State Auditor's Office

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An Audit Report on

Inspections of Compounding Pharmacies at the Board of Pharmacy

August 2015

Report No. 15-039

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Overall Conclusion

The Board of Pharmacy (Board) has designed and implemented inspection processes to help ensure that it conducts inspections of compounding pharmacies in accordance with applicable statutes and administrative rules. In addition, the Board ensures that its inspectors substantially follow those processes.

However, the Board should fully implement and document those processes and improve its monitoring of contractors that conduct inspections of out-of-state compounding pharmacies.

As of February 28, 2015, 7,899 pharmacy facilities were licensed by the state of Texas, and 934 of those were licensed as pharmacies that compound sterile preparations. While there is no separate license designation for pharmacies that compound only preparations that do not require sterility, 2,925 pharmacies self-reported that they were that type of pharmacy (see text box for more information about compounding pharmacies).

Background Information

Through its Enforcement Division, the Board of Pharmacy (Board) is responsible for conducting inspections of pharmacies for compliance with laws and rules. The Board has 12 inspector positions to inspect pharmacies across 9 regions of the state (see Appendix 3).

The Board licenses 11 types of pharmacy facilities, 3 of which are designated for compounding sterile products (see Appendix 2).

Source: The Board.

Compounding Pharmacies

Compounding is a practice in which a licensed pharmacist, a licensed physician, or in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. There are two types of compounding pharmacies: pharmacies that compound sterile preparations and pharmacies that compound only preparations that do not require sterility. Sterile compounding techniques are used for medications such as injections and eye drops that could cause illness or infection if contaminated.

Sources: U.S. Food and Drug Administration Web site and the Board.

The Board has an adequate process for inspecting pharmacies that compound sterile preparations within required time frames; however, it should document that process.

As of December 10, 2013, the Texas Occupations Code and the Texas Administrative Code required the Board to inspect pharmacies that compound sterile preparations prior to initial licensure and upon license renewal if an inspection had not been conducted within the renewal period, which is usually two years. The Board has developed adequate processes to monitor the timeliness of inspections for new licenses and license renewals for pharmacies that compound sterile preparations, and it has generally inspected pharmacies that compound sterile preparations within the required time frames. However, the Board has not documented its processes for ensuring that pharmacies that compound sterile preparations are inspected within the required time frames.

This audit was conducted in accordance with Texas Government Code, Section 321.0132.

For more information regarding this report, please contact James Timberlake, Audit Manager, or John Keel, State Auditor, at (512) 936-9500.

The Board has not established formal goals for the frequency of inspections of pharmacies that compound only preparations not requiring sterility, and it has not developed an adequate process to ensure that it meets its goals for inspecting those pharmacies.

In addition to inspecting sterile compounding pharmacies, the Board also conducts inspections of pharmacies that compound only preparations not requiring sterility. Unlike for pharmacies that have a license for compounding sterile components, there are no statutory requirements, administrative rules, or formal Board policies that specify how often other compounding pharmacies must be inspected. The Board has set an informal, internal goal of inspecting pharmacies that compound preparations not requiring sterility once every three years; however, it has not met that goal. As of March 6, 2015, the Board had inspected 1,864 (64 percent) of the 2,925 reported pharmacies that compound preparations not requiring sterility within the previous three years, and it had inspected 2,265 (77 percent) within the previous 5 years.

The Board has documented processes and forms to help ensure that inspections address all significant federal and state standards; however, the Board has not fully implemented those processes.

The Board's documented policies and procedures for inspections of compounding pharmacies address all significant requirements in federal standards, state statutes, and the Texas Administrative Code. Inspectors consistently used standard forms the Board developed while conducting inspections of compounding pharmacies. However, the Board does not require inspectors to complete and submit a separate inspection form that it developed that is specific to inspections of pharmacies that compound sterile preparations. Without requiring inspectors to document inspections on that form, the Board lacks assurance that its inspectors address all required areas during inspections of pharmacies that compound sterile preparations.

The Board has a documented process to monitor violations and track corrective action plans, and it should report violations to the U.S. Department of Health and Human Services after a reporting mechanism is established.

The Board has a documented process to monitor violations identified during inspections of compounding pharmacies. The inspector initially classifies violations using three categories: needs improvement, warning notice, and refer to legal. The Board is also required to report violations identified during those inspections to the U.S. Secretary of Health and Human Services. However, the U.S. Department of Health and Human Services has not yet implemented a reporting process.

The Board has a process to help ensure that inspections of out-of-state pharmacies that compound sterile preparations are completed within required time frames; however, it should improve its monitoring of the vendors that conduct those inspections.

The Board contracts with three vendors to inspect pharmacies that compound sterile preparations outside of Texas. As of February 28, 2015, 164 pharmacies compounded sterile preparations outside of Texas and were licensed through the Board. The Board implemented a monthly reporting process outlined in the contracts with its vendors to monitor the vendors' inspection performance, but it did not consistently follow that process.

The Board has controls to help ensure that its inspection data is reliable; however, it should strengthen its data entry reviews and restrict the use of generic user accounts.

The Board has information technology controls to help ensure that inspection data in its licensing and inspection system, Versa, is reliable. However, its reviews of inspection data entered into Versa are informal and not documented. The Board also should restrict the use of generic user accounts and either assign each user an individual account or limit the access of all generic user accounts to read-only.

Auditors communicated other, less significant issues related to the Board's inspection processes to Board management separately in writing.

Summary of Management's Response

The Board agreed with the recommendations in this report. The Board's detailed management responses are presented immediately following each set of recommendations in the Detailed Results section of this report.

Summary of Information Technology Review

Auditors reviewed controls related to the Board's licensing and inspection system, Versa. That work included reviewing user access and password requirements and conducting tests to determine data completeness. The Board has adequate controls over its information technology system to help ensure that its inspection and licensing data is reliable.

Summary of Objective, Scope, and Methodology

The objective of this audit was to determine whether the Board has designed and implemented effective processes and related controls to help ensure that it conducts inspections of compounding pharmacies in accordance with applicable state and federal statutes, administrative rules, and Board policies and procedures.

The scope of this audit covered the time period from September 1, 2009, through February 28, 2015, and included inspections of compounding pharmacies in Texas, and inspections of compounding pharmacies outside of Texas that ship medications requiring sterile preparation into Texas.

The audit methodology included gaining an understanding of and evaluating controls over the Board's inspection process for compounding pharmacies, including the qualifications and monitoring of inspection staff and vendors, the documentation of inspection results, the follow-up the Board performs when violations are identified, and the maintenance of accurate data in the Board's information system. Auditors interviewed Board personnel, attended Board meetings, observed inspections, analyzed data, performed testing, and evaluated the results.

Auditors assessed the reliability of the data used for purposes of this audit by (1) determining population completeness and reasonableness; (2) reviewing queries used to generate data; (3) interviewing Board employees and information technology administrators knowledgeable about the data and systems; and (4) reviewing source documentation for inspection data. Auditors determined that the pharmacy inspection and licensing data was sufficiently reliable for the purposes of this audit.

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Detailed Results

Chapter 1

The Board Designed and Implemented Processes for Conducting Inspections of Compounding Pharmacies in Accordance With Applicable Statutes and Administrative Rules; However, It Should Fully Implement and Document Those Processes

The Board of Pharmacy (Board) has processes to help ensure that it inspects pharmacies that compound sterile preparations within the required time frames; however, that process is not formally documented (see text box for information about license types). In addition, the Board has not established formal goals for the frequency of inspections of pharmacies that compound only components that do not require sterile preparation, and it lacks a documented process for selecting those compounding pharmacies for inspection.

Types of Pharmacy Licenses

The Board currently licenses 11 types of pharmacy facilities, 3 of which are designated for pharmacies involved in compounding sterile preparations. Community, institutional, and out-of-state pharmacies engaged in the compounding of sterile preparations are required to obtain the appropriate license to dispense compounded sterile preparations in Texas. There is no license category specific to pharmacies that compound only components that are not required to be prepared under sterile conditions. See Appendix 2 for the types of licenses and number of licensed pharmacies.

Source: The Board.

While the Board has documented processes and forms to help ensure that inspections address all significant federal and state standards, it has not fully implemented those processes. The Board also has a documented process to monitor violations and track the pharmacies' corrective action plans.

Chapter 1-A

The Board Has an Adequate Process to Help Ensure That It Inspects Pharmacies That Compound Sterile Preparations Within Required Time Frames; However It Should Document That Process

The Board has generally inspected pharmacies that compound sterile preparations within required time frames. The Texas Occupations Code and the Texas Administrative Code require the Board to inspect pharmacies that compound sterile preparations prior to initial licensure and prior to license renewal, which usually occurs every two years. Those requirements became effective December 10, 2013. As of February 28, 2015, the Board had licensed 934 pharmacies to compound sterile preparations, 164 of which were located outside of Texas. Of the 770 licensed pharmacies compounding sterile preparations that are located in Texas, 541 renewed their licenses between December 10, 2013, and February 28, 2015. The Board conducted inspections of 531 (98 percent) of those pharmacies as required. (See Chapter 2 for information about inspections of the out-of-state pharmacies that compound sterile preparations.)

The Board has documented policies and procedures to help ensure that new pharmacies, including those that compound sterile preparations, are inspected prior to initial licensure. Pharmacies that apply for a new license must submit

a preinspection checklist form as a part of their applications. After the Board receives that checklist form, it determines whether an applicant meets all preinspection criteria and, if so, it schedules an inspection within 30 days. Before the Board issues a pharmacy license, pharmacies must have a preinspection performed and, if applicable, must correct any deficiencies identified during the inspection.

In addition, the Board has adequate processes to help ensure that pharmacies that compound sterile preparations and that are due for a license renewal are inspected within the required time frame; however, the Board has not documented those processes in its policies and procedures. Significant steps in those processes include:

- When a pharmacy that compounds sterile preparations submits an application for license renewal, the Board's Licensing Division reviews the date of last inspection prior to renewing the license to ensure that the pharmacy was inspected within the pharmacy's last renewal period.
- The Board runs a monthly report that identifies the pharmacies that compound sterile preparations that are due for license renewal within the next six months. The Board's enforcement director then reviews that report to identify pharmacies that have not been inspected during the last renewal period.
- The enforcement director then forwards the list of pharmacies that need inspection to the inspectors in each region. Those inspectors then prioritize their inspection schedules to ensure that each compounding pharmacy on that list receives an inspection before its license expires.
- The enforcement director verifies that inspectors complete the inspections as required. The Board also requires inspectors from each region to submit weekly productivity reports, which Board staff review.

Outsourcing Facilities

An "outsourcing facility" is a facility at one geographic location or address that (1) is engaged in the compounding of sterile drugs; (2) has elected to register as an outsourcing facility; and (3) complies with all of the requirements of Section 503(B) of the federal Food, Drug, and Cosmetic Act.

Sources: Federal Food, Drug, and Cosmetic Act and U.S. Food and Drug Administration Web site.

In addition, the Board provided adequate oversight of the outsourcing facilities in Texas that compound sterile preparations in bulk to sell to other pharmacies (see text box for information on outsourcing facilities). As of February 2015, there were four outsourcing facilities in Texas registered with the U.S. Food and Drug Administration (FDA) and licensed through the Board. Rather than relying on FDA inspections of those facilities, the Board performs inspections of those facilities itself. Between February 2011 and February 2015, the Board conducted a total of 13 inspections of those 4 outsourcing facilities.

Recommendation

The Board should document its processes for ensuring that pharmacies that compound sterile preparations and request a license are inspected within required time frames.

Management's Response

The Texas State Board of Pharmacy agrees with the recommendation and we are working on documenting the processes. We anticipate having this work completed by November 30, 2015.

Person Responsible for Implementation: Director of Enforcement

Deadline for completion: November 30, 2015

Chapter 1-B

The Board Has Not Established Formal Goals for the Frequency of Inspections of Pharmacies That Compound Only Preparations Not Requiring Sterility, and It Has Not Developed an Adequate Process to Ensure That It Meets Its Goals for Inspecting Those Pharmacies

The Board does not have formal policies that establish the frequency of inspections of pharmacies that compound only preparations that do not require sterile components. Unlike pharmacies that have a license for compounding sterile components, there are no statutory requirements or administrative rules that specify how often other compounding pharmacies must be inspected. However, according to the National State Auditors Association, it is a best practice for a regulatory agency, such as the Board, to establish a schedule for the periodic inspection of all regulated entities, which include all types of compounding pharmacies.

While the Board has established an informal, internal goal of inspecting compounding pharmacies that do not require sterility at least once every three years, it has not met that goal. As of March 6, 2015, 2,925 pharmacies self-reported to the Board that they compounded only preparations that did not require sterile components. The Board had inspected 1,864 (64 percent) of those 2,925 pharmacies within the previous 3 years, and it had inspected 2,265 (77 percent) within the previous 5 years.

In addition, the Board has not developed an adequate inspection selection process for pharmacies that compound only preparations not requiring sterility to help ensure that it meets its informal inspection goal. As part of managing their regions, the Board's inspectors are responsible for scheduling inspections of pharmacies that compound only preparations not requiring sterility. The Board provides inspectors with a region roster, which includes information

related to each pharmacy located within that region. Inspectors use that roster to plan which pharmacies they will inspect each week. However, developing a process for selecting pharmacies that compound preparations not requiring sterility for inspection within a specified time frame could help the Board ensure that all types of compounding pharmacies are inspected on a periodic basis.

Inspector Qualifications

The Board has established minimum requirements for its inspector positions, and all 11 inspectors the Board employed as of February 28, 2015, met all requirements. The minimum requirements include:

- Have a four-year college degree.
- Have at least three years of work experience in a pharmacy.
- Possess an active Texas license as a pharmacist or pharmacy technician.
- Be commissioned as an officer of the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Source: The Board.

The Board indicated that the growth in the total number of pharmacies in Texas, as well as turnover in its inspector positions, are the reasons it has not met its goal for inspecting pharmacies that compound only components that do not require sterile conditions at least once every three years. The Board experienced significant turnover in its inspector positions during fiscal year 2014, with 24.2 percent turnover in those positions (see text box for information about minimum qualifications for the Board's inspector positions). That turnover rate was higher than the Board's overall turnover rate of 13.5 percent, and it was higher than the statewide turnover rate of 11.9 percent for inspectors at all state agencies during the same time period.

Recommendations

The Board should:

- Establish and document a formal goal for the frequency of inspections of pharmacies that compound only preparations not requiring sterility based on available staff and resources.
- Develop a process for selecting pharmacies that compound only preparations not requiring sterility for inspection to meet the established goal.

Management's Response

We would like to clarify that there are two types of compounding, sterile and non-sterile compounding. Pharmacies licensed by the Board could be doing only sterile compounding, only non-sterile compounding, doing both sterile and non-sterile compounding, or not doing any compounding.

- *Establish and document a formal goal for the frequency of inspections of pharmacies that compound only preparations not requiring sterility based on available staff and resources.*

The Texas State Board of Pharmacy agrees with the recommendations to document a formal goal for the frequency of inspections of Pharmacies that

compound only non-sterile products. We have established the following goal for inspections of these types of pharmacies. Note: These goals are based on the assumption that field Compliance Officer and Compliance Inspector positions are fully staffed. If the agency experiences turnover in these positions, the goals may not be met.

The goal for the inspections of pharmacies licensed by the Texas State Board of Pharmacy that are compounding only non-sterile products is to inspect these pharmacies at an interval that is between 3 and 4 years from the previous inspection.

Person Responsible for Implementation: Director of Enforcement

Deadline for Completion: September 1, 2015

- *Develop a process for selecting pharmacies that compound only preparations not requiring sterility for inspection to meet the established goal.*

The agency agrees with the recommendation and has established a process for selecting these pharmacies. The agency will generate a report that lists pharmacies that compound only non-sterile products that have not been inspected within the last 2 years on a quarterly basis. The inspectors will use this report to schedule their inspections.

Person Responsible for Implementation: D*irector of Enforcement*

Deadline for Completion: September 1, 2015

Chapter 1-C

The Board Has Documented Processes and Forms to Help Ensure That Inspections Address All Significant Federal and State Standards; However, It Has Not Fully Implemented Those Processes

State and Federal Regulations

Significant state and federal standards include:

- Compounding Quality Act, Federal Drug Quality and Security Act, Title 1, Section 105.
- Texas Pharmacy Act (Texas Occupations Code, Chapters 551-569).
- Title 22, Texas Administrative Code, Chapter 291.
- Texas Controlled Substances Act (Texas Health and Safety Code, Chapter 481).

The Board uses the state and federal standards as a basis for its inspection forms. Pharmacies are evaluated in broad categories including:

- Training requirements.
- Quality control procedures.
- Cleaning and disinfecting procedures.
- Compounding procedures for hazardous preparations.

Source: The Board.

The Board has developed processes and related controls for performing inspections of compounding pharmacies to help ensure that all significant requirements in federal standards, state statutes, and the Texas Administrative Code are addressed during the inspections (see text box for examples of related state and federal regulations). In addition, the Board has documented those processes in its policies and procedures for each class of pharmacy license, which outline the standards specific to that license type. The Board also has created standard forms for its inspectors to use during inspections of all pharmacies, including compounding pharmacies (see Appendix 4 for samples of the forms discussed below).

The Board adequately ensured that its inspectors used the standard forms and followed its processes for performing inspections. The Board was able to provide a hard-copy inspection report for all 121 inspections tested. For all 90 applicable inspections, the inspector (1) completed the notice of inspection and warning notice forms and (2) signed the inspection form. In addition, the pharmacist in charge signed all 89 applicable inspection forms.

Significant steps and forms used in the Board's inspection processes include:

- Pharmacies that apply for a new pharmacy license must complete and submit a preinspection form, which the Board validates and uses to determine whether the pharmacy is prepared for an onsite preinspection.
- When inspectors arrive at a pharmacy, the inspector presents the notice of inspection to the pharmacist in charge, who signs the notice acknowledging the purpose of the inspection.
- The inspector then proceeds to inspect the pharmacy using the guidelines in the Board's documented policies and procedures. That includes reviewing every item on the general inspection form. The general inspection form is used to indicate conditions identified during an inspection. The inspector is required to submit the completed general inspection form to the Board. The Board consistently documented and maintained the results of inspections of compounding pharmacies on that general inspection form.

- For inspections of pharmacies that compound sterile preparations, the Board has developed an additional sterile inspection form that contains requirements specific to those types of pharmacies. However, the Board does not require inspectors to document inspection results using that form. The hard-copy general inspection forms are currently in triplicate and are completed onsite by the inspector. Because the sterile inspection form is not currently available in triplicate, the Board has not fully implemented the use of that form. Without requiring inspectors to complete and submit the sterile inspection form, the Board lacks assurance that its inspectors addressed all required areas during inspections of pharmacies that compound sterile preparations.

- Inspectors classify violations as needs improvement, warning notice, or refer to legal (see Chapter 1-D for descriptions of each type of violation). If a pharmacy is out of compliance with laws or Board rules during an inspection, the inspector presents the pharmacy with a warning notice upon completion of the inspection. Warning notices for inspections of pharmacies that compound sterile preparations include, if applicable, references to violations of the requirements specific to compounding sterile preparations. That provides the Board some assurance that the inspector assessed the pharmacy's compliance with all requirements despite not completing the sterile inspection form. The most severe category of violations during an inspection result in a referral to legal, and disciplinary action may be taken against the pharmacy.

- Inspectors may also request a sample of a compounded drug to send to a lab for testing under the authority of Texas Occupations Code, Sections 556.051 and 556.053. Those samples can be tested for several different elements, including sterility and potency.

In addition to developing the standard inspection forms, the Board provides training to its inspectors to help ensure that inspectors have the required knowledge to conduct inspections. Newly hired inspectors complete an extensive training program before they begin performing inspections independently. That training includes completing a 1-2 week orientation and shadowing an experienced inspector for approximately 12 weeks. The Board also requires all inspectors to attend specialized training for conducting inspections of pharmacies that compound sterile preparations.

Recommendation

For inspections of pharmacies that compound sterile preparations, the Board should require inspectors to complete and submit the sterile inspection form that it developed, instead of submitting only the general inspection form.

Management's Response

The Texas State Board of Pharmacy agrees with the recommendation, however, the sterile inspection form is currently being field tested by the inspectors. This field-testing is an important part of the development of good inspection forms. During this testing process, changes are continually being made in the form as recommended by the inspectors. We anticipate that by the end of November 2015, we will have completed the testing and have the official triplicate inspection form printed and distributed to the inspectors for use in the field.

Person Responsible for Implementation: Director of Enforcement

Deadline for Completion: November 30, 2015

Chapter 1-D

The Board Has a Documented Process to Monitor Violations and Track Corrective Action Plans, and It Should Report Violations to the U.S. Department of Health and Human Services After That Agency Establishes a Reporting Mechanism

The Board has a documented process to monitor violations identified during inspections of compounding pharmacies. The Board is also required to report violations identified during those inspections to the U.S. Secretary of Health and Human Services. However, the U.S. Department of Health and Human Services has not yet implemented a reporting process.

As discussed in Chapter 1-C, during an inspection of a compounding pharmacy, a Board inspector initially classifies violations into one of three categories: needs improvement, warning notice, or refer to legal. The Board's policies provide guidance for inspectors on categorization of the violations. After the pharmacy has addressed all deficiencies identified during an inspection, the Board will close the inspection in Versa, the Board's licensing and inspection system.

Needs Improvement. Needs improvement is the least severe category and includes isolated instances of relatively minor noncompliance. Pharmacies may not be required to submit a corrective action plan to the Board for violations in that category.

Warning Notice. A warning notice involves more significant noncompliance than the needs improvement category. On the warning notice form, the inspector must reference the law or Board rule that the pharmacy violated and provide a narrative explanation. The Board requires corrective action plans from pharmacies for violations that result in a warning notice. The Board may conduct follow-up inspections based on the results of any corrective action plan that a pharmacy submits. (See Appendix 4 for the template used to

document a warning notice.) Auditors reviewed 35 inspections for which violations were noted during the inspection. Of those 35 inspections, 16 resulted in a warning notice that required a corrective action plan. The Board received corrective action plans for all 16 inspections, and the Board appropriately closed those inspections in Versa.

Refer to Legal. Refer to legal is the most severe category of violations, and the Board has a documented process for managing those violations. A pharmacy may be referred to legal if the inspector finds a condition that warrants consideration for disciplinary action. The Board's director of enforcement and general counsel must review inspections that have been referred to legal to determine whether there is sufficient evidence to institute disciplinary action. For all refer to legal violations, the director of enforcement opens a complaint and processes the case in accordance with the Board's established procedures. The Board sends a written notice called a preliminary notice letter to notify the pharmacy that the Board is considering taking disciplinary action for violations identified during the inspection. (See Appendix 4 for an example of a preliminary notice letter.)

The Board's process for identifying and correcting deficiencies was operating effectively. Of the 35 inspections auditors reviewed, 16 had deficiencies identified during a previous inspection conducted within the past 5 years. However, none of the violations identified during the most recent inspection was a repeat violation.

Excerpt from the Compounding Quality Act

In a manner specified by the Secretary of Health and Human Services (referred to as the "Secretary"), the Secretary shall receive submissions from State boards of pharmacy:

(1) describing actions taken against compounding pharmacies; or

(2) expressing concerns that a compounding pharmacy may be acting contrary to Section 503A of the Federal Food, Drug, and Cosmetic Act (Title 21 United States Code, Chapter 353a).

Source: Title 1, Drug Quality and Security Act, Section 105.

The Board has not reported violations identified during inspections of compounding pharmacies to the U.S. Secretary of Health and Human Services, as required by Section 105 of the federal Compounding Quality Act (see textbox for more information). The Compounding Quality Act requires state boards of pharmacy to submit reports in a manner specified by the Secretary of Health and Human Services; however, as of April 2015, the U.S. Department of Health and Human Services had not implemented a mechanism for states to report those violations.

Recommendation

The Board should continue to monitor the development of the reporting mechanism by the U.S. Secretary of Health and Human Services and report violations identified during inspections of compounding pharmacies after that mechanism has been implemented.

Management's Response

The Texas State Board of Pharmacy agrees with the recommendation and once we are notified of the procedures regarding reporting violations, the agency will report these violations to the U.S. Secretary of Health and Human Services.

Person Responsible for Implementation: Director of Enforcement

Deadline for Completion: When we are notified of the procedures for reporting.

Chapter 2

The Board Has a Process to Help Ensure That Inspections of Out-of-state Pharmacies That Compound Sterile Preparations Are Completed Within Required Time Frames; However, the Board Should Improve Its Monitoring of the Vendors That Conduct Those Inspections

The Texas Occupations Code specifies that the Board is responsible for licensing and inspecting out-of-state compounding pharmacies that distribute sterile compounded products in Texas (see text box for additional background information about the statutory requirement). Title 22, Texas Administrative Code, Chapter 291, effective December 10, 2013, required all out-of-state compounding pharmacies that request a new or renewed sterile pharmacy license in Texas to be inspected by the Board or its designee within the previous two years. To meet that requirement, in June 2014 the Board contracted with three vendors to conduct inspections of those pharmacies (see Appendix 5 for the vendors' names and Web sites). As of February 28, 2015, 164 out-of-state compounding pharmacies had sterile pharmacy licenses (see Appendix 5 for a list of those pharmacies).

Background on Texas Occupations Code Requirements for Inspecting Out-of-state Pharmacies

In October 2012, tainted sterile compounded injections prepared by the New England Compounding Center in Massachusetts caused a widespread outbreak of fungal meningitis. Twenty states reported more than 720 cases of illness and 48 deaths caused by the tainted medication. In an attempt to prevent potentially deadly outbreaks caused by sterile compounded drugs distributed in Texas by out-of-state pharmacies, the 83rd Legislature revised the Texas Occupations Code to authorize the Board to inspect out-of-state pharmacies that compound sterile preparations.

Source: Analysis of Senate Bill1100 (83rd Legislature, Regular Session).

The Board ensured that out-of-state compounding pharmacies with active sterile licenses were inspected within the required time frames. The Board denied renewals of licenses to compounding pharmacies that failed to obtain inspections as required. The Board also communicated the status of the denied pharmacy licenses to the public as "delinquent." As of February 28, 2015, 4 (2 percent) of the 164 out-of-state pharmacies that compound sterile preparations that were licensed with the Board failed to have an inspection completed and, therefore, were denied a license renewal.

Inspections of out-of-state pharmacies that compound sterile preparations met the inspection guidelines established by Board policies and the Texas Administrative Code. Between September 1, 2013, and February 28, 2015, the Board's vendors completed 24 inspections of out-of-state pharmacies that compound sterile preparations.[1] Of those 24 inspections, 21 (88 percent) reported violations, with inspectors identifying an average of 8 violations during each of those 21 inspections. Those inspections resulted in as few as 1 violation and as many as 37 violations during an inspection.

In addition, the Board followed its process to issue warning letters to each pharmacy with identified violations, and it effectively monitored and documented the required pharmacy management response. The Board tracks the due dates of licensees' responses to a warning letter, which is 30 days

[1] Due to special circumstances, entities other than the approved vendors conducted two inspections of out-of-state pharmacies that compound sterile preparations. The Board's inspectors conducted one inspection of a compounding pharmacy in Florida, and the Georgia State Board of Pharmacy inspected a compounding pharmacy in Georgia that distributes products in Texas.

from the date of the warning letter. The Board followed up with the pharmacies if it did not receive a response within the required time period or if the response did not adequately address the violation.

On September 1, 2014, the Board implemented a monthly reporting process outlined in the vendor contracts to monitor vendor inspection performance, but it did not consistently follow that process. The vendors are required to submit each inspection report completed and monthly summary reports of their inspection productivity to the Board. The Board received the inspection reports from all vendors; however, between September 1, 2014, and February 28, 2015, one vendor did not submit three monthly summary reports of inspection productivity as required. The Board received the monthly summary reports from the other two vendors. The monthly summary reports include a list of the appointments made, the number of appointments denied, a list of pharmacies inspected, dates of inspection requests, dates of inspection, and the cost of each inspection. Without the monthly summary reports, the Board (1) may not be able to determine whether a vendor's performance meets the Board's expectations or requirements and (2) may continue to contract with a vendor based on erroneous information.

Vendors that perform inspections of out-of-state pharmacies that compound sterile preparations follow the same requirements that Board inspectors use for Texas pharmacies that compound sterile preparations. The contracts with the three vendors that inspect out-of-state compounding sterile pharmacies require that:

- Inspection guidelines meet Board standards and Texas Administrative Code requirements.
- Inspections be documented on the sterile compounding inspection form the Board developed.
- Qualifications of inspectors employed by the vendors be equivalent to the qualifications of inspectors the Board employs.
- Inspectors employed by approved vendors complete online training the Board conducts before they can begin performing inspections.

The Board also licenses out-of-state compounding pharmacies that do not compound sterile preparations but distribute pharmaceuticals in Texas. The Board is not required to inspect out-of-state compounding pharmacies that do not compound sterile preparations. However, it requires those pharmacies to submit documentation with their license renewal applications showing that they have been inspected by their local state boards of pharmacy within three years prior to submitting the application.

Recommendation

The Board should ensure that approved vendors follow the reporting requirements outlined in the contract and use those reports to monitor vendor performance.

Management's Response

The Texas State Board of Pharmacy agrees with the recommendation. As you know, only one of the three vendors had not submitted all required monthly reports, due to a misunderstanding between TSBP and the vendor. Those "missing' reports were submitted to TSBP by the vendor within one week after the SAO brought this oversight to management's attention. TSBP has developed a process to ensure that a TSBP manager or Compliance Program Officer receives and reviews the vendors' monthly reports on a regular basis.

Person Responsible for Implementation: Director of Enforcement

Deadline for Completion: Completed

Chapter 3

The Board Has Controls to Help Ensure That Its Inspection Data Is Reliable; However, It Should Strengthen Its Data Entry Reviews and Restrict the Use of Generic User Accounts

The Board has adequate controls, including documented information technology policies and procedures, over its information technology system to help ensure that its licensing and inspection data is reliable. Versa, which was implemented in May 2011, is the Board's primary information technology system. The Board uses licensing data from Versa to report pharmacy information on its public Web site.

The Board has a process to review inspection data entered into Versa; however, those reviews are informal and not documented. Inspectors initially record all inspections on hard-copy documents and submit those documents on a weekly basis to the Board for data entry into Versa. Auditors compared hard-copy inspection forms to the data in Versa and identified errors in inspection dates and license classes in Versa; however, those errors did not affect the overall reliability of the data for the purposes of this audit. The Board uses inspection data in Versa to identify whether a pharmacy has been inspected, the date of the most recent inspection, and the license class for each pharmacy to help ensure that pharmacies that compound sterile preparations are inspected within the required time frames. Although the Board corrected the identified errors in Versa after auditors brought them to its attention, it is important that the Board have strong controls over data input because it relies on that data to help determine the priority and frequency of pharmacy inspections.

In addition, the Board's user access controls allow the use of generic user accounts and do not sufficiently ensure that the level of user access is appropriate. Auditors reviewed user access to Versa and noted that there are four generic user accounts with more than read-only access. The Board did not have adequate controls in place to ensure that the level of user access for the generic user accounts is appropriate. One of the generic user accounts, for example, has the ability to delete data. An individual could gain inappropriate access to the Board's licensing data through the use of a generic user account and make inappropriate changes or delete records. Without unique user accounts, the Board may not be able to determine who made changes or updates to records in Versa. In addition, more than one individual can be assigned to each generic user account at one time. While the Board stated that it did not assign more than one individual to each generic user account, it was unable to provide documentation to substantiate that assertion.

Recommendations

The Board should:

- Strengthen its review of inspection data entered into Versa by ensuring that all records entered are reviewed for accuracy and completeness and by documenting that review process.

- Restrict the use of generic user accounts and either assign each user an individual account or limit access to all generic user accounts to read-only.

Management's Response

- *Strengthen its review of inspection data entered into Versa by ensuring that all records entered are reviewed for accuracy and completeness and by documenting that review process.*

The Texas State Board of Pharmacy agrees with the recommendations and we have initiated the following procedures to comply with the recommendations. TSBP will assign an in-house Compliance Program Officer to perform reviews of the entry of inspection data on a periodic basis (i.e., the Compliance Officer will "spot check" the accuracy and completeness of data entry of inspection data).

It should also be noted that in a few instances, the information that was data entered into the agency's computer system did not match the information that was handwritten on the inspection report because the inspector had not written the correct information on the inspection report (e.g., incorrect date). In those instances, the individuals who performed the data entry of the inspection information recognized the inspector had made an error and entered the correct information (e.g., correct date of inspection). When these types of issues are detected during the data entry process, the individuals who perform the data entry are now preparing a memo to attach to the inspection report to explain why the data in the inspection report does not match the data in the agency's computer system.

By the end of November 2015, TSBP will have in place a method to document the review process.

Person Responsible for Implementation: Director of Enforcement

Deadline for Completion: November 30, 2015

- *Restrict the use of generic user accounts and either assign each user an individual account or limit access to all generic user accounts to read-only.*

If the agency issues any "generic user accounts" the accounts will be designated "read only" and the generic user will not be able to data enter information nor change any information in the system.

Person Responsible for Implementation: Director of Information Technology

Deadline for Completion: Completed

Appendices

Appendix 1

Objective, Scope, and Methodology

Objective

The objective of this audit was to determine whether the Board of Pharmacy (Board) has designed and implemented effective processes and related controls to help ensure that it conducts inspections of compounding pharmacies in accordance with applicable state and federal statutes, administrative rules, and Board policies and procedures.

Scope

The scope of this audit covered the time period from September 1, 2009, through February 28, 2015, and included inspections of compounding pharmacies in Texas, and inspections of compounding pharmacies outside of Texas that ship medications requiring sterile preparation into Texas.

Methodology

The audit methodology included gaining an understanding of and evaluating controls over the Board's inspection process for compounding pharmacies, including the qualifications and monitoring of inspection staff and vendors, the documentation of inspection results, the follow-up the Board performs when violations are identified, and the maintenance of accurate data in the Board's information system. Auditors interviewed Board personnel, attended Board meetings, observed inspections, analyzed data, performed testing, and evaluated the results.

Data Reliability

Auditors assessed the reliability of the data used for purposes of this audit by (1) determining population completeness and reasonableness; (2) reviewing queries used to generate data; (3) interviewing Board employees and information technology administrators knowledgeable about the data and systems; and (4) reviewing source documentation for inspection data. Auditors determined that the pharmacy inspection and licensing data was sufficiently reliable for the purposes of this audit.

Sampling methodology

Auditors selected nonstatistical samples of pharmacy inspections primarily through random selection designed to be representative of the population.

In those cases, results may be extrapolated to the population, but the accuracy of the extrapolation cannot be measured. In addition, auditors used professional judgment to select a sample of inspections of pharmacies that self-reported they performed sterile compounding for testing. Those sample items generally were not representative of the population and, therefore, it would not be appropriate to extrapolate those results to the population.

Information collected and reviewed included the following:

- The Board's policies and procedures.
- The Board's strategic plans.
- The Board's *Legislative Appropriations Request* for fiscal years 2014 and 2015.
- The House Committee on Public Health's *Interim Report to the 84th Legislature*, December 2014.
- Board records, including pharmacy license applications, pharmacy inspection forms, warning notices and letters, weekly inspector reports, vendor contracts, and inspector time sheets.
- Board personnel files.
- Data from the Board's licensing and inspection database.
- Supporting documentation related to general and application controls over the Board's licensing and inspection database.

Procedures and tests conducted included the following:

- Interviewed the Board's management and staff.
- Tested employee files to determine whether Board policies regarding education, experience, continuing education hours, and licensing were followed.
- Reviewed Board pharmacy inspection policies and procedures and inspection forms for compounding pharmacies to determine whether they aligned with state and federal regulations.
- Compared hard-copy documentation of pharmacy inspections with data in the Board's information system.

- Tested a sample of inspections to verify violation documentation and monitoring.
- Verified that outsourcing facilities are licensed in Texas and tested the inspections of those facilities to determine whether those inspections were performed according to the inspection requirements for pharmacies that compound sterile preparations established in the Board's policies and procedures and the Texas Administrative Code. Also compared Board inspectors' status reports with completed pharmacy inspection forms for pharmacies without violations to determine whether the information was consistent.
- Reviewed contracts with vendors that perform inspections of pharmacies that compound sterile preparations that ship to Texas to verify whether the vendor requirements met the Board's policies and procedures and the Texas Administrative Code.
- Reviewed the Board's process for monitoring contracted inspection vendors.
- Tested inspections that vendors performed of pharmacies that compound sterile preparations to determine whether the inspections were completed according to the Board's policies and procedures.
- Tested inspection data for completeness and reliability.
- Reviewed supporting documentation related to the general and application controls over the Board's licensing and inspection information system.

Criteria used included the following:

- The Board's policies and procedures.
- Texas Occupations Code, Chapter 556.
- Title 22, Texas Administrative Code, Chapter 291.
- *United States Pharmacopeial Standards*, Chapters 795 and 797, the U.S. Pharmacopeial Convention.
- Federal Food, Drug, and Cosmetic Act, Sections 503A, 503B, and 503C.
- *Carrying Out a State Regulatory Program,* A National State Auditors Association Best Practice Document, 2004.
- Title 1, Texas Administrative Code, Chapter 202.

Project Information

Audit fieldwork was conducted from January 2015 through June 2015. We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The following members of the State Auditor's staff performed the audit:

- Karen Mullen, CGAP (Project Manager)
- Amy M. Cheesman, CFE (Assistant Project Manager)
- Katherine M. Curtsinger
- Andrea R. Focht-Williams, MACT, CPA
- Darcy Hampton, MAcy
- Michael Karnes, MBA
- Jack K. Lee
- Trevor Schwendau, MIS
- Nakeesa Shahparasti, MS
- Doug Stearns
- J. Scott Killingsworth, CIA, CGAP, CGFM (Quality Control Reviewer)
- James Timberlake, CIA (Audit Manager)

Appendix 2

Pharmacy License Types

Table 1 presents the types of pharmacy licenses that the Board of Pharmacy (Board) issues and the number of active licenses as of February 28, 2015.

Table 1

Pharmacy License Types		
License Class	**Type of Facility**	**Number of Active Licenses as of February 28, 2015**
A	Community Pharmacy	4,945
A-S	Community Pharmacy Engaged in Sterile Compounding	319
B	Nuclear Pharmacy	37
C	Institutional/Hospital/Ambulatory Surgery Center Pharmacy	734
C-S	Institutional/Hospital/Ambulatory Surgery Center Pharmacy Engaged in Sterile Compounding	451
D	Clinic Pharmacy	369
E	Non-resident (Out of State) Pharmacy	671
E-S	Non-resident (Out of State) Pharmacy Engaged in Sterile Compounding	164
F	Freestanding Emergency Medical Care Center Pharmacy	188
G	Central Prescription Drug or Medication Order Processing Pharmacy	20
H	Limited Prescription Delivery Pharmacy	1
	Total Number of Active Licenses	**7,899**

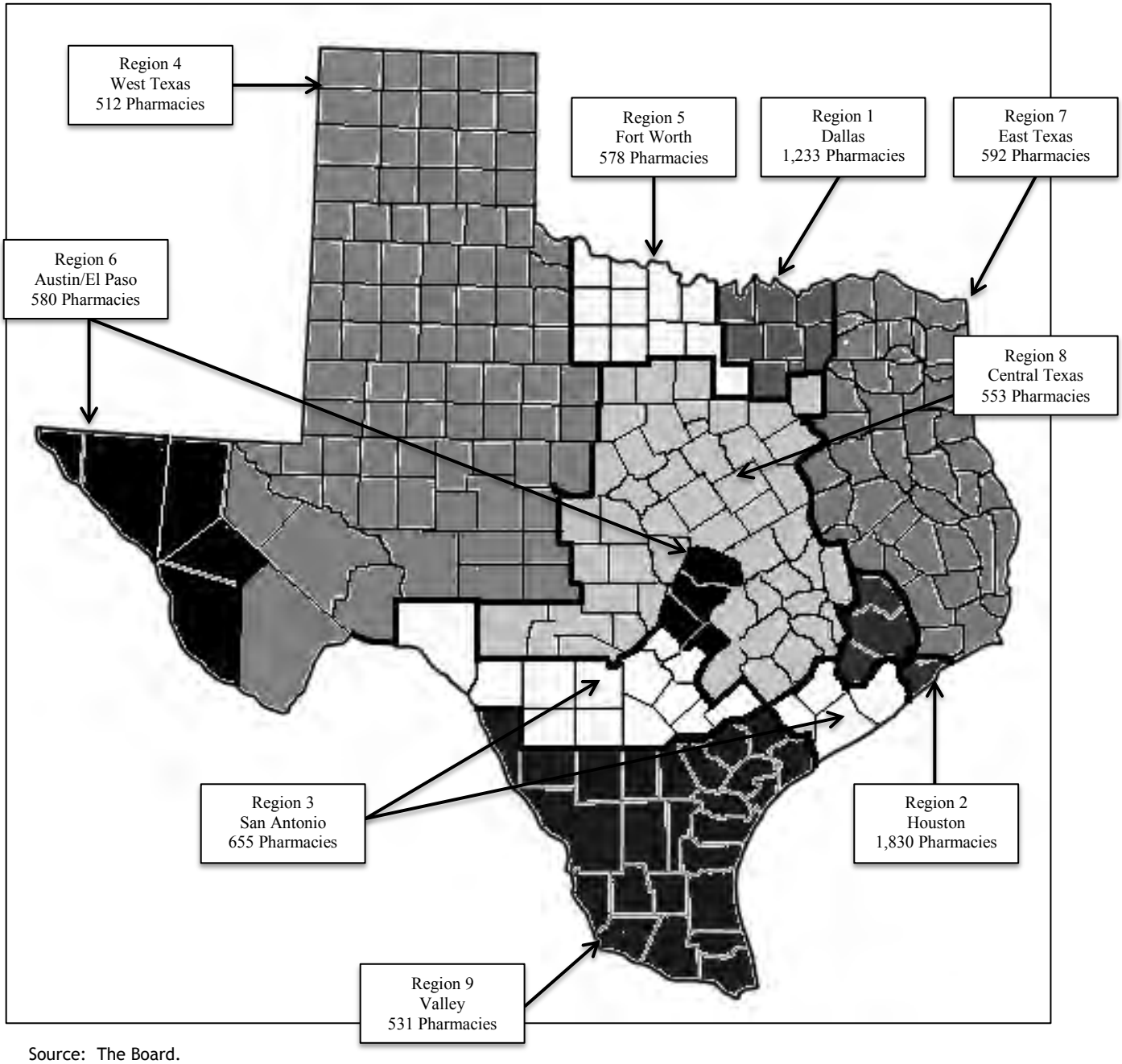
Source: The Board.

Appendix 3

Map of the Board's Enforcement Division's Regions

The Board of Pharmacy (Board) has 12 inspector positions responsible for conducting inspections of pharmacies across 9 regions of Texas. Figure 1 shows those regions. The total number of pharmacies shown in Figure 1 does not include the 835 licensed pharmacies located outside Texas.

Figure 1



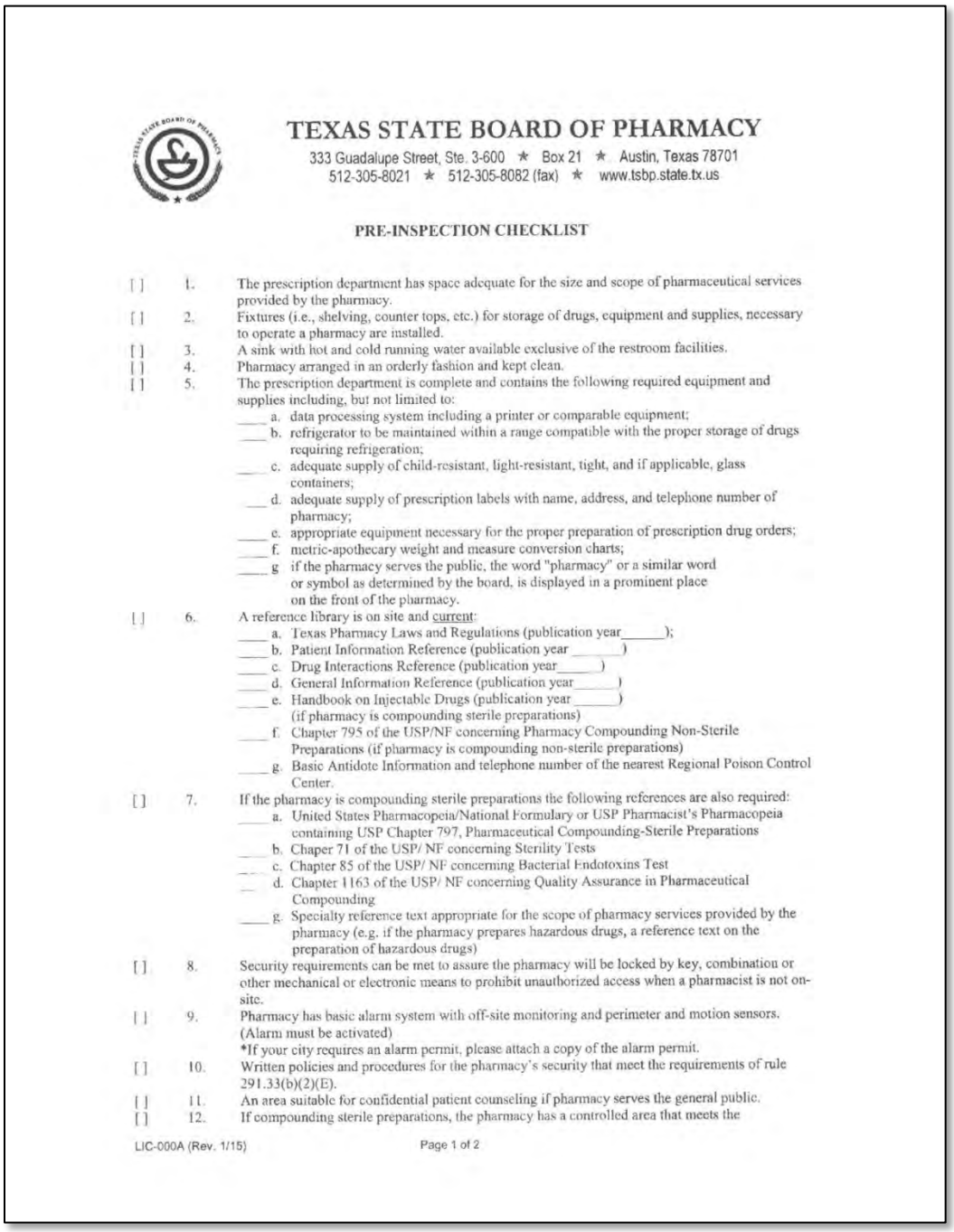
Source: The Board.

Appendix 4

Standard Templates Used During the Inspection Process

The Board of Pharmacy (Board) uses a number of standard templates during its inspection process for compounding pharmacies. Figure 2 shows a preinspection checklist, which pharmacies that apply for a license must submit with their applications.

Figure 2



TEXAS STATE BOARD OF PHARMACY

333 Guadalupe Street, Ste. 3-600 ★ Box 21 ★ Austin, Texas 78701
512-305-8021 ★ 512-305-8082 (fax) ★ www.tsbp.state.tx.us

PRE-INSPECTION CHECKLIST

[ ] 1. The prescription department has space adequate for the size and scope of pharmaceutical services provided by the pharmacy.
[ ] 2. Fixtures (i.e., shelving, counter tops, etc.) for storage of drugs, equipment and supplies, necessary to operate a pharmacy are installed.
[ ] 3. A sink with hot and cold running water available exclusive of the restroom facilities.
[ ] 4. Pharmacy arranged in an orderly fashion and kept clean.
[ ] 5. The prescription department is complete and contains the following required equipment and supplies including, but not limited to:
____ a. data processing system including a printer or comparable equipment;
____ b. refrigerator to be maintained within a range compatible with the proper storage of drugs requiring refrigeration;
____ c. adequate supply of child-resistant, light-resistant, tight, and if applicable, glass containers;
____ d. adequate supply of prescription labels with name, address, and telephone number of pharmacy;
____ e. appropriate equipment necessary for the proper preparation of prescription drug orders;
____ f. metric-apothecary weight and measure conversion charts;
____ g if the pharmacy serves the public, the word "pharmacy" or a similar word or symbol as determined by the board, is displayed in a prominent place on the front of the pharmacy.
[ ] 6. A reference library is on site and current:
____ a. Texas Pharmacy Laws and Regulations (publication year_____);
____ b. Patient Information Reference (publication year _____)
____ c. Drug Interactions Reference (publication year_____)
____ d. General Information Reference (publication year_____)
____ e. Handbook on Injectable Drugs (publication year _____)
(if pharmacy is compounding sterile preparations)
____ f. Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations (if pharmacy is compounding non-sterile preparations)
____ g. Basic Antidote Information and telephone number of the nearest Regional Poison Control Center.
[ ] 7. If the pharmacy is compounding sterile preparations the following references are also required:
____ a. United States Pharmacopeia/National Formulary or USP Pharmacist's Pharmacopeia containing USP Chapter 797, Pharmaceutical Compounding-Sterile Preparations
____ b. Chaper 71 of the USP/ NF concerning Sterility Tests
____ c. Chapter 85 of the USP/ NF concerning Bacterial Endotoxins Test
____ d. Chapter 1163 of the USP/ NF concerning Quality Assurance in Pharmaceutical Compounding
____ g. 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)
[ ] 8. Security requirements can be met to assure the pharmacy will be locked by key, combination or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site.
[ ] 9. Pharmacy has basic alarm system with off-site monitoring and perimeter and motion sensors. (Alarm must be activated)
*If your city requires an alarm permit, please attach a copy of the alarm permit.
[ ] 10. Written policies and procedures for the pharmacy's security that meet the requirements of rule 291.33(b)(2)(E).
[ ] 11. An area suitable for confidential patient counseling if pharmacy serves the general public.
[ ] 12. If compounding sterile preparations, the pharmacy has a controlled area that meets the

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requirements in rule 291.133 (d)(6)(A) if the pharmacy is compounding low- and medium-risk preparations or rule 291.133 (d)(6)(B) if high-risk preparations are being compounded.

[ ] 13. Certified primary engineering control device (e.g. laminar airflow work benches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators).

Submit this form only after all items on this check-list are complete.

A TSBP Inspector will contact you regarding the required pre-inspection, only after the inspector receives a completed pre-inspection checklist. Please provide all contact information below for the owner or owner's representative and Pharmacist-in-charge:

_____ _____
Pharmacy Name Pharmacy Address

_____ _____
Name of Owner or Owner's Representative Signature of Owner or Owner's Representative

_____ Home

_____ Cell

_____ Work
Contact Telephone Numbers (8:00a.m.-5:00p.m./Mon.-Fri.)

_____ _____
Name of Pharmacist-In-Charge Signature of Pharmacist-In-Charge

_____ Home

_____ Cell

_____ Work
Contact Telephone Numbers (8:00a.m.-5:00p.m./Mon.-Fri.)

_____
For TSBP Use Only—Date Pre-inspection Completed

Figure 3 shows a notice of inspection, which inspectors present upon initial entry to a pharmacy during an inspection.

Figure 3

Phcy. Lic. # _____

Expiration Date: ___/___/___

NOTICE OF INSPECTION
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701-3943
(512) 305-8000

____ **Compliance**

____ **Investigation**

Name of Individual	Title	R.Ph. Lic. # Expires
Name of Facility		
Address		
City/State , TX	Zip	Phone # ( )
DEA Registration # Expiration Date	DPS Registration #	Expiration Date
Date	Time of Entry	

PURPOSE OF INSPECTION

___ Routine ___ Pre-Inspection ___ Rank Change

___ New Pharmacy ___ Change of Ownership ___ Reverse Rank Change

___ Complaint ___ Follow-up to Complaint

___ Follow-up to Warning Notice ___ Follow-up to Theft/Loss Report

___ Other_____

ACKNOWLEDGEMENT

This is to acknowledge that Texas State Board of Pharmacy Agent _____ has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I am the _____for the above-described facility;
2. I have read this Notice of Inspection and understand its contents and purpose;
3. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
4. I have had the purpose of the entry into the above-described facility by the Board's agent stated to me; and
5. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

_____
Signature

Witnesses:

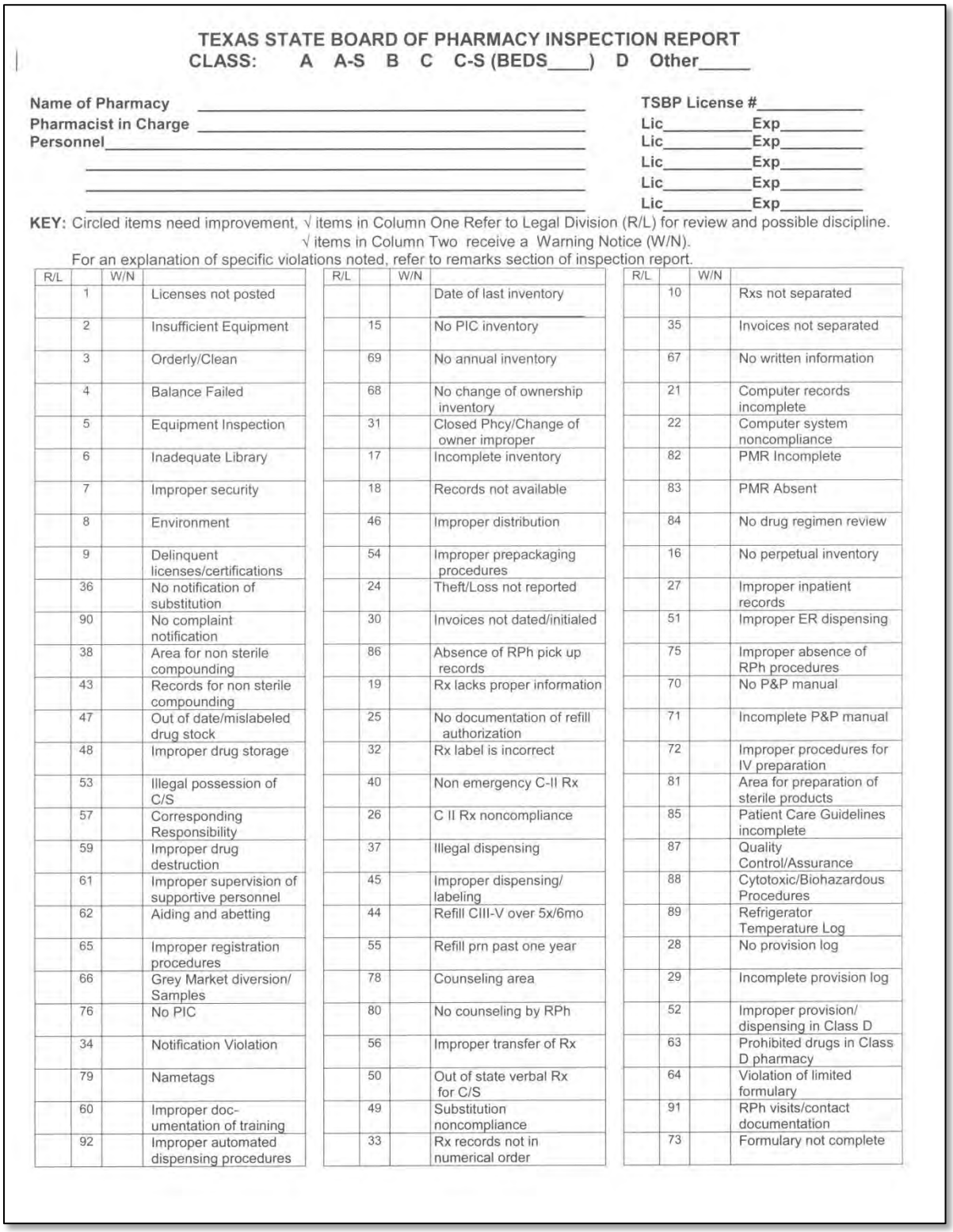
_____
Signature

_____
Signature

09/14

Figure 4 shows the standard checklist that Board inspectors use for all pharmacy inspections.

Figure 4



TEXAS STATE BOARD OF PHARMACY INSPECTION REPORT
CLASS: A A-S B C C-S (BEDS____) D Other_____

Name of Pharmacy _____ **TSBP License #**_____
Pharmacist in Charge _____ **Lic**_____**Exp**_____
Personnel_____ **Lic**_____**Exp**_____
_____ **Lic**_____**Exp**_____
_____ **Lic**_____**Exp**_____
_____ **Lic**_____**Exp**_____

KEY: Circled items need improvement, √ items in Column One Refer to Legal Division (R/L) for review and possible discipline.
√ items in Column Two receive a Warning Notice (W/N).
For an explanation of specific violations noted, refer to remarks section of inspection report.

R/L		W/N	
	1		Licenses not posted
	2		Insufficient Equipment
	3		Orderly/Clean
	4		Balance Failed
	5		Equipment Inspection
	6		Inadequate Library
	7		Improper security
	8		Environment
	9		Delinquent licenses/certifications
	36		No notification of substitution
	90		No complaint notification
	38		Area for non sterile compounding
	43		Records for non sterile compounding
	47		Out of date/mislabeled drug stock
	48		Improper drug storage
	53		Illegal possession of C/S
	57		Corresponding Responsibility
	59		Improper drug destruction
	61		Improper supervision of supportive personnel
	62		Aiding and abetting
	65		Improper registration procedures
	66		Grey Market diversion/ Samples
	76		No PIC
	34		Notification Violation
	79		Nametags
	60		Improper doc-umentation of training
	92		Improper automated dispensing procedures

R/L		W/N	
			Date of last inventory _____
	15		No PIC inventory
	69		No annual inventory
	68		No change of ownership inventory
	31		Closed Phcy/Change of owner improper
	17		Incomplete inventory
	18		Records not available
	46		Improper distribution
	54		Improper prepackaging procedures
	24		Theft/Loss not reported
	30		Invoices not dated/initialed
	86		Absence of RPh pick up records
	19		Rx lacks proper information
	25		No documentation of refill authorization
	32		Rx label is incorrect
	40		Non emergency C-II Rx
	26		C II Rx noncompliance
	37		Illegal dispensing
	45		Improper dispensing/ labeling
	44		Refill CIII-V over 5x/6mo
	55		Refill prn past one year
	78		Counseling area
	80		No counseling by RPh
	56		Improper transfer of Rx
	50		Out of state verbal Rx for C/S
	49		Substitution noncompliance
	33		Rx records not in numerical order

R/L		W/N	
	10		Rxs not separated
	35		Invoices not separated
	67		No written information
	21		Computer records incomplete
	22		Computer system noncompliance
	82		PMR Incomplete
	83		PMR Absent
	84		No drug regimen review
	16		No perpetual inventory
	27		Improper inpatient records
	51		Improper ER dispensing
	75		Improper absence of RPh procedures
	70		No P&P manual
	71		Incomplete P&P manual
	72		Improper procedures for IV preparation
	81		Area for preparation of sterile products
	85		Patient Care Guidelines incomplete
	87		Quality Control/Assurance
	88		Cytotoxic/Biohazardous Procedures
	89		Refrigerator Temperature Log
	28		No provision log
	29		Incomplete provision log
	52		Improper provision/ dispensing in Class D
	63		Prohibited drugs in Class D pharmacy
	64		Violation of limited formulary
	91		RPh visits/contact documentation
	73		Formulary not complete

Remarks

Action Taken

(1) ___ Inspection
(2) ___ Pre-Inspection
(3) ___ Partial Inspection
(4) ___ Visit
(5) ___ Other _____

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

_____ Agent of the Texas State Board of Pharmacy

_____ Authorized Individual for the Pharmacy

_____ Date

_____ Time of Exit

_____ Printed Name and Title of Authorized Individual

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Figure 5 shows the inspection checklist that Board inspectors may use for inspections of pharmacies that compound sterile preparations.

Figure 5

Class E (Non-resident) Pharmacy Inspection Report
Relating to Compounding of Sterile Preparations
for Texas State Board of Pharmacy

Conducted by _____

		TSBP License #
Name of Pharmacy	_____	
Pharmacist in Charge	_____	Lic _____ Exp _____
Personnel	_____	Lic _____ Exp _____
	_____	Lic _____ Exp _____
	_____	Lic _____ Exp _____
	_____	Lic _____ Exp _____

KEY: Satisfactory - substantially complies with TSBP Rule 291.133 with no or only minor deficiencies that require corrections.
Unsatisfactory - fails to substantially comply with TSBP Rule 291.133 (See Notes).

Satisfactory	Code	Unsatisfactory		Notes
			Does pharmacy maintain compounding facilities (Clean room) that are physically designed and environmentally controlled to minimize airborne contamination of critical sites?	
	101		Does the anteroom/ante-zone provide at least ISO Class 8 air quality, under dynamic conditions?	
	102		Does the buffer area provide at least ISO Class 7 air quality, under dynamic conditions?	
	103		If high-risk CSPs are compounded, does the pharmacy have buffer room that provides physical separation from other compounding area?	
	104		Is buffer area segregated from surrounding unclassified spaces, and continuously monitored?	
	105		Is airflow in the buffer area unidirectional?	
	106		Is the buffer area free from sources of water (e.g., sinks) or floor drains?	
	107		Is clean room of sufficient size to support sterile compounding activities?	
	108		Is clean room/controlled area designed such that hand sanitizing and gowning occurs outside the buffer area but allows hands-free access to the buffer area?	
			Does the pharmacy clean room meet the following requirements	
	109		Clean, well-lit, & clear of objects that shed particles?	
	110		Used only for the compounding of sterile preparations?	
	111		Ventilated in a manner to avoid disruption from the HVAC system and room cross drafts?	
	112		Have non-porous & washable floors or floor covering to enable regular disinfection?	
	113		Have walls, ceilings, floors, fixtures, shelving, counters, & cabinets that are smooth, impervious, free from cracks & crevices (e.g., coved, non-shedding & resistant to damage by disinfectant agents?	
	114		Have junctures of ceilings-to-wall coved or caulked to avoid cracks and crevices?	

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Satisfactory	Code	Unsatisfactory		Notes
	115		Does the anteroom/ante-zone contain a sink with hot and cold running water that enables hands-free use with a closed system of soap dispensing?	
	116		Is clean room maintained at a comfortable temperature (e.g., 20 degrees C) or cooler?	
	117		Does buffer area provide at least ISO Class 7 conditions under dynamic working conditions?	
	118		Are drugs/supplies stored on shelves above the floor to permit adequate floor cleaning?	
	119		Contain only the appropriate compounding supplies (e.g., not used for bulk storage for supplies and materials)?	
	120		Are all drugs used for compounding stored at proper temperature?	
			If the pharmacy compounds CSPs in a primary engineering control device, is the device	
	121		Able to maintain at least ISO Class 5 conditions while compounding sterile preparations?	
	122		Located in the buffer area, if applicable, and placed in an ISO Class 7 buffer area?	
	123		Placed in the buffer area so as to avoid conditions that could adversely affect operation?	
	124		Certified by an independent contractor according to the ISO Classification of Particulate Matter in Room Air every 6 months, and when relocated?	
	125		Have pre-filters that are inspected periodically and replaced as needed?	
	126		Is PEC located in a buffer area that has a min. differential positive pressure of 0.02-0.05" water?	
	127		Does clean room have a pressure gauge or velocity meter to monitor pressure differential or airflow between buffer area/room and ante-area/room and between ante-area/room and the the general environment outside the compounding area?	
	128		Are the differential pressures discussed above documented at least every work shift (minimum frequency shall be at least once daily) or by a continuous recording device?	
			TRAINING REQUIREMENTS AND REFERENCE LIBRARY	
			Have applicable pharmacy personnel completed the following training requirements:	
	129		**Prior to September 1, 2015:** Has each pharmacist who compounds (or supervises pharmacy technicians who are compounding sterile preparations) completed, in single course, a minimum of 20 hours of approved education/training?	
	130		Has each technician who compounds sterile preparations completed, in a single course, a minimum of 40 hours of approved education/training	
			Does the pharmacy's training program for personnel who compound sterile preparations include didactic and experiential training? Does training manual include instructions and experience in the following areas:	
	131		Aseptic technique	
	132		Critical area contamination factors	

Satisfactory	Code	Unsatisfactory		Notes
	133		Environmental monitoring	
	134		Structure and engineering controls related to facilities	
	135		Equipment and supplies	
	136		Sterile preparation calculations and terminology	
	137		Sterile preparation compounding documentation	
	138		Quality assurance procedures	
	139		Aseptic preparation procedures, including proper gowning and gloving technique	
	140		Handling of hazardous drugs, if applicable	
	141		General conduct in the clean room	
			Does the pharmacy's training program for personnel who compound or supervise sterile preparations include competency evaluation through demonstration, written testing, and practical testing, including media-fill challenge tests? Is competency evaluated:	
	142		During orientation and training prior to the regular performance of tasks?	
	143		Whenever the QA program yields an unacceptable result?	
	144		At proper intervals (at least on an annual basis for low- and medium-risk level compounding; and at least every six months for high-risk level compounding?	
	145		For all types of manipulations, products, risk levels, and batch sizes that personnel are likely to encounter?	
	146		Are all personnel required to pass gloved fingertip/thumb testing 3 times before compounding sterile preparations?	
			Does the pharmacy maintain required documentation of training and testing of each person who compounds or supervises sterile preparations, to include initial and in-service training and practical testing and media-fill testing? Records must include:	
	147		Name of person receiving the training or completing the testing	
	148		Results of personnel glove fingertip testing	
	149		Date of training, testing and/or media-fill challenge testing	
	150		General description of topics covered in the training or testing or of the process validated	
	151		Name of person supervising the training, testing, and/or media-fill challenge testing	
	152		Signature or initials of the person receiving the training or completing the testing	
	153		Signature of PIC or designee responsible for training, testing, and/or media-fill challenge testing	
			Does the pharmacy maintain a library that includes updated copies, in hard-copy or electronic format, of the following references	
	154		Reference on injectable drug preparations, such as Handbook of Injectable Drug Products	

Satisfactory	Code	Unsatisfactory		Notes
	155		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	
	156		USP/NF containing USP Chapters 71, 85, 795, 797, 1163	
	157		If records are maintained electronically, are all personnel able to access these records?	
			GENERAL OPERATIONAL REQUIREMENTS	
			Does the pharmacy compound commercially available products if:	
	158		Commercial product is not reasonably available from normal distribution channels in a timely manner to meet patient's needs	
	159		Pharmacy maintains documentation from manufacturer that product is unavailable	
	160		The prescriber has requested the drug be compounded	
			The following are applicable if the pharmacy is compounding for CSPs for **office use:**	
	161		Are policies in place for patient monitoring, including policies to ensure that reports of ADEs with a CSP reviewed promptly and thoroughly to correct and prevent future events?	
	162		If a Class A Pharmacy is compounding sterile preparations for a Class C Pharmacy, or a Class C Pharmacy is compounding sterile preparations for another Class C Pharmacy under common ownership, does the pharmacy maintain a written agreement on file?	
	163		If a pharmacy is compounding sterile preparations for a practitioner's office use, does the pharmacy maintain a written agreement, containing all requirement in Rule 291.133 (f)(2) on file?	
	164		Does the pharmacy maintain as part of its written policies and procedures, a written Quality Assurance plan to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations? Does the pharmacy follow Quality Assurance practices?	
	165		Does the pharmacy follow established quality control procedures to monitor the compounding environment and quality of compounded drug preparations?	
	166		Is a pharmacist accessible at all times to respond to questions and needs from patients and other healthcare professionals?	
			Does the pharmacy have all of the following required equipment and supplies:	
	167		Calibrated system or device (e.g., thermometer), if CSPs are stored in the refrigerator	
	168		Calibrated system or device to monitor temperature where bulk chemicals are stored	
	169		If applicable, a Class A prescription balance, or analytical balance and weights	

Satisfactory	Code	Unsatisfactory		Notes
	170		Equipment, including drug containers, and utensils necessary for proper compounding of sterile preparations which are: -- of suitable composition so that surfaces making contact with components are not reactive, additive, or absorptive so as to alter the drug preparations -- cleaned and sanitized immediately prior to and after each use	
	171		Appropriate disposal containers for needles, syringes, and if applicable, hazardous waste	
	172		Packaging and delivery containers to maintain proper storage conditions	
	173		Infusion devices	
	174		Disposable needles, syringes, and other supplies for aseptic mixing	
	175		Disinfectant cleaning solutions	
	176		Hand washing agents with bactericidal action	
	177		Disposable, lint-free towels or wipes	
	178		Appropriate filters and filtration equipment	
	179		Hazardous spill kits, if applicable	
	180		Masks, caps, gowns with tight cuffs, shoe covers, gloves, and beard covers, as applicable	
	181		If pharmacy uses an automated compounding device, does the pharmacy calibrate and verify device for accuracy on a daily basis?	
			COMPOUNDING PROCESS	
			Does the pharmacy have SOPs to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process? Do procedures include the following:	
	182		Facility	
	183		Equipment, including drug containers, and utensils necessary for proper compounding	
	184		Personnel	
	185		Are written procedures for conducting compounding accuracy checks followed?	
	186		Preparation Evaluation	
	187		Quality Assurance	
	188		Preparation Recall	
	189		Packaging	
	190		Storage of Compounds	
	191		Are all drug components manufactured in an FDA-registered facility or have a Certificate of Analysis and of high quality, if not purchased from an FDA-registered facility?	
	192		Are persons with apparent illness or an open lesion compounding sterile preparations?	

Satisfactory	Code	Unsatisfactory		Notes
			PERSONNEL CLEANSING AND GARBING	
			Do compounding personnel remove the following before entering the clean room	
	193		Personal outer garments	
	194		All cosmetics	
	195		All hand, wrist, and other body jewelry or piercings	
	196		Artificial nails or extenders; are natural nails kept neat and trimmed?	
			Do compounding personnel carry out the following activities prior to commencement of compounding process: (NOTE: Procedures should proceed from dirtiest to cleanest activity)	
	197		Donning of head and facial hair covers	
	198		Donning dedicated shoes or shoe covers	
	199		Face mask and eye shields, if applicable	
			Do compounding personnel perform proper hand hygiene, including:	
	200		Do personnel remove debris underneath fingernails using nail cleaner, under warm water?	
	201		Do personnel engage in vigorous hand washing for 30 seconds, while in ante-zone/anteroom, beginning with arms at hands and continuing to the elbows?	
	202		Are hands and forearms to the elbows completely dried using lint-free disposable towels, an electronic hands-free hand dryer, or a HEPA-filtered hand dryer?	
	203		After hand washing, are clean non-shedding gowns with sleeves that fit snugly round wrist and enclosed at the neck donned?	
	204		Once inside the buffer area, and prior to donning sterile powder-free gloves, is antiseptic hand cleansing performed using a waterless alcohol-based surgical scrub? Are hands allowed to dry?	
	205		Are sterile powder-free gloves donned prior to beginning of compounding procedures?	
	206		Is sterile 70% IPA applied to gloves throughout the day & when non-sterile surfaces are touched?	
			QUALITY CONTROL PROCEDURES FOR VERIFYING COMPOUNDING ACCURACY	
	207		Does the pharmacist review all compounding records for accuracy in the compounding process and conduct in-process and final checks in the compounding process?	
	208		Are all compounded sterile preparation that are intended to be solutions visually examined for particulate matter?	

Satisfactory	Code	Unsatisfactory		Notes
			Do pharmacy personnel properly label compounded sterile preparations, to include:	
	209		Generic name(s) or official names of principle active ingredient(s)	
	210		Statement that the CSP has been compounded by the pharmacy	
	211		Beyond-Use Date	
			If compounds are prepared in batch, do labels contain:	
	213		unique lot number	
	214		quantity	
	215		ancillary instructions (e.g., cautionary statements)	
	216		device-specific instructions, where applicable	
			If preparing pharmacy bulk packages, do labels contain:	
	217		the statement "Pharmacy Bulk Package - Not for Direct Infusion" appearing prominently	
	218		information on proper techniques to help ensure safe use	
	219		statement of how long a vial may be used once punctured	
	220		Are CSPs assigned beyond-use dates as specified in labeling, or literature sources, or direct testing? Are beyond-use dates for compounds which lack justification from literature sources or direct testing evidence, assigned as described in USP Chapter <797>	
			CLEANING AND DISINFECTING PROCEDURES	
			Does the pharmacy clean and disinfect all direct and contiguous compounding areas at the following frequencies, pursuant to written procedures developed by the PIC?	
	221		At the beginning of each work shift	
	222		Every 30 minutes during continuous compounding or after compounding if more than 30 min req'd	
	223		Before each batch preparation is started	
	224		When there are spills or known or suspected procedural breaches	
			When cleaning the buffer or clean room are the following procedures followed:	
	225		Are proper residue-free disinfecting agents used?	
	226		Are floors mopped at least once daily when no aseptic operations are in progress?	
	227		Are walls, ceiling, and shelving in the buffer area, ante-area, and segregated compounding area cleaned and disinfected on a monthly basis?	
	228		Are supplies/equipment removed from shipping cartons wiped w/disinfecting agent, such as sterile 70% IPA, and allowed to dry prior to introduction into an ISO 5 classified air space?	
	229		For cleaning procedures above, does pharmacy maintain documentation (i.e., date/time of cleaning, type of cleaning agent(s) used, name(s) of individual(s) carrying out the cleaning)?	
	230		Is cleaning performed by trained personnel using approved agents and procedures described in the written SOPs?	

Satisfactory	Code	Unsatisfactory		Notes
			COMPOUNDING PROCEDURES FOR HIGH-RISK PREPARATIONS	
			If high-risk CSPs are compounded, do these CSPs undergo sterility testing when	
	231		Prepared in groups of more than 25 identical individual single-dose packages?	
	232		Prepared in multiple dose vials for administration to multiple patients or when exposed longer than 12 hours at 2-8 degrees Celsius before they are sterilized?	
	233		Exposed longer than 6 hours at warmer than 8 degrees C before they are sterilized	
	234		Does pharmacy expose sterile ingredients and components used to prepare and package CSPs to to room air quality worse than ISO Class 5 for more than one hour?	
	235		Does pharmacy store opened or partially used packages of manufactured sterile products that lack antimicrobial preservatives in air quality inferior to ISO Class 5?	
	236		Does pharmacy properly store finished high-risk sterile preparations?	
	237		Does pharmacy rinse, while assuring cleanliness, all non-sterile measuring, mixing, and purifying devices thoroughly with sterile, pyrogen-free water, and then thoroughly drain or dry immediately before use for high-risk compounding?	
	238		Does pharmacy ensure that all high-risk compounded sterile aqueous solutions subjected to terminal sterilization are passed through a filter with a nominal porosity not larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter?	
	239		Are pre-sterilization procedures for high-risk CSPs, such as weighing and mixing, completed in no worse than an ISO 8environment?	
	240		For compounding activities that precede terminal sterilization, (e.g., weighing & mixing non-sterile ingredients, do compounding personnel garb and gown the same as when performing in an ISO Class 5 environment?	
	241		Do properly garbed and gloved compounding personnel re-garb and properly re-wash hands, perform aseptic hand cleansing with waterless alcohol-based surgical hand scrub, and don sterile gloves, if exposed to air quality that is either known or suspected to be worse than ISO 7, upon re-entering the ISO 7 buffer area?	
			COMPOUNDING PROCEDURES FOR HAZARDOUS PREPARATIONS	
			If pharmacy prepares hazardous drugs, does the pharmacy comply with the following:	
	242		Personnel wear appropriate protective apparel	
	243		Use appropriate safety and containment techniques	
	244		Dispose of hazardous waste in accordance with all local, state, and federal laws/rules	
	245		Label preparations with proper precautions	

Satisfactory	Code	Unsatisfactory		Notes
	246		Are hazardous drugs prepared in a Class II or III vertical flow biological safety cabinet or compounding aseptic containment isolator located in an ISO Class 7 area that is physically separated from other preparation areas?	
	247		Does the area have not less than 0.01 inches water column negative pressure to be adjacent to positive pressure ISO Class 7 or better ante-area?	
	248		Does the area have a pressure indicator that can be readily monitored for correct room pressurization?	
	249		Meet the requirements for low volume preparation of hazardous drugs?	
	250		Are hazardous drugs stored separately from other inventory in a manner to prevent	
	251		contamination and personnel exposure?	
			RECORDS OF STERILE COMPOUNDED PREPARATIONS	
	252		Does the pharmacy maintain compounding records for all preparations, either electronically or manually, as part of the prescription drug order, medication order, formula record, formula book, or compounding log, for a minimum of two years?	
			Does each record include:	
	253		Date of preparation	
	254		Complete formula	
	255		Signature or initials of pharmacist or technician who performed the compounding	
	256		Signature or initials of pharmacist responsible for supervising the pharmacy tech who compounded the preparation, and conducted in-process and final checks	
	257		Quantity of units of finished products or amount of raw materials	
	258		Container used and the number of units prepared	
	259		Criteria used to determine beyond-use date	
	260		Documentation of performance of quality control procedures	
	261		Are master worksheets for batch compounding complete?	
	262		Are master worksheets developed & approved by a pharmacist for batch preparations?	
	263		Is preparation worksheet for each batch complete?	
			ENVIRONMENTAL SAMPLING	
			Does environmental sampling occur at a minimum, every six months, and when any	
			of the following conditions occur:	
	264		As part of the commissioning and certification of new facilities and equipment	
	265		Following any servicing of facilities and equipment	
	266		As part of the re-certification of facilities and equipment	
	267		In response to identified problems with end products or staff technique	

Satisfactory	Code	Unsatisfactory		Notes
	268		In response to issues with CSPs, observed compounding personnel work practices, or patient related infections (where the CSP is being considered as a potential source of the infection).	
	269		Is certification 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 to ensure that each ISO classified area is within established guidelines?	
	270		Are all certification records maintained and reviewed to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and air changes per hour?	
	271		Is an appropriate environmental sampling plan developed for airborne particles based on a risk assessment of compounding activities performed?	
	272		Is the evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments performed by properly trained individuals for all compounding risk levels? Does pharmacy maintain training personnel are also properly trained?	
	273		Is air sampling performed at least every six months as a part of the re-certification of facilities and equipment	
			GENERAL INFORMATION ITEMS	
	274		Does the pharmacy hold ANY wholesale distributor or manufacturer licenses?	
	275		Is the pharmacy licensed in any other state as a non-resident pharmacy?	
	276		Has the pharmacy been inspected by any other state, FDA, DEA, or other agency? If so, attach copy of most recent inspection report and related documents (i.e., FDA 483 form)	
	277		Does the pharmacy hold, now or in past, any accreditations (DMEPOS, VIPPS, VAWD, Vet-VIPPS, PCAB, etc.). If so, indicate which in the notes area and reasons for discontinuation, if any.	

	COMPOUNDING RISK CLASS DEFINITIONS
	Are preparations to be compounded appropriately identified as **low-risk**? - Not more than three sterile drug packages used - Sterile equipment - Compounded in an ISO Class 5 hood in an ISO Class 7 clean room (if ISO Class 5 hood NOT in ISO 7 clean room, max BUD = 12 hours) - Limited basic closed system aseptic transfers and manipulations
	Are preparations to be compounded appropriately identified as **medium-risk**? - Uses four or more sterile ingredients - Complex aseptic manipulations other than single volume transfer - CSP is to be administered to multiple patients or to one patient on multiple occasions - Compounding process of unusually long duration (dissolution, homogeneous mixing)
	Are preparations to be compounded appropriately identified as **high-risk**? - Made with nonsterile ingredients, nonsterile devices, or nonsterile containers - Prepared with sterile ingredients, but exposed to < ISO Class 5 air - Greater than a six-hour delay before sterilization - Purity of components assumed, but not verified
	Are **immediate use** compounds appropriately identified? - Aseptically compounded - Simple transfer ≤ 3 commercially manufactured non-hazardous preparations - Not more than 2 entries into any container - Administration begins ≤ 1 hour from start of compounding

Key to abbreviations: ISO - International Organization for Standardization; HVAC - Heating, Ventilation & Air Conditioning; PEC - Primary Engineering Control; USP/NF - United States Pharmacopoeia/National Formulary; CSP - Compounded Sterile Preparation; PPE - Personal Protective Equipment; IPA - isopropyl alcohol; BUD - Beyond-Use Date; DMEPOS - Durable Medical Equipment, Prosthetics, Orthotics and Supplies; VIPPS - Verified Internet Pharmacy Practice Site; VAWD - Verified-Accredited Wholesale Distributor; Vet-VIPPS - Vetrinary Verified Internet Pharmacy Practice Site; PCAB - Pharmacy Compounding Accreditation Board; ADE - Adverse Drug Event

REMARKS:

An inspector from a Qualified Vendor has inspected your pharrmacy on behalf of the Texas State Board of Pharmacy. The results of this inspection are noted. The inspection report will be submitted to the Texas State Board of Pharmacy for further review.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

Signature of Inspector

Printed Name of Inspector

Authorized Individual for the Pharmacy

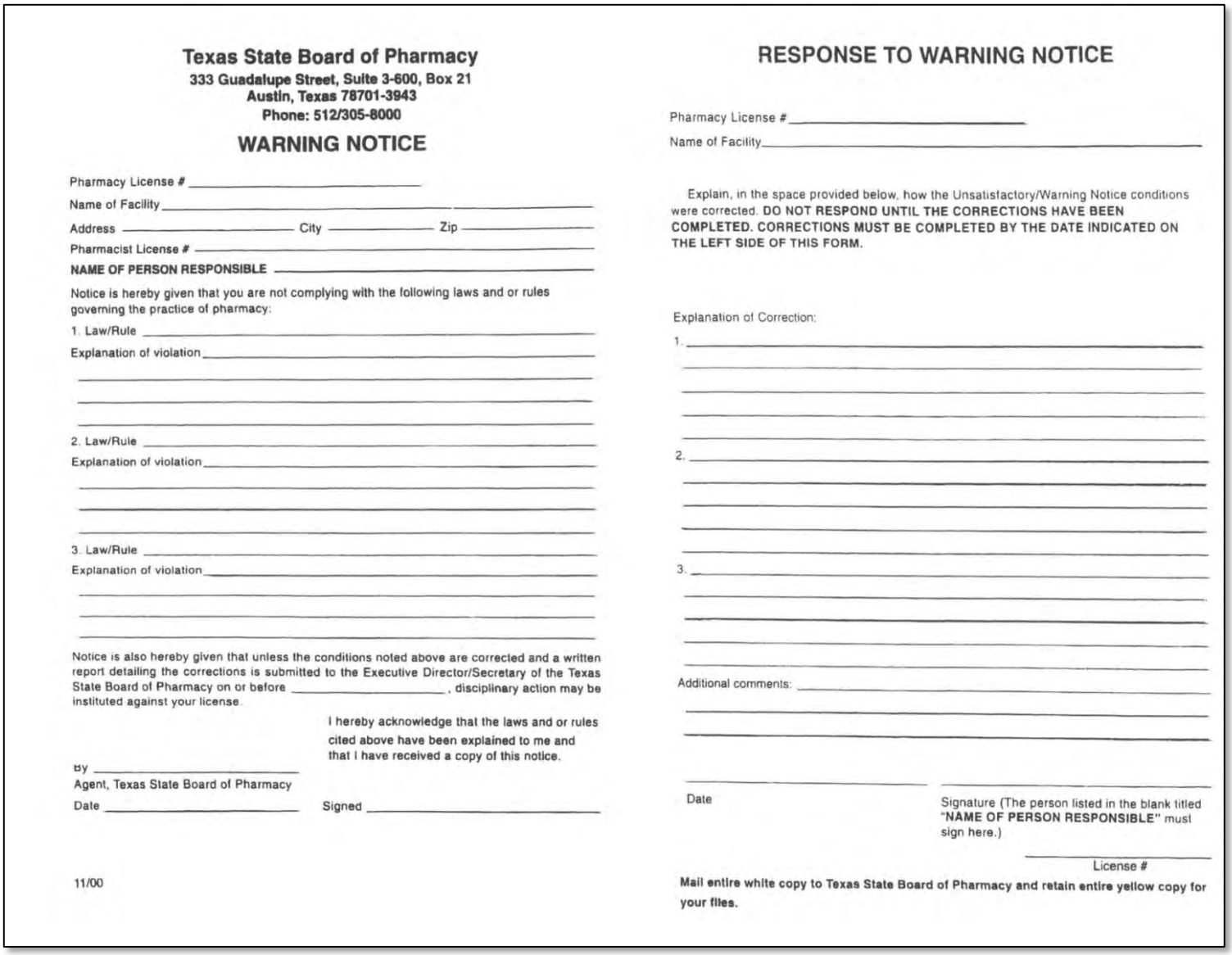
Date

Time of Exit

Printed Name and Title of Authorized Individual

Figure 6 shows a warning notice, which is presented to a pharmacy upon completion of an inspection if noncompliance with laws or Board rules are noted during an inspection.

Figure 6



Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3943
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # _____

Name of Facility _____

Address _____ City _____ Zip _____

Pharmacist License # _____

NAME OF PERSON RESPONSIBLE _____

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule _____

Explanation of violation _____

2. Law/Rule _____

Explanation of violation _____

3. Law/Rule _____

Explanation of violation _____

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before _____, disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By _____
Agent, Texas State Board of Pharmacy

Date _____ Signed _____

11/00

RESPONSE TO WARNING NOTICE

Pharmacy License # _____

Name of Facility _____

Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. **DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.**

Explanation of Correction:

1. _____

2. _____

3. _____

Additional comments: _____

Date

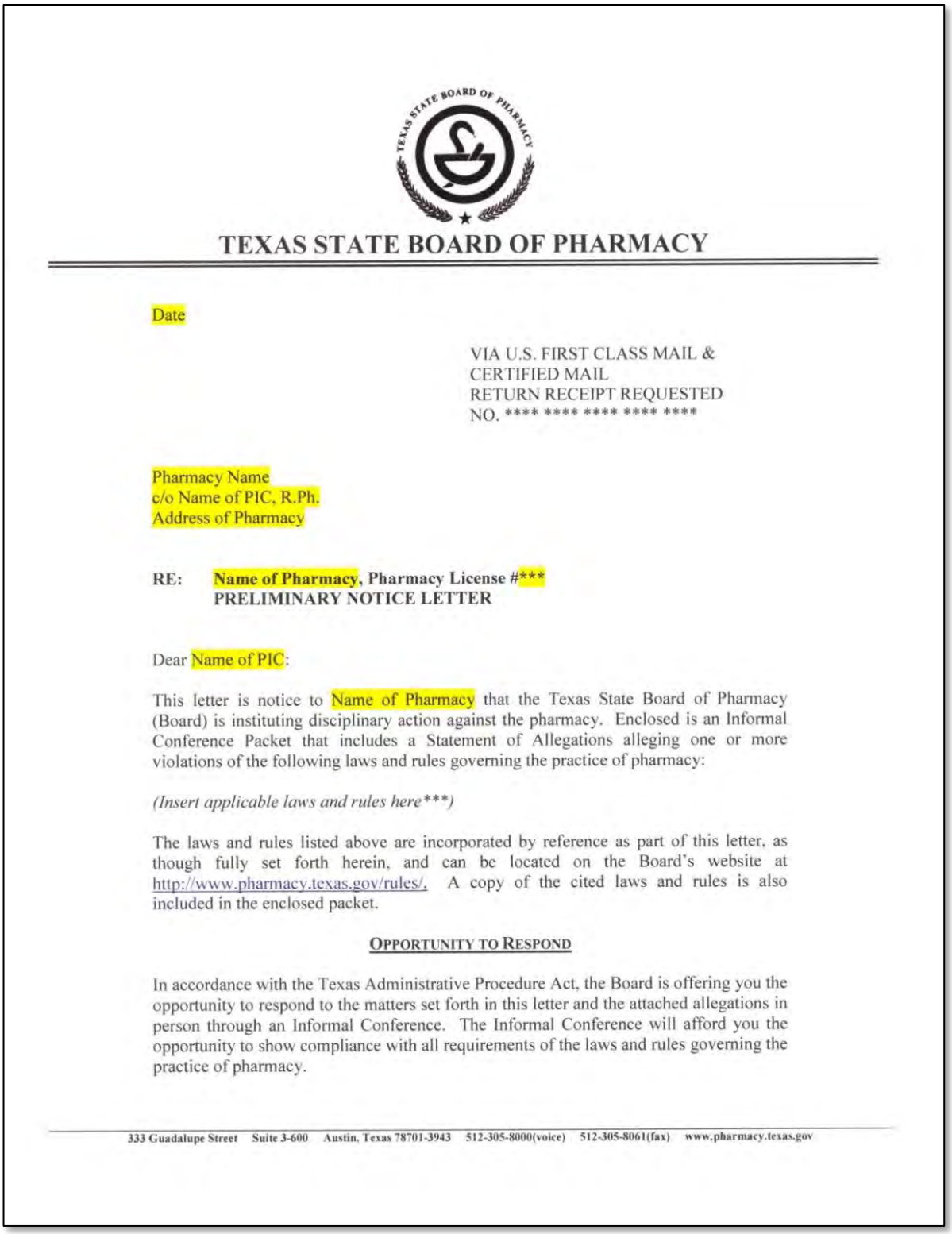
Signature (The person listed in the blank titled "**NAME OF PERSON RESPONSIBLE**" must sign here.)

License #

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.

Figure 7 shows a referral to legal letter, which is initiated for the most severe category of violations identified during an inspection.

Figure 7



TEXAS STATE BOARD OF PHARMACY

Date

VIA U.S. FIRST CLASS MAIL &
CERTIFIED MAIL
RETURN RECEIPT REQUESTED
NO. **** **** **** **** ****

Pharmacy Name
c/o Name of PIC, R.Ph.
Address of Pharmacy

RE: Name of Pharmacy, Pharmacy License #*
PRELIMINARY NOTICE LETTER

Dear Name of PIC:

This letter is notice to Name of Pharmacy that the Texas State Board of Pharmacy (Board) is instituting disciplinary action against the pharmacy. Enclosed is an Informal Conference Packet that includes a Statement of Allegations alleging one or more violations of the following laws and rules governing the practice of pharmacy:

*(Insert applicable laws and rules here***)*

The laws and rules listed above are incorporated by reference as part of this letter, as though fully set forth herein, and can be located on the Board's website at http://www.pharmacy.texas.gov/rules/. A copy of the cited laws and rules is also included in the enclosed packet.

OPPORTUNITY TO RESPOND

In accordance with the Texas Administrative Procedure Act, the Board is offering you the opportunity to respond to the matters set forth in this letter and the attached allegations in person through an Informal Conference. The Informal Conference will afford you the opportunity to show compliance with all requirements of the laws and rules governing the practice of pharmacy.

333 Guadalupe Street Suite 3-600 Austin, Texas 78701-3943 512-305-8000(voice) 512-305-8061(fax) www.pharmacy.texas.gov

NAME
DATE
Page 2

INFORMAL CONFERENCE SCHEDULED

An Informal Conference has been scheduled as follows:

DATE: day, month #, year

TIME: 12:00 a.m./p.m.

PLACE: Office of the Texas State Board of Pharmacy
William P. Hobby Building
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701-3943
Telephone No. (512) 305-8060

PROCEDURE

You may employ an attorney to represent the pharmacy in this matter. Enclosed is an explanation of the disciplinary process including a description of the Informal Conference and other information that you should be aware of during the disciplinary process. Additionally, procedural laws and rules that may affect this matter, including Sections 565.056 and 565.051 of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013), and Section(s) 281.22, 281.64 and 281.65 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2015), can be located at http://www.pharmacy.texas.gov/rules/.

- You or your attorney should contact the Board's office at (512) 305-8060 no later than (date 15 days prior to IC date), to confirm attendance at the Informal Conference.

- Although the law does not require you to submit a rebuttal, if you choose to submit a written rebuttal to the allegations for the Board's consideration, it must be received by the Board by (date 15 days prior to IC date). Your written rebuttal submission will not be considered if it is received after this date.

SECURITY PROCEDURES

All visitors to the William P. Hobby Building will be required to sign a log and receive a visitor's pass. Any individual attending an Informal Conference will need to inform the building's security officer that he/she will be attending an Informal Conference with the Texas State Board of Pharmacy, and provide the officer with a government-issued photo ID. Please allow additional time to go through the security process. Failure to provide a government-issued photo ID may result in delaying an individual's arrival to the Informal Conference.

DEFAULT

FAILURE TO RESPOND TO THE ALLEGATIONS, BY EITHER PERSONAL APPEARANCE AT THE INFORMAL CONFERENCE OR IN WRITING, WILL RESULT IN THE ALLEGATIONS BEING ADMITTED AS TRUE AND THE RECOMMENDED SANCTION MADE AT THE INFORMAL CONFERENCE BEING GRANTED BY DEFAULT.

If you do not respond to this letter on or before Date of IC, the Informal Conference panel will recommend that the Board enter a default Order based upon the allegations set out in the Statement of Allegations. The Board would consider the default Order at the next regularly scheduled meeting.

Please note that this Preliminary Notice Letter applies only to the pharmacy. While we have addressed the letter to the pharmacy in care of the pharmacist-in-charge, this letter does not institute disciplinary action against the license of the pharmacist-in-charge.

The enclosed allegations are being furnished to you so that you will be aware of the specific matters to be discussed at the Informal Conference or presented at a contested case hearing at the State Office of Administrative Hearings, if it is necessary to schedule such a hearing. For your convenience, I have also enclosed a map with directions to our office.

Sincerely,

***
Staff Attorney
***@pharmacy.texas.gov

***/**
Enclosures

cc: pharmacy owner/email to corporate for big chain

TEXAS STATE BOARD OF PHARMACY

Re: Name of Pharmacy License #****

APPLICABLE STATUTES AND RULES

A. ALLEGED VIOLATIONS

The allegations summarized in the enclosed counts provide evidence of violations of the following laws and rules relating to the practice of pharmacy:

Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013):
Insert applicable laws here

• • •

Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2015):
Insert applicable rules here

• • •

B. PROCEDURAL

Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013):

Section 565.056. Informal Proceedings.

(a) The board by rule shall adopt a procedure governing:
  (1) informal disposition of a contested case under Chapter 2001, Government Code; and
  (2) an informal proceeding held in compliance with Chapter 2001, Government Code.

(b) A rule adopted under this section must:
  (1) provide the complainant, if applicable and permitted by law, and the license holder an opportunity to be heard;
  (2) require the presence of an attorney to advise the board or a board employee; and
  (3) if an informal meeting will be held, require notice of the time and place of the informal meeting to be given to the license holder not later than the 45th day before the date the informal meeting is held.

333 Guadalupe Street Suite 3-600 Austin, Texas 78701-3943 512-305-8000(voice) 512-305-8061(fax) www.pharmacy.texas.gov

(c) The attorney must be a member of the board's legal staff, if the board has a legal staff. If the board does not have a legal staff, the attorney must be an employee of the office of the attorney general.

(d) The notice required by Subsection (b)(3) must be accompanied by a written statement of the nature of the allegations against the license holder and the information the board intends to use at the informal meeting. If the board does not provide the statement or information when the notice is provided, the license holder may use that failure as grounds for rescheduling the informal meeting. The license holder must provide to the board the license holder's rebuttal not later than the 15th day before the date of the meeting in order for that information to be considered at the meeting.

(e) On request by a license holder under review, the board shall make a recording of the informal meeting. The recording is a part of the investigative file and may not be released to a third party unless authorized under this subtitle. The board may charge the license holder a fee to cover the cost of recording the meeting. The board shall provide a copy of the recording to the license holder on the license holder's request.

Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2015):

Section 281.22(a), (b)(1)-(4), (c), (d), (h)-(k). Informal Disposition of a Contested Case.

(a) Unless precluded by law, informal disposition may be made of any contested case by stipulation, agreed settlement, consent order, default, or dismissal.

(b) Prior to the imposition of disciplinary sanction(s) against a respondent, the board shall provide the respondent with written notice of the matters asserted, including:
- (1) a statement of the legal authority, jurisdiction, and alleged conduct under which the enforcement action is based, with a reference to the particular section(s) of the statutes and rules involved;
- (2) information the board staff intends to use at an informal conference;
- (3) an offer for the respondent to attend an informal conference at a specified time and place and show compliance with all requirements of law, in accordance with §2001.054(c) of the Administrative Procedure Act; and
- (4) a statement that the respondent has an opportunity for a hearing before the State Office of Administrative Hearings on the allegations;

• • •

(c) The respondent will be provided the opportunity to appear at an informal conference prior to a hearing at the State Office of Administrative Hearings. The notice of the time and place of the informal conference, along with the written notice required in subsection (b) of this section, will be given to the respondent at least 45 days before the date of the informal conference. If such notice is not timely provided, the respondent may reschedule the informal conference.

(d) The respondent shall respond either by personal appearance at the informal conference, or by providing a rebuttal in writing no later than 15 days before the

date of the informal conference. If the respondent chooses to respond in writing, the response shall admit or deny each of the allegations. If the respondent intends to deny only a part of an allegation, the respondent shall specify so much of it is true and shall deny only the remainder. The response shall also include any other matter, whether of law or fact, upon which the respondent intends to rely upon as a defense. If the respondent fails to respond to the notice specified in subsection (b) of this section, the matter will be considered as a default case and the respondent will be deemed to have:

(1) admitted all the factual allegations in the notice specified in subsection (b) of this section;
(2) waived the opportunity to show compliance with the law;
(3) waived notice of a hearing;
(4) waived the opportunity for a hearing on the allegations; and
(5) waived objection to the recommended sanctions made at the informal conference.

• • •

(h) Informal conferences shall be attended by the executive director/secretary or designated representative, legal counsel of the agency or an attorney employed by the office of the attorney general, and other representative(s) of the agency as the executive director/secretary and legal counsel may deem necessary for proper conduct of the conference. The respondent and/or the respondent's authorized representative(s) may attend the informal conference and shall be provided an opportunity to be heard. All communications from the respondent shall be directed to the legal counsel of the agency.

(i) In any case where charges are based upon information provided by a person (complainant) who filed a complaint with the board, the complainant may attend the informal conference, unless the proceedings are confidential under §564.002 and §564.003 of the Texas Pharmacy Act or other applicable law. A complainant who chooses to attend an informal conference shall be provided an opportunity to be heard with regard to charges based upon the information provided by the complainant. Nothing herein requires a complainant to attend an informal conference.

(j) Informal conferences shall not be deemed meetings of the board, and no formal record of the proceedings at such conferences shall be made or maintained unless the respondent requests such a recording in writing at least 15 days before the informal conference. Board staff will arrange for the presence of a court reporter to make the recording. The respondent shall be responsible for the cost of the recording. The recording will be part of the board's investigative file and will not be released to a third party unless authorized under §565.055 of the Act. The board will provide a copy of the recording to the respondent upon request.

(k) Any proposed consent order shall be presented to the board in open meeting for its review. At the conclusion of its review, the board shall approve or disapprove the proposed consent order. Should the board approve the proposed consent order, the appropriate notation shall be made in minutes of the board and the proposed consent order shall be entered as an official action of the board. Should the board

disapprove the proposed consent order, the matter shall be scheduled for public hearing.

If the Texas State Board of Pharmacy finds that grounds exist for discipline, the Board may assess penalties pursuant to Section 565.051 of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013).

Section 565.051. Discipline Authorized.

On a determination that a ground for discipline exists under Subchapter A, or that a violation of this subtitle or a rule adopted under this subtitle has been committed by a license holder or applicant for a license or renewal of a license, the board may:

(1) suspend the person's license;
(2) revoke the person's license;
(3) restrict the person's license to prohibit the person from performing certain acts or from practicing pharmacy or operating a pharmacy in a particular manner for a term and under conditions determined by the board;
(4) impose an administrative penalty under Chapter 566;
(5) refuse to issue or renew the person's license;
(6) place the offender's license on probation and supervision by the board for a period determined by the board and impose a requirement that the license holder:
  (A) report regularly to the board on matters that are the basis of the probation;
  (B) limit practice to the areas prescribed by the board;
  (C) continue or review professional education until the license holder attains a degree of skill satisfactory to the board in each area that is the basis of the probation; or
  (D) pay the board a probation fee to defray the costs of monitoring the license holder during the period of probation;
(7) reprimand the person;
(8) retire the person's license as provided by board rule; or
(9) impose more than one of the sanctions listed in this subsection.

C. DEFAULT

Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2015):

Section 281.22(b)(5), (e), (f) and (g). Informal Disposition of a Contested Case.

• • •

(b) Prior to the imposition of disciplinary sanction(s) against a respondent, the board shall provide the respondent with written notice of the matters asserted, including:

• • •

(5) the following statement in capital letters in 12 point boldface type: FAILURE TO RESPOND TO THE ALLEGATIONS, BY EITHER PERSONAL APPEARANCE AT THE INFORMAL CONFERENCE OR IN WRITING, WILL RESULT IN THE ALLEGATIONS BEING

ADMITTED AS TRUE AND THE RECOMMENDED SANCTION MADE AT THE INFORMAL CONFERENCE BEING GRANTED BY DEFAULT. The notice shall be served by delivering a copy to the respondent in person, by courier receipted delivery, by first class mail, or by certified or registered mail, return receipt requested to the respondent's last known address of record as shown by agency records.

• • •

(e) Default orders.

(1) The informal conference panel may recommend that the board enter a default order, based upon the allegations set out in the notice specified in subsection (b) of this section, adopting the recommended sanctions made at the informal conference. Upon consideration of the case, the board may enter a default order under §2001.056 of the Administrative Procedure Act or direct that the case be set for a hearing at the State Office of Administrative Hearings.

(2) For a contested case before the State Office of Administrative Hearings, the judge may announce a default upon receiving the required showing of proof to support a default, and then recess the hearing, issue an order dismissing the case from the docket of the State Office of Administrative Hearings, and return the file to the board for informal disposition on a default basis in accordance with §2001.056 of the Administrative Procedure Act. The board may then enter a default order or direct the case back to the State Office of Administrative Hearings.

(f) Any default judgment granted under this section will be entered on the basis of the factual allegations in the notice specified in subsection (b) of this section, and upon proof of proper notice to the respondent's address of record. For purposes of this section, proper notice means notice sufficient to meet the provisions of §2001.054 of the Administrative Procedure Act and §281.30 of this title (relating to Pleadings and Notice in a Contested Case).

(g) A motion for rehearing which requests that the board vacate its default order under this section shall be granted if the motion presents convincing evidence that the failure to respond to the notice specified in subsection (b) of this section was not intentional or the result of conscious indifference, but due to accident or mistake, provided that the respondent has a meritorious defense to the factual allegations contained in the notice specified in subsection (b) of this section and the granting thereof will not result in delay or injury to the public or the board.

Appendix 5

Out-of-state Pharmacies That Compound Sterile Preparations Distributed in Texas

In June 2014, the Board of Pharmacy (Board) contracted with three vendors to inspect out-of-state pharmacies that compound sterile preparations that are distributed in Texas. Table 2 lists those three vendors.

Table 2

Vendors Performing Inspections of Out-of-state Pharmacies That Compound Sterile Preparations That Are Distributed in Texas	
Vendor Name	**Web site**
Accreditation Commission for Health Care, Inc.	www.achc.org
National Association of Boards of Pharmacy	www.nabp.net
Superior Laboratory Services, Inc.	www.slsi.net

Source: The Board.

Table 3 lists the 164 out-of-state pharmacies licensed by the Board as of February 28, 2015, and that compounded and distributed sterile preparations in Texas.

Table 3

Licensed Out-of-state Pharmacies That Compounded Sterile Preparations for Distribution in Texas As of February 28, 2015	
Pharmacy Name	**Location**
Medaus Pharmacy	Birmingham, Alabama
Wellness Pharmacy, Inc.	Birmingham, Alabama
Eagle Pharmacy, Inc.	Birmingham, Alabama
Solutions Rx Pharmacy	Birmingham, Alabama
Accurx Pharmacy	Birmingham, Alabama
Triad Rx, Inc.	Daphne, Alabama
Medi-Stat Rx	Foley, Alabama
Roadrunner Pharmacy	Phoenix, Arizona
Vasco Rx	Phoenix, Arizona
Avella of Deer Valley	Phoenix, Arizona
Pharmerica	Phoenix, Arizona
Customceutical Compounding	Phoenix, Arizona
Civic Center Pharmacy	Scottsdale, Arizona
Diamondback Drugs	Scottsdale, Arizona
Pet Health Pharmacy	Youngtown, Arizona
US Compounding, Inc.	Conway, Arkansas

Licensed Out-of-state Pharmacies That Compounded Sterile Preparations for Distribution in Texas As of February 28, 2015	
Pharmacy Name	**Location**
Custom Compounding Center	Little Rock, Arkansas
Cardinal Health 414, LLC	Little Rock, Arkansas
SCA Pharmaceuticals, LLC	Little Rock, Arkansas
Allcare Family Discount Pharmacy	Texarkana, Arkansas
Precision Pharmacy	Bakersfield, California
Roxsan Pharmacy, Inc.	Beverly Hills, California
Bioscrip Infusion Services	Burbank, California
Biorx, LLC	Carlsbad, California
Acariahealth Pharmacy #13, Inc.	Commerce, California
Accredo Health Group, Inc.	Corona, California
Nutrishare, Inc.	Elk Grove, California
Encino Pharmacy	Encino, California
Brooks Health Care	Fresno, California
Central Drugs	La Habra, California
Hartley Medical Center Pharmacy, Inc.	Long Beach, California
BiologicTx	Los Angeles, California
Fusion Rx Compounding Pharmacy	Los Angeles, California
California Pharmacy & Compounding Center	Newport Beach, California
Advanced Compounding Pharmacy	North Hollywood, California
University Compounding	San Diego, California
University Compounding Pharmacy	San Diego, California
Leiter's Compounding	San Jose, California
Conversio Health	San Luis Obispo, California
McGuff Compounding Pharmacy Services, Inc.	Santa Ana, California
Crescent Healthcare, Inc.	Santa Fe Springs, California
Biofusion	Torrance, California
Ionia Pharmacy	Tustin, California
TNH Advanced Specialty Pharmacy II	Van Nuys, California
College Pharmacy	Colorado Springs, Colorado
US Bioservices	Denver, Colorado
Pharmacy Resources, Inc.	Denver, Colorado
Cardinal Health 414, LLC	Denver, Colorado
Brown's Compounding Center	Englewood, Colorado
PICC Lines Plus, LLC	Boynton Beach, Florida
Westlab Pharmacy	Gainesville, Florida
Amex Pharmacy	Melbourne, Florida
Wells Pharmacy Network, LLC	Ocala, Florida
Olympia Pharmacy	Orlando, Florida
Accredo Health Group, Inc.	Orlando, Florida
Palm Beach Pharmaceuticals	Palm Beach Gardens, Florida

Licensed Out-of-state Pharmacies That Compounded Sterile Preparations for Distribution in Texas As of February 28, 2015	
Pharmacy Name	**Location**
APS Pharmacy	Palm Harbor, Florida
Crescent Healthcare, Inc.	Panama City, Florida
Simfarose Pharmaceutical Specialties	Pembroke Pines, Florida
Infuserve America	St. Petersburg, Florida
Pharmalabs, LLC	St. Petersburg, Florida
FMC Pharmacy Services	St. Petersburg, Florida
Diabetic Care Rx	Sunrise, Florida
AnazaoHealth Corporation	Tampa, Florida
Suncoast Radiopharmacy Services, Inc.	Tampa, Florida
Westchase Compounding Pharmacy	Tampa, Florida
Hoye's Pharmacy	Tampa, Florida
Premier Pharmacy Labs, Inc.	Weeki Wachee, Florida
United Pharmacy, LLC	West Palm Beach, Florida
Taylors Pharmacy	Winter Park, Florida
Pharmaceutical Specialties Express	Bogart, Georgia
Innovation Compounding, Inc.	Kennesaw, Georgia
HHI Infusion Services	Burr Ridge, Illinois
Orsini Pharmaceutical Services	Elk Grove Village, Illinois
CVS Caremark	Mount Prospect, Illinois
Martin Avenue Pharmacy, Inc.	Naperville, Illinois
Pure Compounding Pharmacy	Naperville, Illinois
Carepoint Pharmacy	Schaumburg, Illinois
Pharmerica	Indianapolis, Indiana
O'Brien Pharmacy	Mission, Kansas
JCB Laboratories, LLC	Wichita, Kansas
HDM Pharmacy, LLC	Lexington, Kentucky
BET Pharm, LLC	Lexington, Kentucky
Rood and Riddle Veterinary	Lexington, Kentucky
Wickliffe Pharmaceuticals, Inc.	Lexington, Kentucky
Doc Lane's Veterinary Pharmacy, LLC	Lexington, Kentucky
PCA Pharmacy	Louisville, Kentucky
Nutrishare, Inc.	Louisville, Kentucky
Prescription Compounds	Baton Rouge, Louisiana
First Call Pharmacy, LLC	Kenner, Louisiana
LHC Group Pharmaceutical Services	Lafayette, Louisiana
Intrathecal Compounding	Scott, Louisiana
IGG of America, Inc.	Linthicum, Maryland
Freedom Fertility Pharmacy	Byfield, Massachusetts
Village Fertility Pharmacy	Waltham, Massachusetts
Health Dimensions, Inc.	Farmington Hills, Michigan

Licensed Out-of-state Pharmacies That Compounded Sterile Preparations for Distribution in Texas As of February 28, 2015	
Pharmacy Name	**Location**
Diplomat Specialty Pharmacy	Flint, Michigan
Coram Specialty Infusion Services	Mendota Heights, Minnesota
Fairview Home Infusion Pharmacy	Minneapolis, Minnesota
Heartland Home Health Care	Roseville, Minnesota
Vet Rx Pharmacy	Saint Peter, Minnesota
Advanced Infusion Solutions	Ridgeland, Mississippi
Delta Pharma, Inc.	Ripley, Mississippi
Accurate Rx Pharmacy Consulting, LLC	Columbia, Missouri
Foundation Care, LLC	Earth City, Missouri
Essential Pharmacy Compounding	Omaha, Nebraska
Walgreens Infusion Services	Omaha, Nebraska
Meditech Laboratories, Inc.	Las Vegas, Nevada
Anazaohealth Corporation	Las Vegas, Nevada
Partell Specialty Pharmacy (East)	Las Vegas, Nevada
Partell Specialty Pharmacy (West)	Las Vegas, Nevada
Eastern States Compounding Pharmacy	Littleton, New Hampshire
Home Care Services, Inc.	Edison, New Jersey
Hopewell Pharmacy	Hopewell, New Jersey
Bioscrip Infusion Services	Morris Plains, New Jersey
Stokes Pharmacy	Mount Laurel, New Jersey
Mandell's Clinical Pharmacy	Somerset, New Jersey
Wedgewood Village Pharmacy, Inc.	Swedesboro, New Jersey
Biologictx, LLC	Totowa, New Jersey
Basic Home Infusion, Inc.	Wayne, New Jersey
Millers of Wyckoff	Wyckoff, New Jersey
Cardinal Health 414, LLC	Albuquerque, New Mexico
Highland Pharmacy	Albuquerque, New Mexico
Kings Park Slope, Inc.	Brooklyn, New York
Onco360	Great Neck, New York
American Outcomes Management, L.P.	New York, New York
Stanley Specialty Pharmacy	Charlotte, North Carolina
Compounding Pharmacy	Hickory, North Carolina
Greer Pharmacy	Lenoir, North Carolina
BioRx	Cincinnati, Ohio
Lee Silsby Compounding Pharmacy	Cleveland Heights, Ohio
Bioscrip Pharmacy Services	Columbus, Ohio
Jungle Jim's Old Fashioned Pharmacy	Fairfield, Ohio
Heartland Healthcare Services, LLC	Toledo, Ohio
Cyril Home Care Pharmacy	Cyril, Oklahoma
Veterinary Enterprises of Tomorrow	Mountain View, Oklahoma

Licensed Out-of-state Pharmacies That Compounded Sterile Preparations for Distribution in Texas As of February 28, 2015	
Pharmacy Name	**Location**
Optionone, LLC	Oklahoma City, Oklahoma
Arcadia Pharmacy Solutions	Tulsa, Oklahoma
Saffa Infusion Pharmacy	Tulsa, Oklahoma
Strohecker's Pharmacy	Portland, Oregon
US Bioservices	Boothwyn, Pennsylvania
Pentec Health, Inc.	Boothwyn, Pennsylvania
Walgreens Specialty Pharmacy #10997	Carnegie, Pennsylvania
Pharmacy Innovations	Erie, Pennsylvania
Diamond Pharmacy Services	Indiana, Pennsylvania
Biomed Pharmaceuticals	Sharon Hill, Pennsylvania
Hospice Pharmacia	Sharon Hill, Pennsylvania
Synthetopes, Inc.	Conway, South Carolina
Pharmacy Specialties, Inc.	Sioux Falls, South Dakota
Wellness Center Pharmacy, Inc.	Chattanooga, Tennessee
Wells Pharmacy Network, LLC	Dyersburg, Tennessee
Maxor Correctional Pharmacy Services	Franklin, Tennessee
St. Jude Children's Research	Memphis, Tennessee
Excellerx, Inc.	Memphis, Tennessee
DCA Pharmacy	Nashville, Tennessee
Amerita	Nashville, Tennessee
Medquest Pharmacy	North Salt Lake, Utah
Meds for Vets, LLC	Sandy, Utah
Acariahealth Pharmacy, Inc.	Falls Church, Virginia
Homechoice Partners, Inc.	Norfolk, Virginia
Custom Prescriptions	Bellevue, Washington
Key Compounding Pharmacy	Federal Way, Washington
Comprecare	Huntington, West Virginia
Zoopharm	Laramie, Wyoming

Source: The Board.

Appendix 6

Compounding Pharmacy Inspections and License Data by Region

The Board of Pharmacy (Board) conducted 1,154 inspections of compounding pharmacies in fiscal year 2014. The Board also conducted 481 inspections of noncompounding pharmacies in fiscal year 2014. The Board has 12 inspector positions responsible for inspecting pharmacies across 9 regions of the state. Most regions have one inspector; however, the Dallas and Houston regions are assigned two and three inspectors, respectively. Table 4 lists the number of pharmacy inspections by region in fiscal year 2014.

Table 4

Inspections of Pharmacies By Region Fiscal Year2014			
Region	Number of Inspections of Compounding Pharmacies	Number of Inspections of Noncompounding Pharmacies	Total Inspections
Dallas	224	90	314
Fort Worth	117	62	179
East Texas	98	43	141
Central Texas	87	45	132
Houston	216	110	326
Valley	104	32	136
San Antonio	121	38	159
Austin/El Paso	93	42	135
West Texas	79	19	98
Out-of-State	15	0	15
Totals	**1,154**	**481**	**1,635**

Source: The Board.

As of February 28, 2015, 3,859 compounding pharmacies were actively licensed by the Board. Of those, 934 pharmacies were licensed to compound sterile preparations. The remaining 2,925 pharmacies reported to the Board that they compounded only preparations not requiring sterility. Table 5 lists the number of licensed compounding pharmacies by region.

Table 5

Compounding Pharmacies Actively Licensed by the Board As of February 28, 2015			
Region	Number of Pharmacies That Compound Sterile Preparations	Number of Pharmacies That Compound Only Preparations Not Requiring Sterility	Total Number of Compounding Pharmacies
Dallas	146	477	623
Fort Worth	70	252	322
East Texas	66	265	331
Central Texas	55	240	295
Houston	169	610	779
Valley	59	232	291
San Antonio	70	243	313
Austin/El Paso	65	191	256
West Texas	70	192	262
Out-of-State	164	223	387
Totals	**934**	**2,925**	**3,859**

Source: The Board.

Copies of this report have been distributed to the following:

Legislative Audit Committee

The Honorable Dan Patrick, Lieutenant Governor, Joint Chair
The Honorable Joe Straus III, Speaker of the House, Joint Chair
The Honorable Jane Nelson, Senate Finance Committee
The Honorable Robert Nichols, Member, Texas Senate
The Honorable John Otto, House Appropriations Committee
The Honorable Dennis Bonnen, House Ways and Means Committee

Office of the Governor

The Honorable Greg Abbott, Governor

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