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An Audit Report on

Complaint Processing and Enforcement at the Board of Pharmacy

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Complaint Processing and Enforcement at the Board of Pharmacy

Overall Conclusion

The Board of Pharmacy (Board) imposes sanctions and disciplines licensees and registrants in accordance with state laws and regulations. Some sanctions require monitoring to ensure that the licensee complies with the terms of a disciplinary order. The Board has processes in place to monitor compliance with Board-ordered disciplinary actions.

The Board closed 4,980 complaints in fiscal year 2007. Of these, 648 (13.0 percent) resulted in a disciplinary action, such as revocation or suspension of the license or other sanctions.

The number of complaints processed by the Board has increased significantly since fiscal year 2003. The Board began registering pharmacy technicians in fiscal year 2004 and began registering pharmacy technician trainees in fiscal year 2007. The Board received 1,935 complaints in fiscal year 2003 and 5,849 complaints in fiscal year 2007—a 200 percent increase.

The Board's complaint handling process prioritizes the assignment and investigation of complaints relative to the seriousness of the allegations. The Board followed this process.

However, auditors identified some areas for improvement. Specifically:

- The Board did not obtain fingerprints to access criminal histories of applicants. The Texas Administrative Code requires the Board to obtain fingerprints from pharmacist applicants, from pharmacy technician and pharmacy technician trainee applicants, and from pharmacy intern applicants.

Background Information

The Texas Legislature established the Board of Pharmacy (Board) in 1907. The Board is responsible for (1) the licensure and discipline of pharmacies, pharmacists, and pharmacy interns and (2) the registration of pharmacy technicians and pharmacy technicians in training.

As of June 30, 2007, the Board regulated 23,547 licensed pharmacists, 6,275 pharmacies, and 32,260 registered pharmacy technicians. As of January 25, 2008, the Board registered 13,358 pharmacy technicians in training. The Board was appropriated \$3,395,516 for fiscal year 2006 and \$3,356,466 for fiscal year 2007. It had 57 budgeted full-time equivalent employees in fiscal year 2007.

The Board collects various license fees. Specifically:

- \$191 for initial and biennial renewals of licenses for pharmacists.
- \$329 for initial and biennial renewals of licenses for pharmacies.
- \$46 for registration of pharmacy technicians.

For fiscal year 2007 the Board collected \$2,308,334 in fees from pharmacist licenses, \$1,064,079 in fees from pharmacy licenses, and \$811,822 in fees from pharmacy technician registrations.

The Board is governed by a nine-member board appointed by the Governor with the concurrence of the Senate for six-year, overlapping terms. Six members of the board must have been registered pharmacists in Texas for five years immediately preceding appointment and continue to actively practice pharmacy while serving on the board.

- The Board's process for conducting background checks does not ensure that it identifies all criminal offenses committed by licensees and registrants.
- The Board did not meet its statutory due dates for responding to and communicating with complainants regarding the receipt and status of their complaints.
- The Board did not adequately document reviews of complaint information or retain supporting documentation for the complaints that auditors reviewed.

Key Points

The Board sanctions and disciplines licensees and registrants as required by state laws and regulations.

The Board orders disciplinary actions for violations identified through investigations, inspections of pharmacies, and results of criminal background checks. The Board imposed disciplinary actions in accordance with the applicable state laws and regulations in all 60 complaints resulting in disciplinary action that auditors tested.

The Board prioritizes the investigation of complaints according to the seriousness of the allegation.

The Board ensures that the most serious complaints are given priority. Under this process, the Board first investigates complaints that allege a continuing threat to the public welfare, such as complaints that a licensee/registrant has a chemical, mental, or physical impairment or a licensee/registrant is diverting prescription drugs through illegal means.

The Board began registering new groups of pharmacy employees in fiscal year 2004 and fiscal year 2007. This resulted in a significant increase in the Board's workload.

The Board began registering pharmacy technicians in fiscal year 2004 and began registering pharmacy technician trainees in fiscal year 2007. Since registering these new groups, the Board has experienced an increase in the number of complaints received since fiscal year 2003. During fiscal year 2004, the Board received 4,475 complaints. Of these, 47 percent resulted from pharmacy technician applicants with identified prior criminal histories. The Board obtains criminal history information from the Department of Public Safety (DPS), which conducts a search based on an applicant's name and date of birth.

The Board did not obtain fingerprints from pharmacist applicants, from pharmacy technician and pharmacy technician trainee applicants, or from pharmacy intern applicants as required by the Texas Administrative Code.

The Board passed rules requiring pharmacist applicants, pharmacy technician and pharmacy technician trainee applicants, and pharmacy intern applicants to submit fingerprint information with their applications so the Board can access the applicants' criminal history information. However, the Board has not implemented these rules. According to Board management, the requirement to submit fingerprints will be implemented gradually, beginning with the smallest group—pharmacy interns—and expanding to other groups in phases.

The Board's process for conducting background checks does not ensure that it identifies all criminal offenses committed by licensees and registrants.

The Board is required by state statute to obtain from DPS quarterly criminal history updates on all new and existing licensees and registrants. These updates from DPS contain information for approximately 70,000 licensees and registrants and the Board must manually scan this information to identify any new criminal offenses. For all new offenses, Board policy requires that a new complaint be opened to investigate the offense and be entered into its automated system.

Auditors obtained criminal history information from DPS for all current Board licensees and registrants. Auditors compared licensees and registrants with criminal offenses to complaints opened by the Board in fiscal years 2005 through 2007. Auditors identified 90 licensees or registrants with criminal offenses for which the Board had not yet opened complaints. For another 80 licensees or registrants with criminal offenses, the Board stated it opened complaints but did not have supporting documentation. Auditors also brought to the Board's attention four other licensees or registrants with criminal offenses for which a complaint had not been opened. The Board said it would conduct additional research to determine if these were "false hits" from the DPS data base, or whether a complaint should be opened. While these criminal offenses are not all convictions, Board policy states that each offense should be entered as a complaint into its complaint tracking system.

Although these results represent a small number of licensees and registrants, the Board's failure to identify all criminal offenses limits its ability to effectively track these offenses, regulate the practice of pharmacy, and protect the public.

Summary of Management's Response

The Board generally agrees with the findings and recommendations in this report.

Summary of Information Technology Review

The Board cannot ensure that the data in its primary automated system for recording complaints (system) is protected from unauthorized or undetected changes.

Auditors identified more than 1,100 complaints—17 percent of all complaints received by the Board in fiscal years 2005 and 2006—that were modified more than one year after the date that the complaints were closed. The Board did not retain any documentation verifying what changes were made or why. The system does not track which fields were changed or who made the changes.

System security weaknesses expose the Board's data to unauthorized and undetected modifications. The system lacked controls that would limit a user's ability to change the complaint data. As a result, board staff could modify complaint information for reasons that are outside their assigned areas of responsibility without detection.

Other information technology issues were addressed in writing to Board management.

Summary of Objectives, Scope, and Methodology

The audit objectives were to determine whether: (1) the Board processes complaints in a consistent and efficient manner and in accordance with applicable laws and Board rules, and (2) the Board sanctions and disciplines licensees and registrants based upon the results of investigations, inspections, and criminal background checks as required by the Texas Occupations Code and the Texas Administrative Code.

The scope of this audit included complaint processing and enforcement from fiscal years 2005 through 2007. Auditors tested complaints for fiscal years 2005 through 2007 and enforcement sanctions for fiscal year 2007.

The audit methodology consisted of conducting interviews with the Board's management and staff, collecting and reviewing policies and procedures and other documentation, observing informal conferences and case reviews conducted by the Board, performing selected tests of transactions, and analyzing and evaluating the results of testing and observations.

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Detailed Results

Chapter 1

The Board Imposes Sanctions and Disciplines Licensees and Registrants as Required by State Laws and Regulations

The Board of Pharmacy (Board) imposes sanctions and disciplines licensees and registrants in accordance with state laws and regulations. Some sanctions imposed require monitoring to ensure that the licensee complies with the terms of a disciplinary order. The Board has processes in place to monitor compliance with Board-ordered disciplinary actions.

Chapter 1-A

The Board Sanctions and Disciplines Licensees and Registrants as Required by State Laws and Regulations

The Board orders disciplinary actions for violations identified through investigations, inspections of pharmacies, and results of criminal background checks. The Board imposed disciplinary actions in accordance with the applicable state laws and regulations in all 60 complaints resulting in disciplinary action that auditors tested. In addition, all of the disciplinary actions imposed as a result of these 60 complaints were recorded correctly in the database that the Board uses for tracking complaints and disciplinary actions.

Disciplinary Orders

The Board is authorized to discipline a license holder or applicant for a license to practice pharmacy as outlined in Texas Occupations Code, Section 565.001. Disciplinary actions, which are listed in a disciplinary order, may include:

- Issuing a reprimand.
- Assessing administrative fines and fees.
- Placing a licensee on probation.
- Suspending or restricting a license.
- Revoking a license.
- Requiring continuing education.
- Imposing other actions, such as requiring a mental or physical examination or requiring the licensee to report regularly to the Board on matters that are the basis of probation.

Source: Texas Occupations Code, Sections 565.051 and 565.052.

However, the Board did not consistently implement subsequent sanctions when a fine or fee was not paid by the due date. In 18 of 60 (30.0 percent) complaints tested, the licensee or registrant did not remit the Board-imposed fine or fee by the due date stated in the Board's disciplinary order. The Board imposed additional sanctions for late payment of fines on the licensees or registrants cited in 15 of the 18 (83.3 percent) complaints. However, the Board did not impose additional sanctions on pharmacy technicians cited in 3 of the 18 (16.7 percent) complaints. The Board's policy states that a technician's registration will be automatically suspended if fines are not paid by the due date. However, the Board did not suspend the registration for these 3 technicians, who had paid their fines 8, 13, and 38 days after their due dates, respectively.

Auditors tested 29 disciplinary actions imposed against licensees and registrants between June 2007 and August 2007 that were published in the Board's fall 2007 newsletter. All 29 disciplinary actions had been recorded in the Board's License and Registration Verification database, which is available to the public on the Board's Web site.

Recommendation

The Board should ensure that additional actions are taken when pharmacists and technicians do not adhere to the conditions of a Board disciplinary order.

Management's Response

The Texas State Board of Pharmacy (TSBP) agrees with the recommendation and has implemented policy as well as technology modifications to the agency complaint database system to allow the agency to better track license/registrant compliance with due dates included in disciplinary orders and to ensure that additional actions are taken when a licensee does not meet the assigned due dates.

Responsible Party: Executive Director, Director of Enforcement, and Director of Administrative Services and Licensing

Timeline: Completed March 1, 2008.

Chapter 1-B

The Board Has Processes in Place to Monitor Compliance with Board-Ordered Disciplinary Actions

Of 40 cases selected for testing in which a disciplinary action had been imposed, 26 had not reached the end of the sanction's term. The Board was monitoring 25 of these 26 (96.2 percent) cases. The one case that was not actively being monitored involved a pharmacy technician whose registration had already been suspended; therefore, no further action was required.

In addition, 12 of 40 cases tested required further action by the Board, due to the licensee failing to meet the conditions of the Board's disciplinary order. In all 12 cases, the Board carried out the additional actions required. Furthermore, 100 percent (3 of 3) of the cases tested that were referred to the State Office of Administrative Hearings complied with the Board's rules and statutes for handling complaints.

The Board Has Processes for Efficiently and Consistently Processing Complaints; However, Improvements Can Be Made

The number of complaints processed by the Board has increased significantly since fiscal year 2003. The Board began registering pharmacy technicians in fiscal year 2004 and began registering pharmacy technician trainees in fiscal year 2007. The Board had registered more than 32,000 pharmacy technicians as of June 2007. The Board received 1,935 complaints in fiscal year 2003 and 5,849 complaints in fiscal year 2007—a 200 percent increase. Much of this increase was generated from applications from pharmacy technicians who had prior criminal histories (see Chapter 4 for additional details).

The Board has a complaint handling process in place, which includes an online complaint form. The process prioritizes the assignment and investigation of complaints relative to the seriousness of the allegations, and the Board followed this process.

However, auditors identified some areas for improvement in the Board's complaint handling process. Specifically, the Board:

- Did not obtain fingerprints to access criminal histories of applicants. The Texas Administrative Code requires the Board to obtain fingerprints from pharmacist applicants and from applicants for pharmacy technicians, pharmacy technician trainees, and pharmacy intern applicants.
- Did not ensure that all criminal offenses committed by licensees and registrants were identified.
- Did not meet its statutory due dates for responding to and communicating with complainants regarding the receipt and status of their complaints.
- Did not adequately document reviews of complaint information or retain supporting documentation for the complaints that auditors reviewed.

Chapter 2-A

The Board Has a Process to Prioritize the Investigation of Complaints According to the Seriousness of the Allegation

The Board has a process in place to ensure that the most serious complaints received by the Board are investigated on a priority basis. Under this process, the Board first investigates complaints that allege a continuing threat to the public welfare, such as complaints that a licensee or registrant has a chemical, mental, or physical impairment or that a licensee or registrant is diverting prescription drugs through illegal means.

The Board initiated investigations of more serious complaints on a priority basis as indicated by its internal schedule for all complaints that the Board

received in June 2006. The most serious complaints were referred for investigation on the same day that they were received. For complaints containing allegations of a less serious nature, the Board's assignments and investigations of the complaints were in line with the Board's prioritization schedule.

Chapter 2-B

The Board Did Not Obtain Fingerprints from License Applicants, and Its Process for Conducting Background Checks Does Not Ensure That It Identifies All Criminal Offenses Committed by Licensees and Registrants

The Board did not obtain fingerprints from applicants for licenses or registration. As discussed in Chapter 4, a large number of complaints initiated by the Board are related to pharmacy technician and technician trainee applicants who either (1) indicated on their applications that they had prior criminal histories or (2) had prior criminal histories that the Board identified during a background check conducted on all new applicants.

The Board passed rules requiring pharmacist applicants, pharmacy technician applicants, pharmacy technician trainee applicants, and pharmacy intern applicants to submit fingerprint information with their applications so the Board can access the applicants' criminal history information. The rules, detailed in the Texas Administrative Code, took effect between June 2006 and December 2006. However, the Board has not yet begun requiring new applicants to submit fingerprints. According to Board management, the requirement to submit fingerprints will be implemented gradually, beginning with the smallest group—pharmacy interns—and expanding to other groups in phases. The Board does not intend to require fingerprints from current license holders or registrants.

The Board did not identify all criminal offenses committed by licensees and registrants.

As a result, the Board may not implement the appropriate sanctions for pharmacists, pharmacy technicians, pharmacy technician trainees, and pharmacy interns who are convicted of criminal offenses.

As required by state laws and regulations, the Board provides a list of all licensees and registrants to the Department of Public Safety (DPS) on a quarterly basis (see text box for additional details). DPS matches the Board's list against the information in DPS's computerized criminal history system. DPS then provides the Board these results. This report contains the entire list of approximately 70,000 licensees and registrants regardless of whether there is a new criminal offense. As a result, the Board manually scans these results for criminal offenses. If the Board identifies a criminal offense, it must determine whether it is a new offense or one that has already been entered into the Board's automated system for recording complaints. For all new offenses,

**Texas Code of Criminal Procedure
Article 60.061**

This article requires the Board to provide a list of all licensees and registrants to the Department of Public Safety (DPS) on a quarterly basis. This list must contain each individual's name, date of birth, and any other personal descriptive information.

DPS will perform a quarterly match of this list against the convictions maintained in DPS's computerized criminal history system. DPS will report the name of any person found to have a record of conviction to the Board.

Board policy requires that a new complaint be opened and entered into its automated system.

Auditors obtained criminal history information from DPS for all current Board licensees and registrants. Auditors compared licensees or registrants with criminal offenses to complaints opened by the Board in fiscal years 2005 through 2007. Auditors identified 90 licensees or registrants with criminal offenses for which the Board had not yet opened complaints. For another 80 licensees or registrants with criminal offenses, the Board stated it opened complaints but did not have supporting documentation. Auditors also brought to the Board's attention four other licensees or registrants with criminal offenses for which a complaint had not been opened. The Board said it would conduct additional research to determine if these were "false hits" from the DPS data base, or whether a complaint should be opened. While these criminal offenses are not all convictions, Board policy states that each offense should be entered as a complaint into its complaint tracking system.

Although these results represent a small number of licensees and registrants, the Board's failure to identify all criminal offenses limits its ability to effectively track these offenses, regulate the practice of pharmacy, and protect the public.

Recommendations

The Board should consider:

- Ensuring that all pharmacy 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.
- Working with DPS to develop a report that returns only records of licensees or registrants with convictions or arrests.
- Pursuing options to electronically analyze criminal offenses.

Management's Response

(1) Fingerprint Checks

TSBP generally agrees with the findings but must point out that in October 2007, the agency began obtaining fingerprints for pharmacist-intern applicants. Since that date, fingerprint checks for criminal history have been processed through the Department of Public Safety (DPS) and the Federal

Bureau of Investigations (FBI) for 456 pharmacist-interns. In addition, although all applicants for licenses/registrations are not currently subject to the FBI fingerprint check for criminal history, a criminal history background check for all applicants is conducted using the DPS criminal history database.

The rules regarding the use of fingerprints to run criminal histories on license/registration applicants became effective in the fall of 2006. When the rules were presented to the Board, the Board directed staff to “phase-in” the requirement for use of fingerprints to conduct federal criminal history background checks of licensees/registrants. The minutes of the May 9-10, 2006, meeting of the Board record the Board’s direction to staff as follows:

“The Board discussed that fingerprinting would be required of all applicants for license or registration by the Board. They suggested that fingerprinting be phased in, beginning with the smaller applicant populations, which would be interns and pharmacist applicants, then adding technicians and technician trainees.” (emphasis added)

Once the rules became effective TSBP began working with DPS to use the fingerprint criminal history background check for applicants, beginning with pharmacist-interns. A number of delays in implementation of the program with DPS occurred between the fall of 2006 and the fall of 2007. However, in October 2007, the agency began using fingerprints to run criminal history background checks on pharmacist-interns. Other licensees will be “phased-in” in accordance with the Board’s direction.

At the August 5-6, 2008, meeting of the Board of Pharmacy, staff will present to the Board for consideration, suggested amendments to the TSBP rules that will clarify the Board’s intention regarding the submission of fingerprints by applicants.

Responsible Party: Members of the Board, Executive Director, Director of Enforcement, and Director of Administrative Services and Licensing.

Timeline: Modification of rule language projected to be final by January 1, 2009. Implementation of fingerprint checks for all applicants for licenses/registrations is projected to be complete by January 1, 2010.

(2) Quarterly DPS Criminal History Checks of All Licensees

TSBP agrees with the recommendation and will continue to work with DPS to improve the system for running quarterly checks of licensees for criminal history information.

The current system is very labor-intensive for agency employees as explained below. Compounding the problem is the fact that the agency began licensing pharmacy technicians and pharmacy technician trainees in FY2004. From FY2004 to January 2008, the agency registered more than 47,000 pharmacy

technicians/trainees, which increased the number of licensees/registrants to more than 72,000, resulting in a 164% increase in a three-year period.

In addition, this new population of technicians/trainees has a much greater incidence of criminal offenses. Less than 1% of licensed pharmacists have a criminal offense on their records, while 10 to 25% of the technicians/trainees have a criminal offense on their records.

TSBP currently submits an electronic download of all of its licensees/registrants to DPS on a quarterly basis. DPS compares TSBP's licensee/registration database to their criminal history database and uploads electronic batches containing "new" matches of criminal history that occurred during the prior three months on licensees/registrants. Although criminal history matches are provided to the agency in an electronic format, the information on the "new" matches is not segregated from the information on licensees/registrants that do not have "new" matches. Therefore, an agency employee must look at each of the more than 70,000 records and determine first, if there is a match, and secondly, if the match is a "new" match that the agency had not previously received. In the event that TSBP does not have a complaint on the "new" match, a new complaint is entered in the agency's computerized complaint tracking system. To show the enormity of the task, a typical DPS run produces approximately 400 matches out of the more than 70,000 licensees/registrants submitted (approximately a 0.6% "match" rate). The TSBP employee is required to look through the 70,000 records to find the 400 "matches."

Other complicating factors regarding the quarterly background checks are the following:

- *Events other than a change in criminal history cause the "date last updated field" on the DPS criminal history record to change in a person's record. This fact causes records of licensees/registrants to be "matched" when no criminal history has been changed.*
- *Frequently, a record will be updated with the entry of a criminal history event that occurred many years in the past. For example, recently a pharmacist record was updated with an arrest that occurred more than ten years in the past, and that offense was not included on previous quarterly runs.*

Lastly, the report indicates that for fiscal years 2005 through 2007, the auditors identified "80 licensees, registrants, or applicants with criminal offenses" for which the Board indicated that "it opened complaints but did not have supporting documentation." The documentation was not available because the agency's record retention policy specified that complaints that did not result in disciplinary action would be destroyed five years after the date the complaint was closed. However, because it is not unusual to have

“old” criminal history events identified as “new” matches on the DPS quarterly run, as of April 1, 2008, the agency has modified its procedure and will be retaining all complaints relating to criminal offenses for the life of the license/registration.

Responsible Party: Executive Director, Director of Enforcement, and Director of Administrative Services and Licensing.

Timeline: Discussions of the above listed concerns with DPS will begin in the summer of 2008 and continue as needed. As of April 1, 2008, the agency is retaining all complaints containing criminal history background information

(3) Electronic options to analyze criminal offenses

TSBP agrees with this recommendation and will be using suggestions provided by the auditor’s office to develop a more effective method for analyzing this extreme volume of information. Suggestions from the auditor that will be considered are:

- *Development of a program that will compare the DPS run with the TSBP complaint database to identify “matches” not yet entered as a complaint in the TSBP system.*
- *Use of side-by-side monitors to allow TSBP personnel to view the DPS “matches” and the TSBP complaint records simultaneously.*

Responsible Party: Executive Director, Director of Enforcement, and Information Resources Manager.

Timeline: Projected completion date is January 1, 2010, if additional technology purchases are required and earlier if no additional technology is required.

The Board Did Not Meet Statutory Due Dates for Notifying Complainants

State regulations require the Board to notify a complainant no later than 30 days after the Board receives a complaint and provide an estimated time for resolution of the complaint (see text box). The Board did not comply with this statutory due date. The Board did not provide the required notification to the complainant within 30 days for:

Notification Requirements

- Texas Occupations Code, Section 555.006, requires the Board to notify a complainant that it has received the complaint and provide an estimated time for complaint resolution no later than 30 days after the date that the Board received the complaint.
- Texas Occupations Code, Section 555.006, requires the Board to notify all parties to a complaint about the status of the complaint at least every four months until the complaint is resolved.

- 6 of 25 (24 percent) fiscal year 2005 complaints tested by auditors.
- 8 of 27 (30 percent) fiscal year 2006 complaints tested by auditors.
- 6 of 27 (22 percent) fiscal year 2007 complaints tested by auditors.

The Board is also required to provide status updates at least every four months to all parties to a complaint until the complaint is resolved (see text box). However, the Board did not consistently provide the required status updates. Specifically:

- 12 of 17 (71 percent) complaints tested that were still open after 120 days in fiscal year 2005 did not meet the statutory requirements for providing status updates.
- 6 of 15 (40 percent) complaints tested that were still open after 120 days in fiscal year 2006 did not meet the statutory requirements for providing status updates.
- 5 of 11 (45 percent) complaints tested that were still open after 120 days in fiscal year 2007 did not meet the statutory requirements for providing status updates.

The Board developed a backlog of unresolved complaints. According to the Board, this backlog developed because of the significant increase in the number of complaints received against technicians by the Board beginning in fiscal year 2004. Board staff reported the backlog of complaints to its nine-member board, as required by the Texas Occupations Code, with reasonable accuracy. However, for the periods reviewed, the Board did not meet its targets set by the Legislative Budget Board for average number of days it should take the Board to resolve a complaint. For fiscal year 2005, the Board reported to the Legislative Budget Board that the average number of days to resolve a complaint was 197 days. The Legislative Budget Board reduced the Board's target for resolving complaints from 250 days to 120 days for fiscal years 2006 and 2007. The Board reported to the Legislative Budget Board that the average number of days to resolve a complaint was 197 days for fiscal year 2006 and 185 days for fiscal year 2007.

Recommendations

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.
- 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.

Management's Response

TSBP agrees with the recommendations regarding communication with complainants and will implement procedures that:

(1) Prioritize the notification of complainants of the receipt of a complaint within 30-days; and

(2) Ensure that complainants are notified of the status of their complaints every four months.

Responsible Party: Executive Director and Director of Enforcement

Timeline: Projected completion date for an automated system to notify complainants is June 1, 2008.

Chapter 2-D

The Board Did Not Adequately Document the Review of Complaint Information or Ensure That It Retained Supporting Documents

The Board did not adequately document its reviews of complaint information. Also, the Board was inconsistent in the type of documentation it retained in 180 complaint hard copy files reviewed by auditors for fiscal years 2005 through 2007 (60 complaint files from each fiscal year were reviewed).

The Board's Enforcement Division has internal policies and procedures that require (1) all complaint information be reviewed by either the Director of Enforcement or a designee and (2) all complaint data entered into the system be proofed for accuracy using a complaint worksheet that Board staff manually completes when a complaint is first received. The Board did not always follow its internal policies and procedures. Specifically:

- 30 of 60 (50 percent) fiscal year 2005 files reviewed did not contain evidence that a review of the complaint information had been conducted or were missing a copy of the complaint worksheet.

- 26 of 60 (43 percent) fiscal year 2006 files reviewed did not contain either evidence of a review or a copy of the complaint worksheet.

Board management asserted that the Board conducts a review of each complaint, even though documentation of this review may not be present in the complaint file.

The Board also did not consistently retain complaint log sheets, which contain investigative notes. The Enforcement Division uses the log sheets to document the date that a complaint is referred for investigation and other actions taken. Specifically:

- 46 of 51 (90 percent) fiscal year 2005 files tested did not contain a log sheet.
- 47 of 53 (89 percent) of fiscal year 2006 files tested did not contain a log sheet.
- 18 of 51 (35 percent) fiscal year 2007 files tested did not contain a log sheet.

The complaint worksheets and log sheets could provide important documentation to support the accuracy of the information entered into the Board's system for complaint tracking. This documentation is important because the system does not create or retain a transaction history or, if the data has been changed, allow the Board to identify who made changes or what fields may have been changed. Retaining these documents could comprise a valuable part of the internal control over the Board's complaint process. For example, data in more than 1,100 complaint files was changed after the complaints had been closed for more than a year, and the Board was unable to identify what changes had been made because it had not retained any documentation of what had been changed.

Recommendations

The Board should:

- Document the review of complaint information that is required by its internal policies.
- Review its procedures for retaining documentation and determine what might be appropriate for its internal management needs.

Management's Response

TSBP agrees with the recommendations and will implement procedures to document the review of complaint information by agency staff. However, the

agency does not believe maintenance of the two documents mentioned in the report (complaint worksheet and log sheet) will accomplish this goal. Therefore, the agency will implement the use of a new complaint “Control Sheet” that will document review, assignment, and other important events that occur as the complaint is processed. Ultimately, the agency plans to transition to the use of an electronic complaint file that will eliminate the maintenance of a paper file and allow electronic documentation of all activity that occurs during the processing and investigation of a complaint, however; adding the ability for tracking of this information to the agency’s existing outdated computer system is not cost-effective. The members of the Board have approved a request for funds in the agency’s FY2010-2011 Legislative Appropriations Request (LAR) in order to purchase new complaint/licensing software and to migrate all existing data to the new system.

Responsible Party: Executive Director and Director of Enforcement and Director of Administrative Services and Licensing, and Information Resources Manager.

Timeline: Projected implementation of the paper control sheet is September 1, 2008. If funded by the 81st Texas Legislature, the projected date for implementation of a new data processing system is August 31, 2011.

The Design and Operation of the Board's Primary Automated System for Recording Complaints Does Not Ensure That Data Is Protected from Undetected or Unauthorized Changes

The Board cannot ensure that the data in its primary automated system (system) for recording complaints is protected from undetected or unauthorized changes.

Auditors identified more than 1,100 complaints—17 percent of all complaints received by the Board in fiscal years 2005 and 2006—that were modified more than one year after the date that the complaints were closed. The Board did not retain any documentation verifying what changes were made or why. The system does not track which fields were changed or who made the changes.

System security weaknesses expose the Board's data to unauthorized and undetected modifications. The system lacked controls that would limit a user's ability to change the complaint data. As a result, Board staff could modify complaint information for reasons that are outside their assigned areas of responsibility without detection.

System weaknesses include:

- Data used to track complaints can be modified by 24 Board employees without any transaction history or logs being created and retained.
- Complaint records can be deleted from the system without details of the complaint or its status being retained.
- Users can enter a future date in the "date complaint was received" field.

Also, the system's primary vendor will no longer support the underlying technology after 2010. If the Board is still using the same system and the technology fails after 2010, the Board may be prevented from continuing to do business. Even if the Board obtains non-vendor support for this technology, it is likely that the costs to obtain this support will be high.

Twenty-four employees had the ability to modify complaint data elements without a transaction history and logs to allow the Board to detect and review intentional and unintentional changes. Data that could be changed included: (1) complaint-received date, (2) violation codes, (3) subject of complaint, (4) comments detailing the allegation, (5) complaint status, (6) assigned case number, and (7) all dates that track the progress of a complaint. Any one of these 24 employees could alter the allegations submitted by a complainant and change the subject of a complaint without detection. Furthermore, the status of a complaint and the various dates used to track the progress of a complaint's resolution could be modified by one of these employees without detection.

Auditors identified more than 1,100 complaints—17 percent of all complaints received by the Board in fiscal years 2005 and 2006—that were modified

Statutory Requirements for Record Retention

Texas Administrative Code, Section 202.25, requires that appropriate audit trails be maintained to provide accountability for updates to mission critical information.

Texas Occupations Code, Section 555.005, requires the Board to retain a record of complaints, including information about the parties to the complaint, the subject matter of the complaint, a summary of the results of the review or investigation of the complaint, and the complaint's disposition.

more than one year after the date that the complaints were closed. The Texas Administrative Code requires the Board to maintain audit trails that are sufficient to provide accountability (see text box). The Board did not retain any documentation verifying what changes were made or why. The system does not track which fields were changed or who made the changes.

However, for each of the three years that auditors reviewed, complaint information stored in the Board's system matched the hard copy documents for at least 97 percent of the complaints tested. In addition no former employees were found to have access to the system. The Board has several password policies that ensure the use of strong passwords needed to access the system. The password parameters for the system comply with the Boards own password policies.

Four users who work in the Enforcement Division could delete complaints from the system, thereby removing all information about the complaint without a record explaining why or by whom the complaint was deleted. Auditors identified 11 complaints out of more than 12,800 received during fiscal years 2005 through 2007 that were deleted from the Board's complaint tracking system. The Board did not have any documentation or other information explaining why these complaints were deleted. While auditors identified only a small number of deleted complaints, the authorization to delete complaints and the absence of a record explaining why or by whom a complaint was deleted increases the risk that a Board employee could delete a complaint before an investigation is completed.

The system allows a user to enter a future date in the "date complaint was received" field. Properly recording the date on which a complaint was received is important because this date is used to report several performance measure results. This date is also used to determine whether the Board is complying with statutory requirements regarding notifying and updating complainants. Auditors did not identify any errors in the complaint information stored in the Board's system when the information was compared to the hard copy documents in the complaint files. However, allowing a future date to be entered could distort the number of days it takes to resolve a complaint, and this could possibly result in inaccurate information being generated.

Recommendations

The Board should:

- Consider and evaluate options for ensuring its primary automated system used to record complaints has technology support after 2010.

- Ensure that access to complaint data is granted to staff based upon the minimum access needed to complete their job duties.
- 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.
- Retain a record of all deleted complaint files. The Board also should consider disabling the Enforcement Division staff's ability to delete complaints.
- Modify the system so that future dates cannot be entered in the field for the date a complaint was received.

Management's Response

(1) Consider and evaluate options for ensuring its primary automated system used to record complaints has technology support after 2010.

TSBP agrees with this recommendation. The current database system used by the Texas State Board of Pharmacy was originally developed in the 1970's for a DEC10 platform and was converted to a DEC VAX platform during the early 1980's. The system includes the processing of cash, examinations, licensee/registrant initial applications and renewals, and complaints and disciplinary orders. The agency is meeting with representatives of the Department of Information Resources (DIR) and other regulatory agencies to discuss the transition of the TSBP and other "legacy" systems to a new software system. The Board has approved a request for funds in the agency's FY2010-2011 Legislative Appropriations Request (LAR) to purchase new complaint/licensing software and to migrate to the new system.

Responsible Party: Members of the Board of Pharmacy, Executive Director, Director of Administrative Services and Licensing, Director of Enforcement, General Counsel, Director of Professional Services, and Information Resources Manager.

Timeline: If funded by the 81st Texas Legislature, the projected date for transition to a new data processing system is August 31, 2011.

(2) Ensure that access to complaint data is granted to staff based upon the minimum access needed to complete their job duties.

TSBP agrees with this recommendation, and has a system that requires management staff to review and authorize each user's permission to access only the specific data necessary to perform the user's job functions. In addition, as complaints are moved through the review process, multiple

employees, including management staff, view the complaint information. These reviews have not detected unauthorized alteration of the complaint data. The current data processing system does not provide the ability to document each change to fields within the database, and modifying the agency's existing outdated computer system would not be cost-effective. The Board members have approved a request for funds in the agency's FY2010-2011 Legislative Appropriations Request (LAR) to purchase new complaint/licensing software and to migrate all existing data to the new system. The agency will specify that the new complaint/licensing system be able to produce a transaction history that records the field that was changed, when it was changed, and who made the change.

Responsible Party: Director of Enforcement, Director of Administrative Services and Licensing, and Information Resources Manager.

Timeline: Completed. The agency has implemented a system for management review, which includes written authorization for granting permission to access complaint data to employees as needed to complete their job duties. Division Directors submit written authorization to the Information Resources Manager who coordinates the changes with the agency's contractor for computer services. If funded by the 81st Texas Legislature, the projected date for transition to a new data processing system that will maintain a transaction history is August 31, 2011.

(3) 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.

TSBP agrees with this recommendation. However, the current system is able to track only one date of change. This date is updated any time a data field within the complaint record is changed. Modifying the existing outdated computer system to track change information for each of the fields in the complaint record is not cost-effective. The Board members have approved a request for funds in the agency's FY2010-2011 Legislative Appropriations Request (LAR) to purchase new complaint/licensing software and to migrate all existing data to the new system. The agency will specify that the new complaint/licensing system must be able to produce a transaction history that records the fields changed, when they were changed, and who made the change.

Beginning, June 1, 2008, the agency will implement a procedure that will track changes that are made to a complaint record after the complaint has closed. This information will be recorded in a summary field that allows the entry of the date of the change, what was changed, and the person who made the change. Generally, changes made after a complaint is closed are made for the following reasons:

- *Correcting data entry errors that were not discovered during the final review of the complaint.*
- *Updating the comments field in the complaint database to incorporate information received after the complaint is closed. One example: the Texas Pharmacy Act requires professional liability insurance providers to report to the Board an initial notice of claim and a follow-up report after the disposition of claim. Following the receipt of the initial report, a complaint is opened. This complaint is reviewed and handled in accordance with standard procedures, which may include closing the complaint. When the follow-up report is received, the agency does not enter another complaint but updates the comments on the closed complaint to reflect the final disposition of the claim.*
- *Updating identification, received after the complaint is closed. One example: TSBP does not issue registration numbers to pharmacist-interns. Therefore, when the pharmacist-intern becomes a pharmacist, the complaint must be manually updated to add the individual's pharmacist license number.*

Responsible Party: Executive Director, Director of Enforcement, Director of Administrative Services and Licensing, and Information Resources Manager.

Timeline: Completed. A manual system for tracking changes to closed complaints will be implemented by June 1, 2008. If funded by the 81st Texas Legislature, the projected date for transition to a new data processing system that will maintain a transaction history is August 31, 2011.

(4) Retain a record of all deleted complaint files. The Board also should consider disabling the Enforcement Division staff's ability to delete complaints.

TSBP agrees with the recommendation and TSBP will keep a record of complaints that are deleted when the agency needs to delete a complaint (because the complaint is duplicative). However, when complaints have met their record retention time, TSBP must be able to delete these complaints to be in compliance with the agency's approved record retention schedule. Deletion of these complaints is documented on a Record Destruction Form. However, in response to the Auditor's concerns, TSBP reduced the number of persons who have the authority to delete a complaint and only two persons are authorized to delete complaints as specified in the record retention schedule.

TSBP would like to point out that following the audit, TSBP determined that the primary reason for "missing" complaint numbers was not due to agency personnel deleting complaints, but rather due to the computer/user malfunctions described below:

- *If the user gets interrupted or distracted and fails to hit “enter” within a certain length of time, the system will “time out.” In this event, the complaint information entered under that complaint number is lost and the user must begin again, whereupon the computer assigns the next available number.*
- *In certain instances, a user will enter information (e.g., code out of range) that causes a “fatal error” and the complaint is erased from the system. Again when this occurs, the complaint information entered under that complaint number is lost and the user must begin again, whereupon the computer assigns the next available number.*

To account for the complaint numbers that are deleted because of “system errors,” a new report will be generated monthly by the system administrator that lists complaint numbers that do not contain complaint information. This report will document complaint numbers that were not used.

Responsible Party: Executive Director, Director of Enforcement, Director of Administrative Services and Licensing, and Information Resources Manager.

Timeline: Projected completion date for tracking deleted complaint numbers caused by system errors is September 1, 2008.

(5) Modify the system so that future dates cannot be entered in the field for the date a complaint was received.

TSBP agrees with the recommendation, and the computer system has been modified to not accept future dates.

Responsible Party: Executive Director, Director of Enforcement, Director of Administrative Services and Licensing, and Information Resources Manager.

Timeline: Completed in April 2008.

The Board Began Registering New Groups of Pharmacy Employees in Fiscal Years 2004 and 2007

Legislation passed during the 76th legislative session required the Board to begin registering pharmacy technicians effective September 1, 2001. The Board approved rules to require pharmacy technicians to register with the Board by June 1, 2004. The Board registered approximately 32,000 pharmacy technicians between December 2003 and June 30, 2007.

The 79th Legislature passed legislation that requires the registration of pharmacy technician trainees. The Board began registering pharmacy technician trainees during fiscal year 2007 and registered 13,348 pharmacy technician trainees as of January 25, 2008.

The number of complaints processed by the Board has increased since fiscal year 2003, when the Board started registering these new groups (see Table 1).

Table 1

Complaints Received and Closed by the Board and Average Resolution Time						
Fiscal Years 2003 to 2007						
Fiscal Year	Complaints Received	Percent Change from Previous Fiscal Year	Complaints Closed	Percent Change from Previous Fiscal Year	Average Resolution Time (in days)	Percent Change from Previous Year
2003	1,935	5%	1,887	(12%)	153	(31%)
2004	4,475	131%	3,018	60%	118	(23%)
2005	3,086	(31%)	3,327	10%	196	66%
2006	3,549	15%	3,387	2%	207	6%
2007	5,849	65%	4,980	47%	185	(11%)

Source: Unaudited data from the Board.

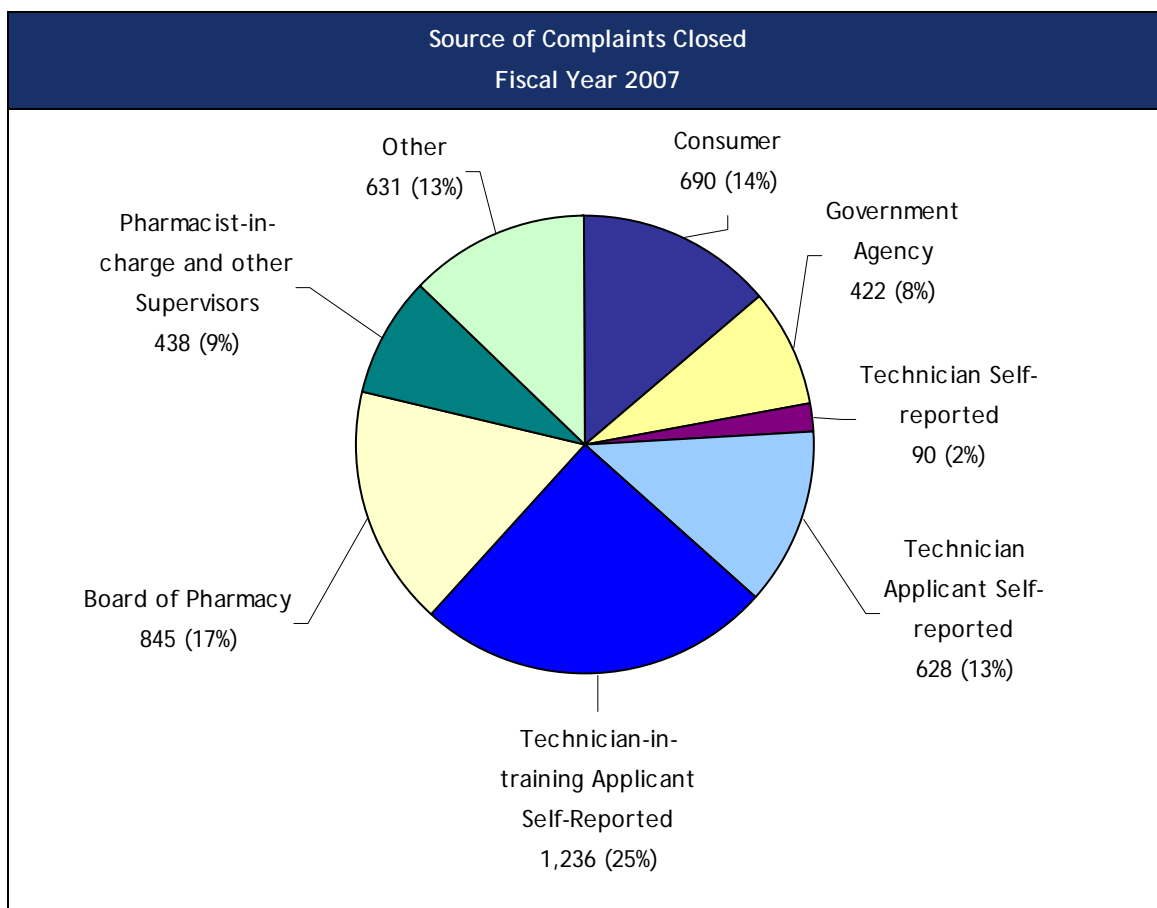
During fiscal year 2004, the Board received 4,475 complaints—2,108 (47 percent) of these complaints were initiated by the Board to investigate pharmacy technician applicants who either (1) indicated on their applications that they had prior criminal histories or (2) had prior criminal histories that were identified during a background check conducted on all new applicants. Texas Occupations Code, Section 568.003, outlines the grounds for disciplinary actions that the Board can take if a pharmacy technician applicant has either been convicted of or placed on deferred adjudication for a felony or certain misdemeanors.

As of June 30, 2007, the Board regulated 23,547 licensed pharmacists, 6,275 pharmacies, and 32,260 pharmacy technicians. As of January 25, 2008, the Board registered 13,358 pharmacy technician trainees. The total number of

individuals and entities regulated by the Board exceeded 75,000 as of January 25, 2008.

Complaints are received from consumers, inspections of pharmacies, or reports from other agencies; complaints also can be internally generated from information obtained through background checks on applicants for licensure or registration. Only 14 percent of the complaints closed in fiscal year 2007 were complaints from consumers (see Figure 1). Applications from technicians in training who had a criminal history or other violation listed in the Texas Occupations Code, Section 568.003, as grounds for disciplinary action generated the largest number of complaints—1,236 (25 percent) of the 4,980 complaints closed in fiscal year 2007 were these types of complaints.

Figure 1

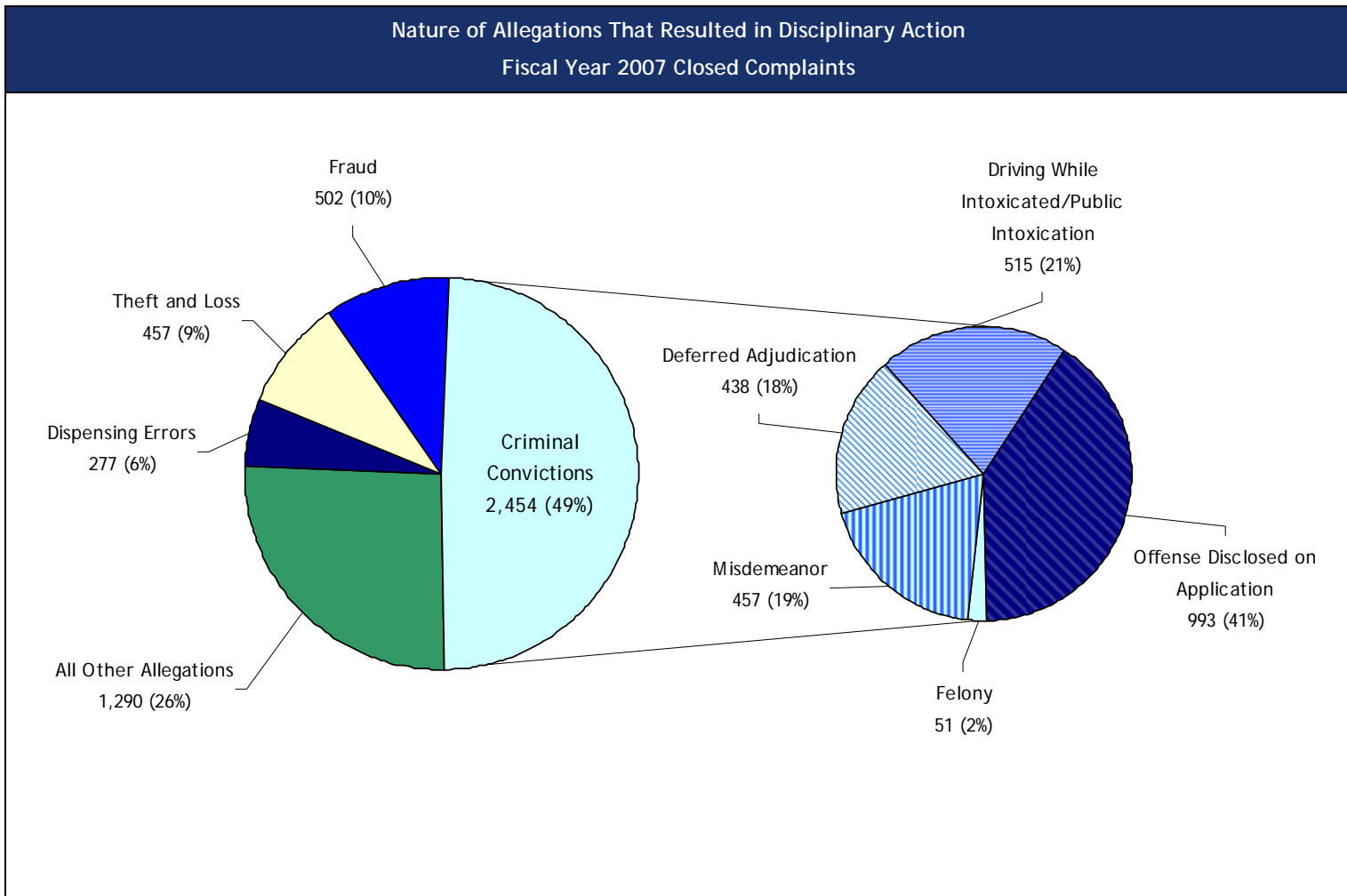


Source: Unaudited data from the Board.

Complaints involve a variety of allegations, including the diversion of drugs, the unauthorized dispensing of drugs, convictions and criminal offenses, dispensing errors, fraud, and other complaints. Convictions and criminal offenses, fraud, and theft and loss were the three largest categories of allegations in complaints closed during fiscal year 2007 (see Figure 2 on the next page). Of the 2,454 complaints relating to convictions and criminal

offenses, 993 were generated as a result of an offense disclosed or discovered on a license or registration application. (See Appendix 2 for information on the source and type of complaints received by the Board since fiscal year 2003.)

Figure 2



Note: Total for breakout of criminal convictions does not sum to 100 percent due to rounding.

"Dispensing Error" includes wrong drug/wrong strength, mislabeling, wrong quantity, outdated drug, wrong packaging/delivery, and no or improper patient counseling.

"Theft/Loss" includes employee pilferage of controlled substances or dangerous drugs.

"Fraud" includes outright fraud, as well as deceit and misrepresentation, falsified responses to a warning notice, falsified application, filled/passed a forged prescription, and insurance and Medicaid fraud.

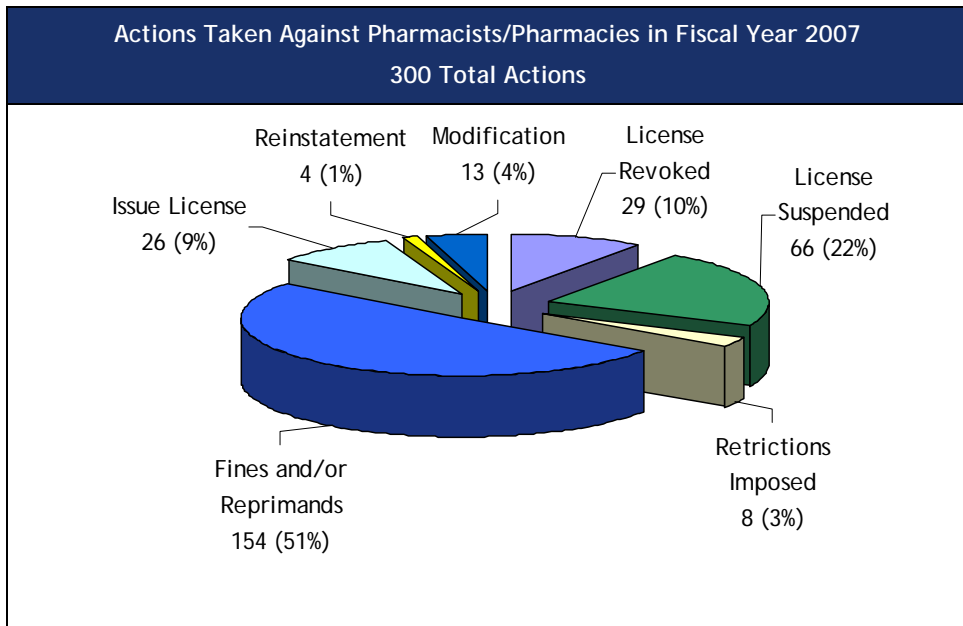
"Other Allegations" include violations of the Texas Pharmacy Act; the Texas Dangerous Drug Act; the Texas Controlled Substances Act; the federal Food, Drug, and Cosmetic Act; Board of Pharmacy rule; or other state laws/rules.

Source: Unaudited data from the Board.

Of the 4,980 complaints that the Board closed in fiscal year 2007, 648 (13.0 percent) resulted in a disciplinary action, such as revocation or suspension of the license or other sanctions.

Of the 300 disciplinary actions taken against pharmacists and pharmacies in fiscal year 2007, 249 (83 percent) resulted in a revocation or suspension of a license, an assessment of a fine, and/or a reprimand (see Figure 3).

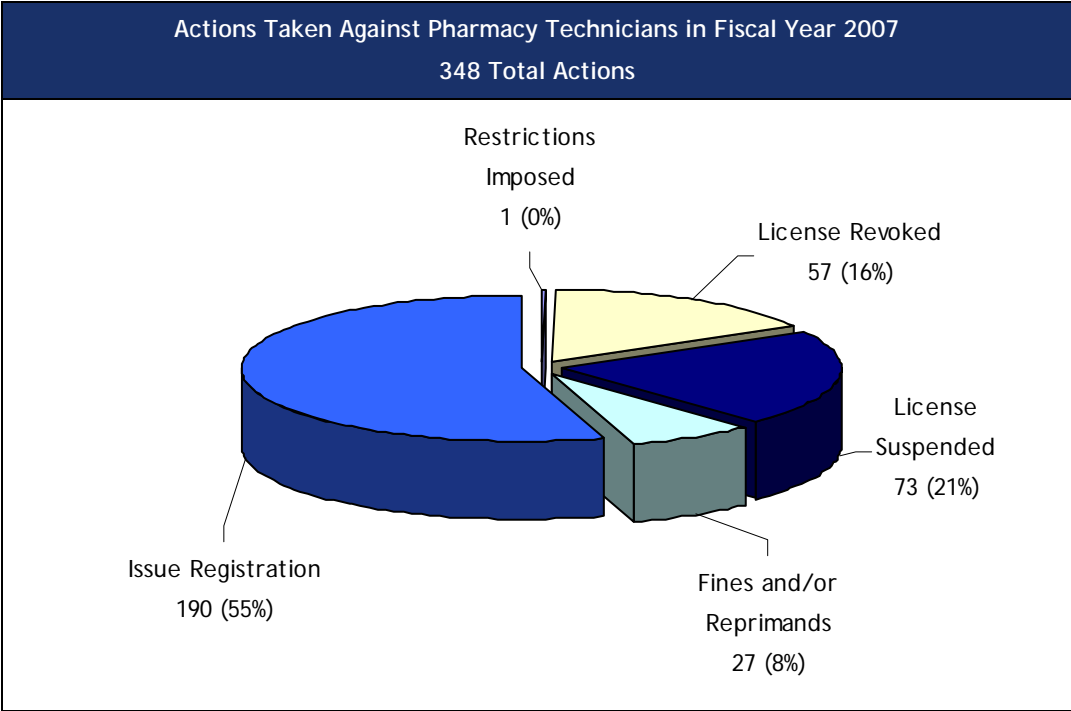
Figure 3



Source: Self-reported, unaudited data from the Board.

Of the 348 disciplinary actions taken against pharmacy technicians in fiscal year 2007, 157 (45 percent) resulted in a revocation or suspension of a license, an assessment of a fine, and/or a reprimand (see Figure 4).

Figure 4



Source: Self-reported, unaudited data from the Board.

Appendices

Appendix 1

Objectives, Scope, and Methodology

Objectives

The objectives of this audit were to determine whether the Board of Pharmacy (Board):

- Processes complaints in a consistent and efficient manner and in accordance with applicable laws and Board rules.
- Sanctions and disciplines licensees and registrants based upon the results of complaint investigations, inspections, and criminal background checks, as required by the Texas Occupations Code and the Texas Administrative Code.

Scope

The scope of this audit included the Board's complaint tracking and enforcement processes for fiscal year 2005 to fiscal year 2007. Auditors tested complaints for fiscal years 2005 through 2007 and enforcement sanctions for fiscal year 2007.

Methodology

The audit methodology included collecting and reviewing information and documentation, observing informal conferences and case reviews conducted by the Board, conducting interviews with Board management and staff, performing selected tests, and analyzing and evaluating the results of testing and observations.

Information collected and reviewed included the following:

- Board internal policies and procedures.
- Interviews with Board management and staff.
- Interview with Legislative Budget Board analyst.
- Report on status of active/pending complaints.
- Data on complaints that the Board received in fiscal years 2005, 2006, and 2007.
- Hard copies of complaint files.

- Procedures for and observations of informal conferences.
- Procedures for and observations of case reviews.
- Enforcement Division organization chart.
- State Office of Administrative Hearings procedures.
- Board worksheets, including complaint worksheet and log worksheet.
- Board complaint process.
- Board policy on receiving mail with funds enclosed.

Procedures and tests conducted included the following:

- Comparing information in the original complaint form with data in the Board's automated complaint tracking system.
- Comparing Board policies and procedures with the supporting documentation within the complaint files.
- Comparing criminal background checks performed with governing statutes.
- Identifying the process from the receipt of a complaint to the assignment and investigation of the complaint and to its final jurisdictional determination.
- Reviewing Board responses to complainants to determine whether the complainants received required notifications by the statutory due dates.
- Analyzing the complaint backlogs reported by staff to the nine-member board to determine whether the backlog was accurately reported.
- Reviewing complaints received by the Board during June 2006 to determine whether the Board followed the hierarchy it established for the classification of and response to complaints.
- Reviewing complaints received by the Board to determine whether the complaints investigated were within the Board's jurisdiction.
- Identifying licensees and registrants that received probation or other disciplinary actions to determine whether the Board updated the relevant information on its Web site.
- Identifying complaints referred to the State Office of Administrative Hearing to determine whether the complaints were handled according to Board rules and statutes.

- Reviewing Board-ordered disciplinary actions to determine whether the disciplinary actions were entered correctly and the fines and fees imposed were recorded properly.
- Reviewing closed complaints to verify whether the Board closed the complaints appropriately.

Criteria used included the following:

- Board internal polices and procedures.
- Texas Administrative Code.
- Texas Occupations Code.
- Texas Code of Criminal Procedures.
- Texas Pharmacy Act.
- Best practices in carrying out a state regulatory program established by the National State Auditors Association.
- *Staff Report on the Texas State Board of Pharmacy, Sunset Advisory Commission Report, February 2004.*
- *Sunset Commission Decisions on Texas State Board of Pharmacy, Sunset Advisory Commission, May 2004.*

Project Information

Audit fieldwork was conducted from January 2008 through February 2008. 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:

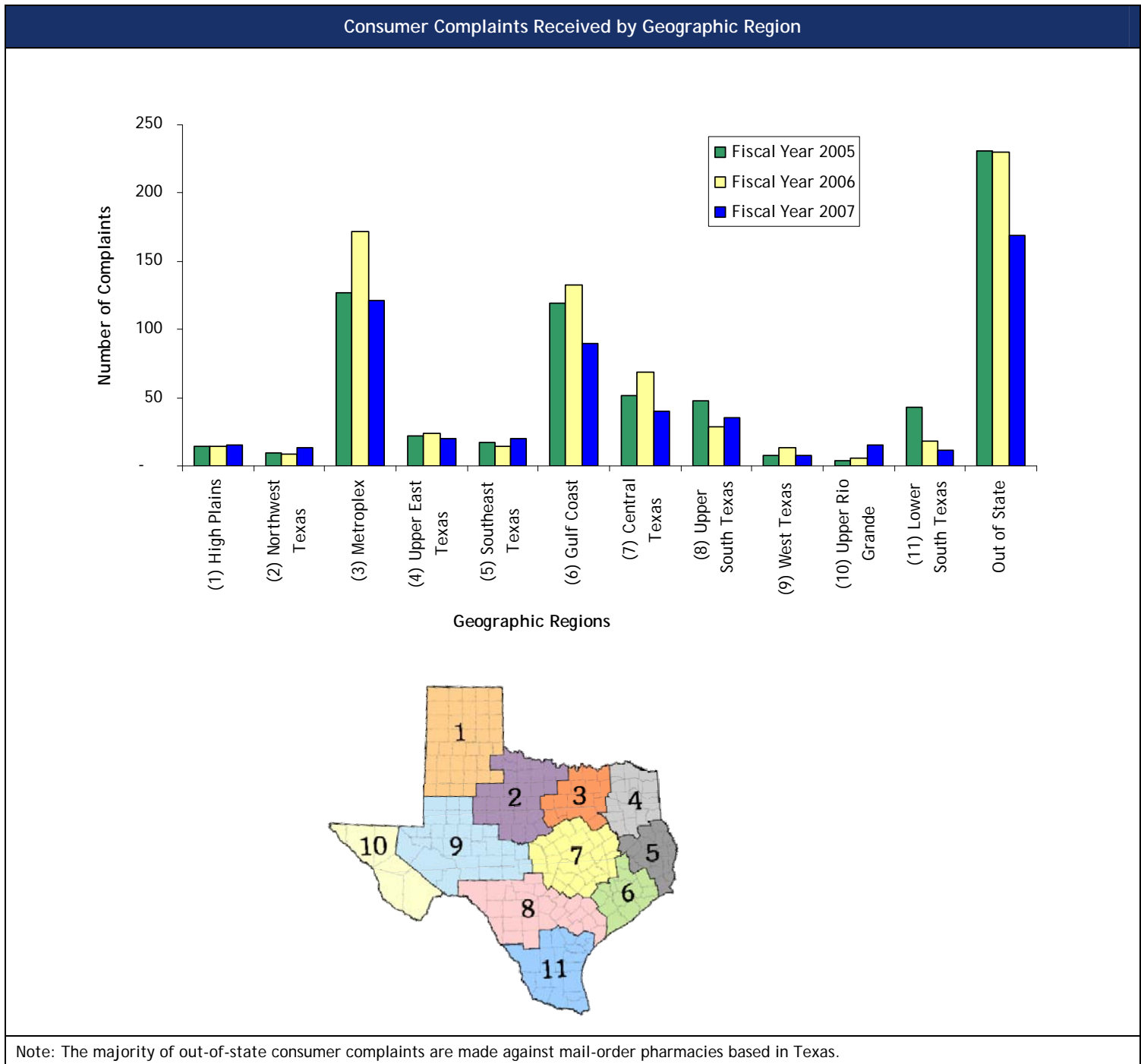
- Kathy L. Aven, CIA, CFE (Project Manager)
- Namita R. Pai, MS, CPA (Assistant Project Manager)
- Dannyaal Cooper
- Melissa Dozier
- Stephen Randall, MBA
- Cesar Saldivar, CGAP

- Brian York
- Michael Yokie, CISA
- J. Scott. Killingsworth, CIA, CGAP, CGFM (Quality Control Reviewer)
- Lisa R. Collier, CPA (Audit Manager)

Information on Source, Nature, and Subjects of Complaints

Figure 5 shows the geographic distribution of consumer complaints received by the Board of Pharmacy (Board) during fiscal years 2005, 2006, and 2007.

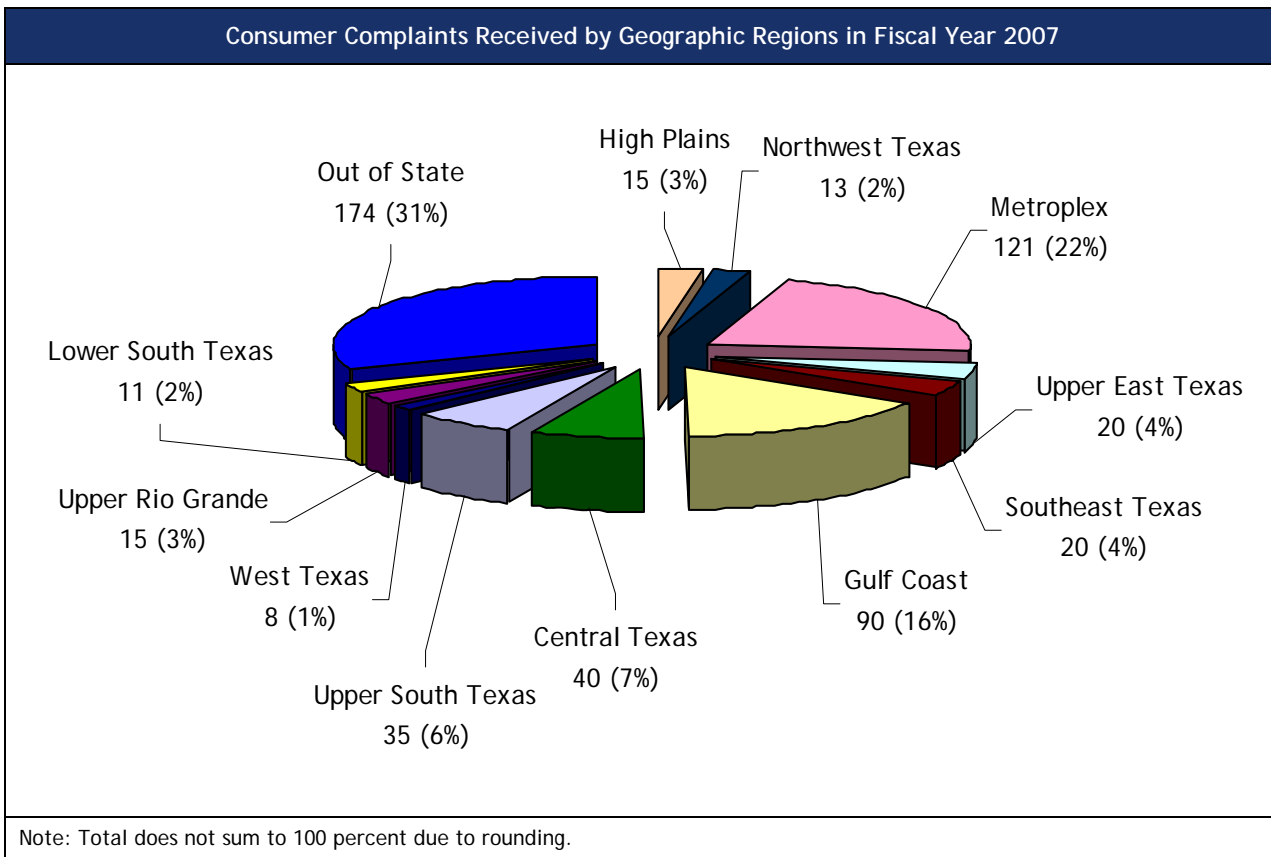
Figure 5



Source: Unaudited complaint data from the Board.

Figure 6 shows the geographic distribution of consumer complaints received by the Board during fiscal year 2007.

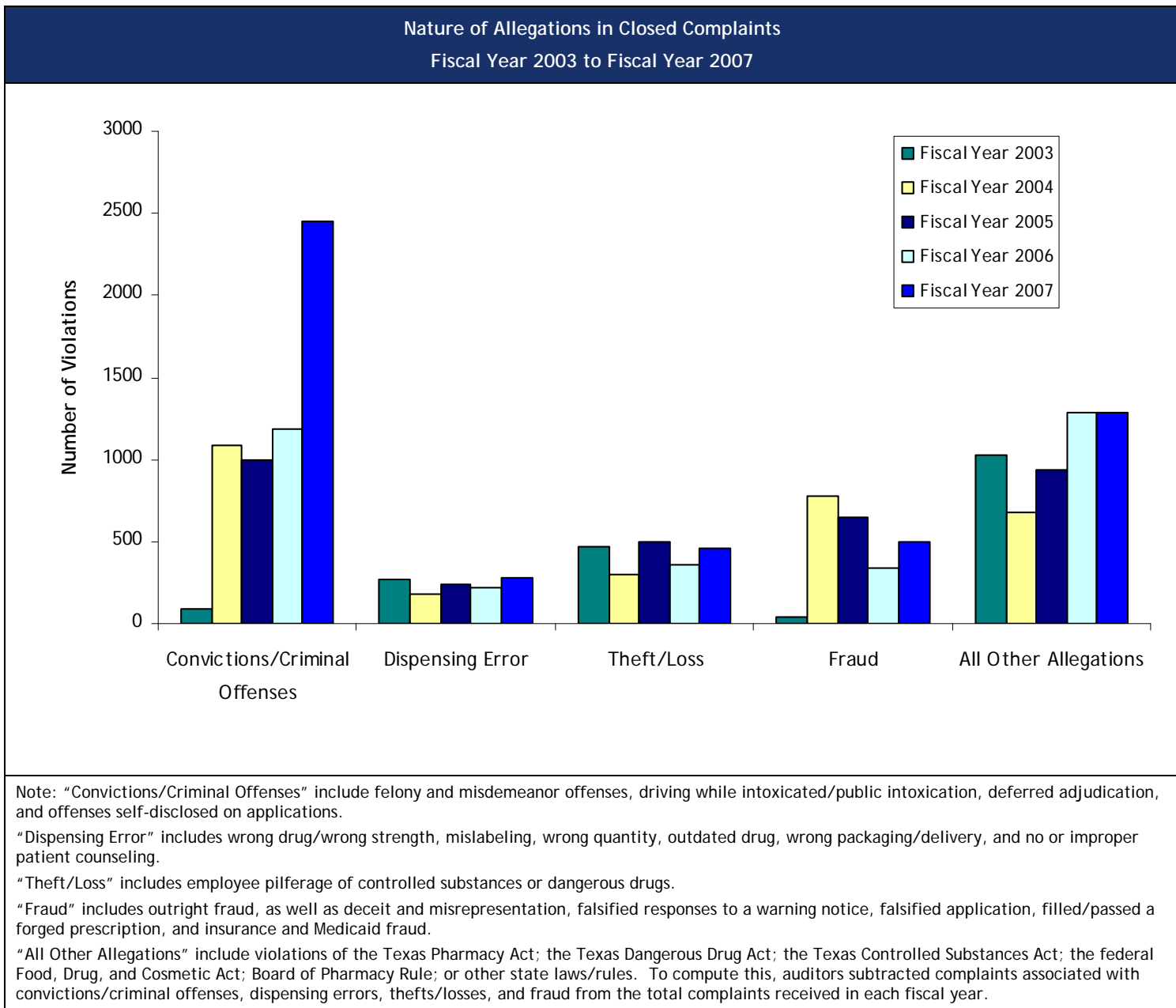
Figure 6



Source: Self-reported, unaudited data from the Board.

Figure 7 lists the nature of allegations in complaints that the Board closed in fiscal year 2003 through fiscal year 2007.

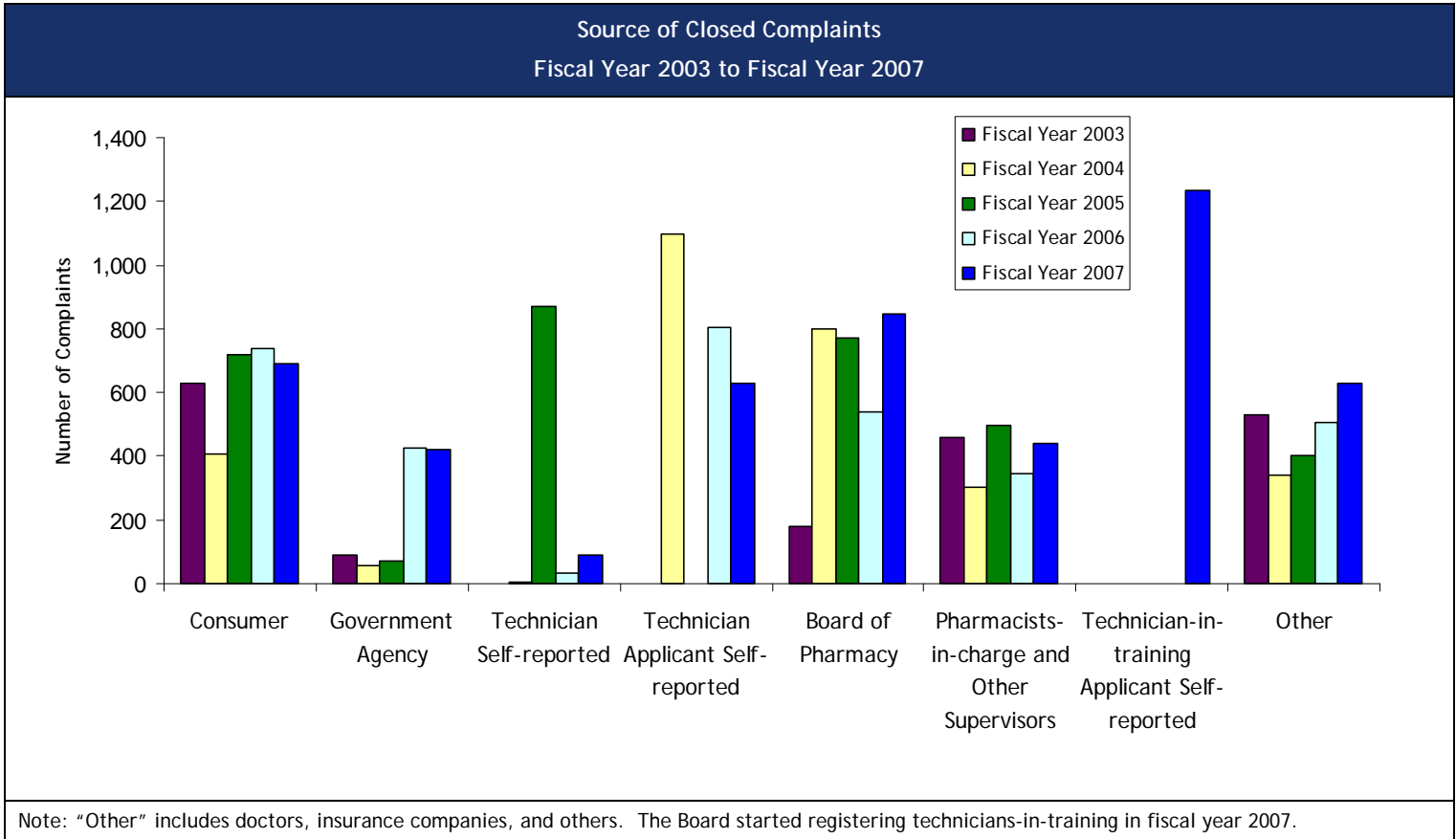
Figure 7



Source: Self-reported, unaudited data from the Board.

Figure 8 lists the source of complaints closed by the Board. Complaints can be generated from information received from consumers, inspections of pharmacies, or reports from other agencies; complaints also can be internally generated from information obtained through background checks on applicants for licensure or registration.

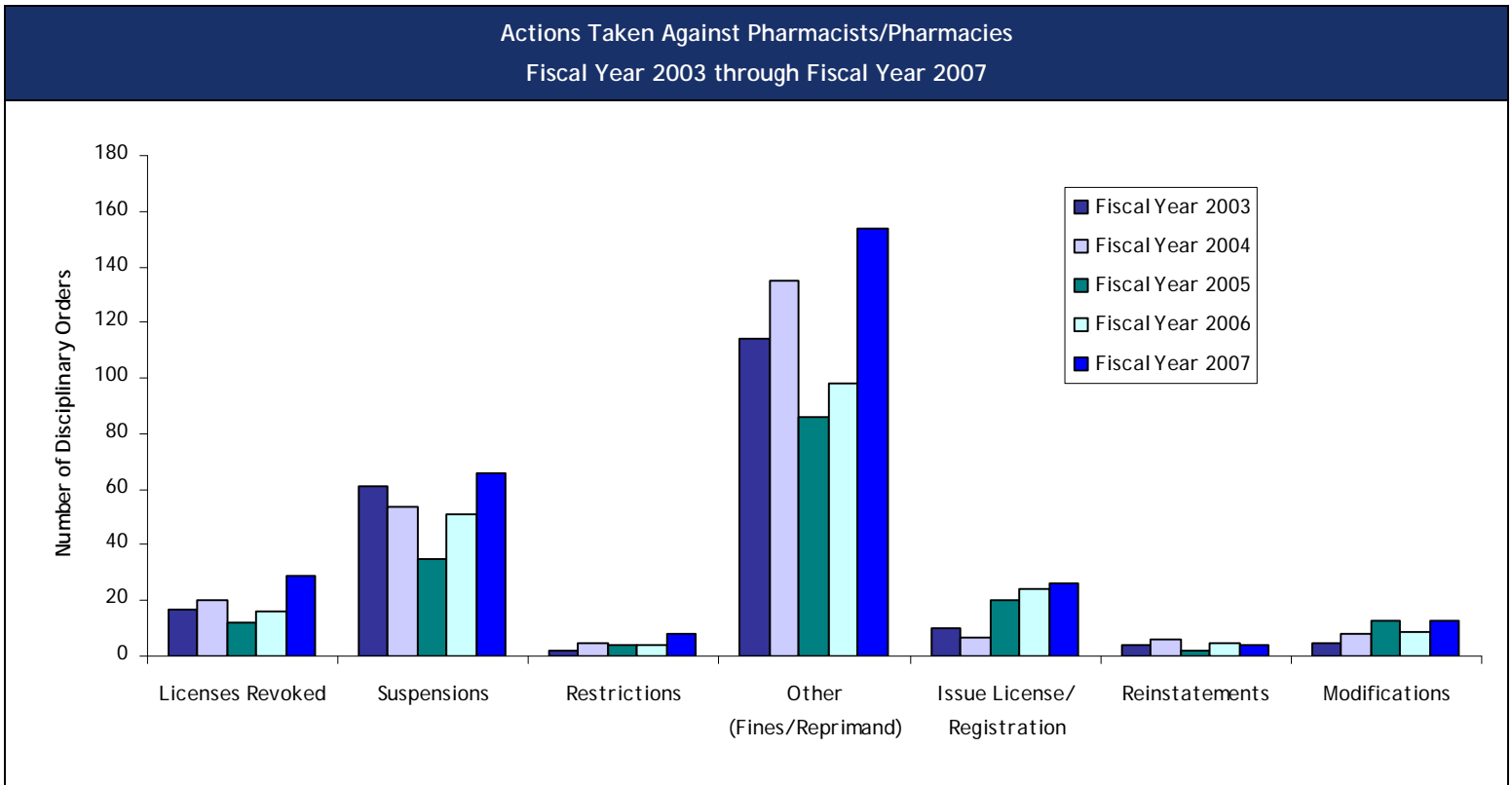
Figure 8



Source: Self-reported, unaudited data from the Board.

Figure 9 shows the actions taken against pharmacists and pharmacies as a result of complaints.

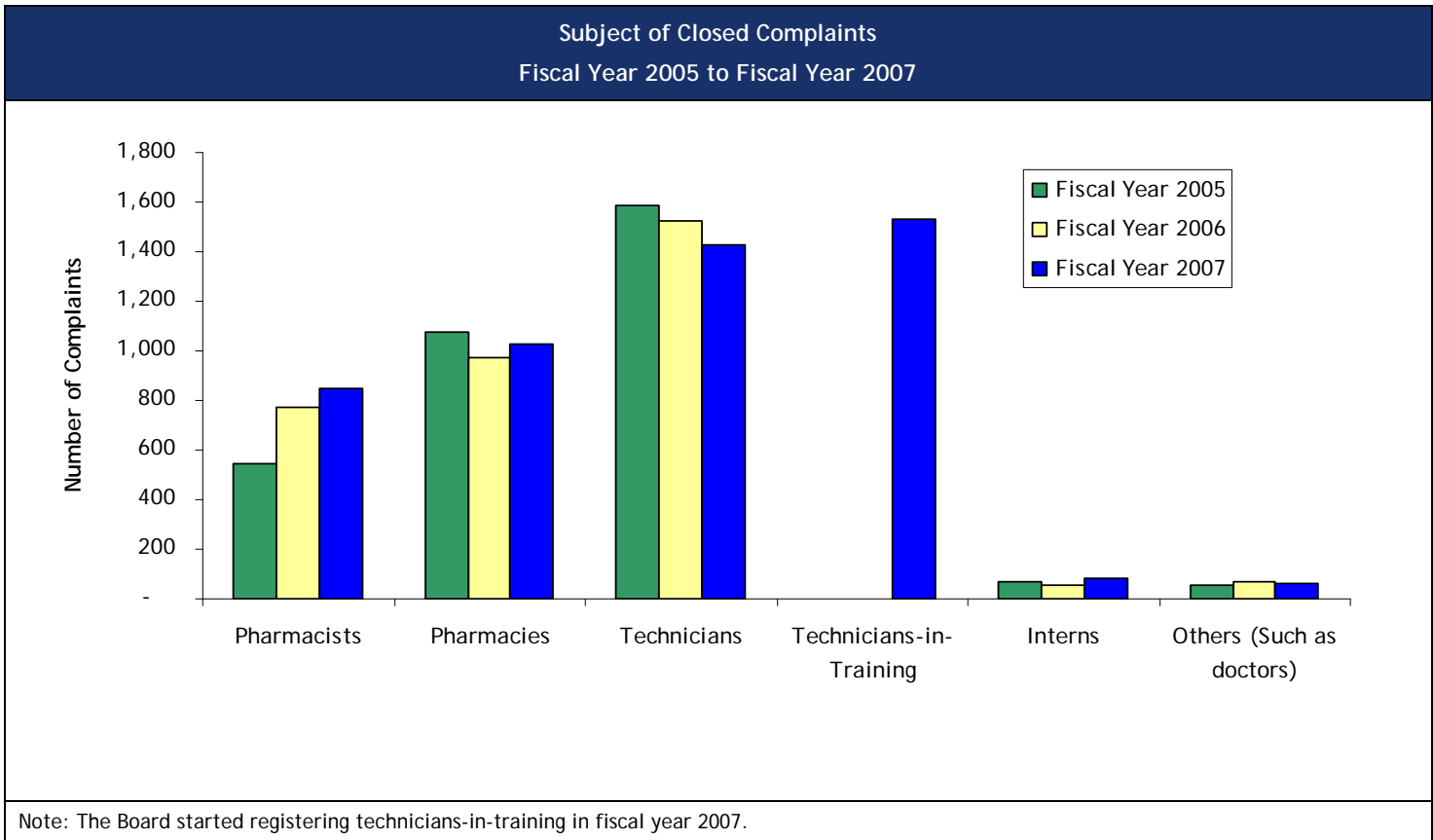
Figure 9



Source: Self-reported, unaudited data from the Board.

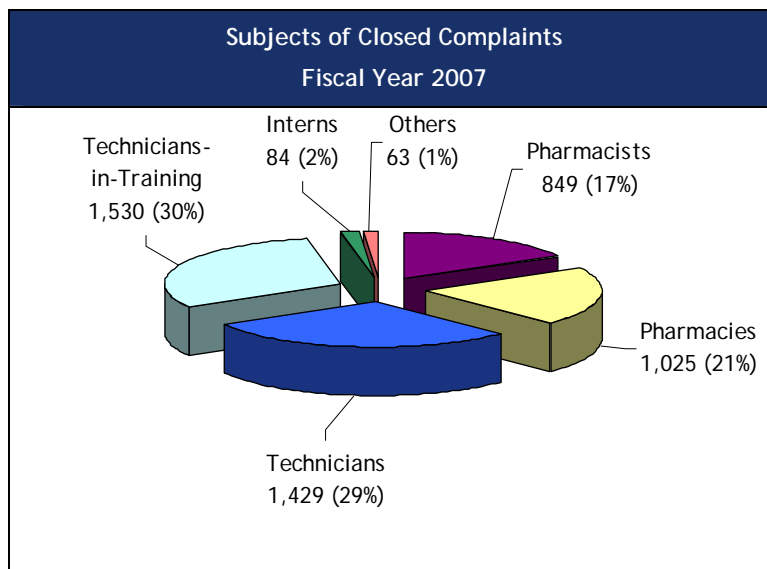
Figures 10 and 11 show the subject of allegations in complaints closed by the Board in fiscal years 2005 through 2007.

Figure 10



Source: Self-reported, unaudited data from the Board.

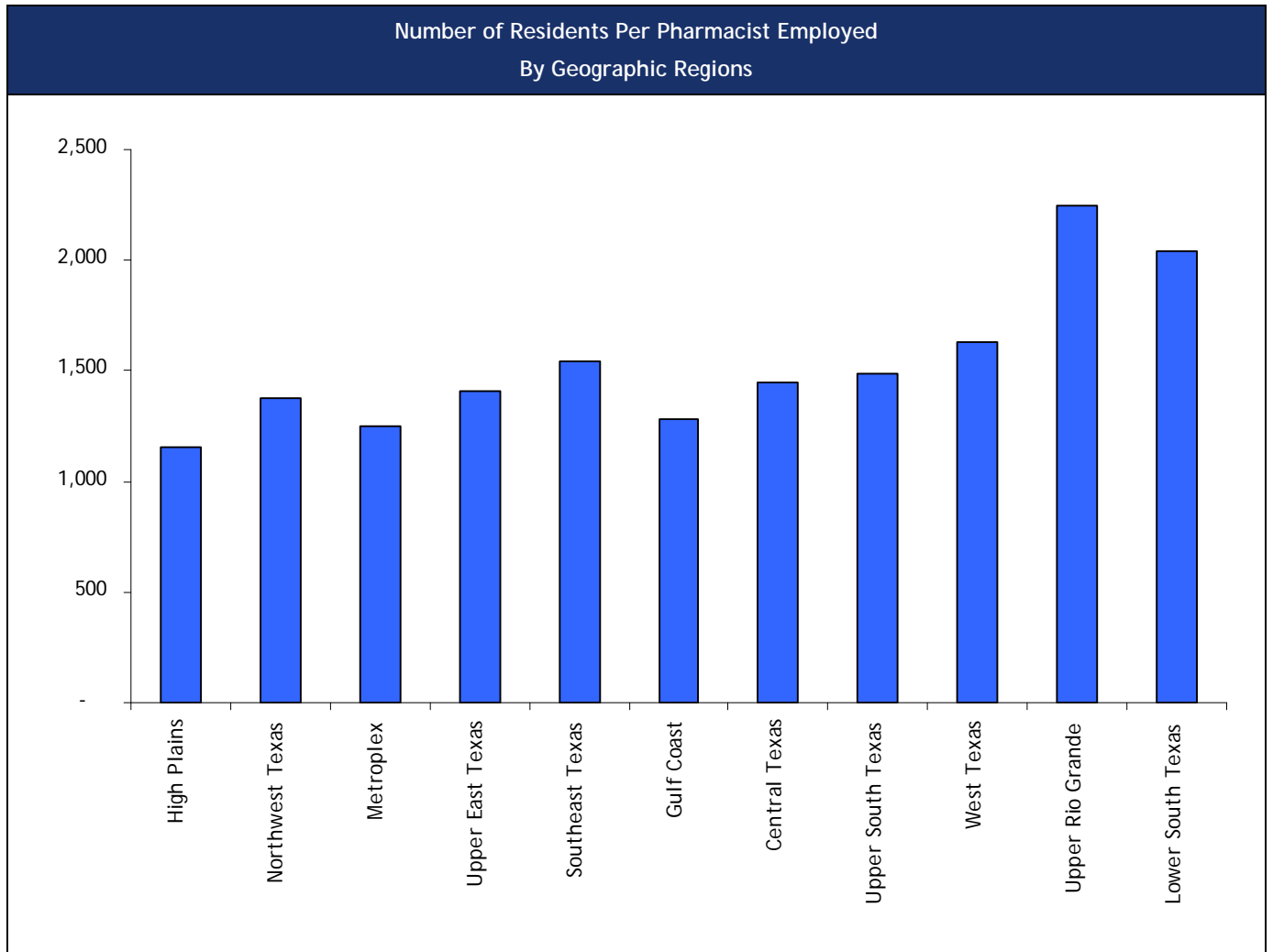
Figure 11



Source: Self-reported, unaudited data from the Board.

Figure 12 lists the number of residents per pharmacist employed in each geographic region in Texas.

Figure 12



Source: Self-reported, unaudited data from the Board.

Copies of this report have been distributed to the following:

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The Honorable David Dewhurst, Lieutenant Governor, Joint Chair
The Honorable Tom Craddick, Speaker of the House, Joint Chair
The Honorable Steve Ogden, Senate Finance Committee
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The Honorable Warren Chisum, House Appropriations Committee
The Honorable Jim Keffer, House Ways and Means Committee

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The Honorable Rick Perry, Governor

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