve the matter. Until the discrepancy is resolved, an inventory count shall be conducted three times daily, after each shift. The summary report shall be maintained for a minimum of three years. If misapplication, misuse, or misappropriation of controlled/scheduled medication leads to an investigation by law enforcement, such information shall be reported pursuant to subsection (i) of this rule.

(E) Discontinued and outdated medications shall be removed from the current medication storage, stored in a separate locked container, and disposed of within 30 days. The drugs designated for disposal shall be recorded on a drug disposal form.

(F) Methods used for drug disposal shall prevent medication from being retrieved, salvaged, or used in any way. The disposal of drugs shall be conducted, documented, and the process witnessed by one other staff member. The documentation shall include:

(i) Name of the resident and date of disposal;

(ii) Name and strength of the medication;

(iii) Prescription number, sample, or OTC lot numbers;

(iv) Amount disposed, reason for disposal, and the method of disposal; and

(v) Signatures of the two staff members who disposed of the drug and witnessed the disposal.

(9) Administration of Medication for Non-Medical Model Facilities.

(A) Prescription medications shall be dispensed only by licensed nurses or other staff who are trained and have the appropriate documented medication certification to dispense medications while under the supervision of a physician or registered nurse. Facilities that do not have licensed nurses or other credentialed staff to dispense medications, non-medical model facilities, shall implement the practice of self-administration of medications.

(B) If medications are dispensed through the practice of self-administration in a non-medical model program, staff trained by a qualified health professional to supervise residents in the self-administration of medications shall monitor the residents during the self-administration process.

(C) Each dose of prescription medication received by the resident shall be documented on the prescription medication administration record and maintained in the resident's medical file. The prescription medication record shall include:

(i) Name of the resident receiving the medication;

(ii) Drug allergies or the absence of known drug allergies;

(iii) Name, strength of medication, and route of administration;

(iv) Instructions for taking the medication, the amount taken, and the route of administration;

(v) Date and time the medication was provided;

(vi) Prescription number, or lot number for sample drugs, and the initial amount of medication received;

(vii) Prescribing physician, advanced practice nurse or physician assistant, and the name of the pharmacy;

(viii) Signature of the resident receiving the medication and the staff member supervising the self-administration of medication;

(ix) The remaining amount of medication after each dose dispensed; and

(x) Comment section for recording a variance, discrepancy, or change.

(D) Each dose of OTC medication received by the resident shall be documented on the OTC medication administration record and maintained in the resident's medical file. The OTC drugs purchased by the resident or supplied for the resident in quantities larger than single dose packages shall be recorded on the OTC drug record. The OTC drug record shall include:

(i) The resident's name;

(ii) The name and strength of the medication dispensed;

(iii) Drug allergies or the absence of known drug allergies;

(iv) The dosage instructions and route of administration;

(v) The initial amount received, OTC lot number, and the expiration date;

(vi) The date and time the medication was dispensed;

(vii) The amount dispensed and the ending count after each dose;

(viii) Comment section for recording reason for OTC drug or other notations; and

(ix) The signature of the resident and the employee who supervised each dose dispensed.

(E) Facility Stock OTC Drugs. Multiple OTC stock drugs supplied in single dose packaging may be recorded on the same form. The medication drug record for facility stock OTC drugs shall include:

(i) The resident's name;

(ii) The name, strength, and route of administration;

(iii) Drug allergies or the absence of known drug allergies;

(iv) The date, time, amount dispensed, and the lot number on the container;

(v) Comment section to record the reason the OTC drug was requested; and

(vi) The signature of the resident and the employee who supervised each dose dispensed.

(10) Training for Monitoring Self-Administration of Medications. All residential employees responsible for supervising residents in self-administration of medication, who do not have credentials to dispense medication, shall complete required training before performing this task.

(A) The initial training for new employees shall be four hours in length.

(B) Employees shall complete a minimum of two hours of review training annually thereafter.

(C) The training shall be provided by a physician, pharmacist, physician assistant, or registered nurse before supervising self-administration of medications. A licensed vocational nurse or paramedic, under supervision, may teach the course from an established curriculum. Topics to be covered shall include:

(i) Prescription labels;

(ii) Medical abbreviations;

(iii) Routes of administration;

(iv) Use of drug reference materials;

(v) Monitoring and observing insulin preparation and administration;

(vi) Storage, maintenance, handling, and destruction of medication;

(vii) Transferring information from prescription labels to the medication administration record and documentation requirements, including sample medications; and

(viii) Procedures for medication errors, adverse reactions, and side effects.

(11) Female Residents. If female residents are housed, access to pregnancy management services shall be available.

(12) Mental Health. Access to mental health services shall be available to residents.

(13) Suicide Prevention. Each facility shall have a written suicide prevention and intervention program reviewed and approved by a qualified medical or mental health professional. All staff with resident supervision responsibilities shall be trained in the implementation of the suicide prevention program.

(14) Personnel.

(A) If treatment is provided to residents by health care personnel other than a physician, psychiatrist, dentist, psychologist, optometrist, podiatrist, or other independent provider, such treatment shall be performed pursuant to written standing or direct orders by personnel authorized by law to give such orders.

(B) If the facility provides medical treatment, personnel who provide health care services to residents shall be qualified and appropriately licensed. Verification of current credentials and job descriptions shall be on file in the facility. Appropriate state and federal licensure, certification or registration requirements, and restrictions apply.

(15) Informed Consent.

(A) If the facility provides medical treatment, the facility shall ensure residents are provided information to make medical decisions with informed consent. All informed consent standards in the jurisdiction shall be observed and documented for resident care.

(B) If the facility provides medical treatment and a resident makes an informed decision to refuse any medical procedure or treatment, the facility shall ensure that written documentation of the resident's refusal is maintained in the resident's medical record.

(16) Participation in Research. Residents shall not participate in medical, pharmaceutical, or cosmetic experiments. This does not preclude individual treatment of a resident based on resident's need for a specific medical procedure that is not generally available.

(17) Notification. Individuals designated by the resident shall be notified in case of critical illness or injury.

(18) Health Records. If medical treatment is provided by the facility:

(A) Accurate health records for residents shall be maintained separately and confidentially;

(B) The method of recording entries in the records, the form and format of the records, and the procedures for maintenance and safekeeping shall be approved by the health authority; and

(C) For the residents being transferred to other facilities, summaries or copies of the medical history record shall be forwarded to the receiving facility prior to or at arrival.

(o) Discharge From Residential Facilities.

(1) Victim Notification. The CSCD director and facility director shall ensure there are procedures, policies, and practices that comply with Texas Government Code §76.016, Texas Code of Criminal Procedure art. 42.21(a) and other applicable laws as to the notifications made to certain crime victims of offenders who are residents in its facilities or subject to its programs.

(2) Discharge. Discharge from residential facilities shall be based on the following criteria:

(A) The resident has made sufficient progress towards meeting the objectives of the supervision plan and program requirements;

(B) The resident has satisfied a sentence of confinement;

(C) The resident has satisfied a period of placement as a condition of community supervision or satisfied the conditions of a pretrial agreement signed by a judge presiding over an established drug court;

(D) The resident has demonstrated non-compliance with program criteria or court order;

(E) The resident manifests a non-emergency medical problem that prohibits participation in or completion of the residential program requirements;

(F) The resident displays symptoms of a psychological disorder that prohibits participation in or completion of the residential program requirements; or

(G) The resident is identified as inappropriate or ineligible for participation in the residential program as defined by facility eligibility criteria, statute, or standard.

(3) Discharge Report. The CSCD director and facility director shall ensure a report is prepared at the termination of program participation that reviews the resident's performance. A copy of the report shall be provided to the receiving CSCD community supervision officer.

(p) Basic Services and Programs.

(1) Each facility shall, at a minimum, provide programs in the following areas which shall include, but not be limited to:

(A) Education programs;

(B) Rehabilitation programs based on the mission of the facility;

(C) Community service restitution or work detail;

(D) Recreational programs; and

(E) Cognitive based programs.

(2) Facilities serving other jurisdictions shall have a procedure in place designed to assist the resident in obtaining employment in the jurisdiction to which the resident will be released. At a minimum, an aftercare or supervision plan shall be provided to the original jurisdiction and shall outline aftercare or supervision strategies best designed to sustain progress.

(3) Each facility shall have a family support program designed to educate family members in the goals of the facility and resident, as well as to incorporate family assistance during and after residency.

(4) Each facility incorporating an employment component shall provide an initial programming phase of no less than 30 days prior to work release. A longer period of programming shall be provided depending upon documented risk/needs assessment and program progress.

(q) Mail, Telephone, and Visitation. The CSCD director and facility director shall have written policies, procedures, and practices which govern the facility's mail, telephone, and visitation privileges for residents, including mail inspection, public phone use, and routine and special visits. The policies shall address compelling circumstances in which a resident's mail both incoming and outgoing may be opened, but not read, to inspect for contraband.

(r) Religious Programs.

(1) The CSCD director and facility director shall have written policies that govern religious programs for residents. The policies, procedures, and practices shall provide that residents have the opportunity to voluntarily practice the requirements of a resident's religious faith, have access to worship and religious services and the use or contact with community religious resources, when appropriate.

(2) Under Texas Civil Practice & Remedies Code §§110.001 - .012, a CSCD or CCF may not substantially burden a resident's free exercise of religion except with the least restrictive measures in furtherance of a compelling interest. Pursuant to Texas Government Code §76.018, there is a presumption that a policy or practice that applies to a resident in the custody of a CCF is in furtherance of a compelling governmental interest and is the least restrictive means of furthering that interest. The presumption may be rebutted with evidence provided by the resident.

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

Filed with the Office of the Secretary of State on August 22, 2016.

TRD-201604285
Sharon Howell
General Counsel
Texas Department of Criminal Justice
Effective date: September 11, 2016
Proposal publication date: July 8, 2016
For further information, please call: (936) 437-6700