STATE OF NORTH CAROLINA

NORTH CAROLINA BOARD OF PHARMACY

FINANCIAL RELATED AUDIT

OCTOBER 2013

OFFICE OF THE STATE AUDITOR

BETH A. WOOD, CPA

STATE AUDITOR

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AUDITOR'S TRANSMITTAL

October 24, 2013

The Honorable Pat McCrory, Governor
The General Assembly of North Carolina
North Carolina Board of Pharmacy
Jack W. Campbell, IV, Executive Director

This report presents the results of our financial related audit at the North Carolina Board of Pharmacy. Our work was performed by authority of Article 5A of Chapter 147 of the *North Carolina General Statutes* and was conducted in accordance with the performance audit standards contained in *Government Auditing Standards*, issued by the Comptroller General of the United States.

The results of our audit disclosed a deficiency in internal control that is considered reportable under *Government Auditing Standards*. This item is described in the *Audit Findings and Responses* section of this report.

North Carolina General Statutes require the State Auditor to make audit reports available to the public. Copies of audit reports issued by the Office of the State Auditor may be obtained through one of the ways listed in the back of this report.

Beth A. Wood

Beth A. Wood, CPA
State Auditor

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BACKGROUND

As authorized by Article 5A of Chapter 147 of the *North Carolina General Statutes*, we have conducted a financial related audit at the North Carolina Board of Pharmacy. There were no special circumstances that caused us to conduct the audit, but rather it was performed as part of our effort to periodically examine and report on the financial practices of state agencies and institutions.

The North Carolina Board of Pharmacy (the "Board") was created under *North Carolina General Statute* 90-85 to license all who engage in the practice of pharmacy and to protect the public health, safety and welfare. The Board is authorized to set standards for academic and practical experience programs prior to licensure; issue permits to operate pharmacies; issue permits to operate device and medical equipment facilities; register pharmacy technicians; register dispensing physicians, physician assistants, nurse practitioners; and annually renew licenses, permits, and registrations. Additionally, the Board is responsible for performing investigations and inspections of pharmacies for compliance with regulations prescribed in *North Carolina General Statute* 90 Article 4A, the Pharmacy Practice Act and Article 5, the Controlled Substance Act.

The Board consists of six Board Members; five pharmacists and one public member. The Board employees 21 staff to collect fees established by *North Carolina General Statute* 90-85.24 and maintain permits, licenses, and registrations; inspect pharmacies and device and medical equipment facilities; and investigate situations that may be violations of the state Pharmacy Practice Act or laws governing the distribution of prescription drugs, devices, or medical equipment.

The Board Members meet on the third Tuesday of each month (except August and December) in the Board's office to conduct business, set policy and hold disciplinary hearings for pharmacists, pharmacies, and other licensees and registrants. These meetings are open to the public unless the Board properly goes into a closed session as permitted by the North Carolina Open Meetings Act.

The Board cannot lobby for or against legislation in Raleigh as noted in *North Carolina General Statute* Chapter 93B, the statute creating and empowering occupational licensing boards. The Board receives no funding from the General Assembly; the Board's activities are supported entirely by statutorily authorized licensing, registration, and permitting fees.

According to Board statistics as of September 30, 2012, the Board regulates 10,620 pharmacists, 2,740 pharmacies, 886 device and medical equipment facilities, 15,052 pharmacy technicians, 257 dispensing physician assistants and nurse practitioners, and 844 dispensing physicians. Additionally, the Board oversees 3,325 pharmacists licensed in North Carolina, but residing in other states, as well as 457 out-of-state pharmacies that provide pharmacy services to North Carolina residents. There were a total of 34,181 persons and entities under the Board's regulation as of September 30, 2012.

AUDIT SCOPE AND OBJECTIVES

The general objective of this financial related audit was to identify improvements needed in internal control over selected fiscal matters. Management is responsible for establishing and maintaining effective internal control. Internal control is a process designed to provide reasonable assurance that relevant objectives are achieved. Errors or fraud may nevertheless occur and not be detected because of the inherent limitations of internal control. Also, projections of any evaluation of internal control to future periods are subject to the risk that conditions may change or that compliance with policies and procedures may deteriorate. Our audit does not provide a basis for rendering an opinion on internal control, and consequently, we have not issued such an opinion.

Our audit scope covered the period October 1, 2011 through September 30, 2012 and included selected internal controls in the following departments:

Department of Financial and Administrative Services

The Department of Finance and Administrative Services is responsible for the general accounting functions of the Board. This department accounts for and as required by *North Carolina General Statute* 93B-2(11)(b) issues annual audited financial reports to Board members, the Governor, the Secretary of State, the Attorney General, the Office of State Budget and Management, and the Joint Regulatory Reform Committee covering all Board financial operations.

Department of Licensing

The Department of Licensing licenses pharmacists, and registers pharmacy technicians, dispensing physicians, dispensing physician assistants and dispensing nurse practitioners. It also issues permits to pharmacies and device and medical equipment facilities. License registration and permit renewals are processed beginning November 1st of each year. Any license, permit, or registration that is not renewed by midnight on March 1st is moved to inactive status. Renewal permits expire on December 31st of each year, but state statute grants licensees, permit holders, and registrants a 60 day grace period in which to renew without penalty. Between March 1st and March 31st a license, permit, or registration may be renewed with a late penalty. Permits, licenses, and registrations that have not been timely renewed (by March 1st) or reinstated (between March 1st and March 31st) are closed.

Department of Investigations and Inspections

The Department of Investigations and Inspections is charged with conducting investigations of licensees, permit holders, or registrants upon receiving or discovering information suggesting violation of the Pharmacy Practice Act or rules that is a potential threat to the public safety, health or welfare. The Department also conducts inspections of the practices of licensees, permit holders, or registrants as prescribed under *North Carolina General Statute* 90-107 and 90-113.

AUDIT SCOPE AND OBJECTIVES (CONCLUDED)

During our audit, we considered internal control related to the following accounts and specific objectives:

Licensing, Permitting and Registering Operations – The Board is responsible for issuing and renewing licenses, permits and registrations to all who engage in the practice of pharmacy in North Carolina. In connection with the issuance and renewal, the Board collects fees as prescribed in *North Carolina General Statute* 90-85.24. We examined internal controls designed to ensure that the Board issued and renewed licenses, permits, and registrations for only qualified applicants. Additionally, we examined internal controls designed to ensure that the Board's collections of fees were as authorized by statutory authority. As of September 30, 2012, the Board reported fee operating revenues of $3.5 million which includes all renewals, reinstatements, permits, and registrations.

Inspections and Investigations – The Board is responsible for timely investigation of potential violations of the Pharmacy Practice Act and inspections of pharmacies for compliance with the Controlled Substance Act. We examined internal control designed to ensure that pharmacy inspections and investigations are completed in a timely manner and violators are prosecuted in accordance with regulatory guidelines.

General Operations – The Board is subject to regulatory requirements established in *North Carolina General Statutes* Chapter 93B – *Occupational Licensing Boards* and Chapter 90, Article 4A – North Carolina Pharmacy Practice Act. We examined internal controls designed to ensure that the Board complied with the following requirements:

- In accordance with *North Carolina General Statute* 93B-2(a), no later than October 31 of each year, each occupational licensing board shall file with the Secretary of State, the Attorney General, and the Joint Regulatory Reform Committee an annual report.
- In accordance with *North Carolina General Statute* 93B-3, each occupational licensing board shall prepare a register of all persons currently licensed by the board and shall supplement said register annually by listing the changes made in it by reason of new licenses issued, licenses revoked or suspended, death, or any other cause.
- In accordance with *North Carolina General Statute* 93B-5(g), within six months of a board member's initial appointment to the board, and at least once within every two calendar years thereafter, a board member shall receive training on the statutes governing the board and rules adopted by the board and related State laws, in order to better understand the obligations and limitations of a State Agency.

METHODOLOGY

To accomplish our audit objectives, we gained an understanding of internal control over matters described in the *Audit Scope and Objectives* section of this report and evaluated the design of the internal control. We then performed further audit procedures consisting of tests of control effectiveness and/or substantive procedures that provide evidence about our audit objectives. Specifically, we interviewed personnel, observed operations, reviewed policies, analyzed accounting records, and examined documentation supporting recorded transactions and balances, as considered necessary in the circumstances. Whenever sampling was used, we applied a nonstatistical approach but chose sample sizes comparable to those that would have been determined statistically. As a result, we were able to project our results to the population but not quantify the sampling risk.

As a basis for evaluating internal control, we applied the internal control guidance contained in professional auditing standards. As discussed in the standards, internal control consists of five interrelated components: (1) control environment, (2) risk assessment, (3) control activities, (4) information and communication, and (5) monitoring.

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

RESULTS AND CONCLUSIONS

The results of our audit disclosed a deficiency in internal control in the inspection process that is considered reportable under generally accepted government auditing standards. This item is described in the *Audit Findings and Recommendations* section of this report. Management's response is presented after the audit finding. We did not audit the response, and accordingly, we express no opinion on it.

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AUDIT FINDINGS AND RECOMMENDATIONS

PHARMACY INSPECTIONS NOT CONDUCTED ON A REGULAR BASIS

The North Carolina Board of Pharmacy (Board) does not inspect all pharmacies on a regular basis. The failure to regularly inspect pharmacies increases the risk of problems and violations that could threaten public health and safety.

Several factors contribute to the lack of regular pharmacy inspections:

- A lack of clear inspection requirements in state law;
- The absence of a Board policy that requires periodic inspections;
- A failure to monitor and track the last inspection dates of pharmacies;
- An inadequate number of inspection staff.

Some Pharmacies Not Inspected For Years

Based on Board records, 35% of pharmacies have not been inspected in four or more years. About 21% were not inspected in the past 6 years or more.

As of September 30, 2012, the Board provided regulatory oversight for about 2,740 pharmacies in North Carolina. In that role, the Board establishes policies, holds hearings, investigates complaints, and inspects pharmacy facilities.

The Board performs both routine pharmacy inspections and inspections that occur as a result of an investigation. Board records showed that 311 out of 2,740 (11%) pharmacies had routine inspections completed between October 1, 2011, and September 30, 2012. Additionally, Board records indicated that 297 investigation-related inspections were completed during the same period.

The Board did not identify whether there was an overlap between the routine inspections and the inspections completed as part of an investigation. Although the Board maintained lists for routine inspections and lists for inspections completed as part of an investigation, these lists were not used to produce monitoring reports to readily identify pharmacies that had not been inspected within a given time frame. Such monitoring is necessary to ensure all pharmacies are regularly inspected to protect public health and safety.

A comparison of active pharmacies[1] on the Board's website to the Board's inspection records since 2006 showed that:

- 652 out of 2656 (25%) were last inspected less than 1 year ago;
- 1090 out of 2656 (41%) were last inspected between 1 and 4 years ago;

[1] Active pharmacies were defined as pharmacies on the North Carolina Board of Pharmacy website as of July 2013 with a permit issue date prior to September 30, 2012. The website list was verified to a pharmacy list generated by Board staff directly from its database.

- 361 out of 2656 (14%) pharmacies were last inspected between 4 and 6 years ago;
- 553 out of 2656 (21%) pharmacies were last inspected over 6 years ago;

Not regularly inspecting pharmacies could allow problems that threaten public health and safety to exist and not be detected in a timely way.

Examples of problems identified in Board investigations performed during the audit period of October 1, 2011, through September 30, 2012 included:

- Patient dispensed wrong medication;
- Mislabeled directions on medication;
- Patient shorted on prescription;
- Pharmacy staff providing false information to patient;
- Pharmacy without pharmacist in charge for 10 months.

It is possible that problems like these could have occurred at any of the more than 2,000 pharmacies that were not inspected during the audit period. Therefore, the lack of regular inspections could prevent problems from being identified and resolved in a timely manner.

Best Practices Require Regular Inspections

Best practices require regular inspections. The *National State Auditors Association's "Best Practices in Carrying Out a State Regulatory Program"* states an agency should develop a systematic process for monitoring, which includes inspecting regulated people's/entities' activities to ensure that they are following applicable requirements and that the public is adequately protected. As part of a good inspection process, the Board would be expected to schedule periodic pharmacy inspections often enough to provide reasonable safeguards to the public. The Board should also monitor inspection progress to ensure all pharmacies are inspected during the operation or life of the pharmacy.

Additionally, the Board cannot function effectively without conducting regular inspections. State law requires the Board to enforce the State's Pharmacy Practice Act and Controlled Substances Act. These Acts establish laws that pharmacies must follow to protect the public health and safety. However, the Board is less able to identify pharmacy noncompliance and enforce corrective action when it does not conduct regular inspections.

Contributing Factors to the Lack of Inspections

There are three factors that contribute to the lack of pharmacy inspections in North Carolina.

First, no state law requires regular pharmacy inspections and the Board has not established a policy mandating how often pharmacies should be inspected. State law requires the Board to enforce the State's Pharmacy Practice Act and Controlled Substances Act, but neither state law, nor Board policy, specifically requires the Board to regularly inspect pharmacies.

Consequently, the Board has primarily focused its efforts on conducting investigations and inspections based on complaints that it receives about pharmacies.

Second, while the Board maintained lists for routine inspections and lists for inspections completed as part of an investigation, these lists were not used to produce monitoring reports to readily identify pharmacies that had not been inspected within a given time frame. Such monitoring is necessary to ensure all pharmacies are regularly inspected to protect public health and safety. Additionally, the Board evaluated its annual inspection coverage by adding together the number of routine inspections and those inspections that occurred as a result of an investigation. This overstates the percentage of pharmacies inspected because the Board did not evaluate whether there was an overlap between the routine inspections and the inspections completed as part of an investigation.

Third, the Board has a small number of inspectors available to perform inspections. The Board has seven staff members dedicated to performing both investigations and inspections of the pharmacies under the Board's regulatory oversight. Consequently, the Board's ability to perform regular inspections at every pharmacy is limited.

Recommendation: The Board should:

- develop a comprehensive plan for inspecting pharmacies to ensure all regulated pharmacies are scheduled for periodic inspection;
- implement procedures to create and monitor inspection tracking reports to ensure pharmacies are being inspected regularly;
- seek the necessary resources to perform regular pharmacy inspections along with required investigations.

Board Response: See Board Response Section

BOARD RESPONSE

Jack W. Campbell, IV
Executive Director

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NORTH CAROLINA

BOARD OF PHARMACY

October 16, 2013

VIA ELECTRONIC MAIL (Pam_Wade@ncauditor.net)

Pamela D. Wade, CPA
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Dear Ms. Wade:

Please find attached a response to the report detailing your audit of the Board of Pharmacy. I appreciate the opportunity to meet with you, Ms. Wood, and Ms. Martin on September 23, 2013 to discuss the audit finding.

Sincerely yours,

Jay Campbell
Executive Director

cc: Gail Brantley
Rhonda Jones

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Agency Response:

The Board of Pharmacy appreciates the observations of the State Auditor. The Board is grateful for constructive feedback that can help improve the Board's ability to protect the public health and safety.

The Board does conduct both an investigations program and an inspections program (and the two are, necessarily, complimentary). The Board agrees that the audit process provided valuable input into how staff can improve its inspection program by better data creation, tracking, and generation – all of which should result in improved inspection efficiency. Board staff has already implemented changes to accomplish this goal.

The Board Conducts an Inspection Program for North Carolina Pharmacies

As the report notes, the Board carries out hundreds of inspections annually, whether "stand-alone" or coupled to a complaint-based pharmacy investigation. In carrying out that program, Board staff used a methodology to monitor inspection rates that should have resulted in the inspection of approximately 25% of the thousands of pharmacies licensed in the state annually. Accordingly, this guidepost method predicted a turn through 100% of licensed pharmacies approximately every four years – a cycle that, consistent with competing obligations, resources, and risk-based targeting (discussed below), is a reasonable one.

Board Information Systems Have Been Upgraded to Improve the Inspection Program

The Board acknowledges that inspections occurred somewhat less frequently than the guidepost method suggested. The reason for this discrepancy, which Board staff itself recognized (and discussed with the on-site auditor), was that the then-paper-based system for tracking routine stand-alone inspections did not sufficiently guarantee that pharmacies selected for inspections were completely new each year.

More specifically, at the time of the audit, all investigation records for a pharmacy permit were stored electronically and linked to the subject pharmacy permit, allowing identification of a pharmacy that had been inspected as part of an investigation. But the same was not true for routine stand-alone inspection reports. Those reports were kept and filed in a paper format that was not easily indexed. This paper-based system resulted in a labor-intensive process to match those inspection reports to the permit database and ensure that new pharmacies were being selected for routine inspections each year. This created a risk that a subset of pharmacies would fall through the cracks and not be inspected within a four-year time frame.

Immediately upon conclusion of the on-site audit, Board staff overhauled the information storage and collection system to minimize the risk that pharmacies would be overlooked during

inspection assignments. The following improvements have been implemented, or are in process to implementation, by Board staff:

1. Inspection check-list forms have been improved for content (including development of new specialized forms for compounding pharmacies and hospital pharmacies) and formatted as on-line PDF documents. Investigators now enter inspection information into the on-line form, review the findings with the pharmacist-manager, and email a copy of the form to the Board office and others as appropriate. The electronic inspection form is saved to the Board's on-line document system, where it is linked to the pharmacy permit.

2. The Board's database now allows staff readily to run electronic reports for all investigators showing inspection dates for pharmacies located within an investigator's assigned geographical area. Consequently, investigators are now better able to identify any pharmacy that has gone an anomalously long period of time without an inspection.

3. As discussed below, the Board is, on its own initiative, acquiring more specific data concerning practices at permitted pharmacies (see further discussion below). This will allow investigators to better employ risk-based factors when identifying pharmacies in need of inspection.

4. Board staff has in process a reevaluation of risk-based inspection processes and will produce a formal document memorializing those policies. If that reevaluation indicates a need, the Board will add additional inspection-specific staff. Fortunately, because the Board is self-funded by licensing revenue, resources available to the Board are predictable and easily shifted to address changing priorities. If a shift of resources is necessary, the Board is entirely capable of making it.

The remaining commentary is provided solely as context to aid readers in understanding the Board's overall investigation and inspection duties and, specifically, how the two mesh.

Both the Pharmacy Practice Act and Effective Policy Demand that Inspections Be Centered On the Board's Responsibilities to Investigate Alleged Violations of Law

In understanding the Board's overall inspection practices, it is important to note that inspection and investigation efforts are – and statutorily are required to be – structured with investigations at their center. North Carolina law is clear as to this primary responsibility: The Pharmacy Practice Act charges the Board to "enforce[e] the provisions of [the Pharmacy Practice Act] and the laws pertaining to the distribution and use of drugs . . .", NCGS § 90-85.6(a), and specifically charges the Board to "promptly conduct an investigation" upon "receiving information concerning a violation of [the Pharmacy Practice Act] that is a threat to the public safety, health, or welfare . . . ." Id. § 90-85.12(a) (emphasis added). Accordingly, Board personnel devote their primary efforts to conducting investigations of alleged violations of law, and to completing those investigations "promptly."

The Board Conducts More than 300 Investigations Per Year, And Completes Them Promptly

The Board performed more than 2,300 investigations between 2006 and 2012 – in excess of 300 per year. These complaint-driven investigations are far more labor- and time-intensive than routine stand-alone inspections. Many concern serious matters such as controlled substance diversion. Many involve collaboration with state administrative agencies, federal administrative agencies, state law enforcement agencies, and federal law enforcement agencies. Nonetheless, Board staff has consistently met its statutory duty to "promptly" investigate complaints. Information compiled by the National Association of Boards of Pharmacy for 2011 showed that the Board closed over 97% of its opened cases within a one-year time frame.

The Board's Investigation Program Compliments the Board's Inspection Program

Prioritizing investigation of pharmacies does not detract from the Board's ability to perform inspections. It enhances that ability. Every investigation of a pharmacy includes an inspection to detect any other potential violations of law. Such inspections are conducted in the same fashion and are just as comprehensive as routine stand-alone inspections. And these inspections are most calculated to address potential public health concerns, as they are inspections of those pharmacies about which complaints have been received.

Moreover, coupling investigations and inspections broadens the Board's "eyes and ears." Investigations are complaint driven. The sources of complaints to the Board vary widely: members of the public, pharmacists, other health care providers, law enforcement agencies (local, state and federal), and administrative agencies (state and federal). Coupling investigations and inspections allows the Board significantly to extend its reach by taking advantage of numerous additional "trip wire" sources of information.

The Board's Inspection Program Is Risk-Based

Risk-based inspections, of course, stand in tension with a goal to ensure all pharmacies are inspected within a given time frame. Risk-based inspections are certainly one of the reasons that the Board's inspection efforts are often focused on pharmacies that are also subject to investigations. The Board also takes into account other risk-based considerations. For example, since the late-2012 public health crisis traced to tainted compounded drug products produced by the Massachusetts-based New England Compounding Center, Board staff have focused on inspecting and re-inspecting pharmacies that produce sterile compounded drug products to ensure safety and compliance with Board rules.

Specifically identified risks, then, will always skew "routine" inspection assignments. But this is a necessary, appropriate, and critical aspect of focused, effective protection of the public health. For example, it is entirely appropriate to prioritize stand-alone inspections of pharmacies preparing high-risk sterile compounds over stand-alone inspections of part-time charitable care pharmacies that dispense a limited number of prescription drugs to a small patient population.

Board staff also conducts a rigorous review of all initial applications for pharmacy permits that involves not only licensing personnel, but also investigative personnel. This reduces the risk of "bad actors" obtaining a permit in the first instance. Significant information and documentation is obtained (including where necessary, by subpoena) from all applicants. A permit applicant must also appear in person at the Board for a further review of the application and to attend an education session on regulatory requirements for practicing in North Carolina. These permit meetings occur every two weeks. This rigorous screening and education process serves a valuable preventative public safety function. It further allows the Board to identify pharmacies that may engage in higher-risk practices (and therefore require more intensive monitoring), even before these pharmacies are permitted.

Although the report did not identify any weakness in the Board's collection of pharmacy-specific data, the review of data collection and use occasioned by the audit prompted Board staff to improve its ability to tailor risk-based inspections. Board staff has improved the data collected and stored about each permitted pharmacy, including: whether the pharmacy distributes prescription drugs in a way that may trigger drug wholesaling or manufacturing laws; whether the pharmacy engages in pharmacy compounding; whether a compounding pharmacy makes sterile products and, if so, what types (low-, medium-, and/or high-risk); whether the pharmacy is accredited, and by whom; whether the pharmacy has ever been denied accreditation; whether the pharmacy has an Internet presence and, if so, detailed information about services provided through the Internet. Each of these pieces of data (along with other data such as prior disciplinary action) assists Board staff in focusing inspection resources in an efficient, and effective, way.

Conclusion

The audit provided a welcome opportunity for Board staff to assess the adequacy and efficiency of its recordkeeping and other information systems. As noted, the Board agrees with the audit finding regarding the Board's methodologies for selecting pharmacies for stand-alone inspections – and nothing in this response is intended to minimize or distract from that agreement. Specifically, the Board's databases at the time did not sufficiently guarantee that pharmacies selected for stand-alone inspections were completely new each year. In response, Board staff has implemented a number of changes and improvements (discussed above) to

remedy this database weakness. Moreover, the audit has prompted the Board to increase the amount of data collected from permitted pharmacies, which will improve staff's ability to perform risk-based inspections in a more formal, programmatic way.

Board members and staff are cognizant of, and devoted to, their critical duty to protect the public health and safety. The Board is grateful that its structure, personnel, and resources allow it to respond quickly, creatively, and efficiently to challenges and opportunities.

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This audit required 412 audit hours at a cost of $31,312.