

JOINT COMMITTEE ON GOVERNMENT AND FINANCE
WEST VIRGINIA OFFICE OF THE LEGISLATIVE AUDITOR

POST AUDIT DIVISION

LEGISLATIVE AUDIT REPORT

West Virginia Board of Pharmacy - Pharmacy Inspection Processes & Procedures

Legislative Auditor: Aaron Allred
Post Audit Division Director: Justin Robinson



GENERALLY ACCEPTED GOVERNMENT
AUDITING STANDARDS STATEMENT

We conducted this performance audit in accordance with Generally Accepted Government Auditing Standards (**GAGAS**). 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.

POST AUDIT DIVISION
Justin Robinson, Director

POST AUDIT DIVISION

POST AUDITS SUBCOMMITTEE MEMBERS

SENATE MEMBERS	HOUSE MEMBERS
<i>President, Craig Blair</i>	Roger Hanshaw, <i>Speaker</i>
Mark Maynard	Brandon Steele
Stephen Baldwin	Chad Lovejoy



West Virginia Board of Pharmacy - Pharmacy Inspection Processes & Procedures

September 14, 2021

LEGISLATIVE AUDITOR'S STAFF CONTRIBUTORS

Aaron Allred.....Legislative Auditor

Justin Robinson.....Director

Adam R. Fridley, CGAP..... Audit Manager

Nicholas Hamilton.....Senior Auditor

Jed Walls Auditor

Ra'Shawn Dunham..... Auditor

Nathan Hamilton.....Referencer

EXECUTIVE SUMMARY: PAGE 1

ISSUE 1: PAGE 3

*The West Virginia Board of Pharmacy Lacks Formal
Policies, Procedures, and Processes for Its Inspection
Function.*

APPENDIX A: PAGE 14

Transmittal Draft Letter

APPENDIX B: PAGE 15

Objective, Scope, & Methodology

EXECUTIVE SUMMARY

The Legislative Auditor conducted this audit on the West Virginia Board of Pharmacy in accordance with W. Va. Code §4-2-5. The objective of this review was to determine the extent to which the Board of Pharmacy (BOP) conducts regular inspections of its permit-holding facilities at least once every other year or more frequently, as set forth by the Board's internal policies, and to evaluate the effectiveness of the Board's inspection process and policies in ensuring oversight and governance (regulatory administration) of such facilities.

Frequently Used Acronyms in This Report

BOP: Board of Pharmacy

NSAA: National State Auditors Association

Report Highlights

Issue 1: The West Virginia Board of Pharmacy Lacks Formal Policies, Procedures, and Processes for Its Inspection Function.

- The Board of Pharmacy does not have formal, written policies, procedures, and processes for its inspection program. Best practices published by the National State Auditors Association indicate that the Board should develop a systematic process for inspecting facilities to ensure that they are following applicable requirements and that the public is adequately protected. Rather, the Board relies heavily on the years of experience and institutional knowledge of its current staff.
- The Legislative Auditor's review of the Board's inspection documentation finds that the Board is not in compliance with the inspection requirements for 34 of 267 sampled pharmacies. Noncompliance results from missing inspection documentation or late inspections.
- Based on the results of this analysis, the Legislative Auditor estimates that the Board did not comply with its informal inspection policy regarding the frequency of routine inspections for 108 of the 847 pharmacies active between 2017 and 2020.

Recommendations

1. The Legislative Auditor recommends that the West Virginia Board of Pharmacy develop and implement formal, written policies, procedures, and processes, incorporating best practices, for its inspection function that clearly explain how an inspection is to be scheduled, conducted, reviewed, recorded, retained, and reported.

2. The Legislative Auditor recommends that the Legislature consider authorizing the Board of Pharmacy to promulgate legislative rules to establish specific requirements related to the pharmacy inspections conducted by the Board.

Post Audit's Response to the Agency's Written Response

On August 24, 2021, the Legislative Auditor transmitted a draft copy of the report to the Board of Pharmacy for comment. To date, the Board has not elected to provide a formal written response.

Issue 1: The West Virginia Board of Pharmacy Lacks Formal Policies, Procedures, and Processes for Its Inspection Function.

Introduction

The West Virginia Board of Pharmacy (the Board) is established in Chapter 30 of the West Virginia Code to regulate the profession of pharmacy and ensure its safe, lawful practice. The Board licenses pharmacists, technicians, trainees, and interns. In addition, it regulates pharmacy facilities in various settings such as manufacturers, wholesalers/distributors, mail order pharmacies, retail pharmacies, hospitals, and extended care facilities. Inspecting in-state pharmacies is one component of fulfilling the Board's mission of ensuring that drugs are dispensed in a safe, clean environment by a licensed pharmacist or technician in accordance with all applicable laws.

The Legislative Auditor conducted a limited-scope audit of the Board's inspection process to determine its effectiveness. As part of this review, the Legislative Auditor evaluated the Board's compliance with its own inspection policies concerning the frequency of inspections at in-state permit holding facilities. The Legislative Auditor selected a random sample of 267 in-state pharmacies from the 847 that were active between 2017 and 2020.

The results of the Legislative Auditor's analysis identified the following issues:

- The Board of Pharmacy does not have formal, written policies, procedures, and processes for its inspection program. Best practices published by the National State Auditors Association indicate that the Board should develop a systematic process for inspecting facilities to ensure that they are following applicable requirements and that the public is adequately protected. Rather, the Board relies heavily on the years of experience and institutional knowledge of its current staff.
- The Legislative Auditor's review of the Board's inspection documentation finds that the Board is not in compliance with the inspection requirements for 34 of 267 sampled pharmacies. Noncompliance results from missing inspection documentation or late inspections.
- Based on the results of this analysis, the Legislative Auditor estimates that the Board did not comply with its informal inspection policy regarding the frequency of routine inspections for 108 of the 847 pharmacies active between 2017 and 2020.

The Legislative Auditor makes the following recommendations:

1. The Legislative Auditor recommends that the West Virginia Board of Pharmacy develop and implement formal, written policies, procedures, and processes, incorporating best practices, for its inspection function that clearly explain how an inspection is to be scheduled, conducted, reviewed, recorded, retained, and reported.
2. The Legislative Auditor recommends that the Legislature consider authorizing the Board of Pharmacy to promulgate legislative rules to establish specific requirements related to pharmacy inspections conducted by the Board.

The West Virginia Board of Pharmacy - Background

The West Virginia Board of Pharmacy comprises 7 members: 5 members who are licensed pharmacists and 2 members of the public that do not perform any services related to the practice of pharmacy. The Board licenses pharmacists, pharmacy technicians, interns, trainees and regulates manufacturers, wholesalers/distributors, and various types of pharmacies. In addition, the Board issues a number of other licenses, permits, and registrations. Figure 1 provides a breakdown of licensees and facilities regulated by the Board.

Figure 1 Licenses, Permits, and Registrations 2015-2020						
License/Permit Type (Fee)	2015	2016	2017	2018	2019	2020
Manufacturer (\$500.00)	14	415	537	637	708	750
Wholesaler/Distributor (\$750.00)	1,240	800	740	722	730	729
Pharmacy (\$110.00)	649	649	644	637	626	655
Mail Order Permit (\$500.00)	591	606	640	643	698	711
Limited Pseudoephedrine (\$200.00)	14	16	14	10	12	12
Pharmacist Total (\$120.00)	4,780	4,942	5,165	5,309	5,649	5,655
--Pharmacist In-State	2,330	2,340	2,424	2,449	2,490	2,437
Pharmacy Technician (\$30.00)	PT- 3,738 TT- 2,816	PT- 3,750 NT-6 TT- 3,441	PT- 3,823 NT-5 TT- 3,889	PT- 3,781 NT-34 TT- 1,151	PT- 3,825 NT-36 TT- 1,136	PT- 3,670 NT-31 TT- 1,065
Pharmacy Intern (\$10.00)	984	966	790	855	847	677
Third Party Logistics (\$750.00)	-	148	159	157	178	195

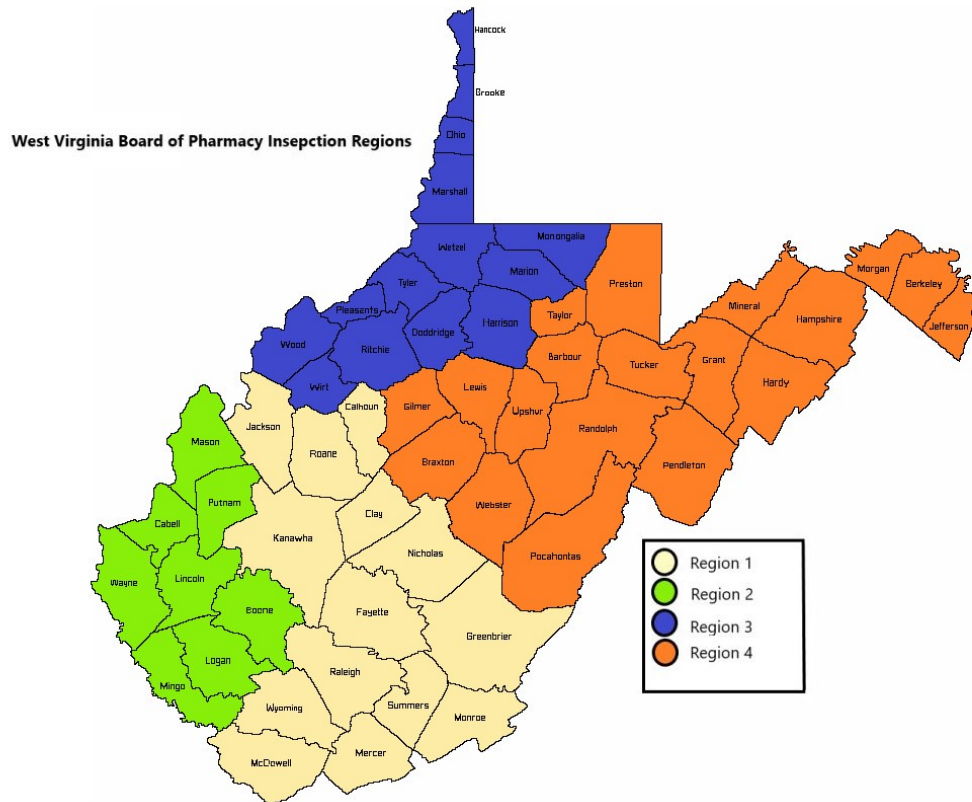
Source: Unaudited data regarding licenses, permits, and registrations provided by the WV Board of Pharmacy.

West Virginia Code empowers the Board to establish requirements for licenses, permits, and registrations; and authorizes the Board to determine the qualifications of any applicant. In addition, the Board is authorized to take disciplinary action against licensees (suspend, revoke, and reinstate licenses), investigate complaints, and conduct inspections of its permit holding facilities. While West Virginia Code authorizes the Board to hire inspectors and conduct inspections, the process for how inspections are performed, and the frequency of inspections is left to the Board's discretion.

The Legislative Auditor determined that between calendar years 2017 and 2020, the Board divided the state into four geographical regions for inspection purposes and assigned one inspector to each region. Figure 2 shows these four regions, as well as the total number of active facilities in each between 2017-2020. These inspectors operate from their homes and travel to pharmacy

facilities in their respective regions. Each inspector is responsible for ensuring all facilities within their region are inspected according to the Board’s policies. One of the Board’s four inspectors is designated as the Chief Compliance Officer, who performs both management and inspection duties. According to the Board, its inspectors, all of whom are licensed pharmacists, **have a combined total of nearly 150 years of experience in a pharmacy setting.**

Figure 2



Source: Created by Legislative Audit staff based on information provided by Board staff.

Total In-State Pharmacies Subject to Inspections By Region 2017-2020	
Region	Facilities
Region 1	326
Region 2	155
Region 3	217
Region 4	149
Total	847

Source: Calculations from Legislative Auditor based on data from the Board.

The Legislative Auditor determined that the Board conducts inspections that fall into one of three broad categories: New Pharmacy Inspections, Routine Inspections, and Pop-In Inspections. The scope and content of these inspections can vary greatly based upon factors such as license type or the type of drugs dispensed.

Inspectors conduct a New Pharmacy Inspections when a pharmacy applies for initial licensing. The Board requires a satisfactory inspection to be completed before the issuance of a Pharmacy Facility License.

New Pharmacy and Routine Inspections are scheduled in advance. Inspectors make contact and schedule inspections with the pharmacist in-charge. Each facility is required to have a pharmacist in-charge. The pharmacist in-charge is preferred to be present during an inspection, but another pharmacist may take their place at the inspector's discretion. The pharmacist in-charge or their designee will provide the inspector with documentation (timesheets, payroll records, inventories, etc.) that the inspector can review.

Routine Inspection Classifications

Routine Inspections, which were conducted by the Board once every two years over the scope of the Legislative Auditor's review, comprise numerous types of inspections based on the type of facility being inspected. These variations in Routine Inspections take into account specific compliance areas based on the applicable laws and industry standards governing each facility type. The Board provided the Legislative Auditor with the following brief descriptions for each major type of routine inspection:

Controlled Substance Permit and Consultant Pharmacist Inspections: These inspections are conducted at nursing homes and other extended care facilities that do not have on-site pharmacies but have controlled prescriptions delivered for residents. These facilities are required to have a consultant pharmacist. Inspectors review the performance of the consultant and how the facility receives, stores, administers, and destroys controlled drugs. These facilities are inspected once every five years¹.

Institutional Pharmacy Inspections: This type of inspection is used for facilities such as hospitals that have on-site pharmacies, but medication dispensing is restricted to patients admitted to the facility. The Board indicates that these medication orders are uniquely different from retail pharmacies.

Outpatient Pharmacy Inspections: This type of inspection includes common retail pharmacies and institutional facilities that have a retail component. Outpatient pharmacy inspection standards are applied to any retail pharmacy regardless of license type.

Non-Sterile Compounding Inspections: This type of inspection is conducted at retail pharmacies that offer a service that requires specialized training to compound medication, that does not require sterile administration. A prescription by a physician is required for compounded medication and medication is put into different forms such as creams, solutions, suspension, and capsules to provide an alternative delivery method than those offered commercially. *The United States Pharmacopeia (Chapter 795)* provides standards for non-sterile compounding inspections that establishes training, competence, procedures, equipment, storage, component selection, labeling, record keeping, documentation, and environmental standards.

Sterile Compounding Inspections: This type of inspection, like non-sterile compounding inspections, is conducted at retail or outpatient pharmacy facilities that offer services that require the same specialized training as compound medication but involves sterile administration such as

¹ Facilities holding a Controlled Substances Only or Consultant Pharmacist permit were not included in the Legislative Auditor's sample of in-state pharmacies discussed later in this report.

injections or infusions. Sterile compounding medication requires a prescription by a physician and provides a dose that is not offered commercially.

Pop-In Inspections Inspectors also conduct random, unannounced Pop-In Inspections. These inspections do not include the same number of items to be reviewed by the inspector as the New Pharmacy or Routine Inspections, but they focus on some of the key elements included in Routine Inspections. Pop-In Inspections are completed at the discretion of the inspector in between the times of routine inspections.

All of the various types of inspections conducted by the Board are done using a standardized inspection report corresponding to the type of inspection. Each report identifies several items that the inspector will check and includes a reference to law, rule, or policy that establishes each requirement. Inspection reports are filled out by the inspector and signed off on by the pharmacist-in-charge upon completion. The Legislative Auditor noted that during the time period from 2017 and 2018, the vast majority of the Board's inspection reports were completed on physical paper forms and filed at the Board's office. Beginning in 2019 and 2020, the Board largely moved to conducting and recording inspections electronically.

The West Virginia Board of Pharmacy Does Not Have Formal Policies, Procedures, and Processes for Its Inspection Function.

The Legislative Auditor sought to evaluate the Board of Pharmacy's inspection process to determine its effectiveness in ensuring facilities are inspected as required. Currently, W.Va. Code only contains one requirement as it relates to inspections conducted by the Board: that all inspectors must be licensed pharmacist. All other aspects of the inspection process are left to the discretion of the Board.

The Board was asked to provide its policies and procedures governing its inspection process. In response, the Board indicated:

*There [are] no formal written policies and procedures for the inspections themselves as the elements of the inspection being conducted are cross-referenced to the particular required rule or statute. **Reliance is upon the inspector's years of practice experience to recognize marginal or significant non-compliance.*** (Emphasis added)

While the Board's inspectors, with their collective professional experience of nearly 150 years, are an important source of institutional knowledge, the Legislative Auditor sought to determine best practices as it relates to regulatory inspection programs.

The Legislative Auditor identified a key set of best practices related to regulatory programs' inspection processes published by the National State Auditors Association (NSAA). The NSAA is an organization dedicated to improving state government by providing opportunities for the free exchange of information and ideas and promoting government accountability, transparency, and the observance of professional audit standards.

According to the NSAA's best practices document entitled, "*Carrying Out a State Regulatory Program*," a regulatory body should develop a systematic process for monitoring and inspecting the regulated entities' activities to ensure that they are following applicable requirements and that the public is adequately protected.

NSAA lists key best practice areas that a regulatory agency should incorporate into its policies and procedures to ensure that it has an adequate inspection program:

Develop Standard Criteria

Best practices dictate that a regulatory agency's inspection process should clearly delineate the types of violations that may occur and how serious those violations are, including which violation (or categories of violations) are considered significant. Moreover, regulatory agencies should establish policies that clearly lay out the corrective actions a regulated entity must undertake, the timeframes for completing corrective actions, and the penalties or consequences for failure to take timely corrective actions.

While the Board's inspections are conducted using standardized inspection report documents that detail the various regulatory and industry standards, the Board lacks any definitive policies that detail significant violations, relying instead on the discretion and experience of its inspectors. The Board further indicates that if significant deficiencies are noted, the pharmacy is issued a Non-Compliance Correction Report and has 10 days to either address the issues noted therein or submit a plan detailing its proposed corrective actions. While these procedures, as verbally explained to the Legislative Auditor, to some degree reflect best practices, the Board should incorporate these specific procedures and timeframes into a comprehensive policy document governing its inspection function.

Inspection Schedules

Following best practices, a regulatory agency should establish a formal schedule for periodically inspecting regulated entities. In formulating a reasonable schedule, best practices suggest several factors an agency should consider, such as ensuring that inspections occur frequently enough to provide appropriate safeguards to public safety, take into consideration facilities that pose greater risk to public safety, and schedule in a manner that ensures compliance with applicable legal or statutory requirements.

Over the audit scope, the Board's informal policy required pharmacies to undergo a routine inspection at least once every other year. The Board informed the Legislative Auditor that beginning in 2020, the Board intended to require routine inspections take place on an annual basis for each permit holding facility. However, the Board does not currently have a formal documented schedule for inspections, and both the frequency and scheduling of inspections is at the discretion of the Board. Incorporating formal scheduling procedures into a comprehensive Board policy could allow inspectors to better manage their workload and allow management to better oversee inspectors' work production to meet the Board's new goal.

Timely, Efficient, and Effective Inspections

The NSAA's best practices contain guidance related to numerous factors that are often indicative of an inspection process that is timely, efficient, and effective in meeting a regulatory agency's goals. A regulatory agency should have policies and procedures designed to ensure the impartiality of its inspectors, such as requiring periodic disclosure of any actual or perceived impairments to their impartiality or rotating inspectors between regions.

In addition, regulatory agencies should have policies and procedures in place detailing how inspections are reviewed and approved by the appropriate supervisor to ensure that the work performed is conducted in a manner that is consistent with all applicable laws, rules, and policies.

Supervisory review is also an important factor in ensuring that the results or conclusions of inspections performed by a regulatory agency are consistent and clearly communicated.

Other key factors for an efficient and effective inspection process are the establishment of performance goals and measures for inspectors and clearly delineating the agency's policies and procedures for follow-up inspections.

Currently, the Board lacks formal policies detailing its processes and considerations related to inspectors' impartiality or supervisory review of inspections. The Board should consider the feasibility of periodically rotating its inspectors across the various regions of the State. In addition, the Legislative Auditor notes that the Board's Chief Compliance Officer has frequently been assigned to Region 1 which contains the most facilities subject to inspections. Assigning the Chief Compliance Officer the State's largest region could create potential conflict and impede that individual's ability to supervise, oversee, and monitor the work performed within the Board's inspection program.

While the Board's training document for new inspectors indicates that inspectors should complete two inspections per day, it is unclear how this expectation is enforced or what types of inspections can be conducted to meet this expectation. Finally, although an inspector may use their judgement and conduct a Pop-In or follow-up inspection for known issues, the Board has no formal policy on follow up inspections.

Record Retention and Data Analysis

Best practices from the NSAA establish a number of guidelines and considerations related to documenting, retaining, and analyzing data from inspections performed by a regulatory agency. Some of these best practices, such as documenting the results of inspections, providing formal notice of the results, and detailing noted issues, are reflected in the Board's use of standardized inspection reports. However, the Board should consider formally establishing additional best practices, in a comprehensive policy document, related to how the Board retains/stores inspection reports (physical vs. digital copies) and the length of time reports are retained.

In addition, the Board should adopt specific policies and procedures for tracking and analyzing data related to violations identified, and corrective actions taken by pharmacies. Maintaining a record of past inspection results and corrective actions could provide useful data to inspectors regarding a licensee's history and past violations.

The Board's Inspection Program Does Currently Reflect Some of the NSAA's Best Practices.

The Board's current practices with respect to its inspection function do incorporate some of the key elements of the NSAA's best practices. The Board has developed a set of standardized inspection reports which list the significant statutory and industry standards to be measured in each inspection. In addition, by having the pharmacist-in-charge (or his/her designee) present for the inspection and required to sign off on the completed inspection form, the Board has taken steps to ensure that the regulated entities are provided with formal notification of the results of each inspection. According to the Board's training document, the Board also provides formal training to its inspectors through hands-on field training and requiring them to attend inspector/investigator trainings provided by the Council on Licensure, Enforcement, and Regulation.

However, the Board should establish and adopt comprehensive, formal policies, procedures, and processes for its inspection function which incorporate all of the key best practices for a regulatory agency's inspection program. Establishment of formal policies, reflective of best

practices, could not only improve the Board's inspection function overall, but will allow the Board to capture some of the institutional knowledge possessed by the experienced inspectors presently employed by it. **Therefore, the Legislative Auditor recommends that the West Virginia Board of Pharmacy develop formal, written policies, procedures, and processes for its inspection process that incorporate best practices by clearly explaining how an inspection is to be scheduled, conducted, reviewed, recorded, retained, and reported.**

The Legislative Auditor Analyzed The Board's Compliance with Its Current, Informal Policy That Each Permit-Holding Facility Be Inspected At Least Once Every Other Year. From 2017 to 2020, The Board Could Not Demonstrate Compliance For an Estimated 13% of Pharmacies.

Although the Board does not currently have a formal set of policies for its inspection process, it informed the Legislative Auditor that it does have the informal policy that each facility should be inspected at least once every 2 years. The Board of Pharmacy describes this process happening in a manner such that if a pharmacy was inspected in March of 2016, then it would be inspected as close to March 2018 as possible. The Board further informed the Legislative Auditor that it intends to shift to annual inspections², rather than once every two years.

Given the lack of formal policies, procedures, and processes, and the Board's stated desire to begin conducting inspections annually, the Legislative Auditor sought to evaluate the Board's level of compliance with its current inspection policy to determine if permit-holding pharmacies are undergoing the required routine inspections.

The Legislative Auditor obtained lists of active licensees for in-state pharmacies for FY 2017 through FY 2020. After eliminating duplicates from these separate lists, the Legislative Auditor identified 847 unique in-state pharmacies that had been active between 2017 and 2020.

The Legislative Auditor sampled 267 facilities out of the total 847 population, including facilities such as independent retail pharmacies, chain retail pharmacies, and hospitals. To determine if pharmacies were subject to the required inspections, the Legislative Auditor worked with the Board's staff to obtain copies of completed inspection reports for each of the 267 in-state pharmacies in the audit sample. For inspections conducted in 2017 and 2018, the Legislative Auditor searched through the Board's paper inspection reports on file at the Board's office. For inspections conducted in 2019 and 2020, the Board facilitated access to its online database allowing the Legislative Auditor to search for the required inspection reports.

Initially, the Legislative Auditor was able to identify some inspection documentation for 225 out of the 267 pharmacies in the sample³. The Board was provided with a list of the 42 in-state pharmacies for which the Legislative Auditor was unable to find all of the necessary inspection documentation and asked the Board to either provide missing inspection reports or an

² Board-provided documentation references the switch from inspections every other year to annual inspections taking effect in October 2020. However, based on the audit scope and conversations with Board staff regarding the impact of COVID-19 on its ability to conduct routine inspections, the entirety of this review relies on inspections occurring once every other year.

³ The Legislative Auditor notes that not all of the 267 pharmacies in the sample were in continuous operation from 2017-2020. Therefore, if a pharmacy only operated for two years within the scope before closure, compliance with the Board's policy would require that pharmacy to have one inspection report.

explanation as to why the reports were not available. The Board was able to supply missing inspection reports or other information to resolve questions regarding several of these pharmacies.

The results of the Legislative Auditor's analysis finds that the Board did not comply with its informal policies regarding inspection frequency for 34 in-state pharmacies. For 12 of the pharmacies in the sample, the Legislative Auditor was unable to locate inspection documentation to confirm the pharmacies were inspected at least once every other year, which includes 10 facilities for which at least one inspection report is missing and 2 pharmacies for which the Legislative Auditor was unable to find any inspection documentation from 2017 to 2020.

In addition, the Legislative Auditor determined that the Board was late in conducting inspections at 22 pharmacies in the sample (i.e., after the required two-year time period). The 22 late inspections ranged from 3 to 359 days late. While four of the late inspections took place within two weeks of the required date for compliance, the average late inspection took place 85 days outside of the required time frame for inspections, with 8 inspections taking place over 90 days late.

In sum, the Legislative Auditor's analysis identified a noncompliance rate of 12.7% within the audit sample. By projecting this percent error rate across the total population of 867 in-state pharmacies subject to inspections from 2017 to 2020, the Legislative Auditor estimates that the Board did not comply with its policy regarding inspections for 108⁴ of the 867 in-state pharmacies either because of missing documentation or late inspections.

The Results of the Legislative Auditor's Analyses Are Consistent with What Other States Have Identified with Respect to Inspections Conducted by State Boards of Pharmacy.

The Legislative Auditor obtained and reviewed several audits from other states that similarly analyzed the inspection programs of their respective Boards of Pharmacy. Arizona, New Hampshire, North Carolina, Pennsylvania, Texas, and Louisiana all issued reports that highlighted non-compliance rates for pharmacy facility inspections, with many of the audit reports highlighting gaps in policies, procedures, or other internal controls as contributing factors.

- The Arizona Auditor General found that the Arizona Board of Pharmacy did not inspect 10% of its pharmacies and nonprescription drug retailers within the timeframes established under Board policy. Moreover, The Auditor General indicated that the Arizona Board of Pharmacy should develop and implement new policies specific to tracking pharmacy inspections and performing sufficient follow-up work to ensure corrective actions were taken.
- The New Hampshire Office of Legislative Budget issued a report in 2015 finding that the New Hampshire Board of Pharmacy succeeded in inspecting only 75% of its licensed facilities within its statutory schedule. Further, the report states "*Our ability to assess the efficiency and effectiveness of Board of Pharmacy (Board) inspections was hampered by inadequate management controls and unreliable data.*" The report made several recommendations aimed at improving Board policies such as updating outdated manuals and agency rules.

⁴ At a 90% confidence interval with a margin of error +/-4%, this means the true number of noncompliant facilities in the total population is expected to be between 77 and 145 pharmacies.

- The North Carolina State Auditor issued reports in 2013 and 2016. In 2013, the Auditor reported serious concerns over the inspection process after finding that 35% of in-state pharmacies had not been inspected within four years. The Auditor recommended the North Carolina Board of Pharmacy develop an inspection plan and policies and procedures for tracking reports for monitoring inspection activity. Notably, the 2016 report indicates that the North Carolina Board of Pharmacy complied with these recommendations and reduced its error rate to 4%.
- The Pennsylvania Auditor found that inspectors had not conducted timely inspections of 41% of Pennsylvania pharmacies and were not meeting their requirement to conduct re-inspections within 30 days of a failed inspection. **The Auditor General specifically noted a lack of written procedures dictating the required frequency for inspections as a contributing factor.**
- In 2015, the Texas State Auditor found that its Board of Pharmacy had an adequate inspection process, but had failed to document it, and recommended the Texas Board of Pharmacy establish and document a formal policy for the frequency of inspections of pharmacies on available staff and resources.
- The Louisiana Legislative Auditor in a 2018 audit report found the Louisiana Board of Pharmacy failed to inspect approximately 10% of its in-state pharmacies within the required timeframes and did not have adequate policies concerning areas such as follow-up inspections for identified violations.

The Legislative Auditor notes that the identified error rates vary considerably from state to state, as identified in these audits (4%-41%). However, a consistent theme throughout each report is the identification of weaknesses or gaps in policies, procedures, processes, and internal controls that govern these pharmacy inspection programs.

Conclusion

The West Virginia Board of Pharmacy was established with an explicit legislative purpose to “promote, preserve and protect the public health, safety, and welfare by the effective regulation of the practice of pharmacy.” Conducting routine inspections of licensed pharmacies in the State of West Virginia is a crucial function undertaken by the Board to achieve this stated purpose. While the Board currently benefits from having staff, particularly in its inspector roles, with significant experience in a pharmacy and regulatory setting, it is the opinion of the Legislative Auditor that experience alone cannot substitute for adequate policies, procedures, processes, and controls.

Comprehensive, formal policies would significantly benefit the Board’s inspection program. Policies and procedures can serve as a guide for new and existing Board inspectors, helps ensure a fair and consistent inspection process, helps with organization, and importantly, would help the Board plan for the future by ensuring that the performance of its inspection program is not solely dependent on the collective knowledge and experience of its staff.

It should be noted that the results of the Legislative Auditor’s analysis with respect to routine inspections conducted by the West Virginia Board of Pharmacy are largely consistent with other states, not just in terms of identified error rates, but also in the identified causes for gaps in performance: weaknesses in or lack of policies, procedures, and processes. It is especially important for the Board to establish comprehensive policies now as it looks to increase the

frequency of its routine inspections to annual inspections as opposed to once every two years. In establishing policies for its inspection program, it is the opinion of the Legislative Auditor that the Board should review and incorporate as many of the key best practices contained in the NSAA's best practice guide as feasible.

Recommendations

1. The Legislative Auditor recommends that the West Virginia Board of Pharmacy develop and implment formal, written policies, procedures, and processes for its inspection process that clearly explain how an inspection is to be scheduled, conducted, reviewed, recorded, retained, and reported.
2. The Legislative Auditor recommends that the Legislature consider authorizing the Board of Pharmacy to promulgate legislative rules to establish specific requirements related to pharmacy inspections conducted by the Board.

WEST VIRGINIA LEGISLATIVE AUDITOR'S OFFICE

Post Audit Division

1900 Kanawha Blvd. East, Room W-329
Charleston, WV 25305-0610
(304) 347-4880



Justin Robinson
Director

August 24, 2021

Michael Goff, Executive Director
West Virginia Board of Pharmacy
2310 Kanawha Blvd. E.,
Charleston, WV 25311

Executive Director Goff:

This letter is to transmit a draft copy of our audit report on the West Virginia Board of Pharmacy. This report is tentatively scheduled to be presented during the September interim meeting of the Post Audits Subcommittee. While the exact date and time of the meeting has not been set, the September interims will be held September 12-14, 2021, and the meeting will be scheduled during those dates. We will inform you of the exact date and time once the information becomes available. It is expected that a representative from your agency be present at the meeting to respond to the report and answer any questions committee members may have during or after the meeting.

If you would like to schedule an exit conference to discuss this draft report or any concerns you may have, please Adam R. Fridley, CGAP, Manager, at (304) 347-4838 by **Monday, August 30, 2021**. In addition, if you desire to provide a written response to be included in the report, we ask that this response be provided by noon on **Monday, September 6, 2021**, for it to be included in the final report. Thank you for your cooperation.

Sincerely,

A handwritten signature in blue ink that reads "Justin Robinson".

Justin Robinson

Enclosure

Joint Committee on Government and Finance

Appendix B

Objective, Scope, and Methodology

The Post Audit Division within the Office of the Legislative Auditor conducted this review as pursuant to Chapter 5, Article 2, Section 5 of the *West Virginia Code*, as amended.

Objectives

The objective of this review was “*To determine the extent to which the Board of Pharmacy (BOP) conducts regular inspections of its permit-holding facilities at least once every other year or more frequently, as set forth by the Board’s internal policies, and to evaluate the effectiveness of the Board’s inspection process and policies in ensuring oversight and governance (regulatory administration) of such facilities.*”

Scope

The scope of this review consists of all inspections performed by the Board of Pharmacy from calendar year 2017 through calendar year 2020. The scope is limited to only those pharmacies that are in-state and subject to regular routine inspections under the Board’s current policies. The scope of this objective also comprises all policies, procedures, or processes governing the Board’s inspection function. The scope will not include inspections of wholesalers or manufactures, nursing homes, or any out of state licensee or facility, nor will the scope evaluate the appropriateness of any inspection results.

Methodology

Post Audit staff gathered and analyzed several sources of information and assessed the sufficiency and appropriateness of the information used as evidence. Testimonial evidence was gathered through interviews or email correspondence with various employees at the Board of Pharmacy. The purpose for testimonial evidence was to gain a better understanding or clarification of certain issues, to confirm the existence or non-existence of a condition, or to understand the respective agency’s position on an issue. Such testimonial evidence was confirmed by either written statements or the receipt of corroborating or physical evidence.

The audit team employed the use of statistical sampling methodologies in order to evaluate performance of the Board’s inspection function with respect to a statistically significant sample of permit-holding pharmacies (267 in the sample; 90% confidence interval, +/-4% margin of error) and used the results from its evaluation of this sample to estimate the Board’s performance across the total population of 847 in-state facilities.

Audit staff analyzed various source documents, such as the inspection reports, that were primarily provided to us by the Board. In addition, the audit team accessed electronic inspection reports and other relevant data related to each permit-holding in-state pharmacy from the Board’s database.

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.



POST AUDITS SUBCOMMITTEE
MEMBERS

SENATE MEMBERS	HOUSE MEMBERS
<i>President, Craig Blair</i>	<i>Roger Hanshaw, Speaker</i>
Mark Maynard	Brandon Steele
Stephen Baldwin	Chad Lovejoy



JOINT COMMITTEE ON GOVERNMENT AND FINANCE
WEST VIRGINIA OFFICE OF THE LEGISLATIVE AUDITOR
- POST AUDIT DIVISION -

Room 329 W, Building 1
1900 Kanawha Boulevard East
Charleston, West Virginia 25305
Phone: (304) 347-4880