

**TEXAS STATE BOARD OF PHARMACY**  
Austin, Texas

**ANNUAL INTERNAL AUDIT REPORT**

Fiscal Year 2020



TEXAS STATE BOARD OF PHARMACY  
Austin, Texas

Annual Internal Audit Report  
Fiscal Year 2020

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# Garza/Gonzalez & Associates

CERTIFIED PUBLIC ACCOUNTANTS

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Board Members  
Texas State Board of Pharmacy  
Austin, Texas

We performed tests of management's assertion about the effectiveness and efficiency of the internal control structure over the Inspections Area (the Area) of the Texas State Board of Pharmacy (TSBP); and, its compliance with the requirements set by applicable sections of the Texas Pharmacy Act; other applicable state and federal requirements; and, TSBP's established policies and procedures, as applicable to the Area, for the 6 months ended February 29, 2020.

The results of our tests disclosed that TSBP's internal control structure over the Area and its established policies and procedures, were generally adequate and no material instances of noncompliance were noted; however, we did identify certain matters that are included in this report, that are opportunities for strengthening internal controls and ensuring compliance with state requirements and TSBP's established policies and procedures. Based on the degree of risk or effect of these matters in relation to the audit objective(s), these matters were rated as either Priority, High, Medium, or Low, which is further described in the "Summary and Related Rating of Observations/Findings and Recommendations", which is included in page 13 of this report.

We also performed a follow-up of the findings and recommendations that were presented in the prior year annual internal audit report. This report reflects the implementation status of those matters; and, includes all information required for compliance with the State of Texas Internal Audit Annual Report requirements.

We have discussed the comments and recommendations from the audit of the Area; and, the implementation status from the follow-up performed, with various TSBP personnel, and we will be pleased to discuss them in further detail; to perform an additional study of these matters; or, to assist you in implementing the recommendations.



May 15, 2020

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## INTRODUCTION

The Texas State Board of Pharmacy (TSBP) is a state agency under the authority of the Texas Pharmacy Act (Texas Occupations Code Title 3, Subtitle J) and is responsible for:

- licensing/registration of Texas pharmacists, pharmacy technicians, and pharmacies;
- establishing regulations for pharmacy practice; and,
- investigating and resolving complaints against licensees and registrants, and taking disciplinary action when necessary.

TSBP is governed by an 11-member Board that is statutorily required to meet at least once every 4 months; although, currently, it meets quarterly. The Board consists of 7 pharmacists, 1 pharmacy technician, and 3 members who represent the public. Board members are appointed for staggered 6-year terms by the Texas Governor with the advice and consent of the Texas Senate.

TSBP's mission is "to promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Texas, through the regulation of: the practice of pharmacy; the operation of pharmacies; and, the distribution of prescription drugs in the public interest."

### **2020 Internal Audit Plan**

Following is the internal audit and other functions performed, as identified in TSBP's *Internal Audit Plan for Fiscal Year 2020*, dated January 14, 2020, and approved by the Board on February 4, 2020:

- Completion of the Fiscal Year 2020 Risk Assessment and Preparation of the Internal Audit Plan
- Inspections
- Follow-up of Prior Year Internal Audit and Preparation of the 2020 Annual Report

This report contains the results of our audit of the Inspections Area; reflects the results of the follow-up procedures performed in the current year of findings that were presented in the prior year internal audit; and, meets the State of Texas Internal Audit Annual Report requirements.

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### INTERNAL AUDIT OBJECTIVES

In accordance with the **International Standards for the Professional Practice of Internal Auditing**, the audit scope encompassed the examination and evaluation of the adequacy and effectiveness of TSBP's system of internal control and the quality of performance in carrying out assigned responsibilities. The audit scope included the following objectives:

- **Reliability and Integrity of Financial and Operational Information** – Review the reliability and integrity of financial and operating information and the means used to identify, measure, classify, and report such information.
- **Compliance with Policies, Procedures, Laws, Regulations and Contracts** – Review the systems established to ensure compliance with those policies, procedures, laws, regulations, and contracts which could have a significant impact on operations and reports, and determine whether the organization is in compliance.
- **Safeguarding of Assets** – Review the means of safeguarding assets and, as appropriate, verify the existence of such assets.
- **Effectiveness and Efficiency of Operations and Programs** – Appraise the effectiveness and efficiency with which resources are employed.
- **Achievement of the Organization's Strategic Objectives** – Review operations or programs to ascertain whether results are consistent with established objectives and goals and whether the operations or programs are being carried out as planned.

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### I. **Compliance with Texas Government Code 2102: Required Posting of Internal Audit Information**

To comply with the provisions of Texas Government Code 2102.015 and the State Auditor's Office guidelines, within 30 days of approval by the TSBP's Board, TSBP will post the following information on its website:

- An approved fiscal year 2021 audit plan, as provided by Texas Government Code, Section 2102.008.
- A fiscal year 2020 internal audit annual report, as required by Texas Government Code, Section 2102.009.

The internal audit annual report includes any weaknesses, deficiencies, wrongdoings, or other concerns raised by internal audits and other functions performed by the internal auditor as well as the summary of the action taken by TSBP to address such concerns.

### II. **Consulting and Nonaudit Services Completed**

The internal auditor did not perform any consulting services, as defined in the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing* or any non-audit services, as defined in the *Government Auditing Standards, 2018 Revision, Sections 3.64-3.106*.

### III. **External Quality Assurance Review**

The internal audit department's most recent *System Review Report*, dated November 16, 2018, indicates that its system of quality control has been suitably designed and conforms to applicable professional standards in all material respects.

### IV. **Internal Audit Plan for Fiscal Year 2020**

The approved Internal Audit Plan (Plan) included one audit to be performed during the 2020 fiscal year. The Plan also included a follow-up of the prior year internal audit recommendations; other tasks, as assigned by the Board members; and, preparation of the Annual Internal Audit Report for fiscal year 2020.

#### **Risk Assessment**

Utilizing information obtained through the inquiries and background information reviewed, 14 audit areas were identified as the potential audit topics. A risk analysis, utilizing 8 risk factors, was completed for each individual audit topic and then compiled to develop an overall risk assessment.

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Following are the results of the risk assessment performed for the 14 potential audit topics identified:

<b>HIGH RISK</b>	<b>MODERATE RISK</b>	<b>LOW RISK</b>
Inspections	HR/Payroll	Fixed Assets/ Fleet Management
Licensing: Pharmacist/ Interns/ Preceptors	Procurement/ Contract Management/ HUB	Compliance Monitoring/ Peer Assistance
Prescription Monitoring Program (PMP)	Accounting & Financial Reporting/ Travel	Licensing: Pharmacy Tech & Trainees
Complaints/Investigations	IT	Records Management
	Licensing: Pharmacies	Risk Management

TSBP met the criteria as established by the *Texas Internal Auditing Act* (Texas Government Code, Chapter 2102), for the implementation of an internal audit activity, for the first time, effective fiscal year 2018. In the prior 2 years, internal audits were performed in the following areas:

Fiscal Year 2019:

- Accounting & Financial Reporting
- Follow-up of Post-Payment Audit Recommendations Dated July 20, 2018
- Follow-up of Prior Year Internal Audit Recommendations

Fiscal Year 2018:

- Prescription Monitoring Program (PMP)

The area recommended for internal audit and other tasks to be performed for fiscal year 2020 were as follows:

<b>Report No.</b>	<b>Audits/Report Titles</b>	<b>Completion Date</b>
1.	Inspections <i>Objective:</i> To determine whether TSBP's policies and procedures and internal processes in place over the Inspections Area (the Area) provide reasonable assurance of compliance with state and federal requirements; and, whether established internal controls are operating effectively.	5/15/2020
1.	Annual Internal Audit Report – Follow-Up of Prior Year Internal Audits	5/15/2020
-	Other Tasks Assigned by the Board or Management.	None

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### V. Executive Summary

#### Inspections

##### Background

Texas Occupation Code (OC) Chapter 556 authorizes TSBP or its representatives to inspect the following areas of pharmacies and facilities that apply for a pharmacy license:

- (1) drug storage and security;
- (2) equipment;
- (3) compounding components, finished and unfinished products, containers, and labeling;
- (4) sanitary conditions;
- (5) required records, reports, or other documents; and,
- (6) certain financial records.

Compliance inspections are required in the following two circumstances:

- **Pre-Inspection:** In accordance with Board rule TAC §291.1, prior to issuance of a resident (in-state) pharmacy license, TSBP must inspect the facility in the presence of the (a) Pharmacist-in-Charge (PIC); and, (b) owner or representative of the owner. A pre-inspection may be waived for applicants that hold an active pharmacy license in Texas in good standing, with the exception of an applicant for a license to compound sterile preparations. Pre-Inspection is always required by OC Sec. 560.052 for facilities applying for a license to compound sterile preparations.
- **Pharmacies compounding sterile preparations:** In accordance with OC Sec. 561.0032, these pharmacies, which are identified as such by adding the suffix of “-S” to the pharmacy class, must be inspected biennially for renewal of their pharmacy license. Inspections of resident pharmacies (class A-S and C-S) are conducted by TSBP inspectors; while, nonresident (out-of-state) pharmacies (class E-S) are inspected by an approved vendor contracted by TSBP to perform such inspections.

Since there is no statute or Board rule for the inspection frequency of all other types of pharmacies, as part of its Compliance Program, TSBP utilizes the compliance inspections performed by its Inspections Area, as a tool for pharmacies to voluntarily comply with various pharmacy laws and regulations that are designed to ensure public health and safety. TSBP’s goal, as outlined in its fiscal year 2019-2023 Strategic Plan, is to conduct compliance inspections each year for 40% of the in-state licensed pharmacies. According to TSBP’s internal database and records, during the 6-month period from September 1, 2019 to February 29, 2020, TSBP conducted, or attempted to conduct, compliance inspections for 1,333 (17.6%) of the 7,571 licensed resident pharmacies. TSBP does not conduct inspections for out-of-state pharmacies other than nonresident sterile compounding pharmacies. During that same 6-month period, 23 (19.7%) of the 117 nonresident sterile compounding pharmacies were inspected by an approved vendor contracted by TSBP.



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The Inspections Area (the Area), which is managed by a Chief Compliance Officer who reports directly to the Executive Director/Secretary, is responsible for performing inspections to ensure TSBP is compliant with OC Chapter 556. The Area's staff either work from the Austin office ("in-house") or remotely from their home office (field staff). The in-house staff consist of the Chief Compliance Officer, 2 Compliance Program Officers, a Senior Compliance Specialist, a Compliance Specialist, and an Administrative Assistant. All field staff are inspectors who are responsible for inspecting pharmacies located in their respective assigned region. Each inspector is assigned a state vehicle and a gas card for work-related travel in their assigned region. Newly hired TSBP inspectors undergo an 18-week training period before he/she begins conducting independent inspections. The training includes a review of compliance and administrative policies and procedures, and traveling to the various regions to observe and assist other inspectors. All TSBP inspectors participate in biweekly Compliance Team conference calls, and quarterly in-person Compliance Team meetings held at the Austin office. Inspectors from contracted vendors must meet the same qualifications as TSBP inspectors, and receive initial and annual training developed by TSBP's Compliance Program Officer.

The Area is in the process of migrating to *Inspection Editor*, a mobile, cloud-based inspection platform that has built-in internal control features to ensure completeness and consistency of inspections. To date, TSBP has migrated class A pharmacy inspections to the *Inspection Editor*. Inspections of all other pharmacy classes are still conducted on triplicate paper forms. The Compliance Specialist manually enters all inspection data, from the inspection reports collected from the inspectors, to *Versa*, TSBP's licensing and monitoring system.

### Inspection Scheduling

Inspectors are responsible for scheduling inspections using their own methodology and the following criteria identified by the Area, in the order of priority:

- (1) Pre-inspections (to meet the 90-day licensure timeline goal)
- (2) Pharmacies compounding sterile preparations (to meet the biennial license renewal cycle requirement)
- (3) New pharmacies or recent ownership change
- (4) Warning Notice follow-up inspections
- (5) Licensee requests
- (6) Requests to inspect (from other TSBP departments)
- (7) Routine inspections

Every quarter, inspectors receive a summary report of the last inspection date for all pharmacies within their respective region. Inspectors are also provided with "Rosters", which is a list of all pharmacies, in their respective region, that includes basic pharmacy information, along with noted deficiencies, if any, in the last 5 fiscal years. Inspectors use this information to plan their weekly travel and to schedule inspections in an efficient manner. In general, priority inspections are scheduled first and those of less priority but in the same geographical area, are scheduled in the remaining timeslots.

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## Inspection Process

Compliance inspections, other than pre-inspections and inspections for which an appointment must be made due to other circumstances (e.g., unusual business hours), are conducted unannounced. Before entering a pharmacy area, the inspector will present official credentials, and the *Notice of Inspection*; and, state the purpose of the entry, as required by OC Sec. 556.052(a). The *Notice of Inspection* includes general information of the licensee, purpose of inspection, and a written notice of the authority for the inspection. A pharmacy representative (PIC, pharmacist-on-duty, administrator, director, owner, or manager) is asked to sign the *Notice of Inspection* to certify the inspector's compliance with the above OC section.

Once the Notice of Inspection is signed, the inspector begins the inspection utilizing the *Inspection Report*, which is a compliance requirements checklist. The Area has developed a separate inspection report for the inspection of pharmacies compounding sterile preparations, and class B pharmacies since their compliance requirements are significantly more complex than those for other types of pharmacies.

The inspector, using the Policy and Procedure Manual (the Manual) as guidance, and with his/her professional judgement, determines one of the 4 compliance statuses for each applicable compliance requirement, called *inspection code*, and marks the inspection report, as shown below, in accordance with TAC §291.19:

<b>Compliance Status</b>	<b>Inspection Report</b>	<b>Note</b>
Compliant	No markings.	—
Compliant with Comments: Needs Improvement (N/I)	Circle code number.	Provide explanation in the <i>Remarks</i> section of inspection report.
Non-Compliant: Warning Notice (W/N)	Check "W/N" column.	Issue a <i>Warning Notice</i> .
Refer to Enforcement/Legal (R/L)	Check "R/L" column.	Provide explanation in the <i>Remarks</i> section; and, refer to Enforcement/Legal.

The Manual is organized by pharmacy class, which allows inspectors to refer to only one applicable subsection when conducting an inspection. For each inspection code, the Manual provides the inspection procedures inspectors must follow, and compliance status criteria along with applicable legal/code citation.

OC 556.051(3) and OC 556.053(3) authorize inspectors to collect samples of sterile or non-sterile compounded products, to be sent to a contracted laboratory for testing. TSBP has developed the *Sample Collection Form* and the *Chain of Custody Form* to ensure proper documentation and accountability of collected samples.

At the conclusion of the inspection, the inspector will review the *Inspection Report* and Warning Notice (WN), if applicable, with the pharmacy's representative. The inspector will sign the *Inspection Report*, obtain signature from the representative acknowledging that the noted conditions were explained, and provide him/her with the pharmacy's copy of the *Inspection Report*.

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The inspector will also obtain the PIC's signature on a *PIC Attestation* in which the PIC acknowledges receipt of inspection documents; and, if WNs were issued, the PIC also affirms that each noted deficiency that requires corrective action will be resolved by the due date as specified by the inspector in the WN. If the PIC was not present during the inspection, the pharmacist-on-duty or other responsible party must sign a *Pharmacist-on-Duty Attestation* affirming he/she will provide all inspection documents to the PIC within 3 business days from the date of the inspection. The PIC attestation must then be submitted to TSBP within 7 days of receipt by the PIC from the pharmacist-on-duty or other pharmacy representative. Submission of the PIC Attestation is considered the pharmacy's written response required by TAC §291.19.

An inspector *may* perform a follow-up inspection at a pharmacy that received a WN; however, the Area has identified priority WNs that are considered significant and warrant a follow-up. Follow-up inspections are scheduled by the inspectors as part of inspection scheduling in the priority listed above.

### Post Inspections

On a weekly basis, TSBP inspectors submit the following to the Austin office:

- Completed inspection reports and related documents – The Compliance Specialist (CS) enters the inspection data into Versa. The Senior Compliance Specialist will review each inspection report for completeness and consistency.
- Weekly Activity Report – The Senior Compliance Specialist reconciles the Weekly Activity Report to inspection reports; while, the Chief Compliance Officer reviews the Weekly Activity Reports.
- Travel Vouchers – These travel vouchers report lodging and meal expenses reported by inspectors; and, are approved by the Chief Compliance Officer and further reviewed to identify travel inefficiencies. Approved travel vouchers are submitted to the Accounting department for reimbursement processing.

### Vendor Inspectors

As documented earlier in this report, prior to issuance of a license, all pharmacies compounding sterile preparations; including, class E-S pharmacies, must have a pre-inspection and then be inspected biennially thereafter as part of the license renewal cycle. Class E-S pharmacies are inspected by a qualified inspector who is employed by one of the 3 approved vendors procured and contracted by TSBP to perform inspections. Each inspector must initially submit his/her photo and curriculum vitae to TSBP, and sign an acknowledgment stating he/she has completed the training and read the Compliance Manual for Class E-S pharmacies. A list of approved vendors and qualified vendor inspectors are posted on TSBP's website.

Class E-S pharmacies seeking licensure/renewal will enter into a contract with one of these vendors to obtain an inspection. In accordance with OC Sec. 556.0551(b), the vendor bills the pharmacy directly for all inspection costs; such as, inspection fee and the inspector's travel expense. Flat rate inspection fees are established in the contract terms between TSBP and the vendors.

At the conclusion of the inspection of a class E-S pharmacy, the vendor inspector will conduct an exit interview, provide a copy of the inspection report to the authorized representative of the pharmacy, and submit the reports to TSBP within 10 business days from the date of the inspection. A Compliance Program Officer will review the inspection report; and, upon approval, issue a WN, if applicable

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### AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

#### Objective

The objective of our audit was to determine whether TSBP's policies and procedures and internal processes in place over the Inspections Area (the Area) provide reasonable assurance of compliance with state and federal requirements; and, whether established internal controls are operating effectively.

#### Scope

The scope of the audit was for the 6-month period from September 1, 2019 through February 29, 2020 (audit period).

#### Methodology

The audit methodology included a review of applicable laws and regulations; TSBP's established policies and procedures; other internal and external documentation; and, interviewing and corresponding with selected TSBP employees.

We obtained and/or reviewed the following internal and external documentation:

- A. Texas Pharmacy Act Sec. 556; 560; and 561.
- B. Texas Administrative Code Title 22, Part 15, Chapter 291.
- C. TSBP Strategic Plan 2019-2023.
- D. Organizational chart of the Area and job descriptions for the Compliance staff.
- E. TSBP Policy and Procedure Manual Section 7 – Compliance Procedures.
- F. Orientation material: *Overview of TSBP Compliance Program & Inspection Process*, March 25, 2020.
- G. Qualified vendor webinar training material: *Inspecting Non-Resident Pharmacies Compounding Sterile Preparations (Class E-S)*, August 16, 2018; and, *Update on Inspecting Non-Resident Pharmacies Compounding Sterile Preparations (Class E-S)*, August 16, 2018.
- H. *Inspection Editor Step-By-Step*, as prepared by the Chief Compliance Officer.

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- I. Sample forms and templates, to include:
  - a. Notice of Inspection
  - b. Inspection Reports
  - c. Warning Notice
  - d. Pharmacist-in-Charge and Pharmacist-on-Duty attestations
- J. List of compliance inspections conducted during the audit period.
- K. Pharmacy Last Inspections (HPC-12507) Report generated on April 9, 2020 and listing of Class E-S inspections conducted during the audit period, as maintained by the Area.

We performed various procedures to achieve the objective of our audit; to include, the following:

1. Reviewed and obtained an understanding of state laws and regulations, and other requirements as applicable to the Area.
2. Reviewed the Area's policies and procedures, forms, templates, and other documentation; and, conducted interviews with selected employees, to obtain an understanding of controls, processes, and current practices in place over the Area, and to evaluate whether such controls adequately ensure compliance with applicable requirements identified in procedure 1 above.
3. Reviewed inspection report templates for inclusion of compliance requirements, as provided by the applicable subsection of the Policy and Procedure Manual.
4. Selected a sample of 25 compliance inspections conducted during the audit period, and tested for the following attributes:
  - a. Inspector completed all required fields in Notice of Inspection and Inspection Report.
  - b. Notice of Inspection is signed by an authorized pharmacy representative in the presence of the inspector.
  - c. Purpose of inspection is proper.
  - d. Inspector utilized correct type of inspection report.
  - e. All noncompliance items noted in the inspection report were communicated to the licensee as either remarks or warning notices with accurate code cited.
  - f. Post-inspection Acknowledgement was completed by the inspector and signed by the pharmacy's authorized representative.

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- g. PIC attestation form was completed, accurate, and was signed and dated either the inspection date (PIC present) or within 7 days of receipt of inspection documents (PIC not present).
  - h. Information (inspection date, inspection #, license #, inspection type, WNs) in inspection report is consistent with the same data entered into *Versa*.
  - i. Information (pharmacy name, license #, class, inspection date) in inspection report, Weekly Report, and travel voucher are consistent.
  - j. Meals and lodging expense reimbursement requests do not exceed the U.S. General Services Administration's (GSA) maximum rates applicable to the inspection location and date.
  - k. Travel voucher was approved by the Chief Compliance Officer.
5. Reviewed the Pharmacy Last Inspections Report and the Class E-S inspections listing to assess the reasonableness of inspection frequency.

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**VI. Observations/Findings and Recommendations**

SUMMARY and RELATED RATING of OBSERVATIONS/FINDINGS and RECOMMENDATIONS

As TSBP’s internal auditors, we used our professional judgment in rating the audit findings identified in this report. The rating system used was developed by the Texas State Auditor’s Office and is based on the degree of risk or effect of the findings in relation to the audit objective(s). The table below presents a summary of the observations/findings in this report and the related rating, as applicable.

<b>Summary of Observations/Findings &amp; Recommendations and Related Ratings</b>		
<b>Finding No.</b>	<b>Title</b>	<b>Rating</b>
1	Review, Approval, and Quality Control	Medium
2	Inspection Report	Medium
3	Inspection Scheduling	Low
4	Written Procedures	Low
5	Code of Professional Responsibility	Low
<i>Observation</i>		
1	Inspection Data Entry	--
2	Travel Reimbursements	--
<p><u>Description of Rating</u></p> <p>A finding is rated <i>Priority</i> if the issues identified present risks or effects that if not addressed could <u>critically affect</u> the audited entity’s ability to effectively administer the programs(s)/function(s) audited. Immediate action is required to address the noted concern(s) and reduce risks to the audited entity.</p> <p>A finding is rated <i>High</i> if the issues identified present risks or effects that if not addressed could <u>substantially affect</u> the audited entity’s ability to effectively administer the programs(s)/function(s) audited. Prompt action is essential to address the noted concern(s) and reduce risks to the audited entity.</p> <p>A finding is rated <i>Medium</i> if the issues identified present risks or effects that if not addressed could <u>moderately affect</u> the audited entity’s ability to effectively administer programs(s)/function(s) audited. Action is needed to address the noted concern(s) and reduce risks to a more desirable level.</p> <p>A finding is rated <i>Low</i> if the audit identified strengths that support the audited entity’s ability to administer the programs(s)/function(s) audited <u>or</u> the issues identified do not present significant risks or effects that would negatively affect the audited entity’s ability to effectively administer the programs(s)/function(s) audited.</p>		

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**OBSERVATIONS/FINDINGS and RECOMMENDATIONS**

Report No.	Report Date	Name of Report	Observations/ Findings and Recommendations	Fiscal Impact/ Other Impact
1	5/15/2020	Inspections	<p><b>1. Review, Approval, and Quality Control</b></p> <p>TSBP has not established a quality assurance process that provides for a formal review and approval of inspections conducted by TSBP field inspectors to ensure inspections consistently meet standards set forth by the Area's Compliance Program.</p> <p><b>Recommendation</b> We recommend that the Area develop and implement a quality assurance process for inspections of resident pharmacies to help management identify issues, deficiencies; and, opportunities for improvement, in a timely manner.</p> <p><b>Management's Response</b> The following procedures are being adopted by the Area to implement the recommendation:</p> <ul style="list-style-type: none"> <li>• The Senior Compliance Office will conduct a detailed review of all inspection reports for consistency with department policies and procedures, agency rules and regulations, and TSBP compliance-related goals and objectives. Area inspectors will submit reports to the Senior Compliance Officer within one week after the inspection is conducted, and the review will be completed within approximately one additional week.</li> <li>• On a monthly basis, the Senior Compliance Officer will generate a report regarding the review process, identifying inconsistencies in TSBP inspector's findings. The report will be reviewed by the Chief of Compliance, in conjunction with the General Counsel and the Executive Director, to determine proper and consistent interpretations.</li> <li>• The Chief of Compliance will coordinate follow-up training regarding inconsistencies that become evident from the inspection report review process during biweekly Compliance Program meetings.</li> </ul> <p><b>2. Inspection Report</b></p> <p>When conducting inspections, TSBP inspectors utilize the <i>Inspection Report</i>, a standardized checklist, that lists compliance requirements, referred to as <i>inspection codes</i>, as provided by applicable sections of the Policy and Procedure Manual (the Manual). For the inspection of class A-S, class B, and class C-S pharmacies, a separate inspection report was developed to reflect the extensive compliance requirements applicable to these pharmacies. However, 78 (43%) of 181 inspection codes found in the applicable subsection of the Manual for class A-S and C-S inspections are not included in the inspection report. As a result, TSBP does not have documentary evidence demonstrating that inspectors inspected all applicable inspection codes. Instead, TSBP currently relies on inspectors' training and expertise for completeness of class A-S, B, and C-S inspections.</p> <p>In addition, TSBP has a draft of the class B inspection manual, which makes reference to a number of inspection codes for class A-S and C-S inspections. Since the manual is in draft form, we did not quantify the number of inspection codes not referenced in the inspection report.</p> <p><b>Recommendation</b> We recommend that the Area finalize the class B inspection manual, reassess the inspection report used for class A-S, class B, and class C-S pharmacies; and/or, develop and implement procedures that will provide evidence that each applicable compliance requirement was inspected.</p>	<p>To ensure inspections consistently meet the Area's Compliance Program standards.</p> <p>To ensure completeness of inspections.</p>



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Report No.	Report Date	Name of Report	Observations/ Findings and Recommendations	Fiscal Impact/ Other Impact
1	5/15/2020	Inspections	<p><b>Management's Response</b> The following procedures are being adopted by the Area to implement the recommendation:</p> <ul style="list-style-type: none"> <li>• The inspection manual for class B pharmacies has been revised to be finalized by the end of the fiscal year.</li> <li>• A re-assessment of the current inspection report form used for resident pharmacies that compound sterile preparations (i.e., class A-S, class B, and class C-S pharmacies) will take place to determine if the 78 inspection items noted should be specifically listed in the inspection report form. In 2015, the compliance team evaluated the inspection report form that was in use for resident pharmacies that engaged in the compounding of sterile preparations at the time (identical to the non-resident [Class E-S] inspection report) and determined that the 78 inspection items could be generally addressed within other inspection item codes. For example, "Code 148 - Results of personnel gloved fingertip testing" could be addressed under Code 142, which is listed in the inspection form and asks the following: "Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation and testing (e.g. media fill testing, gloved fingertip/thumb testing)? Does pharmacy have an on-the-job training program?" For this reason, Code 148 was considered to be a subset of Code 142 and was consolidated with Code 142 to streamline the thirteen-page inspection form into two pages.</li> <li>• As part of the re-assessment of the current inspection report form used for resident pharmacies that compound sterile preparations, the inspection report form will be evaluated for enhancements that are in accordance with the National Association of Boards of Pharmacy's Multistate Pharmacy Inspection Blueprint Program's Universal Inspection Form.</li> <li>• As part of the review process for the Class B policies and procedures, which include additional exceptions and allowances that pertain to nuclear pharmacy settings, further re-assessment will take place to determine whether those policies and procedures should remain as a separate document, or be assimilated into the general policies and procedures for pharmacies that engage in the compounding of sterile preparations.</li> </ul> <p><b>3. Inspections Scheduling</b></p> <p>Inspectors are responsible for scheduling inspections in their assigned regions utilizing their professional judgement and the priority criteria established by the Area. Generally, the inspectors attempt to schedule time-sensitive inspections; such as, pre-inspections and inspections of pharmacies compounding sterile preparations on a priority basis. However, since their methodologies are not documented nor the priority quantifiable, we were unable to assess whether the scheduling is optimal. Our review of the inspections data in <i>Versa</i>, as of March 31, 2020, indicated that 98 of the 4,934 pharmacies that were licensed prior to fiscal year 2015 had not been inspected for 5 or more years.</p> <p><b>Recommendation</b> We recommend that the Area consider the development and implementation of a risk-based, quantifiable tracking methodology at the managerial level to ensure compliance inspections are scheduled based on risk. Risk factors should include the time since the last inspection, priority follow-up inspections, etc.</p>	<p>To ensure compliance inspections scheduling is optimized based on risk.</p>

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1	5/15/2020	Inspections	<p><b>Management's Response</b> The following actions are either currently in progress or will be taken:</p> <ul style="list-style-type: none"> <li>• An assessment of the current methods used by each inspector to prioritize and schedule inspections will be conducted to serve as a basis for development of an optimal standard method.</li> <li>• Each inspector will use a spreadsheet with the type of inspection, class of pharmacy, and any other data determined to be relevant, to assist with prioritizing inspections. The inspector will submit a prospective inspection plan for each week to be reviewed by the Senior Compliance Officer for optimization.</li> <li>• The Senior Compliance Officer will evaluate reports from the agency's database system to monitor progress with quantifying and prioritizing inspections in accordance with policies and procedures.</li> <li>• Monthly reports on the team's prioritization of inspections will be generated for evaluation and development of further training.</li> </ul> <p><b>4. Written Procedures</b></p> <p>Up-to-date written procedures help ensure that all inspections are conducted in a uniform manner. Our review of the Manual identified a number of outdated written procedures; to include, the following:</p> <ol style="list-style-type: none"> <li>a. Effective April 2018, the Area implemented the Pharmacist-in-Charge (PIC) Attestation to replace former procedures in which pharmacies would submit written responses to TSBP upon completion of corrective action required in the WN. Multiple subsections of the Manual were last updated between January 2014 and August 2015, and do not reflect the procedure change.</li> <li>b. Pre-inspection procedures were last updated in November 2005, and have numerous outdated references; including, TAC section number, automatic waivers list, TSBP employee names, and use of mail instead of email.</li> <li>c. Administrative Policies, last updated in January 2015, require submission of monthly time sheets, which has been replaced by the time reporting through CAPPs effective fiscal year 2017.</li> </ol> <p><b>Recommendation</b> We recommend that the Area periodically review and revise, as applicable, the Manual to ensure written procedures reflect current operating procedures.</p> <p><b>Management's Response</b> The policies and procedures for pre-inspections and inspections of all classes of pharmacy and for Area administration will be updated to reflect current operating procedures by the end of the fiscal year. Annual review of policies and procedures will be scheduled and conducted to ensure they remain current.</p>	<p>Written procedures are up-to-date to ensure consistent inspections.</p>

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1	5/15/2020	Inspections	<p><b>5. Code of Professional Responsibility</b></p> <p>Occupations Code Sec. 556.056 requires TSBP to adopt a code of professional responsibility for inspectors that contain the following:</p> <ul style="list-style-type: none"> <li>• procedures to be followed (a) on entering a pharmacy; (b) during inspection of the pharmacy; and, (c) during an exit conference; and,</li> <li>• standards of conduct inspectors must follow in dealing with the staff and management of the pharmacy and the public.</li> </ul> <p>While general conduct standards for inspections are addressed in multiple parts of the Policy and Procedure Manual Section 7, Compliance Procedures, TSBP has not organized such requirements in one location/area to clearly communicate the code to the inspectors.</p> <p><b>Recommendation</b> We recommend that TSBP adopt a stand-alone code of professional responsibility to effectively communicate the expectations to TSBP and vendor inspectors.</p> <p><b>Management's Response</b> A code of professional responsibility will be developed and adopted specifically for Area inspectors by the end of the fiscal year. The code will be reviewed with new inspectors and reviewed on a yearly basis with current inspectors.</p>	Compliance with Occupations Code Sec. 556.056.

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			<p style="text-align: center;">OBSERVATIONS</p> <p><b>1. Inspections Data Entry</b></p> <p>Inspectors email their completed inspection reports on a weekly basis to the Compliance Specialist, who manually enters the inspection data into <i>Versa</i>. These manual tasks contribute significantly to the Compliance Specialist's workload, resulting in backlogs of inspection data pending entry into <i>Versa</i>. A <i>Versa</i> report generated on March 26, 2020 included inspections data only through February 6, 2020.</p> <p><b>Recommendation</b> We recommend that TSBP evaluate the current job distribution and consider allowing inspectors to enter inspection report data into <i>Versa</i>, where appropriate. Furthermore, TSBP should consider developing an interface between <i>Versa</i> and <i>Inspection Editor</i> to automate the data feed from the platform to the database.</p> <p><b>Management's Response</b> Requiring the field inspectors to enter inspection report data into <i>Versa</i> would reduce the amount of time inspectors are able to conduct inspections during the week. Reducing the number of inspections conducted would result in fewer pharmacies being inspected, creating a longer time between inspections for most pharmacies.</p> <p>The agency has explored the development of an interface between <i>Versa</i> and <i>Inspection Editor</i>. However, the agency does not have the necessary funding to implement the interface at this time.</p> <p><b>2. Travel Reimbursements</b></p> <p>In accordance with Government Code Sec. 660.007, state agencies must ensure each travel arrangement is the most cost effective considering all relevant circumstances. The following was disclosed based on our review of December 2019 travel vouchers:</p> <ul style="list-style-type: none"> <li>• For quarterly staff meetings held at the Austin office, TSBP allows inspectors to individually book lodging instead of utilizing the agency's travel coordinator to perform this task. For the meeting held on December 11 through 13, 2019, inspectors incurred lodging expenses for 2 or 3 nights, depending on their home office location, with an average nightly rate from \$96.56 to \$140. Exceptions to the use of state travel contracts under TAC §20.408, which are generally claimed by the inspectors in their travel vouchers, is not justified for travel to the Austin office for quarterly meetings.</li> <li>• The state only allows actual costs for meals not to exceed the GSA rates, and does not allow per diem. All inspectors requested meal reimbursements at a flat rate of \$36 per day for a full-day travel. Since their lodging receipts typically included complimentary breakfast, it would appear reasonable for only the actual cost of lunch and dinner to be reimbursable, not to exceed the GSA rates.</li> </ul> <p><b>Recommendation</b> We recommend that the Compliance department utilize the agency's travel coordinator when booking lodging for quarterly meetings; and, provide travel expense training to the inspectors.</p>	<p>To improve overall efficiency of inspection processes.</p> <p>Conservation of state funds as required by Government Code Sec. 660.007.</p>

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			<p><b>Management's Response</b> The following actions are either currently in progress or will be taken:</p> <ul style="list-style-type: none"> <li>• Additional in-service training will be scheduled for all Area inspectors to increase understanding of the State of Texas' Travel Management Program, including Title 34 TAC §20.408, regarding exceptions to the use of contract travel services. The agency allows a maximum of \$36 per day for meals during a full day of over-night travel while conducting state business. If the employee's travel does not require an overnight stay, the meal expense is only reimbursable if the employee is outside of his/her designated headquarters for at least six consecutive hours. A requirement for field staff to submit receipts with requests for reimbursement for actual meal costs incurred during travel status is being implemented.</li> <li>• Field inspectors will be instructed to secure lowest rates available when making hotel arrangements in compliance with state requirements and agency policies.</li> <li>• In addition, the use of remote technology for staff meetings has proven to be a viable option. The agency will be considering continuing to use remote technology for at least half of the quarterly staff meetings to decrease expenses related to travel.</li> </ul>	

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1	4/17/2020	2020 Follow-up	<p style="text-align: center;"><b>Follow-Up of Prior Year Audits</b></p> <p><i>Following is the status of the recommendations made during fiscal year 2019 that had not been fully implemented.</i></p> <p><u>Accounting &amp; Financial Reporting (Report date 3/1/2019)</u></p> <p><b>1. Semiannual Security Attestation Submission</b></p> <p>TSBP should implement procedures to ensure the <i>SFS Users Semiannual Security Access Attestation</i> is submitted to the Comptroller in a timely manner.</p> <p><b>2. AFR/USAS Balances</b></p> <p>TSBP should implement procedures that ensure financial information in USAS reconciles to supporting data sources.</p> <p><i>Explanation for FY20 Status</i></p> <p>Reconciliation of fiscal year 2019 AFR/USAS to Accounts Payable listing and to SPRS payroll payable were not provided for our review.</p> <p style="text-align: center;">OBSERVATION</p> <p><b>1. AFR Submission Deadlines</b></p> <p>TSBP should implement procedures to ensure compliance with the Comptroller's AFR submission deadlines.</p> <p><i>Explanation for FY20 Status</i></p> <p>Our review of TSBP's AFR submission records indicated the following instances where submissions were made after the respective deadlines.</p> <table border="1" data-bbox="581 1470 1323 1764"> <thead> <tr> <th>Submission Requirement</th> <th>Deadline</th> <th>Submission</th> </tr> </thead> <tbody> <tr> <td>Certification of Physical Inventory CPA Form 73-283</td> <td>9/20/2019</td> <td>[Not provided]</td> </tr> <tr> <td>General Revenue Reconciliation Certification</td> <td>9/28/2019</td> <td>11/26/2019</td> </tr> <tr> <td>Other Notes and Disclosures (ONDSS)</td> <td>10/1/2019</td> <td>12/2/2019</td> </tr> <tr> <td>Long-Term Liability Note Certification (LTLN)</td> <td>10/1/2019</td> <td>11/25/2019</td> </tr> <tr> <td>Disclosure, USAS and Global Certification (CNRC)</td> <td>10/1/2019</td> <td>Not Completed</td> </tr> </tbody> </table>	Submission Requirement	Deadline	Submission	Certification of Physical Inventory CPA Form 73-283	9/20/2019	[Not provided]	General Revenue Reconciliation Certification	9/28/2019	11/26/2019	Other Notes and Disclosures (ONDSS)	10/1/2019	12/2/2019	Long-Term Liability Note Certification (LTLN)	10/1/2019	11/25/2019	Disclosure, USAS and Global Certification (CNRC)	10/1/2019	Not Completed	<p style="text-align: center;"><b>Fully Implemented</b></p> <p style="text-align: center;"><b>Incomplete/Ongoing</b></p> <p style="text-align: center;"><b>Incomplete/Ongoing</b></p>
Submission Requirement	Deadline	Submission																				
Certification of Physical Inventory CPA Form 73-283	9/20/2019	[Not provided]																				
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### **VII. External Audit Services Procured in Fiscal Year 2020**

TSPB procured the internal audit services documented in the approved Internal Audit Plan for fiscal year 2020. No other external audit services were performed.

### **VIII. Reporting Suspected Fraud and Abuse**

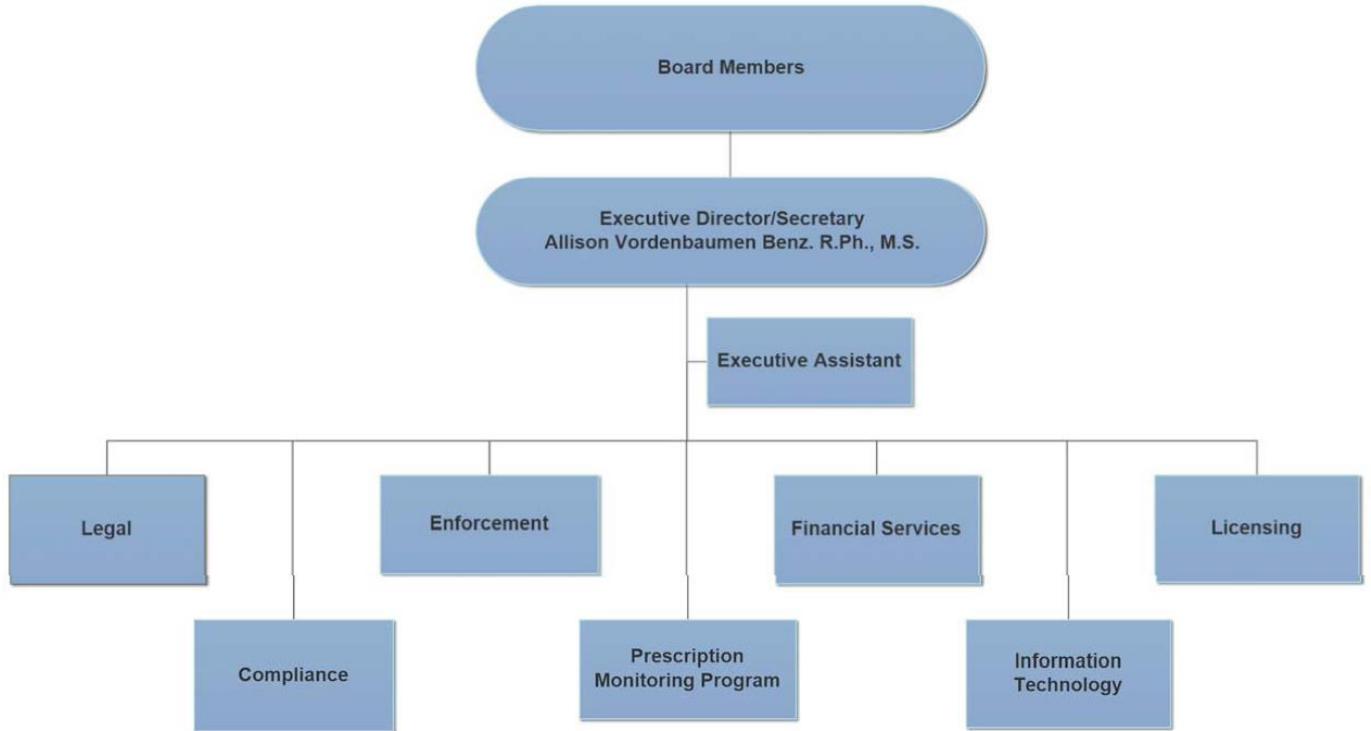
TSPB has provided information on their website home page on how to report suspected fraud, waste, and abuse to the State Auditor's Office (SAO) by posting a link to the SAO's fraud hotline. TSPB has also developed a Fraud Prevention and Detection Plan that provides information on how to report suspected fraud, waste, and abuse to management and/or the SAO.

### **IX. Proposed Internal Audit Plan for Fiscal Year 2021**

The risk assessment performed during the 2020 fiscal year was used to identify the following *proposed* area that is recommended for internal audit and other tasks to be performed for fiscal year 2021. The Internal Audit Plan for Fiscal Year 2021 will be developed and presented to the Board, for acceptance and approval, at a later date.

- Licensing: Pharmacists/ Interns/ Preceptors
- Follow-up of Prior Year Internal Audits
- Other Tasks Assigned by the Board

**X. Organizational Chart**



Source: TSBP