OVERSIGHT OF PHARMACY BENEFIT MANAGERS

DEPARTMENT OF INSURANCE

PERFORMANCE AUDIT SERVICES
ISSUED MAY 2, 2018

LOUISIANA LEGISLATIVE AUDITOR
1600 NORTH THIRD STREET
POST OFFICE BOX 94397
BATON ROUGE, LOUISIANA 70804-9397

LEGISLATIVE AUDITOR
DARYL G. PURPERA, CPA, CFE

ASSISTANT LEGISLATIVE AUDITOR
FOR STATE AUDIT SERVICES
NICOLE B. EDMONSON, CIA, CGAP, MPA

DIRECTOR OF PERFORMANCE AUDIT SERVICES
KAREN LEBLANC, CIA, CGAP, MSW

FOR QUESTIONS RELATED TO THIS PERFORMANCE AUDIT, CONTACT
GINA V. BROWN, PERFORMANCE AUDIT MANAGER,
AT 225-339-3800.

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LOUISIANA LEGISLATIVE AUDITOR
DARYL G. PURPERA, CPA, CFE

May 2, 2018

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

This report provides the results of our performance audit on the Louisiana Department of Insurance's (LDI) oversight of Pharmacy Benefit Managers.

The report contains our findings, conclusions, and recommendations. Appendix A contains LDI'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 LDI for their assistance during this audit.

Sincerely,

Daryl G. Purpera, CPA, CFE
Legislative Auditor

DGP/aa

1600 NORTH THIRD STREET • POST OFFICE BOX 94397 • BATON ROUGE, LOUISIANA 70804-9397
WWW.LLA.LA.GOV • PHONE: 225-339-3800 • FAX: 225-339-3870

Louisiana Legislative Auditor

Daryl G. Purpera, CPA, CFE

Oversight of Pharmacy Benefit Managers
Louisiana Department of Insurance

May 2018

Audit Control # 40160015

Introduction

PBMs administer prescription drug coverage by acting as intermediaries between pharmacies, drug manufacturers, and consumers. The number of PBMs operating in Louisiana has increased significantly over a 10-year period, from five in 2007 to 32 in 2017.

We evaluated the Louisiana Department of Insurance's (LDI) oversight of Pharmacy Benefit Managers (PBMs). The mission of LDI is to regulate the insurance industry by licensing producers, adjusters, and insurers, and to serve as an advocate for the state's insurance consumers. Per Louisiana Revised Statute (R.S.) 22:1657, all PBMs are licensed by LDI as third-party administrators[1] and must have a license to operate in the state. LDI is also required to address and resolve consumer complaints against PBMs and has the discretion to perform regulatory reviews of most PBMs.[2]

This audit focuses on LDI's oversight of PBMs in the state. LDI is the only agency with licensing authority over PBMs and can revoke or suspend licenses if PBMs do not adhere to statutory requirements. Regulating PBMs is important because PBMs influence drug costs to consumers, determine which pharmacies consumers can use to fill prescriptions, and decide which drugs will be available to the consumer. Beginning in 2005, the Legislature began enacting more stringent laws to better regulate PBMs, including provisions to increase the transparency of drug pricing. Exhibit 1 summarizes the current PBM laws that LDI has the authority to enforce.

[1] A third-party administrator is any person who directly or indirectly solicits or effects coverage of, underwrites, collects charges or premiums from, or adjusts or settles claims on residents of this state, or residents of another state from offices in this state, in connection with life or health insurance coverage or annuities, or plans of self-insurance providing accident and health protection or self-insurance of workers' compensation coverage, or any individual, partnership, corporation, or other person who contracts directly or indirectly with a group self-insurance fund.

[2] Per R.S 22:1016, LDI does not have the statutory authority to enforce state laws, other than regulations involving licensing and financial solvency, when the PBMs are acting as an agent for prepaid plans under Medicaid. These PBMs are regulated by the Louisiana Department of Health (LDH).

Exhibit 1 Louisiana Laws Regulating PBMs		
Area	**Description**	**Law Citation (Date Effective)**
Consumer Payments for Prescriptions	States that an individual shall not be required to make a payment for a pharmacist's services in an amount greater than the pharmacist or pharmacy providing the services may retain from all payment sources.	R.S. 22:1060.6 (January 1, 2017)
Pharmacist Payments for Prescriptions	Any claim for payment for covered prescription drugs, other products and supplies, and pharmacist services submitted by a pharmacist or pharmacy to a health insurance issuer as an electronic claim that is electronically adjudicated shall be paid not later than the fifteenth day after the date on which the claim was electronically adjudicated.	R.S. 22:1854(A) (January 1, 2005)
Pharmacy Record Audits/Payment Recoupments	Outlines the criteria PBMs are to follow when conducting an audit of a pharmacy and the payment recoupment resulting from that audit.	R.S. 22:1856.1 (June 5, 2014)
Price Calculation	States that when a reimbursement under a contract to a pharmacist or pharmacy for prescription drugs is made using a formula, that formula must use the most current nationally-recognized reference price or amount in the actual or constructive possession of the health insurance issuer, its agent, or any other party responsible for reimbursement for prescription drugs. Requires that health insurance issuers, their agents, and other parties responsible for reimbursement for prescription drugs update the nationally-recognized reference prices or amounts used for calculation of reimbursement for prescription drugs no less than every three business days.	R.S. 22:1857 (January 1, 2005)
Provider Fee	Requires that PBMs reimburse pharmacists for the 10-cent provider fee they pay to the Louisiana Department of Health and Hospitals.	R.S. 22:1860.1 (January 1, 2015) R.S. 46:2625(A) (1992)
Claim Liability	Prohibits a PBM from charging or holding a pharmacist or pharmacy responsible for any fee related to a claim that is not apparent at the time of claim processing, not reported on the remittance advice of an adjudicated claim, or after the initial claim is adjudicated.	R.S. 22:1860.2 (August 1, 2016)
Maximum Allowable Costs	Requires that PBMs provide pharmacies access to its Maximum Allowable Cost (MAC) List. Requires PBMs to update their MAC Lists on a timely basis, but in no event longer than seven calendar days from a change in the methodology.	R.S. 22:1863, 22:1864(B), R.S. 22:1865 (August 1, 2014)*
***Before this law went into effect in 2014, LDI addressed MAC pricing complaints under R.S. 22:1857. **Source:** Prepared by legislative auditor's staff using state law.		

According to LDI, other areas not addressed by state law, such as spread pricing, drug rebates, use of a formulary, mail order prescriptions, and specific provisions for specialty drugs should be included in PBM contracts with insurers. Because these areas all pose risks that may result in increased costs to consumers and the state, we are conducting a subsequent audit that will examine whether state contracts with PBMs for health insurance and workers' compensation insurance contain sufficient provisions to protect both the state and the consumer.

The objective of this audit was:

To evaluate the Louisiana Department of Insurance's oversight of Pharmacy Benefit Managers.

Overall, we identified areas where LDI could use its authority to strengthen its oversight of PBMs. These areas are summarized on the next page and in detail in the remainder of the report. Appendix A includes LDI's response, and Appendix B outlines our scope and methodology.

Objective: To evaluate the Louisiana Department of Insurance's oversight of Pharmacy Benefit Managers.

Overall, we identified areas LDI could use its authority to strengthen its oversight of PBMs. Specifically, we found the following:

- **Although LDI has the discretion to conduct regulatory reviews of PBMs, it has not conducted any.** Because LDI is the only agency that has licensing authority over PBMs, it should consider developing a proactive process to review them for compliance with state laws.

- **LDI did not always collect sufficient supporting documentation before closing complaints and did not always ensure complaints were resolved in a timely manner.** In addition, based on survey responses from pharmacists across the state, it appears that some do not file complaints because they believe LDI does not fully investigate them.

- **LDI should consider developing guidelines in rules and regulations that specify consequences, such as fines, when PBMs violate state laws.** For example, during its complaint investigations from calendar year 2011 through August 2017, LDI validated a total of 14 complaints in favor of the complainant, not the PBM. However, LDI did not fine the PBMs for these violations.

These issues are explained in more detail on the following pages.

Although LDI has the discretion to conduct regulatory reviews of PBMs, it has not conducted any. Because LDI is the only agency that has licensing authority over PBMs, it should consider developing a proactive process to review them for compliance with state laws.

Regulation of PBMs is important because their role has changed beyond traditional claims processing. PBMs are now involved in drug utilization review, developing a drug plan formulary, determining which pharmacies are included in a prescription drug plan's network, deciding how much network pharmacies will be reimbursed for their services, and operating mail order and specialty pharmacies. PBMs have grown significantly in Louisiana over the past 10 years, from five in 2007 to 32 in 2017, and are now involved in the majority of prescription drug transactions.

State law (R.S. 22: 1984 and R.S. 22:1644) gives LDI the discretion to perform regulatory reviews of PBMs and gives the department access to the books and records of PBMs for the purpose of examination, audit, and inspection. These reviews may include company financial reports, results of insurance solvency standards testing, results of prior examinations

and office reviews, management changes, consumer complaints, and such other relevant information as may be required by the Commissioner of Insurance. However, LDI has never conducted any regulatory reviews of PBMs. According to LDI management, it considers their investigations into complaints as regulatory reviews. However, investigating complaints is not a proactive approach to monitoring a PBM's compliance with state law.

Because LDI is the only agency with licensing authority over PBMs and the only agency that can suspend or revoke licenses for violations of law, LDI should consider developing a proactive process to ensure PBMs comply with all state laws. As stated previously, beginning in 2005 the Legislature began enacting stronger laws to more effectively regulate PBMs under LDI's authority in Title 22. For example, R.S. 22:1860.1 requires that PBMs reimburse pharmacists the 10-cent provider fee that they pay to LDH on every prescription. LDI cannot enforce compliance with this law if it does not have a proactive process, such as regulatory reviews, to monitor PBMs. Although LDI may investigate complaints if violations of these laws are reported by consumers or pharmacists, having a proactive process would provide more assurance that LDI is sufficiently enforcing these laws.

Recommendation 1: LDI should consider developing a proactive process to monitor PBMs' compliance with state law. This process could include conducting a certain number of regulatory reviews of PBMs every year.

Summary of Management's Response: LDI disagrees with this recommendation and stated that by investigating the 42 complaints, it has conducted regulatory reviews. In addition, it stated that it has the authority to conduct a market conduct examination and has done so when appropriate. However, market conduct examinations are rare and impose a significant cost on the Department and the entity being examined. See Appendix A for LDI's full response.

LLA Additional Comments: Although investigation of complaints can be part of a regulatory review, solely reacting to complaints is not a proactive approach for monitoring a PBM's compliance with state law. We recognize that regulatory reviews are at the Commissioner's discretion; however, the increase in the number of PBMs and the recent enacting of more stringent state laws governing PBMs warrants a more proactive process to ensure compliance with these laws.

LDI did not always collect sufficient supporting documentation before closing complaints and did not always ensure complaints were resolved in a timely manner.

According to R.S. 36:687, LDI's Division of Consumer Services is responsible for receiving and processing all consumer complaints. In addition, R.S. 22:41(15) gives policyholders the right to file a complaint with LDI against any insurance company, producer, or adjuster, and have that complaint investigated by the department. From January 2011 through August 2017, LDI received a total of 84 complaints against 11 PBMs, of which 42 were within its jurisdiction.[3] These complaints were submitted by pharmacies and consumers for several reasons, including late reimbursements, maximum allowable cost (MAC) pricing issues, or not paying the provider fee. Exhibit 2 shows a summary of complaints received during this timeframe.

Exhibit 2
Summary of Complaints Against PBMs
Calendar Years 2011-2017*

Category	Example	No.	%
Not Updating or Providing MAC Pricing	Pharmacy was reimbursed at a lesser price than the cost of filling a prescription because the MAC pricing was not updated or the PBM would not provide information as to where the pharmacy could purchase pharmaceuticals at a lower cost.	25	60%
Late Reimbursement	PBM did not reimburse the pharmacy within 15 days as required by R.S. 22:1854.	6	14%
Not Paying Sales Tax or LDH Fee	PBM did not reimburse the pharmacist for the $0.10 LDH provider fee or did not include the sales tax of the prescription in the reimbursement.	4	9%
Interference with Medical Practice/ Refusal to Fill Prescription	PBM refused to fill a specialty prescription as prescribed by a doctor (i.e., increased dosages for unique circumstances) or will only reimburse for generics even if they cause adverse side effects in the patient.	2	5%
Withholding Reimbursement/ Claim Denial	Pharmacy was not reimbursed for a prescription.	2	5%
Unfair Recoupment of Reimbursements	Pharmacist was reimbursed for a prescription, then the PBM retroactively recouped that reimbursement, which is a possible violation of R.S. 22:1856.1.	2	5%
Unlawful Audit Practice	Pharmacy stated there was an audit of claims after the period allowable by state law, which is a possible violation of R.S. 22:1856.1.	1	2%
Total		**42**	**100%**

*As of August 2017.
Source: Prepared by legislative auditor's staff using complaint data from LDI's Regulated Management System.

[3] In addition to prepaid plans under Medicaid, LDI does not have the authority to address certain complaints related to certain other plans, such as the Employee Retirement Income Security Act (ERISA) of 1974. ERISA is a federal law that sets minimum standards for most voluntarily-established pension and health plans in private industry to provide protection for individuals in these plans. For example, self-insured company health plans fall under the jurisdiction of ERISA. For these complaints, LDI provided the complainants with the contact information for the U.S. Department of Labor, who does have jurisdiction over these types of complaints.

LDI did not collect sufficient supporting documentation before closing 25 (60%) of the 42 complaints filed against PBMs. As a result, LDI cannot ensure it resolved the complaints accurately. Although LDI currently has standards and guidance for receiving and entering complaints into its data system, it has not developed guidance on what documentation PBMs must provide during complaint investigations before complaints can be closed. For example, one complaint by a pharmacy stated the PBM failed to update MAC pricing in a timely manner. In response to this complaint, the PBM submitted a letter to LDI stating it reimbursed the pharmacy properly according to current formulary prices. However, LDI did not require the PBM to provide supporting documentation showing that the amount it reimbursed the pharmacy was indeed the formulary price at the time of reimbursement. Instead, the complaint was resolved and closed based solely on the PBM's response letter. According to LDI management, the agency has started requiring PBMs to submit documentation that supports the resolution of the complaints before the complaints are closed. Exhibit 3 shows a summary of documentation LDI used to close complaints.

Exhibit 3
PBM Complaint Documentation
Calendar Years 2011- 2017*

Category	No. of Complaints
No Supporting Documentation Collected	25
No Documentation Necessary	7
Proof of Timely Payment	4
Receipt of Payment	4
Contract Provided	2
Total	**42**

*As of August 2017.
Source: Prepared by legislative auditor's staff using complaint data from LDI's RMS system.

LDI did not always resolve complaints in a timely manner. It is LDI's policy to resolve complaints within an average of 42 days. Of the 42 complaints LDI received on PBMs from January 2011 through August 2017, it did not resolve 32 (76%) within 42 days and took an average of 79 days to resolve all complaints. According to LDI management, PBMs do not always respond in a timely manner to the department's inquiries regarding complaints. This delays the department's ability to investigate them. To ensure that PBMs respond timely, LDI should consider assessing fines as allowed by R.S. 22:1995. According to state law, the department can fine a PBM $250 if it does not respond to LDI's complaint inquiries within 15 days. However, LDI did not assess any fines on PBMs that did not respond in a timely manner.

It appears from survey responses submitted by pharmacists across the state that some pharmacists do not file complaints because they believe that LDI does not always sufficiently investigate them. We sent a survey to 9,692 pharmacists across the state and asked whether LDI was sufficiently addressing complaints. Of the 498 pharmacists who responded to questions regarding LDI's complaint process,[4] 258 (52%) stated that LDI was not addressing PBM complaints sufficiently. We provided LDI management with the results of the survey so it

[4] If a pharmacist does not interact with a PBM directly, this section was not applicable.

could obtain an understanding of the perceptions of their stakeholders. Exhibit 4 shows examples of some of the specific comments pharmacists made regarding LDI's complaint process.

Exhibit 4 Example of Survey Results
"I have filed many complaints against PBMs, most of which are closed because LDI takes the word of the PBM without consulting me about the complaint. LDI fails to follow through. I have called them many times with supporting documentation and had my complaint reopened. The lack of follow through and support has caused me to give up on LDI."
"[LDI] does not investigate. They take PBMs word as final opinion."
"Complaints have been made. We are told [LDI] will look into it, but nothing changes."
"I can't say the complaints are being sufficiently addressed because [PBMs] keep doing the same things over and over."
"When I first opened, I had a complaint about "clawbacks" that was immediately dismissed and not looked at."
"PBMs are not being monitored and are allowed to manipulate the reimbursement of pharmacy claims. These issues have been brought forward and nothing is being done to police these activities."
"From what I have seen PBM complaints are falling on "DEAF EARS." No one seems willing to investigate and take action..."
"LDI should closely investigate complaints when the complaint makes it to [LDI]."
"[LDI] should investigate and take seriously each and every complaint and claim against PBMs."
"My complaint to [LDI] was QUICKLY dismissed and not addressed or even looked at."
Source: Prepared by legislative auditor's staff using results from the pharmacy survey.

LDI should consider hiring staff with relevant expertise to investigate complaints. We found that Kentucky has staff with medical expertise to investigate complaints. Kentucky has also recently enacted legislation to strengthen its oversight of PBMs and moved its PBM complaint process under a separate division within its Department of Insurance. That department has two medical professionals on staff to address PBM complaints. Since the new legislation was enacted, the number of complaints against PBMs increased from approximately 30 to more than a thousand in one year. As mentioned earlier, not having sufficient staff was the primary reason LDI gave for not proactively conducting regulatory reviews of PBMs.

Recommendation 2: LDI should develop guidance regarding the types and amount of supporting documentation that is required when investigating and closing PBM complaints.

Summary of Management's Response: LDI disagrees with this recommendation but stated it would work to develop broad guidelines which will detail what types of documents should be obtained. See Appendix A for LDI's full response.

Recommendation 3: LDI should ensure it resolves complaints within an average of 42 days, as required by policy.

Summary of Management's Response: LDI disagrees with this recommendation and stated it does ensure health complaints are handled within an average of 42 days, but that PBM complaints are more complicated and require more time to process. See Appendix A for LDI's full response.

LLA Additional Comments: Although LDI calculates its average response time using all types of complaints, we calculated the average time it took to resolve PBM complaints, which was 79 days. Since 42 days was the only benchmark LDI established, we used it for comparison purposes.

Recommendation 4: LDI should enforce R.S. 22:1995 and fine PBMs for not responding to complaints in a timely manner.

Summary of Management's Response: LDI agrees with this recommendation and stated that they should have fined these PBMs. See Appendix A for LDI's full response.

Recommendation 5: LDI may wish to consider evaluating whether it should hire a medical professional or other expert with knowledge on addressing complaints dealing with the pharmacy industry to address complaints on PBMs.

Summary of Management's Response: LDI disagrees with this finding and stated the statistically insignificant number of complaints filed against PBMs does not justify such an expenditure at this time. LDI stated it will re-evaluate whether medical professionals are needed on staff in the future if the situation changes. See Appendix A for LDI's full response.

LLA Additional Comments: LDI cites the small number of complaints as a reason for not hiring a medical professional or other expert with knowledge of the pharmacy industry. However, based on our survey results, the small number of complaints may indicate that complaints are not submitted because pharmacists do not believe they will be sufficiently investigated.

LDI should consider developing guidelines in rules and regulations that specify consequences, such as fines, when PBMs violate state laws.

R.S. 22:1654(B)(1) gives LDI the discretion to suspend or revoke the license of a third party administrator, which includes PBMs, or impose a fine not to exceed $5,000 per violation to $25,000 in aggregate, if a PBM violates any lawful rule or order of the commissioner or any provision of the insurance laws of this state. However, LDI has not established any guidelines

specifying when it will issue fines when PBMs violate state law. For example, during its complaint investigations from calendar year 2011 through August 2017, LDI validated a total of 14 complaints in favor of the complainant, not the PBM. Of these 14, eight involved the PBM not updating the Maximum Allowable Cost (MAC) pricing, which is required by state law. However, LDI did not fine the PBMs for these violations. While R.S. 22:1864(B) specifically requires that PBMs provide updates to its MAC list within seven calendar days, the law does not contain any penalty provisions should PBMs not comply with this requirement. Therefore, LDI should consider using its rulemaking authority granted in R.S. 22:1861 to develop rules for PBMs and establish fines as allowed in R.S. 22:1654(B)(1).

Recommendation 6: LDI should consider developing consequences, such as fines, when PBMs violate state laws and ensure that consequences are enforced.

Summary of Management's Response: LDI disagrees with this recommendation and states that they cannot create by rule or regulation that which is not allowed by statute. See Appendix A for LDI's full response.

LLA Additional Comments: R.S. 22:1654(B)(1) gives LDI the discretion to impose a fine if a PBM violates any lawful rule or order of the commissioner or any provision of the insurance laws of this state. LDI could use its rulemaking authority granted in R.S. 22:1861 to develop rules for PBMs and establish fines as allowed in R.S. 22:1654(B)(1) when PBMs violate state law.

APPENDIX A: MANAGEMENT'S RESPONSE

LOUISIANA DEPARTMENT OF INSURANCE
JAMES J. DONELON
COMMISSIONER

April 12, 2018

Mr. Daryl G. Purpera, CPA, CFE
Louisiana Legislative Auditor
1600 North Third Street
Baton Rouge, LA 70804

Re: Louisiana Legislative Auditor Performance Audit Report
Department of Insurance's Oversight of Pharmacy Benefit Managers

Dear Mr. Purpera:

Thank you for the opportunity to respond to your report of the performance audit of the Department of Insurance's ("Department") oversight of Pharmacy Benefit Managers ("PBM"). We appreciate the work of the Louisiana Legislative Auditor ("Auditor") and his staff and offer the following response.

1. ***Although LDI has the discretion to conduct regulatory reviews of PBMs, it has not conducted any. Because LDI is the only agency that has licensing authority over PBMs, it should consider developing a proactive process to review them for compliance with state law.***
Recommendation 1: LDI should consider developing a proactive process to monitor PBMs compliance with state law. This process could include conducting a certain number of regulatory reviews of PBMs every year.

La. R.S. 22:1984(A) gives the Commissioner of Insurance ("Commissioner") discretion to conduct regulatory reviews of entities regulated by the Department. Such reviews include, but are not limited to, "consumer complaints." The Auditor has interpreted this statute to require pro-active reviews of regulated entities. We disagree. The plain language of La. R.S. 22:1984(A) gives the Commissioner the discretion to conduct, or not conduct, regulatory reviews as he deems appropriate. Additionally, by investigating the very consumer complaints at issue in this audit report, we have in fact conducted regulatory reviews.

This audit covered the period of calendar year 2011 through August 2017. The Department received 42 complaints against PBMs during this period.

P. O. BOX 94214 • BATON ROUGE, LOUISIANA 70804-9214
PHONE (225) 342-5900 • FAX (225) 342-3078 • http://www.ldi.la.gov

During that same period the Department received more than 16,000 complaints against all regulated entities. The number of complaints against PBMs were statistically insignificant, representing just one quarter of one percent, and would not have justified such a costly and labor intensive approach as suggested by the Auditor in recommending pro-active reviews. When the Department has reason to believe a regulated entity is conducting insurance business in an improper way, we have the authority to conduct a market conduct examination on the entity and have done so when appropriate. However, market conduct examinations are rare and impose significant cost on the Department and entity being examined. The Department performs market conduct examinations when necessary, but on a limited basis, as the costs borne by the entity are ultimately passed on to policyholders.

The Department held numerous meetings to discuss regulatory issues involving PBMs with the Louisiana Independent Pharmacy Association during the audit period. Information conveyed during these meetings was helpful to the Department's investigation of PBM issues and led, in part, to a $250,000 fine against a PBM. That fine amount was the largest fine the Department is permitted by law to impose.

After receiving only 42 complaints against PBMs during the six years of the audit period, the Louisiana Board of Pharmacy began prompting licensed pharmacists to file complaints which were forwarded to the Department. The Department received approximately 50 such complaints in the first two months of 2018. Of those, 7 became official LDI complaints.

The Auditor surveyed 9,692 Louisiana licensed pharmacists concerning their perception of the Department's handling of PBM complaints. Only 498 responded to the survey with 258 stating that they were in some manner displeased with the Department's handling of PBM complaints. The dissatisfied respondents represented 2.7 percent of the survey population while 2.5 percent expressed satisfaction with their complaint handling experience representing 5.2 percent of the survey population. Yet the auditor relies upon a flawed survey to support its conclusion that the pharmacists are displeased with our service. The Auditor failed to obtain information from 9,194 licensed pharmacists who may have decided not to respond because they were satisfied with the Department's performance in addition to the 240 who expressed satisfaction with the Department.

2. ***LDI did not always collect sufficient supporting documentation before closing complaints, and did not always ensure complaints were resolved in a timely manner.***

We understand that some of our complaint files could have contained more documentation supporting the Department's findings. However, according to the Auditor's survey, at least 48% of respondents thought the Department was adequately handling complaints. Additionally, complainants always have the opportunity to discuss the Department's conclusions and request further investigation if they believe our efforts were insufficient.

Finally, the Department has set its overall performance standard for health complaint handling at an average of 42 days. This is the Departments internal goal and is not set by law. The standard is to handle all health complaints including PBM payments made to independent pharmacists within an average of 42 days. The Auditor has selected a subset of health complaints and criticized the Department for missing the average. Clearly, if we are to average 42 days or less, some may take longer than the average. The fact that these particular 42 complaints were handled on average within 79 days has no negative implications on our performance standard. Even with these complicated complaints taking longer than the average, we still exceeded the performance standard by more than 10 days, averaging approximately 32 days to handle all health complaints.

Recommendation 2: LDI should develop guidance regarding the types and amount of supporting documentation that is required when investigating and closing PBM complaints.

While the Department maintains policies and procedures for our handling of complaints, we have never maintained formal guidance as narrowly tailored as that recommended by the Auditor. We have always believed Department examiners should have discretion to handle complaint files in the manner they deem appropriate in order to best investigate their complaint files. Removing the examiner's discretion would be a mistake and would result in a level of micro managing that would prove unworkable. However, in an effort to satisfy the Auditor, we will work to develop broad guidelines which will detail what types of documents should be obtained for the 3,000 to 4,000 complaints investigated by the Department every year.

Recommendation 3: LDI should ensure it resolves complaints within an average of 42 days, as required by policy.

As stated above, the Auditor seems to be missing the point of an average. The Department does ensure health complaints are handled within an average of 42 days. The Department consistently exceeds this standard by averaging 32 days.

Recommendation 4: LDI should enforce R.S. 22:1995 and fine PBMs for not responding to complaints in a timely manner.

In four (4) complaints, it appears the PBM did not timely respond as directed by the Department. We agree with the Auditor that the PBMs should have been fined in these instances.

Recommendation 5: LDI may wish to consider evaluating whether they should hire a medical professional or other expert with knowledge on addressing complaints dealing with the pharmacy industry to address complaints on PBMs.

As stated above, the statistically insignificant number of complaints filed against PBMs does not justify such an expenditure at this time. The Department will re-evaluate whether medical professionals are needed on staff in the future if the situation changes.

3. ***LDI should consider developing guidelines in rules and regulations that specify consequences, such as fines, when PBMs violate state laws.***

La. R.S. 22:11 gives the Commissioner the authority to "promulgate rules and regulations necessary for implementation of this Title." Rules and regulations are used to implement existing law. The legislature, not the Commissioner, is able to create penalties for violation of state law. We cannot create by rule or regulation that which is not allowed by statute.

Further, the insurance code already provides for penalties for any violation of the insurance code. Such penalties can be found at La. R.S. 22:13, 1654, 1964(12), *et seq.* This recommendation seems better suited as a consideration for the legislature.

Notwithstanding, we have supported HB 436 of the 2018 Regular Legislative Session as part of the Department's legislative package. HB 436 increases transparency for providers who interact with PBMs and gives the Department more oversight over PBMs.

Thank you for the opportunity to provide this response to the performance audit report.

With best wishes and warmest personal regards, I remain

Very truly yours,

James J. Donelon
Commissioner of Insurance

APPENDIX B: SCOPE AND METHODOLOGY

We conducted this performance audit under the provisions of Title 24 of the Louisiana Revised Statutes of 1950, as amended. Our audit evaluated the Louisiana Department of Insurance's (LDI) oversight of pharmacy benefit managers (PBMs). Our audit focused on all current licensed PBMs and focused on complaints from calendar year 2011 through August 2017. The audit objective was:

To evaluate the Louisiana Department of Insurance's oversight of Pharmacy Benefit Managers.

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 reasonable basis for our findings and 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 Louisiana Revised Statutes and Administrative Code for laws and regulations regarding LDI's responsibilities for licensing, monitoring, and responding to complaints of PBMs.
- Interviewed LDI staff to determine LDI's process for licensing, monitoring, and responding to complaints of PBMs.
- Evaluated LDI's policies and procedures for issuing licenses, monitoring, and responding to complaints of PBMs.
- Obtained all licensing documentation from LDI for all PBMs currently licensed in the state and created a data collection instrument to determine if all PBMs were licensed properly according to state law.
- Developed and conducted a statewide survey of pharmacists to obtain their feedback regarding issues, challenges, and practices of LDI's oversight of PBMs in the state. We sent the survey to 9,692 licensed pharmacists across the state and received 2,135 responses, for a response rate of 22%.
- Obtained all complaints and documentation used to resolve each complaint beginning in calendar year 2011 through August 2017 from LDI. Using complaint documentation, created a data collection instrument to determine if LDI responded sufficiently and timely resolved complaints.