

Complaint Processing and Enforcement at the Board of Pharmacy

John Keel, CPA State Auditor

December 6, 2012

Members of the Legislative Audit Committee:

The Board of Pharmacy (Board) has fully or substantially implemented 6 (67 percent) of 9 recommendations that auditors selected for follow-up from *An Audit Report on Complaint Processing and Enforcement at the Board of Pharmacy* (State Auditor's Office Report No. 08-035, June 2008). (See text boxes for background information on the prior audit report and implementation status definitions).

Of the six recommendations fully or substantially implemented:

- The Board substantially implemented one recommendation related to following up on Board disciplinary orders to ensure that they are appropriately addressed.
- The Board fully implemented two recommendations related to (1) ensuring that applicants submit fingerprints before a license or registration is issued and (2) notifying complainants of the receipt of a complaint within 30 days as required by the Texas Occupations Code.
- The Board fully or substantially implemented three recommendations related to strengthening controls in its information system.

While the Board has made significant progress in implementing the prior audit recommendations, it should continue its efforts to improve controls related to unresolved complaints, complaint reviews, and user access to complaint data. Specifically:

- The Board should improve controls to ensure that it updates complainants about the status of unresolved complaints every four months as required by the Texas Occupations Code.
- The Board should consistently document its reviews of complaint information.
- The Board should actively monitor user access to complaint data and implement policies and procedures for the addition, modification, deletion, and review of user access to its information system.

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

SAO Report No. 13-010

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Background Information

In June 2008, the State Auditor's Office issued An Audit Report on Complaint Processing and Enforcement at the Board of Pharmacy (State Auditor's Office Report No. 08-035). Auditors selected 9 of the 13 recommendations in that report for follow-up based on the Board of Pharmacy (Board) management's original responses to the recommendations, the Board's subsequent self-reported recommendation implementation status and implementation dates, and the level of risk.

Implementation Status Definitions

Fully Implemented - Successful development and use of a process, system, or policy to implement a prior recommendation.

Substantially Implemented -Successful development but inconsistent use of a process, system, or policy to implement a prior recommendation.

Incomplete/Ongoing - Ongoing development of a process, system, or policy to address a prior recommendation.

Not Implemented - Lack of a formal process, system, or policy to address a prior recommendation.

Table 1 provides additional details on the Board's implementation of prior State Auditor's Office recommendations.

Table 1

Status of Implementation of Prior Audit Recommendations				
No.	Recommendation	Implementation Status as Reported by the Board	Implementation Status as Determined by Auditors	Auditor Comments
1	The Board should ensure that additional actions are taken when pharmacists and technicians do not adhere to the conditions of a Board disciplinary order.	Fully Implemented	Substantially Implemented	The Board ensured that the Board disciplinary orders for technicians that auditors tested complied with the conditions of the related Board orders. However, auditors were unable to test Board disciplinary orders for pharmacists because either (1) the Board orders were still open at the time of follow-up and sufficient time had not passed since implementation of the recommendation or (2) the Board orders had affected the pharmacists' licenses and ability to practice pharmacy.
2	The Board should consider ensuring that all pharmacist applicants, pharmacy technician applicants, pharmacy technician trainee applicants, and pharmacy intern applicants submit fingerprints before a license or registration is issued. Otherwise, the Board should consider modifying the Texas Administrative Code to reflect the Board's intent to implement the requirement to submit fingerprints in phases.	Fully Implemented	Fully Implemented	Auditors reviewed all licenses and registrations issued after September 12, 2011, (the date on which administrative requirements became effective). The Board had evidence that it conducted a background check requiring fingerprints. In addition, the Board followed the appropriate process by issuing licenses and registrations only to eligible applicants.
3	The Board should prioritize the notification of complainants of a complaint's receipt within 30 days of receiving the complaint, as required by the Texas Occupations Code.	Fully Implemented	Fully Implemented	For all 30 complaints tested, the Board notified complainants within 30 business days of receiving their complaints.

	Status of Implementation of Prior Audit Recommendations					
No.	Recommendation	Implementation Status as Reported by the Board	Implementation Status as Determined by Auditors	Auditor Comments		
4	The Board should establish a process to ensure that all parties to a complaint are provided an update on the status of unresolved complaints every four months, as necessary, until a complaint is resolved.	Fully Implemented	Incomplete/Ongoing	The Board implemented a new information system on May 31, 2011. After it implemented the new system, the Board did not send out update letters to complainants for approximately seven months (June 1, 2011, through January 6, 2012). According to the Board, the system's reporting feature that extracted data for update letters was not available.		
				The Board began sending update letters in January 2012 using monthly system-generated reports of complainants whose complaints had been in the system for at least 120 days. Auditors reviewed two monthly reports to determine whether they captured all of the necessary complainants. The reports generally captured all of the complainants to whom the Board needed to send an update. However, 2 (2 percent) of 84 complainants in January 2012 did not receive an update letter because a correspondence box was not checked in the Board's information system.		
				Auditors were unable to determine whether the Board sent update letters to complainants on time because the Board did not document the dates on which it mailed those letters. The mail date in the Board's information system is automatically populated with the last day of the month, rather than the date on which the Board mailed the letter. Since the system uses the mail date to calculate the due date for the update letters, this increases the risk that the update letters sent after the initial mailing will not be mailed within the required time frame.		
5	The Board should document the review of complaint information that is required by its internal policies.	Fully Implemented	Incomplete/Ongoing	The Board did not document the review of complaint information consistently as required by its policies and procedures. For 7 (23 percent) of 30 complaints tested, the Board did not have evidence that it conducted a review.		

Status of Implementation of Prior Audit Recommendations					
No.	Recommendation	Implementation Status as Reported by the Board	Implementation Status as Determined by Auditors	Auditor Comments	
6	The Board should ensure that access to complaint data is granted to staff based upon the minimum access needed to complete their job duties.	Fully Implemented	Incomplete/Ongoing	The Board did not actively monitor user access to its information system and did not have policies for adding, modifying, deleting, or reviewing user access to its information system. Auditors tested 143 active and inactive users with access to complaint data and found the following: 12 (14 percent) of 85 active users tested had inappropriate access to delete complaint data. The Board modified those users' access after auditors brought this matter to its attention. 13 (15 percent) of 85 active users tested were no longer Board employees, but the Board had not disabled their access. 57 (40 percent) of 143 active and inactive users tested were former employees and were listed as inactive in the Board's information system. However, the Board did not properly restrict the former employees' access rights and gave supervisors access to the password to modify the data under the former employees' user IDs. This increases the risk that complaint data could be modified inappropriately and that history screens would not accurately reflect who changed complaint data.	
7	The Board should ensure that transaction histories and logs are created and retained to allow the Board to detect and investigate unauthorized changes. The transaction history should include what data fields were changed, when they were changed, and who made the change.	Fully Implemented	Fully Implemented	The Board implemented a new information system on May 31, 2011. The new system (1) automatically generates a change log and record history to record user actions for each complaint and (2) identifies the user who made the change. All 30 complaints tested had transaction histories that included what data fields were changed, when they were changed, and who made the change.	
8	The Board should retain a record of all deleted complaint files. The Board also should consider disabling the Enforcement Division staff's ability to delete complaints.	Fully Implemented	Substantially implemented	The Board's new information system retains a record of deleted complaints, and the Board has the ability to obtain reports on all deleted complaint files from the Health Professions Council, which administers the new information system. However, the Board did not use that information to ensure the deletions were appropriate. As discussed in recommendation 6 above, auditors identified 12 staff who had inappropriate access to delete complaint data. The Board determined that having the ability to delete a complaint is a necessary business function; therefore, it should regularly review deletions to ensure they are appropriate.	

	Status of Implementation of Prior Audit Recommendations					
No.	Recommendation	Implementation Status as Reported by the Board	Implementation Status as Determined by Auditors	Auditor Comments		
9	The Board should modify the system so that future dates cannot be entered in the field for the date a complaint was received.	Fully Implemented	Fully implemented	The Board's new information system does not allow the processing of a future date in the complaint receipt field.		

Recommendations:

The Board should:

- Continue to monitor pharmacist and technician compliance with disciplinary orders and document the results of that monitoring.
- Implement controls to ensure that it provides complainants with an update on the status of unresolved complaints every four months as required by the Texas Occupations Code.
- Consistently document the review of complaint information that its internal policies and procedures require.
- Develop and implement policies and procedures for periodic review of user access to its information system. Those policies and procedures should address adding, modifying, or deleting user accounts for its information system.
- Deactivate user accounts and change information system access to read-only access for all individuals
 whose employment has been terminated. The Board also should discontinue providing supervisors with
 access to former employees' user accounts.
- Develop and implement procedures to review deleted complaints regularly to ensure that deletions are appropriate.

The Board agreed with the above recommendations, and its management's response is in the attachment to this letter.

Sincerely,

John Keel, CPA State Auditor

Attachment

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cc: Members of the Board of Pharmacy

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Attachment

Section 1

Objective, Scope, and Methodology

Objective

The objective of this audit was to determine the implementation status of prior State Auditor's Office recommendations and evaluate whether management has taken corrective actions to address selected recommendations in *An Audit Report on Complaint Processing and Enforcement at the Board of Pharmacy* (State Auditor's Office Report No. 08-035, June 2008).

Scope

The scope of this audit included reviewing the implementation status of the Board of Pharmacy's (Board) prior audit recommendations in *An Audit Report on Complaint Processing and Enforcement at the Board of Pharmacy* (State Auditor's Office Report No. 08-035, June 2008) from June 1, 2011, through August 23, 2012.

Methodology

The audit methodology included identifying and collecting information on the implementation of the prior audit recommendations. To determine the implementation status of the recommendations, auditors conducted interviews, reviewed the Board's policies and procedures, and performed selected tests and procedures.

Auditors assessed the reliability of Board data associated with complaints, licensees, and registrants by (1) reviewing query language used to pull data from the Board's system, (2) analyzing key data elements for completeness and reasonableness, and (3) interviewing Board employees knowledgeable about the data. Auditors determined that the data was sufficiently reliable for the purposes of this audit.

To determine the implementation status of prior recommendations, auditors selected and tested purposive, non-representative samples. Specifically:

- Auditors selected 30 disciplinary orders to test whether the Board took additional actions when technicians did not adhere to the conditions of Board disciplinary orders.
- Auditors selected 30 external complaints to test whether the Board notified the complainants of the receipt of the complaints as required by the Texas Occupations Code.

 Auditors selected 30 complaints to test whether the Board's reviews and transaction histories for complaints complied with Board policies and procedures.

Because auditors did not use a statistical sample, findings cannot be generalized and may not represent the entire population of Board disciplinary orders or complaints.

Information collected and reviewed included the following:

- An Audit Report on Complaint Processing and Enforcement at the Board of Pharmacy (State Auditor's Office Report No. 08-035, June 2008) and supporting audit documents.
- Board policies and procedures for disciplinary orders and complaint processing.
- Board disciplinary orders issued from June 2011 through May 2012 and supporting documentation for the sample selected.
- Licenses and registrations applied for and issued from September 2011 through July 2012.
- Complaints received by the Board from June 2011 through May 2012 and supporting documentation for the sample selected.
- List of Board employees as of July 31, 2012, from the Uniform Statewide Payroll/Personnel System.
- List of complaints deleted in the Board's system as of August 23, 2012.
- Information that supported the Board's implementation of information technology recommendations, including a list of users, roles, and privileges with access to complaint data and a screenshot from the Board's system showing that the Board cannot enter a future date in the field where it records the date on which it receives a complaint.

Procedures and tests conducted included the following:

- Interviewed management and key personnel at the Board.
- Tested a sample of disciplinary orders to determine whether the Board took additional actions when pharmacists and technicians did not adhere to the conditions of a Board disciplinary order.
- Tested all pharmacist, pharmacy technician, pharmacy technician trainee, and pharmacy intern applicants licensed or registered after September 12, 2011, when new administrative rules became effective, through July 31,

2012, to determine whether the Board performed a criminal background check.

- Tested a sample of external complaints to determine whether the Board notified complainants of its receipt of the complaint within 30 days.
- Analyzed the population of external complaints received between June 1, 2011, and May 31, 2012, to determine whether the Board provided all parties to complaints with an update on the status of unresolved complaints every four months until the complaints were resolved.
- Tested a sample of complaints to determine whether the Board documented its review of complaint information as required by its internal policies and procedures.
- Tested user access controls for complaint data.
- Tested a sample of complaints to determine whether the Board created and retained transaction histories and logs.
- Tested controls in the Board's information system for deleted complaint records and the date received field.

<u>Criteria used</u> included the following:

- Board internal policies and procedures for enforcement and complaint processing.
- Title 22, Texas Administrative Code, Chapter 283.
- Title 22, Texas Administrative Code, Chapter 297.
- Title 1, Texas Administrative Code, Chapter 202.
- Title 3, Texas Occupations Code, Chapters 555, 565, and 566.

Project Information

Audit fieldwork was conducted from July 2012 through September 2012. We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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

- Stacey Williams, CGAP (Project Manager)
- Isaac Barajas (Assistant Project Manager)
- Rachel Lynne Goldman, CPA
- Lisa M. Thompson
- Kristin Alexander, MBA, CFE, CIA (Quality Control Reviewer)
- Ralph McClendon, CISSP, CCP, CISA (Audit Manager)

RECOMMENDATION #1 – Continue to monitor pharmacist and technician compliance with disciplinary orders and document the results of that monitoring.

Management's Response

The Texas State Board of Pharmacy (TSBP) agrees with the recommendation. The agency will continue to monitor compliance with all disciplinary orders. To ensure that licensees are in compliance with the conditions of Disciplinary Orders, TSBP uses several monitoring systems, including computer-generated "past-due" reports and Excel spreadsheets. Designated Enforcement Specialists are responsible for reviewing these reports and taking appropriate action for non-compliance with Orders. Excel spreadsheets are checked daily for "critical" due dates, such as license status changes (e.g., when a license or registration must be changed from "active" to "suspended"). The computerized "past-due" reports are printed monthly and Enforcement *Specialists check these for non-compliance issues. In November 2012,* management staff began a more thorough oversight of the process to ensure that non-compliance issues are addressed in a timely manner. However, the Enforcement Specialist who is responsible for monitoring compliance of Disciplinary Orders entered on impaired pharmacists is resigning, effective November 27, 2012. As a result, timeliness may be affected during this transition period. We anticipate this vacancy will be filled, the training/orientation period completed, and the accuracy of past-due reports will be completed by February 1, 2013.

<u>Responsible Party</u>: Executive Director/Secretary and Director of Enforcement

<u>Timeline</u>: The new procedures and verification of the report will be completed by February 1, 2013

RECOMMENDATION #2 – Implement controls to ensure that it provides complainants with an update on the status of unresolved complaints every four months as required by the Texas Occupations Code.

Management's Response

The Texas State Board of Pharmacy agrees with the recommendation. As of October 1, 2012, TSBP has modified the procedures for sending status letters to complainants that will assure the letters are sent by the due dates specified in the Texas Pharmacy Act.

Responsible Party: Executive Director/Secretary and Director of

Enforcement

<u>Timeline</u>: Completed as of October 1, 2012

RECOMMENDATION #3 – Consistently document the review of complaint information that its internal policies and procedures require.

Management's Response

The Texas State Board of Pharmacy agrees with the recommendation. For the great majority of complaints, management review of complaint information by managers is documented in the computer system. For those complaints that do not contain documentation of review in the computer system (those complaints that are closed by non-managers), beginning December 1, 2012, TSBP managers will manually document their review of the complaint information on the file copy of the complaint form.

<u>Responsible Party</u>: Executive Director/Secretary and Director of Enforcement

Timeline: This new procedure will be implemented on December 1, 2012

RECOMMENDATION #4 – Develop and implement policies and procedures for periodic review of user access to its information system. Those policies and procedures should address adding, modifying, or deleting user accounts for its information system.

Management's Response

The Texas State Board of Pharmacy (TSBP) agrees with the recommendation. As of August 27, 2012, the following policies have been implemented.

- All requests for user access changes (additions, modifications and deletions) must be accompanied by the appropriate change request form and must be authorized by the division director.
- Annual audits will be conducted by the Information Technology personnel, in cooperation with division directors, to insure all account permissions are accurate and appropriate for the position.

<u>Responsible Party</u>: Executive Director/Secretary and Director of Information Technology

Timeline: Completed as of August 27, 2012

RECOMMENDATION #5 – Deactivate user accounts and change information system access to read-only access for all individuals whose employment has been terminated. The Board also should discontinue providing supervisors with access to former employees' user accounts.

Management's Response

The Texas State Board of Pharmacy (TSBP) agrees with the recommendation. As of October 1, 2012, the accounts and passwords of terminated employees are disabled on the date of termination. The appropriate supervisor will complete any necessary changes or maintenance to data entered by the terminated employee using their own account and password.

<u>Responsible Party</u>: Executive Director/Secretary and Director of Information Technology

<u>Timeline</u>: Completed as of October 1, 2012

RECOMMENDATION #6 – Develop and implement procedures to review deleted complaints regularly to ensure that deletions are appropriate.

Management's Response

The Texas State Board of Pharmacy (TSBP) agrees with the recommendation. As of October 2, 2012, TSBP is receiving a monthly report of all complaints that were deleted during the prior month. This report is reviewed by the Director of Enforcement to ensure all deletions are appropriate (e.g., complaints that have met the record retention deletion date).

<u>Responsible Party</u>: Executive Director/Secretary and Director of Enforcement

Timeline: Completed as of October 2, 2012