

**A SPECIAL PERFORMANCE AUDIT
OF THE
DEPARTMENT OF STATE**

***BUREAU OF PROFESSIONAL AND
OCCUPATIONAL AFFAIRS***

DECEMBER 2009

Bureau of Departmental Audits

December 28, 2009

The Honorable Edward G. Rendell
Governor
Commonwealth of Pennsylvania
225 Main Capitol Building
Harrisburg, PA 17120

Dear Governor Rendell:

This report contains the results of the Department of the Auditor General's special performance audit of the Pennsylvania Department of State (department) for the period July 1, 2002 through June 30, 2007. Specifically, our audit focused on the Bureau of Professional and Occupational Affairs (BPOA), and the Bureau of Commissions, Elections, and Legislation. This audit was conducted pursuant to Sections 402 and 403 of the Fiscal Code and in accordance with generally accepted government auditing standards (GAGAS). The aforementioned 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.

Our audit found that the department's inadequate monitoring delayed the resolution of complaints against certain licensed practitioners, including 21 percent of the complaints reviewed by the auditors. In addition, we found that pharmacy inspectors did not timely inspect all pharmacies within the department's purview. Moreover, auditors found that pharmacy inspectors are not timely re-inspecting pharmacies that failed prior inspections. Our auditors also discovered that the inadequate review/monitoring of inspection reports results in the department not ensuring that inspectors are properly completing inspection forms and that the conclusions reached are reasonable. Furthermore, the lack of written procedures for conducting pharmacy inspections could result in inspectors reaching inaccurate and inconsistent conclusions. Finally, the insufficient records retention policy and tracking system eliminated the audit trail, including the reasons why pharmacies failed inspections.

Additionally, our audit report discloses the discovery of significant control weaknesses with regard to the printing of professional licenses. Our auditors found that because one individual performs the entire process, there was lack of segregation of duties, and the potential exists for misappropriating blank license paper and creating fraudulent licenses. Auditors also noted a lack of supervisory review or oversight during license printing. The department has no written standard operating procedures for printing licenses.

We also demonstrate that untimely license renewals and the lack of independent confirmation may result in medical doctors, chiropractors, and pharmacists practicing with lapsed licenses. In addition, we found deficiencies in the department's post-auditing of licensees' continuing education hours. Moreover, post-audit procedures are not documented and a supervisory review is not performed. Our auditors also could not verify the license renewal population and sample size used by BPOA.

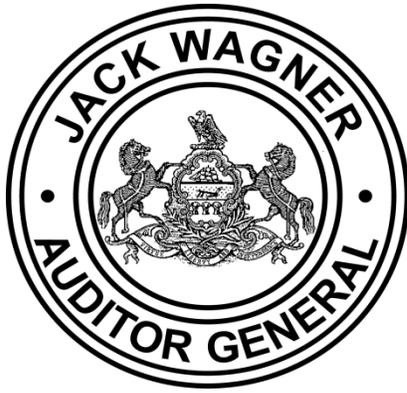
We offer 23 recommendations to strengthen the department's policies, controls, and oversight. These recommendations, if implemented properly, will enhance the well-being of residents of the Commonwealth, while protecting them from potentially fraudulent and unethical practitioners. We will follow up at the appropriate time to determine whether and to what extent all recommendations have been implemented.

Sincerely,

JACK WAGNER
Auditor General

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RESULTS IN BRIEF

The Department of the Auditor General conducted a special performance audit of the Pennsylvania Department of State (department) for the period July 1, 2002 through June 30, 2007. Specifically, our audit primarily focused on the Bureau of Professional and Occupational Affairs and the Bureau of Commissions, Elections, and Legislation. This audit resulted in 6 findings and 23 recommendations. We found the following:

- **Finding No. 1** We discuss the department's inadequate monitoring of consumer complaints, which has delayed the resolution of some complaints. The department permits individuals to file a Statement of Complaint Form with its Professional Compliance Office (PCO) relating to a licensee believed to have practiced or provided services that were unethical, immoral, below an acceptable standard, or beyond the scope of the profession. According to the department, complaints should typically be closed within three years; however, there are situations beyond its control that result in complaint resolution taking longer. Our audit revealed that the department had 464 complaints related to individuals regulated by the State Board of Medicine, State Board of Pharmacy, and State Board of Chiropractic open for greater than three years, with two being open since 1997 (more than nine years). In addition, our sample of 34 open and closed complaints disclosed that seven (21 percent) contained delays that the department could have reduced or eliminated if it had adequately monitored such complaints.

We recommend that the department develop written procedures for monitoring complaints, including requiring the monitoring activities to be documented and retained. Moreover, the department should monitor the status of all open complaints to ensure that they are expeditiously proceeding through the complaint process.

- **Finding No. 2** We found that pharmacies lacked required inspections. The Bureau of Enforcement and Investigation (BEI) investigates transgressions committed by licensees governed by the department's 29 licensing boards and commissions. The Pharmacy Act requires that the State Board of Pharmacy inspect all pharmacies, except health care facilities, and it requires pharmacy inspectors to be licensed pharmacists. Pharmacy guidelines require the annual inspection of each pharmacy. Our audit found that of the 2,979 active pharmacies as of September 26, 2007, inspectors did not timely inspect 1,217 (41 percent) pharmacies. In addition to finding that inspectors have not conducted annual pharmacy inspections timely, auditors also found that inspectors are not timely re-inspecting pharmacies that failed their prior inspections. If the pharmacy fails an inspection, the inspector is required to return and re-inspect the pharmacy within 30 days.

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We recommend that the department develop a written methodology to ensure that all pharmacies are inspected annually. In addition, it must ensure that all re-inspections of pharmacies that failed an inspection are performed within 30 days. Moreover, we recommend that the department develop a thorough training process for all personnel to ensure complete understanding of all necessary policies and procedures pertaining to the inspection of pharmacies. Finally, the department should consider seeking a legislative change eliminating the requirement that inspectors must be licensed pharmacists.

- **Finding No. 3** We explain the control weaknesses uncovered with respect to the administration of the pharmacy inspection program. Specifically, the inadequate review/monitoring of inspection reports results in the department not ensuring that inspectors are properly completing inspection forms and that conclusions reached are reasonable. In addition, the lack of written procedures for conducting pharmacy inspections could result in inspectors reaching inaccurate and inconsistent conclusions. Furthermore, the insufficient records retention policy and tracking system eliminated the audit trail, including information regarding why pharmacies failed inspections.

We recommend that the department develop standard written procedures for the inspection of all pharmacies and ensure that it disseminates such procedures to all regional personnel involved in the inspection function. Moreover, it should develop a standardized records retention policy to allow sufficient time for auditors to review the documentation, and it should modify its software system to include fields for explaining why a pharmacy failed an inspection and for discretionary comments.

- **Finding No. 4** We discuss the significant control weaknesses found with regard to the printing of professional licenses. One of the responsibilities of the department's Bureau of Professional and Occupational Affairs (BPOA) includes printing official license certificates (licenses) for the 29 professional licensing boards and commissions falling within its purview. BPOA employs one technician to print the licenses, operating from within an exclusive print shop. The technician uses several printers and a computer to print licenses as well as other official documents. At the end of each day, employees of the Pennsylvania Industries for the Blind and Handicapped (PIBH) pick up the printed licenses for placement into envelopes for mailing. Additionally, the technician compares the amount of license paper used to the number of licenses printed using a reconciliation sheet.

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Because one individual performs the entire process, there is a lack of segregation of duties, and the potential exists for misappropriating blank license paper and creating fraudulent licenses. Auditors also noted a lack of supervisory review or oversight during license printing. In addition, other than the daily reconciliation process, personnel or management perform no other procedures to ensure accountability of blank license paper. The department also has no written standard operating procedures for printing licenses. Finally, auditors discovered that unauthorized employees could use the printers located in the print shop; such access could potentially lead to the illicit printing of licenses.

We recommend that the department require the supervisor to oversee the license printing process and another individual or manager to oversee the duties of the supervisor, if the supervisor is printing licenses. The department should count the amount of blank license paper on a weekly basis and compare to usage for the period to ensure it has accounted for all paper. Moreover, it should develop and implement written standard operating procedures for the license printing process and not allow employees external to the print shop to use the print shop computers.

- **Finding No. 5** We note that untimely license renewals and the lack of independent confirmation may result in medical doctors, chiropractors, and pharmacists practicing with lapsed licenses. Auditors reviewed the Bureau of Professional and Occupational Affairs' (BPOA) process for renewing medical licenses, chiropractic licenses, and pharmacist licenses. Each of the aforementioned types of practitioners must renew their licenses every two years. Licensees who attempt to renew their licenses beyond 30 days after license expirations are processed as reactivations. Using data provided by the department for the most recent biannual license expiration dates available during audit execution, we noted that 6,013 licensees failed to timely renew their licenses by the license expiration dates. Consequently, licenses for 11 percent of medical doctors and five percent of pharmacists and chiropractors lapsed or the practitioners did not timely renew them. BPOA does not contact the licensees or obtain independent confirmation that they are no longer practicing in Pennsylvania.

We recommend that BPOA inquire with practitioners who allow their licenses to lapse and have not reactivated their licenses in order to obtain written affirmations that they are no longer practicing. At a minimum, BPOA should request independent confirmation that a licensee has not practiced, based on a lapsed license, when seeking reactivation. Furthermore, it should reconsider its decision not to prosecute licensees that continue to practice in Pennsylvania for up to six months after the expiration of a license.

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- **Finding No. 6** We found deficiencies in the department's post-auditing of licensees' continuing education (CE) hours. Each application for a renewal license processed by BPOA requires a licensee to acknowledge on the form whether or not the applicant has completed the mandated number of CE hours, which varies depending on the type of license being renewed. Renewal applications received and processed prior to the expiration of the license, as well as up to 30 days afterwards, are subject to a random post-audit to verify that the applicants have met all CE requirements. In a review of BPOA's completed post-audits, our auditors found that four percent of practitioners failed their post-audit, with the failure rate of chiropractors being more than nine percent. While our auditors found that BPOA staff accurately concluded on post-audits, the deficiencies noted in our special performance audit include delays in the post-auditing of licenses by BPOA. In addition, post audit procedures are not documented and a supervisory review is not performed. Our auditors also could not verify the license renewal population and sample size used by BPOA.

We recommend that BPOA ensure that it performs CE post-audits in a timely manner. It should also develop a written methodology for selecting samples to be post-audited, including a requirement that all renewals are subject to the post-auditing sampling. BPOA should require the retention and review of sampling documentation to ensure adherence with the sampling methodology. Moreover, it should develop written procedures for performing CE post-audit procedures and perform supervisory review of CE post-audits.

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BACKGROUND

The Pennsylvania Department of State (department) has cabinet-level status within the executive branch of state government. The governor appoints the Secretary of the Commonwealth and the Senate of Pennsylvania must confirm the appointment. Today, the Secretary of the Commonwealth and the department perform numerous functions such as overseeing the registration of charitable organizations, corporations, specialized professions, and/or occupations. In addition, the Secretary also oversees the state's electoral process and serves as custodian of the Commonwealth's election returns for various levels and branches of government, including national, state, and local contests.

The Administrative Code of 1929, as amended, remains the legal foundation for the position of the Secretary of the Commonwealth. It also established an organizational structure of bureaus and divisions within the Pennsylvania Department of State; the structure changed over time to include specialized bureaus to ensure that the department is able to fulfill its duties in accordance with applicable laws.

Four of the aforementioned specialized bureaus were subject to review as part of the audit conducted by the Department of the Auditor General; they include the Bureau of Professional and Occupational Affairs, the Bureau of Enforcement and Investigation, the Bureau of Commissions, Elections, and Legislation, and the department's Professional Compliance Office (Legal Office).

Bureau of Professional and Occupational Affairs

The Bureau of Professional and Occupational Affairs (BPOA) has existed as an organizational entity within the department for more than four decades, assuring that certain professional and technical services offered and provided to Pennsylvania residents are acceptable and comply with applicable laws. It advances this undertaking by providing administrative, logistical, and legal support services to 29 distinct professional and occupational licensing boards and commissions that fall within its purview.¹ The entity's supervisory head is the Commissioner of the Bureau of Professional and Occupational Affairs, who serves as a member of all boards and commissions, with the exception of the State Board of Certified Real Estate Appraisers and the Navigation Commission for the Delaware River and its Navigable Tributaries.

¹ The General Assembly, through the adoption of legislation, created two new boards subsequent to our audit period, bringing the current complement within BPOA to 29.

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The 29 boards and commissions perform their designated functions by utilizing BPOA personnel to process applications for licenses as well as authorizing the issuance of licenses for individuals and specific types of facilities; once authorized, personnel from the BPOA's print shop imprint an applicant's information on special license paper. A third party vendor then disseminates each individually printed license to the appropriate applicants. Additionally, BPOA conducts a continuing education (CE) post-audit after each license renewal period and captures a five percent random sample of renewal applicants that received approval for licensure. BPOA verifies that licensees from the sample have accumulated the required CE credits by requiring them to submit documented proof that demonstrates successful completion.

BPOA considers licensees who renew after the expiration of the official renewal period to be reactivations. A reactivation of a license requires an applicant to submit all documented proof of adherence with all mandated CE requirements.

In an effort to serve the public more effectively, BPOA updated the way in which it disseminates licensure information, creating and implementing a modern licensing software system, which it unveiled in 2001. By accessing the software system, the public is able to retrieve information on approximately 1 million businesses, health, and real estate professionals licensed in Pennsylvania and verify the licensure status of professionals and businesses regulated by the various boards and commissions.² Additionally, the software, known as License 2000, can be used by licensees to renew their licenses online via the Internet.

The boards and commissions, comprised of seven to seventeen members appointed by the governor and confirmed by the Senate of Pennsylvania, are responsible for the oversight of a specific skilled and/or highly technical trade, which they fulfill through professional licensure, enforcement, and administration. The intent of professional licensure is to protect the health, safety, and welfare of the public from fraudulent and unethical practitioners employed in such trades. In performing its duties and responsibilities with regard to licensure, BPOA functions as a self-sustaining organizational entity, using restricted funds rather than allocations from the Commonwealth's General Fund. This funding mechanism, created by Act 124 of 1978 and known as the Professional Licensure Augmentation Account, allows for the collection of fees and fines to support its operations.³

The Department of the Auditor General examined three licensing boards within BPOA, including the State Board of Medicine, the State Board of Pharmacy, and the State Board of Chiropractic. Auditors selected the State Boards of Medicine and Pharmacy because of their integral role in ensuring the health of the general populace, while auditors selected the State Board of Chiropractic because it received a significant number of complaints in the years prior to the start of the audit.

² History of the Secretary of the Commonwealth, the Pennsylvania Department of State & the Great Seal of the Commonwealth (p 31), published by the Pennsylvania Department of State, 1986, revised 2003.

³ Governor's Executive Budget 2009-2010 (E36.6), Pennsylvania Office of the Budget website, www.budget.state.pa.us ("Current and Proposed Commonwealth Budgets"), accessed September 30, 2009.

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- The Medical Practice Act (Act 112 of 1985, as amended, provides for the composition, powers and duties of the State Board of Medicine. It confers on the board the power to regulate the practice of medicine in Pennsylvania through a process of licensure and certification of individual practitioners within the medical profession. Consequently, it also has authority to take disciplinary or corrective action against the individuals it regulates. The State Board of Medicine also reviews the facilities and qualifications of medical colleges whose trainees or graduates desire to obtain licensure, certification, or to graduate medical training in the Commonwealth of Pennsylvania.
- The Pharmacy Act (Act 699 of 1961, as amended) governs the practice of pharmacy in the Commonwealth and specifies the powers and duties of the State Board of Pharmacy, including the duty to make or order inspections of all pharmacies, except health care facilities. Regulations contained in Title 49, Chapter 27 of the Pennsylvania Code address general practice standards, the storage and security of drugs, dispensing requirements, facility requirements, licensure requirements, pharmacy internships, and continuing education. The State Board of Pharmacy may impose fines and penalties on individual pharmacists, as well as on facilities issued a permit by the board to operate as a pharmacy under the Pharmacy Act.
- The State Board of Chiropractic originated with the Chiropractic Practice Act (Act 188 of 1986, as amended). The Act confers powers and duties on the board and provides for the licensing of chiropractors and the regulation of the practice of chiropractic in the Commonwealth. Practitioners of the chiropractic profession must adhere to the provisions of licensure and all other approved regulations promulgated by the board and contained in Title 49, Chapter 5 of the Pennsylvania Code. The State Board of Chiropractic may impose fines and penalties on practitioners that violate the provisions of licensure.

Professional Compliance Office (Legal Office)

The department's Professional Compliance Office (PCO) handles complaints from the public regarding department bureaus, including concerns related to practitioners of professions and occupations governed by the 29 boards and commissions. However, the PCO works independently of all boards and commissions; it is responsible for determining if it is necessary to investigate and/or prosecute a licensee. The Pennsylvania Supreme Court created this separation when it ruled in *Lyness v State Board of Medicine* (1992). The court agreed with the petitioner in the original case and found that, at the time, because the board acted as prosecutor and ultimate fact-finder, it violated notions of fairness and due process. Consequently, the decision prohibits members of all boards and commissions from being involved in the decision-making process to investigate and prosecute a licensee.

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Bureau of Enforcement and Investigation

The department's Bureau of Enforcement and Investigation (BEI) complements the operations of the 29 boards and commissions by investigating allegations of professional misconduct brought forth against practitioners required to adhere to licensure. In addition, BEI conducts inspections of facilities that also must possess requisite licenses and comply with the provisions of licensure. While BEI's headquarters are located in Harrisburg, it also maintains regional offices in Philadelphia, Pittsburgh, Harrisburg, and Scranton. A Regional Director manages each regional office and oversees clerical staff and several categories of inspectors, including pharmacy inspectors.

Act 48 of 1993, as amended, provides BPOA with the power to adopt a schedule of civil penalties for noncompliance with regulations enacted by the various boards and commissions. Consequently, inspectors, in an effort to enforce adherence, may issue citations to businesses and facilities granted a permit to operate but in violation of established regulations.

Bureau of Commissions, Elections, and Legislation

The Bureau of Commissions, Elections, and Legislation (BCEL) supports the Secretary of the Commonwealth in the execution of formal duties such as the issuance of commissions; authenticating various documents; overseeing Pennsylvania's electoral process, and serving as the caretaker of legislation and resolutions passed by the General Assembly.

Because the Secretary of the Commonwealth certifies and is the custodian of the election returns for various national, statewide, and local offices, a key function of the BCEL is to assist in the implementation of prescribed duties as outlined in the Pennsylvania Election Code. It coordinates its efforts with county election boards.

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AUDIT OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

The objectives of this special performance audit were to determine:

- whether the Department of State (department) is appropriately monitoring consumer complaints in accordance with the Bureau of Professional and Occupational Affairs' (BPOA) guidelines, laws, and regulations (see Finding No. 1);
- whether an appropriate system is in place to ensure monitoring and oversight of the license renewal process and whether the system is effective and efficient (see Findings No. 2, 3, 4, 5, and 6);
- whether application documentation for new practitioners are appropriately reviewed/examined for required attributes prior to license certification (no findings noted);
- whether adequate controls are in place to ensure collected licensing BPOA monies are appropriately expended (no findings noted); and
- whether the Bureau of Commissions, Elections, and Legislation (BCEL) developed a voluntary certification and poll worker training program for county election officials and determine the adequacy of the training program (no findings noted).

Scope

Our audit covered the department's duties and responsibilities with regard to respective BPOA objectives for the period July 1, 2002 through June 30, 2007 for the State Board of Medicine, State Board of Pharmacy, and State Board of Chiropractic as well as with regard to the BCEL objective for the period July 1, 2002 through June 30, 2006, including follow-up procedures performed and concluded as of March 12, 2008.

Methodology

The methodology in support of the audit objectives included:

- obtaining and reviewing appropriate laws, policies, and procedures related to the State Board of Medicine, State Board of Pharmacy, and State Board of Chiropractic regarding licensure and consumer complaints;
- obtaining and reviewing federal and state law regarding a voluntary poll worker training program within BCEL;

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- conducting interviews with BPOA management, license evaluators, and staff, Bureau of Enforcement and Investigation management, four Regional Directors, a Pharmacy Inspector, professional compliance office management and prosecutors in charge, Bureau of Finance and Operations management, and BCEL management and staff and performing walkthroughs to assess controls and gain an understanding of the program;
- obtaining, compiling, and analyzing medical, pharmacy, and chiropractic data related to pharmacy inspections, complaint data, and license renewal data from BPOA management. Using the data, we applied sampling methods to select 231 items to include open and closed complaints, inspection reports, new license applications, license reactivations, and license renewals;
- performing annual analytical reviews of expenditures for each of the three boards for the period July 1, 2002 through June 30, 2007; and
- validating the daily reconciliations completed by the print shop technician for the period July 1, 2006 through June 30, 2007.

FINDINGS AND RECOMMENDATIONS



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FINDINGS AND RECOMMENDATIONS

Finding No. 1 – Inadequate Monitoring Has Delayed the Resolution of Some Complaints

Condition: The Department of State (department) permits citizens to file a Statement of Complaint Form with its Professional Compliance Office (PCO) on a licensee who they believe has practiced or provided services that were unethical, immoral, below an acceptable standard, or beyond the scope of the profession. The PCO receives thousands of complaints each year regarding various department bureaus, including the Bureau of Professional and Occupational Affairs (BPOA). However, the complaint process, which according to the PCO was revamped in August 2006, can take years to complete. We found that inadequate monitoring has delayed the resolution of some complaints.

We obtained complaint data of licensees that had an active license for the State Board of Medicine, State Board of Chiropractic, and State Board of Pharmacy, including complaints that remained open as of June 30, 2007 (open complaints) and complaints that were closed during the fiscal year ended June 30, 2007 (closed complaints). Using the complaint files, we categorized the number of years the complaint had been open for the three boards:

Table 1

| Complaint Status | Less Than 1 Year | Between 1 and 2 Years | Between 2 and 3 Years | Between 3 and 5 Years | Greater Than 5 Years | Total Complaints |
|-------------------------|-------------------------|------------------------------|------------------------------|------------------------------|-----------------------------|-------------------------|
| Open* | 1,565 | 450 | 294 | 83 | 5 | 2,397 |
| Closed** | 3,745 | 1,264 | 560 | 346 | 30 | 5,945 |
| Total | 5,310 | 1,714 | 854 | 429 | 35 | 8,342 |

* (as of June 30, 2007)

** (between July 1, 2006 and June 30, 2007)

Of the 8,342 complaints, 7,241 (83 percent) related to the individuals regulated by the State Board of Medicine, 850 (10 percent) related to the individuals regulated by the State Board of Pharmacy, and 251 (7 percent) related to the individuals regulated by the State Board of Chiropractic. Additionally, of the 464 complaints open for greater than three years, two complaints had been open since 1997 (more than nine years).

The department stated that, typically, complaints should be closed within three years, but that there are situations beyond its control that result in complaint resolution taking longer. These situations can include ongoing criminal and civil cases or lack of cooperation by parties involved, resulting in the issuances of subpoenas. To determine the reasonableness of the amount of time the complaint had been open, we selected 20 open complaints and 14 closed complaints and requested case file information. According to department management, the case files were considered confidential; therefore, we were not permitted to review the documentation contained in these complaint files. As a result, our conclusions are based on information gathered through interviews with a Senior Prosecutor in Charge, who explained each complaint, including what transpired during the complaint process and the status of the complaint.

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Finding No. 1

From the information obtained for our sample of 34 cases, we determined that seven (21 percent) contained delays that could have been reduced or eliminated if the complaints were adequately monitored. The department provided the following reasons:

- Two complaints were reassigned to several prosecutors. The Senior Prosecutor in Charge indicated that the one complaint that remained open for at least three years had “fallen through the cracks” and the other, which resulted in three separate investigations being conducted by the department, had been open for six years.
- Two complaints had no action occurring for approximately two years. The Senior Prosecutor in Charge indicated that the prosecutor was on extended leave for one complaint, but could not provide a reason for the second complaint.
- The prosecutor allowed a licensee 14 months to respond to an Order to Show Cause when the limit for response is 30 days.
- The prosecutor took 14 months to file an Order to Show Cause. The Senior Prosecutor in Charge indicated that 14 months was too long.
- The prosecutor assigned took little to no action with the complaint during a four-year period.

In addition to the above, the Senior Prosecutor in Charge indicated that workload and priority may be a factor in deciding which complaints to work on first. These delays indicate that improvements are needed in how the department monitors complaints.

Criteria: The department must consider complaints to be a high priority and address them expeditiously to ensure patients/patrons are receiving health care services by professionals that practice ethically, morally, and within their professional boundaries. Every effort must be made to resolve complaints without undo delays. A monitoring system, to include written policies and procedures, must be in place to ensure that complaints are properly and expeditiously moving through the complaint process.

Cause: Although the department explained that it has a monitoring process in place, whereby each month the Senior Prosecutors in Charge review the status of complaints with each prosecutor, this monitoring process is not documented and no evidence was provided to verify the review process occurred. If this process was adequately performed, we believe that these delays would have been minimized or eliminated completely.

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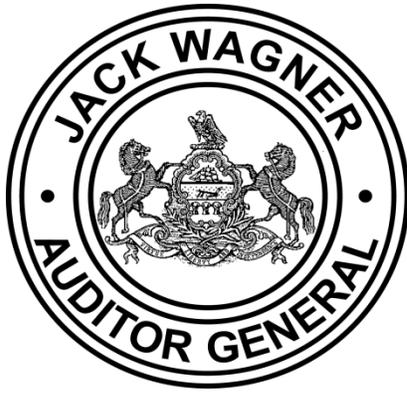
FINDINGS AND RECOMMENDATIONS

Finding No. 1

Effect: Unnecessary delays during the complaint process prolong the issuance of discipline, including fines, reprimands, license suspension, or license revocation, as well as the decision to dismiss or take no action.

Recommendations: We recommend that the department:

1. Develop written procedures for monitoring complaints, including requiring the monitoring activities to be documented and retained; and
2. Monitor the status of all open complaints to ensure that the department is expeditiously proceeding through the complaint process.



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Finding No. 2 – Pharmacies Lacked Required Inspections

Condition: The Bureau of Enforcement and Investigation (BEI), within the Department of State (department), provides the department’s boards and commissions with inspection and law enforcement. For the State Board of Pharmacy, BEI performs inspections of retail pharmacies located in Pennsylvania. According to the Chairman of the State Board of Pharmacy, “The board considers routine pharmacy inspections to be integral to the protection of the citizens of the Commonwealth.”⁴ However, as noted below, BEI has not inspected pharmacies as required.

The Pharmacy Act requires the State Board of Pharmacy to inspect all pharmacies, except health care facilities, and requires pharmacy inspectors (inspectors) to be licensed pharmacists. The routine inspection form includes specific prescription-related issues, including whether outdated drugs are properly segregated, prescriptions are verified by a registered pharmacist, and prescription refill authorizations are properly documented. Upon completion of each onsite inspection, the inspector will check either “pass” or “fail” on the inspection form, sign the form, have the pharmacist sign the form, and give a copy of the form to the pharmacist.

The department has a complement of six pharmacists to perform inspections on applicable pharmacies statewide. The Philadelphia and Pittsburgh regions each have two inspectors and the Harrisburg and Scranton areas each have one inspector. According to policy, each pharmacy is required to be inspected annually. We obtained pharmacy inspection data from the department, including the date of the last inspection. Based on September 26, 2007 data, which identified 2,979 active retail pharmacies, we noted that 1,217 pharmacies (41 percent) had not been timely inspected, as shown by region below:

**Table 2
1,217 Pennsylvania Pharmacies Overdue for Inspection**

| Dates of Last Inspection | Harrisburg Region 614 Pharmacies* | Philadelphia Region 932 Pharmacies* | Pittsburgh Region 850 Pharmacies* | Scranton Region 583 Pharmacies* | Total Inspections | Years Overdue |
|----------------------------------|--|--|--|--|--------------------------|----------------------|
| Prior to July 2000 | 176 | 1 | 2 | 1 | 180 | >6 |
| July 2000 – June 2002 | 16 | 4 | 39 | 48 | 107 | >4 - 6 |
| July 2002 – June 2004 | 68 | 38 | 41 | 86 | 233 | >2 - 4 |
| July 2004 – June 2006 | 86 | 154 | 221 | 236 | 697 | >0 - 2 |
| Total Number of Late Inspections | 346 | 197 | 303 | 371 | 1,217 | |

* - Open (active) as of September 26, 2007.

⁴ “Chairman’s Message”, Pennsylvania State Board of Pharmacy Newsletter, Winter 2006/2007, p. 2.

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Finding No. 2

As indicated in Table 2, more than 50 percent of the pharmacies in both the Scranton Region and Harrisburg Region had not been timely inspected. Furthermore, of the Harrisburg Region's 614 pharmacies, 176 (29 percent) were last inspected prior to July 2000, or more than six years overdue. Management attributes the Harrisburg Region's lack of inspections to the vacancy of the pharmacy inspector position for five years. Additionally, we found one pharmacy in Philadelphia that had not been inspected since 1989.

In addition to finding that inspectors have not been conducting annual pharmacy inspections timely, we also found that inspectors are not timely re-inspecting pharmacies that failed their prior inspections. If the pharmacy fails an inspection, the inspector is required to return and re-inspect the pharmacy within 30 days. We obtained inspection data of all inspections performed from July 1, 2005 through September 26, 2007. Using the pharmacies that remained open as of September 26, 2007, we identified 273 pharmacies that failed an inspection. Of the 273, only 22 (8 percent) were re-inspected within 30 days. Table 3 categorizes the remaining 251 pharmacies not re-inspected within 30 days by region and the time period between inspection and re-inspection:

**Table 3
251 Pennsylvania Pharmacies Not Re-Inspected Within 30 Days**

| Time Between Inspection and Re-Inspection | Harrisburg Region | Philadelphia Region | Pittsburgh Region | Scranton Region | Total Inspections |
|---|-------------------|---------------------|-------------------|-----------------|-------------------|
| 2 – 3 Months | 0 | 70 | 7 | 1 | 78 |
| 4 – 6 Months | 2 | 80 | 10 | 4 | 96 |
| 7 – 9 Months | 4 | 28 | 8 | 1 | 41 |
| 10 – 12 Months | 4 | 8 | 8 | 0 | 20 |
| 13 – 18 Months | 0 | 6 | 3 | 0 | 9 |
| 19 – 24 Months | 0 | 7 | 0 | 0 | 7 |
| Total | 10 | 199 | 36 | 6 | 251 |

As the table indicates, we found that re-inspections for 77 pharmacies took between 7 and 24 months. Additionally, of the 251 pharmacies, 14 also failed their re-inspections.

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Criteria: The Pharmacy Act (Act 699 of 1961, as amended) requires the board to inspect pharmacies prior to granting the pharmacy a license.⁵ Additionally, the act requires the board to conduct “inspections of all pharmacies, except health care facilities...”⁶ Although the act does not specify how often pharmacies must be inspected, the State Board of Pharmacy’s *General Pharmacy Guidelines Under Act 48* (Act 48 of 1993, as amended, provided the authority to adopt a schedule of civil penalties related to operating a business or facility licensed by a licensing board⁷) reinforces promulgated rules and regulations identifying the need to “conduct a routine unannounced inspection of every non-institutional pharmacy at least once a year.” Additionally, with respect to pharmacies that fail their inspections, the guidelines state that the inspector will inform pharmacy personnel that the pharmacy will be re-inspected in 30 days. Management confirmed that all pharmacies that fail an initial inspection should be re-inspected in 30 days.

Cause: Management believed that there was nothing in writing regarding how often pharmacies should be inspected, although the goal for performing pharmacy inspections had always been on a two-year cycle. Management stated that the BEI does not have the manpower to complete all pharmacy inspections within one year. Additionally, management stated that the inability to recruit and retain a full complement of Pharmacy Inspectors had led to a significant delay in the timely inspection of pharmacies operating in the Commonwealth of Pennsylvania. Specifically, management indicated that the starting salary for pharmacy inspectors, who must be licensed pharmacists, was low and non-competitive. As a result, individuals seeking these positions are often retired pharmacists, who do not remain in the positions very long. Additionally, travel may be another deterrent in filling/retaining these positions.

Upper management’s decentralized approach to conducting inspections has contributed to the deficiency of pharmacies not being inspected. The regional offices or inspectors use their judgment to determine the timetable and pharmacy location to perform routine inspections. However, this method does not ensure that all pharmacies are timely inspected.

Effect: The lack of annual pharmacy inspections or the timely re-inspections of pharmacies that failed an inspection has the potential to jeopardize the health, safety, and welfare of Pennsylvanians.

⁵ 63 P.S. § 390-6(k)(3).

⁶ *Id.* § 390-6(k)(6). The Department of Health inspects pharmacies in health care facilities.

⁷ 63 P.S. § 2205(a).

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Finding No. 2

Recommendations: We recommend that the department:

3. Develop a written methodology to ensure that all pharmacies are inspected annually as required by the Act 48 guidelines;
4. Ensure that all re-inspections of pharmacies who failed an inspection are performed within 30 days as required by the Act 48 guidelines;
5. Develop a thorough training process for all personnel to ensure complete understanding of all necessary policies and procedures pertaining to the inspection of pharmacies; and
6. Consider seeking legislative change to no longer require pharmacy inspectors to be licensed pharmacists.

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Finding No. 3 – Control Weaknesses Found in the Inspection Program of Pharmacies

Condition: Based on interviews with BEI management, directors at each of the four regional offices, and a pharmacy inspector; review of laws relating to the State Board of Pharmacy and policies provided by the department; and audit test procedures, we found the following weaknesses with respect to administering the pharmacy inspection program.

- **Inadequate review/monitoring of inspection reports results in the department not ensuring that inspectors are properly completing inspection forms and that conclusions reached are reasonable**

Regional directors are responsible for supervising pharmacy inspectors. We found that they are not reviewing and approving pharmacy inspection reports. The Scranton regional director stated that he does not review any inspection reports. The Pittsburgh regional director stated that he tries to review inspection reports, but does not sign/document his review. The Philadelphia regional director stated that he does not review any inspection reports. He instructs his secretary to review the inspection reports. The Harrisburg regional director stated that she only reviews and signs inspection reports with citations. As a result, regional directors are not ensuring that all inspection reports are properly completed and that conclusions reached are reasonable. During the audit, we reviewed 38 inspection reports and noted that the conclusions appeared to be consistent.

Additionally, all failed inspection reports are to be sent to BEI's headquarters for review. Management indicated that BEI's Deputy Director reviews failed inspections, but does not sign the inspection reports because they are destroyed after his review. Therefore, no evidence was provided to the auditors to substantiate that this review occurred.

- **Lack of written procedures to conduct pharmacy inspections could result in inspectors reaching inaccurate and inconsistent conclusions**

BEI management stated that the department has not developed written procedures for pharmacy inspectors to conduct inspections because inspectors are required to be licensed pharmacists; therefore, written procedures are unnecessary. BEI's Deputy Director explained that new inspectors receive on-the-job training by another pharmacy inspector and use their knowledge of the law to complete the inspection report. The inspection form consists of 12 yes/no questions. Due to a lack of written procedures, inspectors must use judgment in determining whether pharmacies "pass" or "fail" their inspections. Therefore, the inspectors may not be consistently passing or failing pharmacies.

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- **Insufficient records retention policy and tracking system eliminated the audit trail, including why pharmacies failed an inspection**

BEI's records administrative policy indicates that inspection reports shall be kept for at least six months or until the regional director dictates. As a result of this policy, each region retains inspection reports differently. This precluded us from obtaining more than half of the inspection reports that we had requested. Of the 82 reports requested, the department could only provide copies of 38.

BEI's lack of records retention is compounded by a lack of information being data-entered into the License 2000 system. The system is used for processing licenses, tracking inspections, and tracking complaints. However, the system does not record why an inspector failed a pharmacy. Even if the pharmacy passed the inspection, the system does not provide a comments section to note discretionary problems. Although pharmacies that fail inspections are required to be re-inspected within 30 days, as noted in Finding No. 2, re-inspections are not always conducted timely. Based on the current retention policy, pharmacy inspectors will not have the prior inspection report to review when conducting the re-inspection and would have to remember why the pharmacy failed its original inspection.

Criteria: The Pharmacy Act (Act 699 of 1961, as amended) requires the board to inspect all pharmacies prior to granting the pharmacies licenses.⁸ Additionally, the act requires the board to "make or order inspections of all pharmacies, except health care facilities...."⁹

As part of properly administering the inspection program of pharmacies, prudent business practices dictate that department management must be aware of all written policies and guidelines that govern the program to ensure that program personnel adhere to them; upper management must provide sufficient direction, control, supervision, and monitoring over pharmacy inspections, including the development of adequate written policies and procedures, to ensure that inspections are completed timely, accurately, and consistently; sufficient information and documentation must be maintained for use by inspectors as well as for reporting and analysis purposes by upper management; and appropriate documentation must be retained and made available for audit purposes.

⁸ 63 P.S. § 390-6(k)(3).

⁹ *Id.* § 390-6(k)(6).

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Cause: With respect to inadequate review/monitoring of pharmacy inspection reports, management indicated that all reports should be properly reviewed without exception. However, according to our interviews, the regional directors failed to perform adequate reviews.

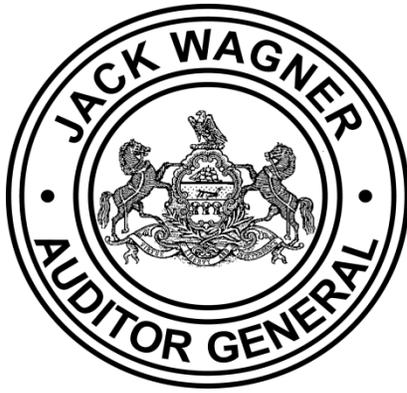
Concerning a lack of written procedures to conduct inspections, management stated that it is unnecessary to have written procedures because all pharmacy inspectors have to be licensed pharmacists and the inspection form is self-explanatory. We disagree. Written procedures, along with adequate monitoring and supervision, would ensure that inspectors conduct and conclude on pharmacy inspections accurately and consistently.

With regard to not maintaining inspections, BEI's policy allows the regional directors to make this decision. Additionally, BEI management indicated that it is not necessary to retain the reason why a pharmacy failed its inspection.

Effect: A lack of centralized oversight, direction, and communication within the operational structure of BEI results in the inadequate monitoring of pharmacies. This deficiency also contributes to the backlog of pharmacies not being inspected in a timely manner. As such, the department lacks assurances that pharmacies are adhering to the health and safety provisions outlined in the pharmacy regulations.

Recommendations: We recommend that the department:

7. Develop standard written procedures for the inspection of all pharmacies and ensure that such procedures are disseminated to all regional personnel involved in the inspection function;
8. Develop a standardized records retention policy to allow sufficient time for auditors to review the documentation; and
9. Modify the License 2000 system to include fields for explaining why a pharmacy failed and for discretionary comments.



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FINDINGS AND RECOMMENDATIONS

Finding No. 4 – Significant Control Weaknesses Found Regarding the Printing of Professional Licenses

Condition: One of the responsibilities of the Department of State’s Bureau of Professional and Occupational Affairs (BPOA) includes printing official license certificates (licenses) for the 29 professional licensing boards falling within its purview. Although the audit did not find potential fraudulent activity, the audit found significant control weaknesses regarding the printing of licenses and the accountability and security of the confidential license paper.

BPOA employs one technician to print the licenses, operating from within an exclusive print shop. The technician uses several printers and a computer to print licenses as well as other official documents. Using the computer system, each day the technician brings up the licenses to be printed, reviews the information to ensure it is complete, records the number of licenses to be printed on his reconciliation sheet, and then prints the licenses. Once printed, he briefly scans through the printed licenses to ensure they are printed correctly. If an error occurs, he can reprint the license(s). At the end of each day, the printed licenses are picked up by employees of the Pennsylvania Industries for the Blind and Handicapped (PIBH) for placement into envelopes for mailing. Additionally, the technician compares the amount of license paper used with the number of licenses printed using his reconciliation sheet to ensure all license paper is accounted for.

Based on interviews and documentation review, we found the following significant control weaknesses:

- **Lack of segregation of duties**

License printing is performed by one technician. This technician receives and controls the license paper, prints the licenses, destroys licenses that are incomplete or printed incorrectly, prepares the licenses for pick up by the PIBH, and performs the daily reconciliation. The technician’s back-up is his supervisor. The supervisor performs the technician’s duties in the same manner. Due to one individual performing the entire process, there is a lack of segregation of duties, and the potential exists for misappropriating blank license paper and creating fraudulent licenses.

- **Lack of supervisory review**

Based on our interviews, we noted that no supervisory review or oversight is performed during license printing, including verifying that the license paper used agrees to the licenses printed, overseeing license destruction, and reviewing daily edit reports. The following explains the deficiencies in detail:

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- The supervisor failed to ensure the accountability of the license paper used compared with the licenses printed. According to the supervisor, it is unnecessary for him to review the daily reconciliation sheet prepared by the technician because the form is self-explanatory and the amount of paper used will always agree with the number of licenses printed.
- The supervisor failed to oversee the destruction of licenses with printing errors. As previously indicated, the process of destroying a license is performed solely by the technician. The supervisor does not observe the destruction process, does not review or approve what was being destroyed, and does not require all destruction documentation to be retained.
- The supervisor failed to review the technician's computer activity. The License 2000 system records the operational history, including changes, edits, and processes performed. The technician has the capability to change and edit license information prior to printing a license. According to the BPOA system administrator, the technician can change the name and/or address of the licensee in the License 2000 system prior to printing the license. Therefore, the technician could potentially change the name and address of a licensee and print the license, and then change the name and address back to the original licensee and print the license again without being detected.

- **Lack of license paper accountability**

Other than the daily reconciliation process, no other procedures are performed to ensure blank license paper accountability. Inventory is not periodically performed to ensure that the remaining amount of paper in the print shop is correct. Failing to perform a periodic inventory could allow a box of blank license paper to be taken and not be detected.

- **Lack of physical security**

In addition to reconciliation and accountability weaknesses, we found the door locks leading to the print shop did not function adequately.

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Finding No. 4

- **No written standard operating procedures**

The department has no written standard operating procedures for printing licenses, including license paper accountability, reconciliation, paper destruction, preparation for mailing, and supervisory review. The supervisor, who had previously printed licenses, said that there never were any written procedures. The supervisor had been taught on-the-job and he, in turn, taught the current technician through on-the-job training.

- **Unrestricted employees have print shop printer access**

Based on interviews, we also found that the printers in the print shop can be used by other department employees. Occasionally, other employees print letters or other large printing projects on the printers in the print shop. In fact, such access has resulted in non-license projects being printed on blank license paper positioned in the print trays in error. The supervisor did not know how many department employees have access to the printers. This weakness could allow other employees to print unauthorized licenses even if they did not have License 2000 software on their computers.

Criteria: A strong system of controls dictates that confidential and important documentation is properly secured, safeguarded, and appropriately used. These controls would include adequate physical security, segregation of duties, supervisory oversight, inventory accountability and written standard operating procedures. Additionally, the printer use within the print shop should be limited to only individuals who are printing licenses.

Cause: Regarding the lack of segregation of duties, BPOA management indicated that the print shop duties are entrusted to one individual and confirmed that no one reviews the print shop process.

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The lack of supervisory review of the print shop process, including reconciling the licenses printed to the paper used, destroying the licenses, and reviewing the computer activity of the technician reports, is because the supervisor stated that he trusts what the technician does. As a result, there is no need for the supervisor to review the reconciliation process or the destruction process performed by the technician. Additionally, management stated that there are no reports available that verify the daily computer activities of the technician. Although the License 2000 system tracks the history of a employee user by his/her user identification (ID), according to management, the only reason a user ID report would be run would be if a licensee called with a complaint. Management also stated that there are no other controls in place to verify that the technician made appropriate changes. Furthermore management commented that this is not a lack of oversight, but rather at some point you have to put faith in your people. Relying solely on trust and faith as the only controls is not adequate and could lead to improprieties.

With regard to the doors not functioning adequately, management admitted that it was aware of this situation.

Additionally, management had no explanation as to why the print shop operation lacked written procedures.

Finally, the supervisor indicated that the printers in the print shop are used for large print projects. Personnel external to the print shop are to call the technician or the supervisor to notify them that they need to use one of the printers. The technician will ensure that the blank license paper is removed from the printer before giving the individual authorization to print. According to the supervisor, problems only arise if the individual wishing to print forgets to call prior to printing. We disagree. Allowing personnel access to the print shop printers greatly increases the risk that individuals within the department could inappropriately create fraudulent licenses.

Effect: Failing to have adequate controls at several levels dramatically increases the risk that improprieties, including inappropriate use of the license paper, will occur and not be detected. Additionally, given that trust and faith are the major controls utilized by the department, the department cannot be assured that inappropriate use of official licenses has not occurred.

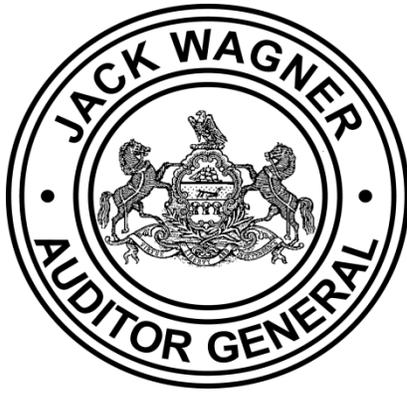
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Recommendations: We recommend that the department:

10. Require the supervisor to oversee the license printing process, including performing the daily reconciliation or reviewing and approving the daily reconciliation sheets ensuring agreement with independent sources, observing and approving the destruction of licenses; and reviewing the computer activity performed by the technician;
11. Require another individual or manager to oversee the duties of the supervisor, if the supervisor is printing licenses;
12. Count the amount of blank license paper on a weekly basis and compare with usage for the period to ensure all paper is accounted for;
13. Ensure that doors leading to the print shop are functioning properly;
14. Develop and implement written standard operating procedures for the license printing process; and
15. Not allow employees external to the print shop to use the print shop printers.



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FINDINGS AND RECOMMENDATIONS

Finding No. 5 –Untimely License Renewals May Result in Medical Doctors, Chiropractors, and Pharmacists Practicing With Lapsed Licenses

Condition: We reviewed the Bureau of Professional and Occupational Affairs' (BPOA) process of renewing medical licenses, chiropractic licenses, and pharmacy licenses (collectively, licenses) and found that, as a result of untimely license renewals and the lack of independent confirmation, practitioners could be practicing with lapsed licenses.

Medical doctors, chiropractors, and pharmacists must renew their licenses every two years. BPOA sends a renewal reminder to licensees approximately 90 days before a license expires. Applicants can renew their licenses online or through a paper renewal application. Generally, the renewal process requires the licensee to complete and sign the renewal form, including acknowledging that the continuing education requirements have been met, and paying the required renewal fee. Once received, BPOA processes the renewal, prints the license, and sends the new license to the licensee. If the renewal is not processed at the time of expiration, the license is considered lapsed. However, BPOA continues to process renewal applications of lapse licenses up to 30 days after license expiration.

Licensees who attempt to renew their licenses beyond 30 days after license expiration are processed as reactivations. These licensees must complete a reactivation application, which requires the individual to attest that he/she has attained the required number of continuing education hours, and a Verification Practice/Non-Practice Form, which requires the individual to attest to whether the individual has practiced in his/her profession in Pennsylvania since the license has lapsed. Additionally, the application requires the individual to provide documentation to prove that he/she completed the required number of continuing education hours and to pay the appropriate fees.

Using data provided by the department for the most recent biannual license expiration dates available during audit execution (through March 2008)¹⁰, we noted that 6,013 licensees failed to timely renew their licenses by the license expiration dates as shown in Table 4. As a result, these licensees potentially could be practicing with a lapsed license. BPOA does not contact the licensee or obtain independent confirmation that the licensee is no longer practicing in Pennsylvania:

¹⁰ The next cycle for licensees' renewals for medical doctors, chiropractors, and pharmacists would have been between September 1, 2008 through December 31, 2008.

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Finding No. 5

Table 4

| License Type (license expiration date) | Number of Licensees* | Number of Licenses That Lapsed at the Expiration Date | Number of Lapsed Licenses Renewed/Reactivated as of June 30, 2007 | | | Number of Licenses Not Reactivated by June 30, 2007 |
|---|----------------------|---|---|-----------------------|--------------------|---|
| | | | Within 30 Days | Between 2 to 6 Months | More Than 6 Months | |
| Medical Doctors (December 31, 2006) | 38,280 | 4,316 | 1,282 | 538 | ** | 2,496 |
| Pharmacists (September 30, 2006) | 25,899 | 1,185 | 717 | 114 | 24 | 330 |
| Chiropractors (September 1, 2006) | 9,802 | 512 | 267 | 59 | 25 | 161 |
| Totals | 73,981 | 6,013 | 2,266 | 711 | 49 | 2,987 |

*-For pharmacists and chiropractors, the numbers of licensees are from 2007 annual reports from the department's legal office to the respective state boards. For medical doctors, this is an estimate based on the number of medical doctors selected for continuing education post-audits (see Finding No. 6.)

**-Information is not available because June 30, 2007 is only six months after the license expiration date of December 31, 2006.

Based on the information shown in Table 4, licenses for 11 percent of medical doctors and five percent of pharmacists and chiropractors had lapsed or were not timely renewed. We found the following shortcomings in how BPOA handled situations where licensees with expired licenses applied to renew or reactivate their licenses after they have lapsed:

Renewals received within 30 days of license expiration or lapsed date

For licensees who apply to renew their licenses within 30 days after license expiration, BPOA does not charge additional fees and does not question whether the professional has continued to practice subsequent to the license expiration date. As a result, BPOA allows practitioners to practice on a lapsed license.

Reactivations received between two and six months of license expiration or lapsed date

For former licensees who apply for license reactivation between two and six months of the license expiration date, BPOA requires the individuals to attest to whether they have practiced on a lapsed license. If an individual states that he/she has not practiced on a lapsed license in Pennsylvania, BPOA does not make any attempt to independently verify that the information is true. If the individual admits that he/she has practiced, BPOA, through prosecutorial discretion, has decided not to refer the individual for prosecution. As a result, BPOA allows practitioners to practice on a lapsed license for up to six months without discipline and only charges a reactivation fee and a \$5 per month late fee.

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Reactivations received more than six months after license expiration date

For former licensees who apply for license reactivation more than six months after the license expiration date, BPOA also requires the individuals to attest to whether they have practiced on a lapsed license. If the individual states that he/she has not practiced on a lapsed license in Pennsylvania, BPOA does not make any attempt to verify that information is true. However, if the individual admits that he/she has been practicing on a lapsed license, BPOA will take formal action. Depending on the circumstances, formal action may result in a fine or other form of discipline, including probation or license revocation.

Licensees who do not renew/reactivate their licenses

Based on interviews, correspondence, and our review of renewal and reactivation documentation, we noted that BPOA does not take a proactive approach to ensuring that licensees who do not renew/reactivate their licenses are no longer practicing in Pennsylvania. BPOA does not attempt to contact them or to obtain independent confirmation that the licensees are not practicing in Pennsylvania. According to the BPOA Commissioner, "The regulations for each Board make it incumbent upon each licensee to renew their license. The regulations are clear in designating responsibility. The responsibility is to the licensee not the department." By putting the onus on the licensee, BPOA is, in essence, making an assumption that licensees who do not renew are not continuing to practice. This assumption is not acceptable.

Criteria: Citizens rely on the professional licensure process to ensure that these professionals have initially met the educational, experience, and ethical requirements necessary to adequately perform their professional duties and to ensure that these professionals continue to meet these necessary requirements throughout their careers and service to the public. Therefore, it is the responsibility of licensing agencies to verify that individuals holding themselves out to be a licensed professional are, in fact, licensed professionals. This would include not only investigating complaints that citizens file with the department, as discussed in Finding No. 1, but would also include an up-front proactive approach to ensuring that practicing professionals are licensed. Unlicensed professionals that violate the law must be dealt with appropriately.

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A person who holds him/herself out as a licensee from the State Boards of Medicine, Chiropractic, and Pharmacy must have an active license. With respect to the State Board of Medicine, state regulations require a person licensed by the Board to register biennially to retain the right to engage in practice.¹¹ Additionally, the Medical Practice Act of 1985 (Act 112 of 1985, as amended) states, “It shall be unlawful for any person to practice, or attempt to offer to practice, medicine and surgery, or other areas of practice requiring a license . . . without having at the time of so doing a valid, unexpired, unrevoked and unsuspended license . . . issued under this act.”¹²

With respect to the State Board of Chiropractic, “A licensee shall register each biennial period to retain the right to practice in this Commonwealth.”¹³ Additionally, unprofessional conduct includes continuing to practice chiropractic on a lapsed license.¹⁴

With respect to the State Board of Pharmacy, “A licensed pharmacist shall renew the license every 2 years, in even-numbered years.”¹⁵ Additionally, “It is unlawful for a person not licensed as a pharmacist by the Board to engage or allow another person to engage in the practice of pharmacy....”¹⁶

Cause: By placing the sole onus of license renewals and reactivations on the licensee, BPOA is potentially allowing unlicensed professionals to continue to practice in the Commonwealth. According to the BPOA Commissioner, the decision to not prosecute all professionals that practice on a lapsed license “was established under a previous administration and was deemed appropriate by the current BPOA legal supervisor, because its goal is to make good use of limited resources and produce fair and equitable results.” We disagree with this position. Fair and equitable results are not being met if BPOA allows any professionals to serve Commonwealth citizens based on lapsed licenses.

¹¹ 49 Pa. Code § 16.15.

¹² 63 P.S. § 422.38.

¹³ 49 Pa. Code § 5.17.

¹⁴ 49 Pa. Code § 5.81(1)(v).

¹⁵ 49 Pa. Code § 27.31(b).

¹⁶ 49 Pa. Code § 27.12(b).

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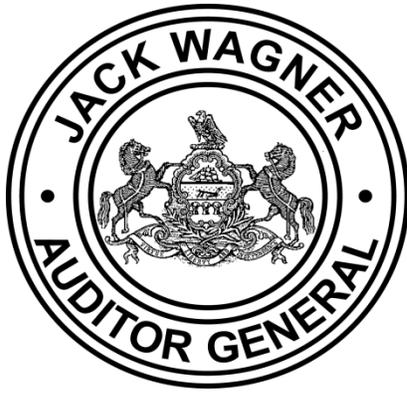
Finding No. 5

With respect to BPOA not independently verifying that reactivation applicants who acknowledge in writing that they have not practiced on a lapsed license have not actually so practiced, BPOA relies on the statement contained on the Verification Practice/Non-Practice Form which states, "I understand that any false statement is subject to the penalties of 18 Pa. C.S. Section 4904 relating to unsworn falsification to authorities and may result in the suspension or revocation of my license and/or certification." Additionally, BPOA relies on citizens, co-workers, etc. to notify BPOA that a professional is practicing on a lapsed license through its complaint process. Although the statement on the form may deter some individuals from making dishonest statements and the complaint process may detect some professionals practicing based on a lapsed license, we believe that these methods are not sufficient to ensure that all professionals who practice based on lapsed licenses are known to BPOA and dealt with properly.

Effect: Failing to ensure that professionals such as doctors, chiropractors, and pharmacists are practicing based on current licenses deters or reduces confidence in the licensing process by Commonwealth citizens. Renewing a license allows BPOA to verify that professionals are complying with continuing education requirements and to verify whether the professional has been convicted of various crimes.

Recommendations: We recommend that BPOA:

16. Inquire with practitioners who allow their licenses to lapse and have not reactivated their licenses to obtain written affirmations that they are no longer practicing;
17. At a minimum, request independent confirmation that a licensee has not practiced based on a lapsed license when seeking reactivation. This could be from an employer, practicing partner, hospital, or other means; and
18. Reconsider its decision to not prosecute licensees that continue to practice in Pennsylvania for up to six months after license expiration.



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Finding No. 6 – Deficiencies Found in the Department’s Post-Auditing of Licensees’ Continuing Education Hours

Condition: The Bureau of Professional and Occupational Affairs (BPOA) is responsible for processing new and renewal license applications. The renewal application requires a licensee to acknowledge on the application form whether or not the licensee had completed the required number of continuing education (CE) hours, which varies depending on the type of license being renewed. Renewal applications received and processed prior to the expiration of the license, as well as up to 30 days afterwards, are subject to a random post-audit to verify that the CE requirements have been met. We received the following results of BPOA’s CE post-audits for 1,914 medical doctors (MD), 887 pharmacists, and 177 chiropractors performed subsequent to their respective 2006 renewal periods:

Table 5

| Type of License | Number of Licensees* | Number of Licensees Audited | Results of Post-Audits (as of June 30, 2007) | | |
|-----------------|----------------------|-----------------------------|--|--------|---------|
| | | | Passed | Failed | Pending |
| Medical Doctors | 38,280 | 1,914 | 1,028 | 19 | 867 |
| Pharmacists | 25,899 | 887 | 821 | 59 | 7 |
| Chiropractors | 9,802 | 177 | 161 | 16 | 0 |
| Total | 73,981 | 2,978 | 2,010 | 94 | 874 |

*-For pharmacists and chiropractors, the numbers of licensees are from 2007 annual reports from the department’s legal office to the respective state boards. For medical doctors, this is an estimate based on the number of medical doctors selected for continuing education post-audits, which is to represent five percent of the population.

Licensees who pass their post-audits have met their CE requirements. Licensees who fail their post-audits have not met their CE requirements and are referred to the department’s Professional Compliance Office (PCO) for prosecution. Post-audits that are pending are not yet completed. Based on the information presented in Table 5, of the 2,104 (2,010 and 94) post-audits that are completed overall, 94 (four percent) failed their post-audit, with the failure rate of chiropractors being more than nine percent. We selected a sample of completed post-audits from each board to verify whether BPOA staff accurately determined whether the CE requirements had been met and found that staff accurately concluded on post-audits. Although BPOA’s post-audit conclusions appear accurate, we noted the following deficiencies in BPOA’s post-audit procedures and methodology.

- **Delays noted in the post-auditing of licenses**

The above table shows that 867 MD post-audits (45 percent) were still pending and not completed as of June 30, 2007, six months after the license renewal date. BPOA management indicated that the delay in performing MD audits was due to staff being overwhelmed in processing new licenses. In addition, seven pharmacist audits remained open as of June 30, 2007, nine months after the license renewal date.

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- **Post-audit procedures are not documented and supervisory review is not performed**

BPOA management acknowledged that written procedures for performing the CE post-audit do not exist. Additionally, management stated that it does not have a written methodology for selecting its CE post-audit sample. Management indicated that it always randomly selects five percent of the renewal population for sampling. Finally, management stated that supervisors do not review the post-audits performed by staff.

- **License renewal population and sample size could not be verified by auditors**

We attempted to obtain documentation to verify that the number of licenses selected for the three CE post-audits equated to five percent of the population. BPOA management stated that this documentation was not available. This lack of documentation also precluded us from verifying whether the population of renewals, from which the sample was selected, included all license renewals processed by BPOA.

Criteria: The responsibility for issuing licenses to professionals includes ensuring that professionals have achieved the required education and training, as well as ensuring that professionals comply with the required number of continuing education hours. To satisfy this responsibility, management must have a strong system of controls, including written procedures for processing license applications and performing a CE post-audit, and a process of reviewing work performed by staff. BPOA's written procedures for verifying CEs should encompass an efficient sample methodology, a requirement to maintain documentation showing that samples complied with the methodology, and time frames for completing the process. Additionally, the methodology should ensure that all license renewals are included as part of the population and subject to sampling.

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Cause: BPOA indicated that delays in performing CE post-audits may be a result of extensions granted to licensees who need additional time to obtain the necessary CE documentation or may be a result of other work priorities. Management indicated that it is not concerned with a delay in performing CE post-audits because, when staff does perform the post-audits, licensees who fail to meet the CE requirements will be referred to PCO for prosecution. Additionally, management's passive attitude toward completing CE post-audits when time allows is disappointing. BPOA's decision to renew licenses based on the licensees' written acknowledgement that the CE requirements have been met and to only subsequently post-audit a sample of these renewals makes the timeliness of the CE post-audit critical. If licensees have not completed the CE requirements, BPOA should not have renewed the license. Delaying this post-audit allows licensees to continue to practice for months without discipline or without needing to rectify the deficiency.

Regarding a lack of written sample methodology, BPOA management stated that it is not aware of there ever being any. Regarding a lack of post-audit procedures, staff indicated that there has never been any and they were taught through on-the-job training. Regarding the lack of supervisory review, management indicated that once an individual has been adequately trained, supervisory review is not necessary. Finally, regarding the maintaining of population and sample size calculation documentation, management indicated that it has never done that.

Effect: Failing to timely complete CE post-audits allows licensees to continue to practice for months without any discipline and without requiring the licensee to rectify the lack of CE hours. Additionally, this delay may result in citizens seeking services of these professionals who otherwise would not if they knew these professionals had received disciplinary action.

Failure to have written procedures for sampling and lack of maintaining how the sample was selected increases the risk that the procedures were not performed efficiently or correctly and eliminates the documentation necessary to verify that the sample was properly selected. Additionally, failing to have written CE post-audit procedures and failing to perform supervisory review increases the risk that CE post-audits may not be performed correctly, which could result in concluding that a licensee had the proper number of CEs when, in fact, he/she did not.

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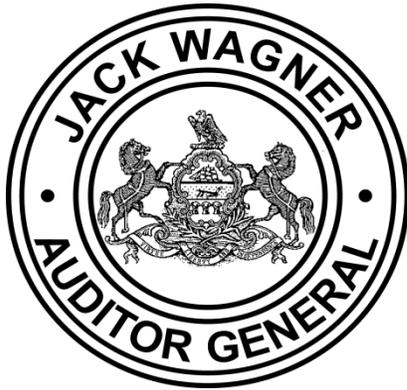
FINDINGS AND RECOMMENDATIONS

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Recommendations: We recommend that BPOA:

19. Ensure that CE post-audits are performed timely;
20. Develop a written methodology for selecting samples to be post-audited, including a requirement that all renewals are subject to the post-audit sampling;
21. Requiring sampling documentation to be maintained and reviewed to ensure adherence with the sampling methodology;
22. Develop written procedures for performing CE post-audit procedures; and
23. Perform supervisory review of CE post-audits.

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Department of State's Response to Draft Audit Report and Auditor's Conclusions

The department's response was submitted by Secretary of the Commonwealth Pedro A. Cortés, in a letter dated October 9, 2009. The department's response to each finding is reproduced verbatim below, followed by our auditors' conclusions.

RESPONSE OF THE PENNSYLVANIA DEPARTMENT OF STATE TO THE AUDITOR GENERAL'S AUDIT OF THE BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS FROM JULY 1, 2002 THROUGH JUNE 30, 2007

October 9, 2009

Introduction

The Department of the Auditor General (Auditor General) informed the Pennsylvania Department of State (Department) of its intent to conduct a special audit on December 18, 2006. The focus of the audit was to be on the duties and responsibilities of the Department within several of its bureaus.

The audit period initially spanned July 1, 2002 through June 30, 2006. The Department was later informed by the Auditor General that the audit period for the Bureau of Professional and Occupational Affairs (BPOA) was being extended to June 30, 2007. Now, over two years later, the Auditor General has completed this special audit.

The time lapse is significant. The Auditor General's report fails to address, consider or acknowledge any of the significant remedial and innovative steps that the Department initiated beginning in 2003 to improve operations. Indeed, the Department implemented nearly all of these improvements prior to the termination of the audit period. As a result, many of the recommendations set forth in this audit are moot. This response will ensure that the Auditor General and the citizens of this Commonwealth have a complete and accurate understanding of the measures taken by the Department to enhance the quality of service it provides.

Some of the findings and recommendations in the Auditor General's report are based on a flawed understanding of the Department's organization, particularly in regard to the unique relationships between BPOA and the Bureau of Enforcement and Investigation (BEI). To some extent, the audit ascribes duties to these bureaus that are not within the function or distinct role each fulfills in the Department. BPOA provides administrative support to the professional and occupational licensing boards. The Office of General Counsel (OGC) assigns attorneys to serve BPOA as board counsels and prosecutors. BEI principally provides investigative, inspection and enforcement services to BPOA. These distinctions are important to note, and the necessity of separating the administrative, investigative and prosecutorial duties will be discussed further in the responses that follow.

Below are the specific responses to each of the findings and recommendations contained in the special performance audit.

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Finding No. 1 – Inadequate Monitoring Has Delayed the Resolution of Some Complaints.

Department Response. The Auditor General’s report ignores that the Department instituted an entirely new procedure for the expeditious handling of consumer complaints against licensed professionals that is presently yielding outstanding results for the number of cases closed and the time it takes to close a complaint.

We agree with the Auditor General that the system of monitoring consumer complaints had been inadequate. That is why in August 2006, the Department created a Charging Unit to expedite the handling of complaints and to advance the disposition of disciplinary cases. The Charging Unit determines which cases can be handled expeditiously after the filing of a complaint and which cases require a more in-depth review. In the fall of 2006, the Department also initiated a prosecution unit that focuses on medical cases.

The Department’s changes yielded dramatic results – the Charging Unit reduced an accumulation of 12,000 cases by 40 percent to 7,200 cases. Additionally, the Charging Unit reduced the average time to close a medical, pharmacy or chiropractic case to 198 days.

The report also does not take into account the sufficient monitoring procedures already in place to ensure that open complaints are carefully considered and monitored. Those monitoring procedures include an automated computer system established in July 2003. The computer system identifies complaints that have fallen below acceptable time periods for action. Additionally, the report fails to consider that the Department began a special prosecution project in 2006 designed to move any case not resolved within three years.

Moreover, OGC already had direct supervisory controls in place to monitor prosecutor performance. Once a month, support staff generates a status report on the list of cases assigned to a prosecutor for the prosecutor and his or her direct supervisor. This report provides the prosecutor and his or her supervisor with an effective monitoring device of performance.

Recommendation 1 – Develop written procedures for monitoring complaints, including requiring the monitoring activities to be documented and retained.

Department Response. The Department implemented the recommendation prior to the release of the report. The Department has already instituted a written procedure for monitoring complaints and the entire monitoring process was computerized in 2003.

Recommendation 2 – Monitor the status of all open complaints to ensure that the Department is expeditiously proceeding through the complaint process.

Department Response. The Department implemented the recommendation prior to the release of the audit report. The supervisor, along with the case prosecutor, monitors the status of all complaints. This ensures that the Department is expeditiously proceeding through the complaint process.

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Auditors' Conclusion: We commend department management for being proactive with regard to implementing the recommendations presented in Finding No. 1. Management indicated at the exit conference that the recognition of these weaknesses resulted from a combination of discussions held with the auditors during audit execution as well as its own ongoing self-assessment. We would like to emphasize that department management must ensure that monitoring activities regarding complaints are documented and retained. Although the department has stated that the recommendations have been implemented, we have not validated these claims. However, we will follow up at an appropriate time to determine whether and to what extent these recommendations have been implemented.

We also would like to comment on the extension of the audit period and the length of time needed to complete the audit. After initially establishing a period end date of June 30, 2006, during audit planning in the spring of 2007, we found that the most recent renewal period dates for the licenses we were examining were between September and December 2006. Due to this reason as well as department management indicating that the complaint process had been revamped in August 2006, we were compelled to extend the audit period to June 30, 2007.

Regarding department management indicating that certain recommendations are not within BPOA's purview, we clarified at the exit conference that recommendations are within the department's purview and thus applicable.

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Finding No. 2 – Pharmacies Lacked Required Inspections.

Department Response. In regards to the Board of Pharmacy, BEI’s priorities are as follows: (1) investigation of specific complaints against a pharmacy or individual pharmacist to ensure public safety; (2) initial inspection of new pharmacies and confirmation that closed pharmacies have properly ceased operations; (3) re-inspection of failed pharmacies; and (4) regular inspection of operating pharmacies.

The Auditor General’s report indicates that “[a]ccording to ***policy*** (emphasis added), each pharmacy is required to be inspected annually.” For this position the Auditor General cites the introductory page of the Pharmacy portion of the Act 48 Manual, entitled “General Pharmacy Inspection Guidelines Under Act 48.”

However, this page in the manual is not an expression of the Department’s policy and was never meant to be. The Act 48 Manual (current edition dated September 29, 2008) is a training manual utilized by the inspectors, investigators, and paralegals in the issuance of citations. The primary purpose of the training manual is to provide a listing of citable offenses for each board and guidelines on issuance of appropriate citations.

The Department updates the manual when a new citable offense is added for any board. Other portions of the manual are not generally reviewed or updated.

The Department cannot determine the date of the original training manual or the original author of this introductory page. The earliest version available indicates the Pharmacy portion of the training manual was updated in November 2000.

The Department’s ***goal*** is to inspect licensed businesses once over two years. It has never been the position or policy of this Department that any licensed business be inspected once every year. In fact, the difficulties in recruiting and retaining pharmacy inspectors present the Department with significant challenges in meeting its goal of biennial inspections.

In late 2004, the Department conducted a “Work Force Review” of the appropriate number of staff for BEI. One of the assumptions utilized in the review was that licensed facilities were to be inspected once every two years. The “Work Force Review” was presented to the State Board of Pharmacy on January 18, 2005. The board, at that time, decided to continue to maintain its level of funding for six inspectors rather than impose a goal of annual inspections.

The Auditor General’s report incorrectly notes that the Department “employs” six pharmacy inspectors. While the Department is authorized to employ six pharmacy inspectors, because of constraints, which are more fully explained below, the Department was unable to fully staff all the positions during the audit period.

The Department admits difficulties in randomly inspecting pharmacies every two years. A major challenge is that the Pharmacy Act requires inspectors to be a licensed pharmacist. The classification for a pharmacy inspector is a Drug Program Specialist 1, which is at Pay Scale Group 6. The current pay range for PSG 6 is \$36,988 to \$56,235. New pharmacists in the private sector earn, on average, \$90,000 per year.

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This significant disparity in potential salary makes recruiting qualified pharmacy inspectors challenging. Nevertheless, in 2006, the Department made a concerted effort to fill the vacant positions for Pharmacy Inspections by publishing the job vacancies in a number of industry forums, enlisting the assistance of Pharmacy board members, reaching out to minority communities and working with our Human Resource Office.

The Department also attempted to obtain legislation to amend the Pharmacy Act to reduce the qualifications to eliminate the requirement that an inspector be a licensed pharmacist. Since the starting salary is \$36,988 and recent pharmacy graduates with no job experience are commanding salaries approaching \$80,000 to \$100,000, the pool of eligible candidates is minimal or non-existent. The Human Resource Office, on BEI's behalf, repeatedly opened job positions only to have no applicants or a refusal to accept the position based on the salary offered.

The situation reached a crisis point in year 2006 when there were 2.75 pharmacy inspectors for the entire state. An inspector would perform between 400 and 500 inspections a year. As a result of the initiatives noted above the number of inspectors available in year 2007 increased to 5.17. The total number of annual inspections performed increased from 1,265 to 2,429. The Department currently employs five inspectors. The most recent job posting resulted in one applicant who refused the job offer.

The inspectors the Department has been able to recruit are retired pharmacists who wish to continue to work for a short period of time. At the time of the audit, the median age of the Department's pharmacy inspectors was 76 years. The current median age is 66 years.

The result is a dramatically higher turn over rate of employees compared to employees of other classifications and significant periods of time when pharmacy inspector positions remain vacant. Positions have been vacant from one to seven years.

Despite these constraints, BEI has significantly increased the number of routine inspections in the past two years.

Recommendation 3 – Develop a written methodology to ensure that all pharmacies are inspected annually as required by the Act 48 guidelines.

Department Response. The Department asserts that this recommendation is based upon an inaccurate baseline assumption. Recent changes to the Act 48 Manual clarify the goal of the Department with respect to inspecting licensed businesses.

Recommendation 4 – Ensure that all re-inspections of pharmacies who failed an inspection are performed within 30 days as required by the Act 48 guidelines.

Department Response. The Auditor General's report mistakenly relies on a document that is not a matter of policy. The goal for the re-inspection of all licensed businesses is not 30 days; the target is 45 to 90 days depending upon the severity of the violations and the other stated priorities of the inspectors. In fact, a re-inspection is purposefully not done within a 30-day period to allow the licensee to correct any deficiencies.

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If a pharmacy inspection prompts formal disciplinary action, then the pharmacy will not be inspected until directed by the prosecuting attorney or until the legal action is finalized. This policy is required by the Prosecution Division of OGC.

Prior to the expiration of the audit period, management recognized that re-inspections were not being performed for significant periods of time. In November 2007 the Department initiated a monthly report that reminds the inspectors of the pharmacies that require re-inspection. The report indicates the length of time since that inspection, which allows the inspectors to prioritize re-inspection of failed pharmacies.

An inspection is a snapshot in time. It determines whether in that moment a pharmacy is in conformity with requirements. Its utility to ensure future compliance is rooted in the professionalism of the individual licensee and the expectation that regulations will continue to be enforced. The regulatory scheme encompassed in the Pharmacy Act relies upon the judgment, knowledge and experience of the licensed pharmacy inspectors to accomplish its goal.

Recommendation 5 – Develop a thorough training process for all personnel to ensure complete understanding of all necessary policies and procedures pertaining to the inspection of pharmacies.

Department Response. Pharmacy inspectors are educated, licensed pharmacists with knowledge of the profession that far exceeds requirements of a step-by-step manual. A content review of a pharmacy inspection by an individual non-pharmacist supervisor would add little or nothing to the goal of public safety.

A new pharmacy inspector is provided with appropriate documentation, including the Pharmacy Act, Pharmacy Regulation, Act 48 Manual, and the inspection forms. New inspectors conduct inspections under the oversight of an experienced pharmacy inspector.

Prior to the completion of the audit period, in 2006, the Department started a Pharmacy Inspector Round Table Session during the Annual BEI Training Event. This session allows the pharmacy inspectors, BEI Deputy Director, board counsel, and board prosecutors to discuss relevant changes to the regulations and current trends in pharmaceutical practice.

During the year, any identified practice issues are immediately addressed and communicated to all the inspectors.

The Department notes that this recommendation will be taken into consideration if the law changes so that pharmacy inspectors are no longer required to be licensed pharmacists.

Recommendation 6 – Consider seeking legislative change to no longer require pharmacy inspectors to be licensed pharmacists.

Department Response. It is the Department's long standing position to eliminate the 1985 requirement that inspectors be licensed pharmacists. Prior to 1985, inspections were completed by non-licensee inspectors. The licensing requirement has not resulted in a notable increase in inspection failure rate or prosecutions.

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Some bills in previous legislative sessions addressed the license requirement for inspector positions. Most recently, in the last legislative session, the Department supported House Bill 1194, which would have provided the Department flexibility in hiring for the pharmacy inspector position.

Going forward, the Department would like to work closely with the Auditor General to pursue this legislative change.

Auditors' Conclusion: The department generally disagrees with Recommendations 3, 4, and 5, but agrees with Recommendation 6.

Regarding Recommendations 3 and 4, during the exit conference, management stated that it is not the policy of the department to inspect pharmacies annually nor to re-inspect pharmacies within 30 days after failing an inspection. We explained at the exit conference that during audit execution, department management provided these written guidelines as part of obtaining policies and procedures regarding pharmacy inspections. As such, we utilized these guidelines as criteria and performed related test work. The department must ensure that the entire Act 48 manual is accurate and up-to-date on a regular basis.

As a result of management's statement at the exit conference, we performed additional test work using the department's stated criteria of a goal of two years, and found that 839 inspections has not been performed within two years, indicating that improvement is needed.

Putting aside the argument of what criteria to use, at the exit conference we inquired with management as to whether a written methodology would be developed to ensure that pharmacies that had not been inspected for several years (i.e., as of June 30, 2007, 180 pharmacies had not been inspected in more than seven years) are inspected in the near future. Management responded that it will consider such a plan.

In addition to late inspections, we also performed additional test work to determine the number of pharmacies not timely re-inspected using the department's stated criteria of 90 days and found that 173 pharmacies had not been re-inspected within 90 days, indicating that improvement is needed.

Regarding Recommendation 5, based on discussion at the exit conference, management indicated that it would think about reconsidering this recommendation.

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Finding No. 3 – Control Weaknesses Found in the Inspection Program of Pharmacies.

Contrary to the deficiency identified as “Effect” in the report, the overall regulatory scheme mandated by the Pharmacy Act provides assurances that pharmacies are adhering to health and safety provisions.

The audit report has a fundamental flaw in that it assumes that results cannot be relied upon in the absence of redundant procedures and that the Department has an abundance of resources. These redundant procedures would result in ineffective use of resources with no corresponding improvement in either performance or reliability. The fact that passed inspection reports are not preserved and retained adds nothing to the purpose of regular inspections, i.e., to ensure safe operation of pharmacies.

Prior to the end of the audit period, the aforementioned “Work Force Review” recommended establishing new Regulatory Enforcement Inspector Supervisor positions. The positions were approved in September 2007. Previously, the Regional Directors were the direct line supervisors. The directors’ span of control ranged from 24 to 41 persons. This unreasonable span of control did not allow for consistent review of investigation and inspection reports. The new supervisor positions allow for much closer oversight of work product, with the span of control now ranging from seven to 13 persons.

Recommendation 7 – Develop standard written procedures for the inspection of all pharmacies and ensure that such procedures are disseminated to all regional personnel involved in the inspection function.

Department Response. The Department reiterates the position presented in response to Recommendation 5.

Recommendation 8 – Develop a standardized records retention policy to allow sufficient time for auditors to review the documentation.

Department Response. The retention of inspection reports is in accordance with the needs of the Department. Failed inspections are retained until the pharmacy passes a re-inspection or the initial or re-inspection is sent for prosecution. The inspection report then becomes a part of the legal file and is retained accordingly.

The Department is currently in the final testing of a computerized mobile inspection system. One of the key enhancements of the system will allow the Department to retain a computerized inspection report, pass or fail, for an indefinite period of time.

Recommendation 9 – Modify the License 2000 system to include fields for explaining why a pharmacy failed and for discretionary comments.

Department Response. The Department initiated this recommendation prior to the end of the audit period and anticipates full implementation when the mobile inspection system is operational. The computerized mobile inspection system includes fields for explaining why a pharmacy failed and for discretionary comments as recommended.

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Auditors' Conclusion: Although the department acknowledges that Recommendation 9 will be implemented in the future, the department's written response disagrees with Recommendations 7 and 8. However, after our discussion at the exit conference, management indicated that it would reconsider its position based on the two points that we presented:

- 1) Based on how the inspection form is written, the extent to what an inspector is to review to determine compliance is left to the discretion of the inspector. For example, one question states, "Are all prescriptions verified by a registered pharmacist?" There is no indication whether the inspector looked at 2 prescriptions, 20 prescriptions, or 200 prescriptions. We believe that there should at least be a minimum number established by written procedures.
- 2) A consistency concern exists regarding whether a pharmacy should pass or fail its inspection. To elaborate, the inspection form consists of 12 yes/no questions. Given, a lack of procedures, inspectors must use judgment as to when a pharmacy "passes" or "fails" an inspection. For example, one inspector could "pass" a pharmacy with three questions checked "no," but another inspector could "fail" a pharmacy for the same three questions checked "no." We believe that there is significant risk that this could be occurring.

For Recommendation 8, regarding development of a standardized records retention policy, management's implementation of a new computerized inspection system will allow the inspection forms to be retained indefinitely. However, we again recommend that a standardized records retention policy be developed for inspection forms to ensure that they are retained for a certain number of years.

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Finding No. 4 – Significant Control Weaknesses Found Regarding the Printing of Professional Licenses.

The internal control structure established by our License 2000 (L2K) System prevents fraudulent licensing or misappropriation of funds from within the revenue office, and the Department is pleased the audit report recognized that there was no finding of fraudulent activity or even “potentially fraudulent” activity regarding the printing of licenses.

The printing of licenses is a segregated, multi-step process that one person cannot complete. A “license record” has to be created by BPOA board administrative staff before the print shop can actually print the license. Adequate internal control prevents the print shop technician from establishing a license record for printing. Likewise, our administrative staff that inputs the license record does not have the capability to print a license. The L2K application through the system administrator limits the roles for each user as well as their “permissions” or tasks they can perform within the system. Once a license is issued and sent to the print cue by our administrative board staff, the print technician cannot alter its face.

Even though we have not experienced any breaches in security, the Department nonetheless implemented a comprehensive reorganization of the revenue office and print shop operations that has brought about enhanced security to BPOA printing operations. Specifically, the revenue office moved to a reconstructed office area in 2008 that includes security measures such as pass-key locks on both doors and limited personnel access to the revenue office.

Notably, staff stores the security paper used to print licenses behind a chain link fence that is located in the newly constructed print shop and is secured with a lock. The relocation and remodeling of the print shop has brought about an additional level of security for professional licensure paper.

Also, the revenue office and print shop operation has compiled a written procedure manual. This manual has been implemented and distributed as of September 2007. It is worth noting that prior to 2003 there were no policy and procedure manuals in existence at BPOA.

Recommendation 10 – Require the supervisor to oversee the license printing process, including performing the daily reconciliation or reviewing and approving the daily reconciliation sheets ensuring agreement with independent sources, observing and approving the destruction of licenses; and reviewing the computer activity performed by the technician.

Department Response. The Department implemented the recommendation prior to the release of the report. The supervisor reviews and signs the daily reconciliation reports as well as initials licenses that will be destroyed. When the print shop technician is absent the Director of Operations will review and sign the report. The director will also initial any licenses that should be destroyed. Those licenses are marked with a permanent marker, copied and then destroyed. The copy is stored in a perpetual file.

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Recommendation 11 – Require another individual or manager to oversee the duties of the supervisor, if the supervisor is printing licenses.

Department Response. The Department implemented the recommendation prior to the release of the report. The Director of Operations has oversight responsibility if the supervisor is printing licenses.

Recommendation 12 – Count the amount of blank license paper on a weekly basis and compare to usage for the period to ensure all paper is accounted for.

Department Response. The Department implemented the recommendation prior to the release of the report. The supervisor takes a weekly inventory.

Recommendation 13 – Ensure that doors leading to the print shop are functioning properly.

Department Response. The Department implemented the recommendation prior to the release of the audit report. Pass-key locks exist on the doors to the revenue office and the print shop.

Recommendation 14 – Develop and implement written standard operating procedures for the license printing process.

Department Response. The Department implemented the recommendation prior to the release of the audit report. A written procedures manual was implemented in 2007.

Recommendation 15 – Not allow employees external to the print shop to use the print shop printers.

Department Response. The Department implemented the recommendation prior to the release of the audit report. The Department removed access to the print shop printers from all computers located outside of the print shop.

Auditors' Conclusion: We applaud department management for being proactive with regard to implementing the recommendations presented for Finding No. 4. Management indicated at the exit conference that the recognition of these weaknesses resulted from a combination of discussions held with the auditors during audit execution as well as its own ongoing self assessment. Although the department has stated that the recommendations have been implemented, we have not validated these claims. However, we will follow up at an appropriate time to determine whether and to what extent these recommendations have been implemented.

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With respect to the department's comment regarding the print technician not being able to alter the face of licenses, we disagree based on the evidence obtained during audit execution. During interviews with the print shop technician, print shop supervisor, the system administrator, and Deputy Commissioner, it was explained to us that any staff member has the capability to change names and addresses in the computer system. If the print shop technician would change a name or address, it would be recorded in the computer system's history; however, there are no daily edit reports printed to verify if any changes had been made. Again, we are encouraged by management's comments that the technician's computer activities will be reviewed by the supervisor.

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Finding No. 5 – Untimely License Renewals May Result in Medical Doctors, Chiropractors, and Pharmacists Practicing With Lapsed Licenses.

Department Response. The audit revealed that nearly 92 percent of the professionals licensed by the three boards under audit renewed their licenses timely. This outstanding statistic demonstrates that our licensees take their licensure obligations seriously and faithfully fulfill their obligations under the law.

The Department does attempt to contact those who have not renewed or reactivated their licenses. After the renewal period is over, BPOA staff identifies each expired license by running a system query. Within a week after the license expires, each licensee with an expired license is sent a follow up renewal post card. The second renewal notice is friendly in nature and communicates to the licensee that they need to renew their license in order to practice in Pennsylvania. The Department has been sending this second renewal notice since April 2006.

The factual description of renewing medical, pharmacy and chiropractic licenses in the audit report fails to take into account that licensure renewal at BPOA is a “ministerial” function under the law. Assuming all renewal requirements are met, BPOA administrative staff under the Department’s purview is directed by law to renew or reactivate a license even if it is lapsed.

The Department does not allow a licensee to practice on a lapsed license nor does it condone such activity. If there is a lapsed license, a continuing education (CE) violation or certain criminal activities, BPOA board administrators are required to notify the board prosecutors of the violation. The board prosecutors have the discretion to bring an action. BPOA administrative staff cannot bring such actions.

The board prosecutors established a guideline that licensees will not face disciplinary action for a license lapsed less than six months. This decision-making process is carried out pursuant to prosecutorial discretion based on sound legal considerations that also take into account limited fiscal resources.

As mentioned in the introduction, it appears that the Auditor General does not fully understand how the Department functions with respect to professional licensure. Although BPOA, OGC and BEI all work to support the boards, their roles and responsibilities are clearly defined, limited and separated. The investigative duties of BEI and the prosecutorial work of OGC cannot be commingled with the adjudicatory role of the boards or the administrative functions of BPOA. The Pennsylvania Supreme Court’s decision in *Lyness v. State Board of Medicine*, 529 Pa. 535, 605 A.2d 1204 (1992), mandates that the Department conduct its operations in this manner.

In *Lyness*, the court found that a violation of due process occurs when an administrative board, such as the State Board of Medicine, determines both that professional licensing prosecution should be initiated, and then acts as the ultimate fact-finder. Prior to *Lyness*, the licensing board could decide to open and investigate, prosecute, and adjudicate a case. As a result of the *Lyness* decision, the board may only serve as the adjudicator.

Accordingly, it is important for the Auditor General to understand and give consideration to the dictates of the *Lyness* case in making findings and recommendations relating to BPOA.

APPENDIX A

On another issue, the Department submits that the report is purely speculative when it claims that any licensee that did not timely renew their license is potentially practicing with a lapsed license. Based on experience, there may be many reasons why a practitioner fails to renew a professional license, and it does not necessarily mean that every practitioner who fails to renew a license is practicing on a lapsed license. For example, a licensee may not renew a license because he or she may have relocated out of the Commonwealth, retired from the profession or even passed away.

Recommendation 16 – Inquire with practitioners who allow their licenses to lapse and have not reactivated their licenses to obtain written affirmations that they are no longer practicing.

Department Response. The Department corresponds with all licensees who do not renew their license. Because staff members are proactive and send a second renewal notice to those whose license expires after the renewal period, the Department believes we meet the intent of the recommendation.

Recommendation 17 – At a minimum, request independent confirmation that a licensee has not practiced based on a lapsed license when seeking reactivation. This could be from an employer, practicing partner, hospital, or other means.

Department Response. Considering the constraints of the *Lyness* decision, the Auditor General's recommendation is investigative in nature and not within the scope of work done at BPOA. BEI investigates practice issues through inspection and investigation. Violators are prosecuted through OGC.

Recommendation 18 – Reconsider its decision to not prosecute licensees that continue to practice in Pennsylvania for up to six months after license expiration.

Department Response. The Auditor General's recommendation is not within the decision-making purview of BPOA. Per *Lyness*, the recommendation is an unjustified encroachment of prosecutorial discretion, which is a critically important principal in our system of jurisprudence.

Auditors' Conclusion: With regard to Recommendation 16, we do not agree with the department's comment that the renewal postcard sent to licensees who failed to renew by the expiration date meets the intent of this recommendation. Although the post card will remind practitioners to renew their license, the postcard does not provide any written assurance that practitioners who did not renew are, in fact, not practicing. At the exit conference, management explained that using this postcard is a practical and cost beneficial approach to ensuring that licensees that are still practicing renew their licenses. However, we believe that this approach is not sufficient.

APPENDIX A

With regard to Recommendations 17 and 18, department management indicates that these recommendations are not within BPOA's purview. Although this may be true, we clarified at the exit conference that these recommendations are within the department's purview and thus applicable. Management responded that limited resources within BEI make Recommendation 17 impractical. However, we believe that relying solely on statements made by the licensee regarding whether he/she has practiced subsequent to license expiration is not sufficient and should be independently confirmed.

Based on the department's response, the finding and recommendations remain as stated.

APPENDIX A

Finding No. 6 – Deficiencies Found in the Departments Post-Auditing of Licensees’ Continuing Education Hours.

Department Response. The audit report fails to note that BPOA does not have the authority to deny the renewal of a license of a practitioner who has not completed the CE requirement. Much like the lapse license cases, the renewal of a professional license is a “ministerial” function under the law. Consequently, BPOA administrative staff has no discretion to deny or reject the renewal of license based on a failure to complete CE. Under the law, BPOA must renew the license and then refer it to prosecutors who are empowered to determine whether action should be taken against the licensee for failing to complete CE requirements.

Similarly, the Department disagrees with claims, concerns and characterizations made in the audit report regarding the delays in performing CE post-audits. The audit report does not take into account the fact that delays in performing CE post-audits are not the result of any discretionary action by staff. A CE post-audit is a quasi-legal process that must include fairness and due process. BPOA administrative staff has an obligation to provide a licensee with a time extension to compile proof of CE completion. It would be patently unfair and perhaps legally indefensible if BPOA staff imposed, as the audit report seemed to suggest, fixed, unchangeable and unyielding time lines on when a licensee must submit CE certification.

Finally, the Department notes that like most governmental agencies or private practices we must prioritize our duties and maximize our limited resources. We concede that all CE audits were not completed within a six-month period but it is important to point out that they were completed within nine to 12 months of the renewal. The audit report revealed that less than five percent of the licensees who were audited were non-compliant. In the time that lapsed between the end of the Auditor General’s fieldwork and the issuance of the audit report, the Auditor General should have asked for the results of the 867 pending audits for medical doctors and incorporated those findings for a more comprehensive report.

Recommendation 19 – Ensure that CE post-audits are performed timely.

Department Response. The Department is committed to implementing this recommendation and is in the process of ensuring that CE post-audits are performed timely.

Recommendation 20 – Develop a written methodology for selecting samples to be post-audited, including a requirement that all renewals are subject to the post-audit sampling.

Department Response. The Department is committed to implementing this recommendation. Our licensing system is programmed to select a random five percent sample. We will request the systems sampling methodology from our vendor. This information will be incorporated into the CE audit section of our procedure manuals.

Recommendation 21 – Require sampling documentation to be maintained and reviewed to ensure adherence with the sampling methodology.

Department Response. The Department reiterates the position presented in response to Recommendation 20.

APPENDIX A

Recommendation 22 – Develop written procedures for performing CE post-audit procedures.

Department Response. The Department implemented the recommendation prior to the release of the report. Prior to 2003, there were no policy and procedure manuals in existence at BPOA.

Recommendation 23 – Perform supervisory review of CE post-audits.

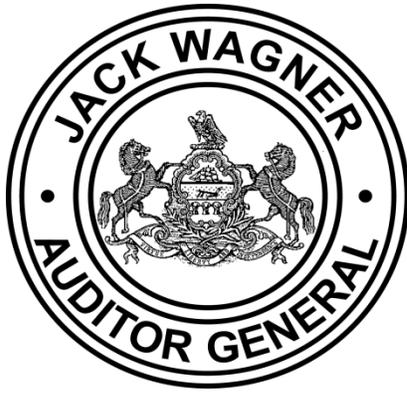
Department Response. The recommendation will be implemented. The senior staff in BPOA will be meeting with all Division Chiefs to conduct a supervisory review of CE post-audits.

The Department would note, however, that OGC has determined that BPOA's CE post-audit procedure and processes are appropriate, expeditious, and fair, and the bureau operates with reasonable speed. Nonetheless, as noted, the Department will appropriately follow up pursuant to the recommendations in the CE post-audits.

Auditors' Conclusion: We commend the department for its willingness to implement/address all of our recommendations regarding its post-auditing of licensees' continuing education hours.

Contrary to the department's statement that we are suggesting BPOA staff impose "fixed, unchangeable and unyielding time lines," we recommend that the CE post-audits be completed in a timely manner. We consider post-audits pending and not completed six to nine months after the license renewal date to be untimely.

With respect to Recommendation 22, whereby the department stated that the recommendation has already been implemented, we have not validated that information. However, we will follow up at an appropriate time to determine whether and to what extent all these recommendations have been implemented.



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