REGULATION OF THE PRACTICE OF PHARMACY

LOUISIANA BOARD OF PHARMACY

PERFORMANCE AUDIT SERVICES
ISSUED JUNE 20, 2018

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LOUISIANA LEGISLATIVE AUDITOR
DARYL G. PURPERA, CPA, CFE

June 20, 2018

The Honorable John A. Alario, Jr.,
President of the Senate
The Honorable Taylor F. Barras,
Speaker of the House of Representatives

Dear Senator Alario and Representative Barras:

This report provides the results of our performance audit of the Louisiana Board of Pharmacy (LABP). The purpose of the audit was to determine whether LABP effectively regulated the practice of pharmacy during fiscal years 2013 through 2016 to ensure compliance with the Louisiana Pharmacy Practice Act (Louisiana Revised Statutes 37:1161-1251).

The report contains our findings, conclusions, and recommendations. Appendix A contains LABP's response to this report. I hope this report will benefit you in your legislative decision-making process.

We would like to express our appreciation to the management and staff of LABP for their assistance during this audit.

Sincerely,

Daryl G. Purpera, CPA, CFE
Legislative Auditor

DGP/aa

LABP

Louisiana Legislative Auditor

Daryl G. Purpera, CPA, CFE

Regulation of the Practice of Pharmacy
Louisiana Board of Pharmacy

June 2018

Audit Control # 40170015

Introduction

We evaluated whether the Louisiana Board of Pharmacy (LABP) effectively regulated the practice of pharmacy during fiscal years 2013 through 2016 to ensure compliance with the Pharmacy Practice Act.[1] LABP was established in 1888 as a regulatory agency and is responsible for licensing all pharmacies and individuals that engage in or assist in the practice of pharmacy or operate a pharmacy.[2] We conducted this audit because even though LABP is created under the authority of the Louisiana Department of Health (LDH),[3] neither LDH nor any other entity provides oversight of LABP's operations. In addition, the dispensing of addictive medications such as opioids and sedatives, as well as overdose deaths from prescription drugs, has increased in recent years. In 2016, Louisiana was one of the top states for the number of opioid prescriptions dispensed, averaging 98.1 prescriptions per 100 persons, with the national average being 66.5 prescriptions.

The **mission** of LABP is to regulate the practice of pharmacy to protect the health, safety, and welfare of the citizens of Louisiana.

R.S. 40:973 requires that every facility or person that manufactures, distributes, or dispenses any controlled dangerous substances (CDS)[4] – such as physicians, dentists, veterinarians, and hospitals – within the state obtain a license from LABP. During fiscal year 2017, LABP regulated more than 40,000 entities, as summarized in Exhibit 1.[5] LABP is also responsible for inspecting pharmacies and facilities or persons authorized to distribute CDS and enforcing the Pharmacy Practice Act by investigating allegations against licensees and permit holders and issuing sanctions for violations.

Exhibit 1
Entities Regulated by LABP
Fiscal Year 2017

Credential Type	Number
CDS License - Facility or Person	20,193
Pharmacy Technician	8,613
Pharmacist	5,372
Special Activity Permit	2,934
Pharmacy	1,983
Equipment Permit*	1,487
Pharmacy Intern	1,094
Total	**41,676**

***Includes emergency drug kits, durable medical equipment, etc.
Source: Prepared by legislative auditor's staff using information provided by LABP.

[1] Louisiana Revised Statutes (R.S.) 37:1161-1251
[2] R.S. 37:1201 and 37:1221
[3] R.S. 37:1171
[4] Controlled dangerous substances (CDS) are drugs or prescription medications that are regulated by the government due to their risk for abuse.
[5] Some individuals and/or facilities may have more than one credential. For example, a pharmacy will have a pharmacy permit and a CDS license.

LABP is comprised of 17 Board members appointed by the Governor, including two licensed pharmacists from each of the eight pharmacy districts and one public member from the state at-large. In addition, LABP has 20 employees to perform administrative functions and assist with licensing, monitoring, and enforcement responsibilities. LABP is funded solely through self-generated revenues. In fiscal year 2017, LABP's total revenue of approximately $3.2 million included fees from license and permit applications and renewals, as well as fines assessed to licensees and permit holders. The majority of LABP's expenditures were for salaries, benefits, and operating costs. Exhibit 2 provides a breakdown of LABP's revenues and expenditures for fiscal years 2013 through 2017.

Exhibit 2
LABP Revenues, Expenditures, and Net Income
Fiscal Years 2013 through 2017

Category	Sub-Category	2013	2014	2015	2016	2017	Total	Percent of Total
Revenues	Licenses	$2,009,977	$2,150,890	$2,268,823	$2,319,060	$2,424,518	**$11,173,268**	**68.9%**
	Prescription Monitoring Program (PMP) Fees	487,685	462,825	482,225	512,000	519,100	**2,463,835**	**15.2%**
	Enforcement Actions*	226,464	276,198	682,820	484,496	242,505	**1,912,483**	**11.8%**
	Other (admin fees, investments, etc.)	125,169	169,481	181,165	197,134	5,629	**678,578**	**4.2%**
	Total	**$2,849,295**	**$3,059,394**	**$3,615,033**	**$3,512,690**	**$3,191,752**	**$16,228,164**	**100.0%**
Expenses	Salaries and Benefits	$1,518,265	$1,845,482	$1,928,317	$1,919,434	$2,254,379	**$9,465,877**	**69.7%**
	Operating Expenses	555,944	548,855	477,803	419,402	421,801	**2,423,805**	**17.8%**
	Professional Services	477,673	369,338	221,369	243,793	311,483	**1,623,656**	**12.0%**
	Other (insurance, acquisitions, etc.)	25,863	10,853	16,848	15,254	4,544	**73,362**	**0.5%**
	Total	**$2,577,745**	**$2,774,528**	**$2,644,337**	**$2,597,883**	**$2,992,207**	**$13,586,700**	**100.0%**
Net Income		**$271,550**	**$284,866**	**$970,696**	**$914,807**	**$199,545**	**$2,641,464**	

*Includes fines and administrative and investigative costs
Source: Prepared by legislative auditor's staff using information from LABP.

The objective of this performance audit was to:

Evaluate LABP's regulation of the practice of pharmacy to ensure compliance with the Pharmacy Practice Act.

Overall, we found that LABP has established licensing, inspection, complaint, and enforcement procedures that comply with state law and conform to most regulatory best practices.[6] However, we identified some areas where the Board could improve, which are summarized on the next page and discussed in further detail throughout the remainder of the report. Appendix A contains LABP's response to this report, and Appendix B details our scope and methodology. Appendix C contains the number and types of violations enforced by LABP, and Appendix D summarizes the most common enforcement actions imposed by LABP during fiscal years 2013 through 2016.

[6] Carrying Out a State Regulatory Program," A National State Auditors Association Best Practices Document, NSAA, 2004.

Objective: Evaluate LABP's regulation of the practice of pharmacy to ensure compliance with the Pharmacy Practice Act.

Overall, we found that LABP has established licensing, inspection, complaint, and enforcement procedures that comply with state law and conform to most regulatory best practices. Specifically, LABP monitors the license application process to ensure that it efficiently issues licenses and permits and ensures that it thoroughly trains compliance officers in the practice of pharmacy. In addition, LABP has established a method for receiving complaints, maintains a record of all enforcement actions taken against licensees, and makes information about disciplinary actions available to the public. However, we identified the following areas where LABP could strengthen its oversight processes:

- **Although LABP conducted most of its required inspections in a timely manner, it did not inspect 505 (9.7%) of 5,229 pharmacies and CDS licensees according to required timeframes during fiscal years 2013 through 2017. Additionally, 42 (9.1%) of 464 CDS licensees were not inspected at all during a four-year period.** According to LABP, this was because it did not have enough compliance officers and prioritized inspections of high-risk licensees over low-risk licensees.

- **LABP's policy does not specify which violations require follow-up inspections or require compliance officers to document follow-up inspections.** We found that LABP did not conduct follow-up inspections on five (45.5%) of 11 pharmacies placed on probation during fiscal years 2013 through 2016. As a result, management cannot ensure that follow-up inspections are conducted when required and that violations are corrected.

- **LABP's enforcement process helps ensure that violations are addressed in a consistent manner. However, LABP did not complete investigations for 152 (10.8%) of 1,410 enforcement cases in accordance with its internal timeliness goal of 180 days during fiscal years 2013 through 2016.** LABP should establish formal timeframe requirements for its enforcement process, including completing investigations and closing enforcement cases, to help mitigate potentially dangerous situations for the public.

These areas are explained in more detail throughout the remainder of the report along with recommendations to strengthen LABP's regulation of the practice of pharmacy.

Although LABP conducted most of its required inspections in a timely manner, it did not inspect 505 (9.7%) of 5,229 pharmacies and CDS licensees according to required timeframes during fiscal years 2013 through 2017. Additionally 42 (9.1%) of 464 CDS licensees were not inspected at all during a four-year period.

State law charges LABP with inspecting any licensed or permitted person or facility to determine if any provisions of law governing the legal distribution of drugs or the practice of pharmacy are being violated.[7] Specifically, R.S. 40:973(E) authorizes LABP to inspect pharmacies, CDS licensees, and applicants for licensing in accordance with the Board's rules and regulations. While the law does not specify how often LABP should conduct these inspections, LABP's current guidelines for inspection frequencies state that all pharmacies and CDS licensees must be inspected at least every two years, but more frequently if they have issues of noncompliance and/or complaints. LABP inspects sterile compounding pharmacies more frequently since these pharmacies create customized medications such as those that will be directly injected into the patient, inserted into the eye, or applied to the skin. These medications carry a high risk of infection or other medical problems and thus must be prepared according to federal standards for compounding sterile preparations. Exhibit 3 summarizes LABP's inspection criteria. We used these criteria to analyze inspection data contained in eLicense, which is LABP's electronic database for tracking licenses, inspections, and enforcement information.

Exhibit 3
LABP Inspection Criteria
Fiscal Years 2013 through 2017

Timeframe	Inspection Criteria
Pharmacies and CDS Licensees	
July 1, 2012 – August 10, 2016	Every 3 years
August 11, 2016 – current	Every 2 years
Sterile Compounding Pharmacies	
July 1, 2012 – August 10, 2016	Every 3 years
August 11, 2016 – December 14, 2016	Every 2 years
December 15, 2016 – current	Every 18 months

Source: Created by legislative auditor's staff using information provided by LABP.

During fiscal years 2013 through 2017,[8] LABP did not conduct 505 (9.7%) of 5,229 inspections of pharmacies and CDS licensees according to required timeframes and did not inspect 42 (9.1%) of the 464 CDS licensees at all.[9] The 505 inspections that were late were

[7] R.S. 37:1182

[8] We expanded our scope by one year for this analysis so that we could evaluate LABP's performance in conducting inspections under its current inspection frequency requirements, which were implemented during fiscal year 2017.

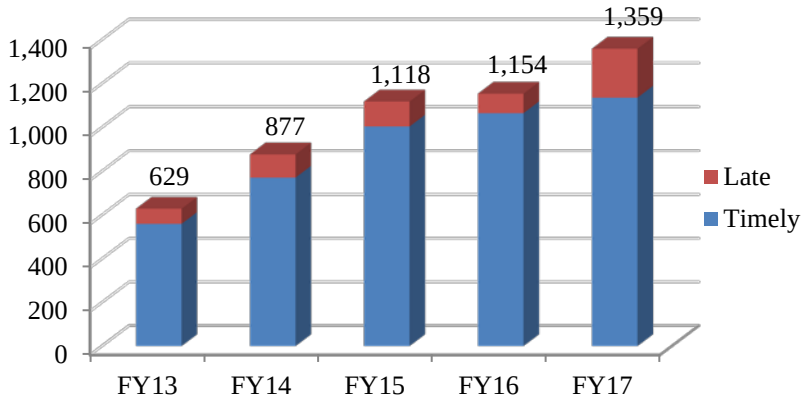
[9] While LABP regulates more than 20,000 CDS licensees, it is only required to inspect those that are not regulated by another state-level licensing board. For the other CDS licensees, the burden of inspecting falls on the agency that issues the primary license, such as the state Dental, Medical, Nursing, and Veterinary Boards.

between 11 and 1,909 days late, 70 of which were sterile compounding pharmacies with more frequent inspection requirements. We also found that LABP should have conducted an additional 59 inspections during our audit scope according to its inspection criteria, including seven sterile compounding pharmacies. In addition, LABP did not inspect 42 (9.1%) of 464 CDS licensees at all.

According to LABP, it prioritized inspections of sterile compounding pharmacies and other high-risk licensees over low-risk CDS licensees during this time period as part of a national response to the New England Compounding Center (NECC) incident in 2012.[10] LABP stated that the 42 CDS licenses that were not inspected posed a very small risk of harm to the public because they included university researchers, hospital-based clinics, crime labs, and animal euthanasia technicians that do not compound sterile products or dispense drugs to patients.

LABP also stated that it did not have enough compliance officers until late 2016, which prevented it from completing all necessary inspections within the required timeframe. In October 2016, the Board promoted an employee to the Chief Compliance Officer position, which had been vacant since 2009, and hired an additional compliance officer in March 2017. These staffing changes allowed LABP to increase the total number of inspections conducted and start to resolve the backlog of late inspections. Exhibit 4 shows the number of inspections conducted during fiscal years 2013 through 2017 as well as the number of inspections completed that were late.

Exhibit 4
Pharmacy and CDS Licensee Inspections Conducted
Fiscal Years 2013 through 2017



Note: While it appears that LABP's performance regarding the timeliness of inspections was declining in FY17, compliance officers were catching up on inspections that were not completed as required in previous years. In addition, LABP revised its inspection criteria in FY17 to be more stringent, as shown in Exhibit 3.
Source: Prepared by legislative auditor's staff using information from LABP's eLicense system.

[10] A fungal meningitis outbreak in 2012 that sickened more than 700 individuals and resulted in 76 deaths was traced to tainted steroid medications shipped out from the NECC's Boston facility. NECC was found to have operated in a filthy, unsanitary environment; compounded, sold, and shipped drugs to persons without valid prescriptions; and that those drugs contained expired or contaminated ingredients.

Recommendation 1: LABP should ensure that all pharmacies and CDS licensees are inspected in accordance with timeframes stipulated in policy.

Summary of Management's Response: LABP agrees with this recommendation and stated that with an increase in the frequency of inspections as well as an increase in the level of documentation in the inspection reports, the Board is considering an increase in the number of its compliance officers. The Board's six compliance officers are currently operating at capacity and occasionally struggle to complete their assigned inspections and investigations in a timely manner. See Appendix A for LABP's full response.

LABP's policy does not specify which violations require follow-up inspections or require compliance officers to document follow-up inspections. We found that LABP did not conduct follow-up inspections on five (45.5%) of 11 pharmacies placed on probation during fiscal years 2013 through 2016. As a result, management cannot ensure that follow-up inspections are conducted when required and that violations are corrected.

LABP's current inspection guidelines require compliance officers to document violations on an inspection report, including whether all permits are current and whether the premises are clean and orderly. According to best practices, a regulatory program should follow-up as needed to determine whether issues have been corrected.[11] LABP's inspection guidelines state that compliance officers are required to conduct unscheduled follow-up visits to confirm compliance when pharmacies are noncompliant with regulations pertaining to three inspection categories. These three categories include pharmacies not having a licensed pharmacist on duty, inadequate lighting and ventilation, and inadequate drug security and control. However, LABP's guidelines do not specify which violations within each category are severe enough to warrant the follow-up inspection nor do they require that compliance officers document follow-up inspections, as discussed in the following sections.

While LABP's inspection guidelines designate the general categories of violations that require follow-up inspections, they do not specify which violations within each category require follow-up inspections. We reviewed eLicense inspection data and found that during fiscal years 2013 through 2016, LABP identified 116 instances of noncompliance involving the three categories mentioned above. According to LABP, compliance officers are permitted to use their judgment when determining if a specific violation is severe enough to warrant a follow-up inspection. For example, if a pharmacy had a few light bulbs not working, the compliance officer would mark them as noncompliant under the "Adequate Lighting/

[11] "Carrying Out a State Regulatory Program," A National State Auditors Association Best Practices Document, NSAA, 2004.

Ventilation" category, but would not conduct a follow up visit. In contrast, if the air conditioning was not working during a hot summer month, a follow-up visit would be conducted.

Since LABP's inspection guidelines do not clarify which issues within each category require a follow-up visit, compliance officers may not be consistently conducting follow-up visits when appropriate. In addition, LABP does not require compliance officers to document follow-up inspections in eLicense. As a result, management cannot ensure that compliance officers are performing all follow-up visits as required by policy and ensuring that violations are corrected.

Requiring that all follow-up inspections be documented is important, as LABP cannot ensure that follow-up inspections were conducted on five (45.5%) of 11 pharmacies placed on probation during fiscal years 2013 through 2016. LABP is authorized to place pharmacies on probation when they violate the Pharmacy Practice Act. According to LABP, compliance officers conduct follow-up inspections to ensure that licensees are complying with the terms of probation, such as the development and maintenance of a perpetual inventory system for controlled substances. However, LABP does not require compliance officers to document these follow-up inspections, so it cannot ensure they are conducted. We reviewed eLicense data and found that LABP did not conduct follow-up inspections on five (45.5%) of 11 pharmacies placed on probation during fiscal years 2013 through 2016.[12] These pharmacies were on probation for various reasons including unlawful possession of controlled substances, failure to report the theft or loss of controlled substances, failure to remove expired medications from pharmacy inventory, distribution of samples to physicians, illegal sale of products, and repeated occasions of negligence or incompetence in the practice of pharmacy. Two of the five pharmacies were still on probation as of August 2017, but there are no documented follow-up inspections for the remaining three pharmacies that have since been removed from probation. According to LABP staff, in the future, they will require compliance officers to document all follow-up inspections in eLicense.

Recommendation 2: LABP should clarify which violations are severe enough to warrant follow-up inspections so that compliance officers know when follow-up inspections are required to be conducted.

Summary of Management's Response: LABP agrees with this recommendation and stated that the Board will consider new policies for its inspections and compliance checks. In addition, enforcement personnel will be informed of such policies, and performance reviews will incorporate policy compliance assessments. See Appendix A for LABP's full response.

Recommendation 3: LABP should require that follow-up inspections are documented and formally tracked in eLicense so it can ensure that compliance officers are conducting all required follow-up inspections.

[12] The remaining six pharmacies did receive a follow-up inspection that was documented.

Summary of Management's Response: LABP agrees with this recommendation and stated that the Board has implemented new data entry procedures for eLicense to record follow-up inspections separately from other types of inspections. See Appendix A for LABP's full response.

LABP's enforcement process helps ensure violations are addressed in a consistent manner. However, LABP did not complete investigations for 152 (10.8%) of 1,410 enforcement cases in accordance with its internal timeliness goal of 180 days during fiscal years 2013 through 2016.

State law charges LABP with overseeing the disciplinary actions of individuals and facilities that engage in the practice of pharmacy.[13] LABP opens an enforcement case to track alleged violations of pharmacy law, administrative matters such as requests for reinstatement of a license or permit, and licensees on probation. Alleged violations are uncovered in a variety of ways including complaints from concerned citizens and practitioners, notification from other regulatory entities, or during inspections conducted by LABP staff. During fiscal years 2013 through 2016, LABP opened and closed 1,410 enforcement cases to determine if the licensee or permit holders violated the Pharmacy Practice Act. For these 1,410 cases, LABP determined that the licensee or permit holders violated the Pharmacy Practice Act in 593 (42.1%) cases involving a total of 1,273 violations. The most common violation involved 264 (20.7%) dispensing issues such as dispensing the wrong quantity of a medication or dispensing a prescription without proper authorization. Appendix C summarizes all violations by fiscal year for fiscal years 2013 through 2016.

LABP's enforcement process helps ensure violations are addressed in a consistent manner. When there is proof that a licensee or permit holder has violated provisions of the Pharmacy Practice Act, R.S. 37:1241 allows LABP to apply a range of enforcement actions from warnings to probation and suspension. Enforcement actions range from informal non-disciplinary actions such as field corrections[14] or letters of noncompliance for minor violations when no harm is done to a patient, to formal disciplinary actions such as letters of reprimand, probation, and suspension for more serious offenses. In addition, LABP may assess a fine up to $5,000 for each offense.[15] From fiscal year 2013 through 2016, LABP collected more than $1.6 million from enforcement actions, including fines assessed and legal and administrative costs recouped from investigation.

According to best practices, a state regulatory agency must impose appropriate and consistent enforcement actions that address the violations cited against the people and/or entities

[13] R.S. 37:1241 and R.S. 37:1182

[14] A field correction is an informal, non-disciplinary enforcement action in which the LABP compliance officer uses an educational approach to achieve compliance.

[15] According to LABP staff, fines for one offense may be assessed for multiple days. In addition to fines, LABP can assess administrative fees and costs related to the investigation.

accused.[16] To help ensure that it imposes actions consistently, LABP staff tracks all enforcement cases and provides the Board members information pertaining to how the Board addressed similar violations in the past. For example, during fiscal years 2013 and 2016, LABP consistently handled 148 (99.3%) of 149 cases with dispensing errors that did not harm the patients with field corrections and required that the licenses of those that divert controlled substances be revoked or surrendered in 19 (95.0%) of 20 cases. Appendix D contains all enforcement actions that LABP imposed during fiscal years 2013 through 2016.

While LABP does not have formal criteria for how long compliance officers have to complete investigations, 152 (10.8%) of 1,410 investigations were not completed in accordance with LABP's internal timeliness goal of 180 days. When an enforcement case is opened by LABP, a compliance officer is assigned to investigate the case. Based on the results of the investigation, the enforcement case will then be closed with a variety of dispositions, including a determination that there was no violation, a field correction, a voluntary agreement to stop practicing, or a conference with the LABP Violations Committee which can result in formal enforcement actions issued by the Board. While LABP does not have formal guidelines or requirements for how quickly a case should be closed and enforcement actions imposed, it does have an informal goal of completing the investigation component of the case within 180 days. Best practices[16] state that regulatory agencies must impose enforcement actions in a timely manner, and according to the Texas Sunset Advisory Commission, investigations that are unreasonably long can prolong potentially dangerous situations for the public and disrupt a licensee's practice.[17]

To evaluate LABP's timeliness in issuing enforcement actions, we reviewed the 1,410 enforcement cases that were opened and closed between fiscal years 2013 and 2016. We found that these cases were open for an average of 117 days and in 1,258 (89.2%) of these cases, the investigations were completed within 180 days. Of the remaining 152 (10.8%) cases, the investigations took longer than 180 days to complete, but only 10 cases ultimately resulted in formal disciplinary action by the Board. In these 10 cases, the violations included dispensing prescriptions without the required permit and dispensing prescription refills without authorization from the prescriber.

According to LABP, an investigation may take more than 180 days to complete if it involves a joint or overlapping investigation with another agency such as the Federal Drug Administration, U.S. Drug Enforcement Agency (DEA), local/state/federal law enforcement agency, or other state regulatory boards. For example, one enforcement case was open for a year and a half because the DEA requested LABP postpone its investigation until the DEA could complete its own. A case may also take more than 180 days to close if the compliance officer does not complete the investigation in a timely manner. According to LABP, in the future the Chief Compliance Officer will more closely scrutinize each compliance officer's caseload and turnaround time of investigations.

[16] "Carrying Out a State Regulatory Program," A National State Auditors Association Best Practices Document, NSAA, 2004.
[17] "Sunset Licensing and Regulation Model," Texas Sunset Advisory Commission, October 2017

Recommendation 4: LABP should establish formal timeframe requirements for its enforcement process, including completing investigations and closing enforcement cases, to help mitigate potentially dangerous situations for the public.

Summary of Management's Response: LABP agrees with this recommendation and stated that the Board will consider new policies for its complaint investigations. In addition, enforcement personnel will be informed of such policies, and performance reviews will incorporate policy compliance assessments. See Appendix A for LABP's full response.

APPENDIX A: MANAGEMENT'S RESPONSE

Louisiana Board of Pharmacy

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June 12, 2018

Daryl G. Purpera, CPA, CFE
Louisiana Legislative Auditor
1600 North Third Street
Baton Rouge, LA 70804-9397
Via e-mail: dpurpera@lla.la.gov

Re: Audit Report No. 40170015 – Regulation of the Practice of Pharmacy

Dear Mr. Purpera:

The report found that the Board has established licensing, inspection and enforcement procedures that comply with state law and conform to most regulatory best practices. However, the auditors identified some opportunities for the Board to improve its processes. The report presented findings and recommendations toward that end. In summary, we agree with all of the report's recommendations, and as noted below, we have already initiated some of the recommended actions.

Finding 1: Although LABP conducted most of its required inspections in a timely manner, it did not inspect 505 (9.7%) of 5,229 pharmacies and CDS licensees according to required timeframes during fiscal years 2013 through 2017, and 42 (9.1%) of 464 CDS licensees were not inspected at all during a four-year period.

Recommendation 1: LABP should ensure that all pharmacies and CDS licensees are inspected in accordance with timeframes stipulated in policy.

As noted in the report, the Board revised its policy for frequency of pharmacy inspections in August 2016 to require an inspection at least once every two years as opposed to the previous three-year threshold. The Board strengthened the policy by instructing staff to withhold a pharmacy permit renewal for any pharmacy that had not been inspected within the two year period prior to the date of the renewal application.

During the same time, the Board collaborated with other state boards of pharmacy to develop a national standardized inspection blueprint for pharmacies providing basic pharmacy services as well as compounding of sterile preparations. For the inspection of pharmacies compounding sterile preparations, the blueprint includes a minimum frequency requirement of at least once every 18 months, reflecting the increased level of risk for patient harm associated with such services. The Louisiana Board adopted that standard in December 2016. Therefore, pharmacies compounding sterile preparations must be inspected at least once every 18 months and all other pharmacies at least once every 24 months. In addition, the inspection forms associated with the national blueprints require the compliance officer to record findings for approximately double the previous number of criteria.

With an increase in the frequency of inspections as well as an increase in the level of documentation in the inspection reports, the Board is considering an increase in the number of its pharmacist compliance officers. The Board currently has six compliance officers. Those compliance officers are currently operating at capacity and occasionally struggle to complete their assigned inspections and investigations in a timely manner.

Finding 2: LABP's policy does not specify which violations require follow-up inspections or require that compliance officers document follow-up inspections. We found that LABP did not conduct follow-up inspections on five (45.5%) of 11 pharmacies placed on probation during fiscal years 2013 through 2016. As a result, management cannot ensure that follow-up inspections are conducted when required and that violations are corrected.

Recommendation 2: LABP should clarify which violations are severe enough to warrant follow-up inspections so that compliance officers know when follow-up inspections are required to be conducted.

The Board will consider draft new policies for its inspections and compliance checks. Enforcement personnel will be informed of such policies, and performance reviews will incorporate policy compliance assessments.

Recommendation 3: LABP should require that follow-up inspections are documented and formally tracked in eLicense so it can ensure that compliance officers are conducting all required follow-up inspections.

The Board has implemented new data entry procedures for eLicense to record follow-up inspections separately from other types of inspections.

Finding 3: LABP's enforcement process helps ensure that it addresses violations in a consistent manner. However, LABP did not complete investigations for 152 (10.8%) of 1,410 enforcement cases in accordance with its internal timeliness goal of 180 days during fiscal years 2013 through 2016.

Recommendation 4: LABP should establish formal timeframe requirements for its enforcement process, including completing investigations and closing enforcement cases, to help mitigate potentially dangerous situations for the public.

The Board will consider draft new policies for its complaint investigations. Enforcement personnel will be informed of such policies, and performance reviews will incorporate policy compliance assessments.

Thank you for the opportunity to reply to the audit findings and recommendations. We also appreciate the auditors' assistance during the audit and sharing the best practices reference document. We are confident your review will help us improve the Board's regulation of the practice of pharmacy.

For the Board:

Carl W. Aron
President

APPENDIX B: SCOPE AND METHODOLOGY

This report provides the results of our performance audit of the Louisiana Board of Pharmacy (LABP). We conducted this performance audit under the provisions of Title 24 of the Louisiana Revised Statutes of 1950, as amended. This audit generally covered the period of July 1, 2012, through June 30, 2016, with some inspection analyses covering through June 30, 2017. Our audit objective was to:

Evaluate LABP's regulation of the practice of pharmacy to ensure compliance with the Pharmacy Practice Act.

We conducted this performance audit in accordance with generally-accepted *Government Auditing Standards* issued by the Comptroller General of the United States. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and our conclusions based on our audit objective. We believe the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective. To answer our objective, we reviewed internal controls relevant to the audit objective and performed the following audit steps:

- Researched and reviewed relevant state statutes and regulations relating to LABP.
- Researched pharmacy board audits, program models, and practices in other states.
- Interviewed relevant LABP staff and pharmacy profession stakeholders, such as the Louisiana Independent Pharmacies Association and the Louisiana Pharmacist Association.
- Attended multiple board meetings and administrative hearings to observe proceedings and LABP's interaction with licensees that have alleged violations.
- Obtained and analyzed enforcement data contained in LABP's eLicense system from fiscal years 2013 through 2016 and inspection data from fiscal years 2013 through 2017. We expanded our scope by one year for the inspection analysis so that we could evaluate LABP's performance in conducting inspections under its current frequency criteria, which were implemented during fiscal year 2017.
- Used Audit Command Language (ACL) software to determine the timeliness of enforcement processes as well as the consistency of sanctions handed down by LABP during our scope.
- Discussed the results of our analysis with LABP management and provided LABP with the results of our data analysis.

APPENDIX C: VIOLATIONS ENFORCED BY LABP, BY TYPE FISCAL YEARS 2013 THROUGH 2016

Type of Violation	FY 2013	FY 2014	FY 2015	FY 2016	Total
Dispensing issue	22	72	104	66	**264**
Departed from minimum standards of pharmacy practice	8	42	76	67	**193**
Illegal or improper operation of a pharmacy	6	47	33	25	**111**
Acquisition, attempted acquisition, or assisting in acquisition of credential by fraud or misrepresentation	6	18	29	40	**93**
Reasonable suspicion of impairment	16	30	16	16	**78**
Diversion or distribution of prescription or controlled substance	23	17	12	5	**57**
Failure to provide information legally requested by the board	3	4	17	30	**54**
Gross negligence, incompetence, or misconduct	1	17	10	21	**49**
Practicing without or with an expired credential	6	14	11	4	**35**
Prescription Monitoring Program violation	12	12	4	3	**31**
Evaded, or assisted another person in evading any laws or regulations pertaining to the practice of pharmacy			1	29	**30**
Failure to disclose prior administrative action	3	3	5	19	**30**
Failure to disclose prior criminal history	1	3	7	18	**29**
Unprofessional conduct	4	3	9	9	**25**
Violation of probationary or monitoring terms	1	4	9	10	**24**
Failure to designate a Pharmacist-in-Charge timely		8	11	3	**22**
Inadequate record keeping	2	5	12	3	**22**
Circumvention of authority of Pharmacist-in-Charge		4	13	3	**20**
Possession of Controlled Dangerous Substance	5	2	9	4	**20**
Failure to notify Board of disciplinary action by another agency	2		10	7	**19**
Disciplinary action in another jurisdiction	4	2	1	8	**15**
Failure to maintain confidentiality of protected health information	4	5		2	**11**
Failure to comply with sterile compounding standards	2	5			**7**
Practicing beyond professional competence or scope of credential		6			**6**
Convicted of a felony		1	3	1	**5**
Criminal Background Check report (LABP received a "rap-back" from Louisiana State Police)		4			**4**
Fail to comply with continuing education requirements	2		1	1	**4**
Fail to comply with Medical Assistance Trust Fund requirements	2	2			**4**
Durable Medical Equipment issue		3	1		**4**
Improper advertising	1		2		**3**
Fail to maintain policy and procedure manual or adequate reference materials		1		1	**2**
Failure to submit to medical evaluation	1				**1**
Failure to timely notify Board of employment change				1	**1**
Total	**137**	**334**	**406**	**396**	**1,273**

Source: Prepared by legislative auditor's staff using information provided by LABP.

APPENDIX D: ENFORCEMENT ACTIONS IMPOSED BY LABP FISCAL YEARS 2013 THROUGH 2016

Enforcement Action	Number*
Field Correction (educational approach to achieve compliance)	275
Fine (maximum $5,000 per offense)	152
Suspension or Surrender (inactive permit/license, unable to practice)	150
Probation/Restriction (active permit/license but restricted in some manner)	100
Letter of Reprimand	62
Revocation (permit/license removed by LABP)	56
Letter of Noncompliance	55
Letter of Warning	22
Issue Cease and Desist Order	18
Relinquishment (permit/license returned to LABP for non-disciplinary reason)	5
Total	**895**

*A single case may have more than one enforcement action, such as probation and a fine.
Source: Prepared by legislative auditor's staff using information provided by LABP.