

STATE OF NORTH CAROLINA

OFFICE OF THE STATE AUDITOR

BETH A. WOOD, CPA



NORTH CAROLINA BOARD OF PHARMACY

INSPECTION PROCESS FOLLOW-UP

PERFORMANCE AUDIT

DECEMBER 2016



NC OSA
The Taxpayers' Watchdog

EXECUTIVE SUMMARY

PURPOSE

This audit evaluates whether the North Carolina Board of Pharmacy (Board) took appropriate corrective action to address recommendations made in the *North Carolina Board of Pharmacy* audit report issued by the Office of the State Auditor in October 2013.

BACKGROUND

The Board was created under North Carolina General Statute Chapter 90 Article 4A 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 before licensure; issue permits to operate pharmacies; issue permits to operate durable medical equipment facilities; register pharmacy technicians; register dispensing physicians, physician assistants, nurse practitioners; and annually renew licenses, permits, and registrations.

The Board is responsible for performing investigations and inspections of pharmacies for compliance with regulations prescribed in North Carolina General Statute Chapter 90 Article 4A, the Pharmacy Practice Act and Article 5, the Controlled Substance Act.

KEY FINDINGS

- Office of the State Auditor recommendations to develop an inspection plan, create tracking reports for monitoring inspection activity, and seek additional staff were implemented
- Inaccurate data in the inspection database, such as permit type and blank fields, increases the risk of late or missed inspections

KEY RECOMMENDATIONS

- The Board should implement a formal review process to help ensure the accuracy and completeness of data in the inspection database
- The Board should train permit holders so that all permit holders can enter their permit data into the inspection database accurately and completely

The key findings and recommendations in this summary may not be inclusive of all the findings and recommendations in this report.

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Office of the State Auditor



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AUDITOR'S TRANSMITTAL

The Honorable Pat McCrory, Governor
Members of the North Carolina General Assembly
Mr. Gene Minton, President, North Carolina Board of Pharmacy
Mr. Jack W. Campbell IV, Executive Director, North Carolina Board of Pharmacy

Ladies and Gentlemen:

We are pleased to submit this performance report titled Board of Pharmacy Inspection Process Follow-Up. The audit objective was to determine whether the Board of Pharmacy took appropriate corrective action to address recommendations made in the *North Carolina Board of Pharmacy* audit report issued by the Office of the State Auditor in October 2013.

The North Carolina Board of Pharmacy's Executive Director, Jack Campbell, reviewed a draft copy of this report. His written comments are included starting on page 8.

This audit was conducted in accordance with Article 5A of Chapter 147 of the North Carolina General Statute.

We appreciate the courtesy and cooperation received from management and the employees of the North Carolina Board of Pharmacy during our audit.

Respectfully submitted,

A handwritten signature in cursive script that reads 'Beth A. Wood'.

Beth A. Wood, CPA
State Auditor



**Beth A. Wood, CPA
State Auditor**

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Article 5A, Chapter 147 of the North Carolina General Statutes, gives the Auditor broad powers to examine all books, records, files, papers, documents, and financial affairs of every state agency and any organization that receives public funding. The Auditor also has the power to summon people to produce records and to answer questions under oath.



BACKGROUND

This audit was conducted as a result of the findings reported in the October 2013 audit titled, *North Carolina Board of Pharmacy*. The October 2013 audit evaluated the North Carolina Board of Pharmacy's (Board) inspection process and presented concerns with inspections not being conducted on a regular basis. The audit found that 35% of the State's then 2,656 (in-state) regulated pharmacies had not been inspected in at least four years.

The 2013 audit recommended the following for the Board to take appropriate corrective action:

- 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 pharmacy inspections along with required investigation

The North Carolina Board of Pharmacy 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 before licensure; issue permits to operate pharmacies; issue permits to operate durable 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 Chapter 90 Article 4A, the Pharmacy Practice Act and Article 5, the Controlled Substance Act.

The Board consists of six Board Members - five licensed pharmacists and one public member. The Board employs 25 staff members who are led by an Executive Director.

Currently, the Board regulates and issues permits to approximately 3,482 pharmacies and 871 Durable Medical Equipment (DME) facilities.¹ Approximately 669 of the permits are held by out-of-state pharmacies and DME facilities.²

¹ DME facilities administer durable medical equipment such as prosthetics, canes, crutches, walkers and bathtub grab bars.

² The Board does not inspect out-of-state entities. Rather, the Board's staff reviews disciplinary action reports of out-of-state entities to determine whether the Board should take action. These reports are produced by the National Association of Boards of Pharmacy.



OBJECTIVE, SCOPE, AND METHODOLOGY

The objective of this audit was to determine whether the Board of Pharmacy (Board) took appropriate corrective action to adequately address recommendations made in the *North Carolina Board of Pharmacy* audit report issued in October 2013.

The audit scope included pharmacies or durable medical equipment (DME) facilities that were active³ between November 2013 and August 2016. The audit scope does not include inactive or closed pharmacies or DME facilities.

To accomplish the audit objective, auditors interviewed personnel, observed operations, reviewed policies, analyzed records, and examined documentation supporting transactions, as considered necessary. Whenever sampling was used, auditors applied a nonstatistical approach. Therefore, results could not be projected to the population. This approach was determined to adequately support audit conclusions.

Because of the test nature and other inherent limitations of an audit, together with limitations of any system of internal and management controls, this audit would not necessarily disclose all performance weaknesses or lack of compliance.

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

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

³ Active pharmacies were defined as pharmacies or DME facilities that were fully operating during the scope of the audit. The status was obtained directly from the Board's inspection database.



FINDINGS, RECOMMENDATIONS, AND RESPONSES

1. OFFICE OF STATE AUDITOR RECOMMENDATIONS IMPLEMENTED

The Board of Pharmacy (Board) implemented recommendations to improve its inspection process as recommended in the October 2013 audit titled *North Carolina Board of Pharmacy* by developing a comprehensive plan for performing inspections, implementing procedures to create inspection tracking reports, and obtaining the resources necessary to perform regular and timely inspections.

Developed Comprehensive Plan For Performing Inspections

The Board developed a comprehensive plan for performing inspections. Specifically, the Board:

- Performed a concentrated effort⁴ to catch-up on inspections of pharmacies and Durable Medical Equipment (DME) facilities, which reduced facilities that had never been inspected or not inspected in the past four calendar years from 35% to 4%
- Created an electronic inspection database that manages and tracks completed and upcoming inspections
- Designed the electronic inspection database so that each permitted pharmacy and DME facility is automatically assigned a routine inspection date
- Established risk-based inspection frequencies so that riskier pharmacies⁵ are inspected more frequently
- Redesigned its inspection districts to allow adequate coverage of pharmacies and DME facilities by the inspectors

The plan's implementation significantly improved the timeliness and coverage of pharmacy and DME facility inspections.

The October 2013 audit report found that 35% of the Board's then 2,656 (in-state) pharmacies had not been inspected in four or more years.

As of February 2016, auditors found that only 4% of the Board's 2,813 in-state pharmacies had not been inspected within the last four years.⁶ According to Board management, these facilities will be inspected in calendar year 2016.

Implemented Inspection Tracking Reports

The Board developed an inspections tracking report that captures inspection activity maintained in the inspection database. The report also contains a listing of pharmacies and DME facilities and the planned date of their next inspection.

⁴ The effort to catch-up on past-due inspections took place from November 2013 to March 2014. This effort allowed the Board to create a baseline for scheduling all inspections going forward.

⁵ For example, sterile compounding pharmacies are considered the most risky because they physically make medicine that enters directly into the bloodstream or body tissue when consumed.

⁶ Figure is derived from data within the inspection database.

The Investigations and Inspections Coordinator (Coordinator) generates and sends the reports to the inspectors quarterly. Inspectors use these reports to plan their inspection schedules.

The tracking reports identify pharmacies and DME facilities that had not been inspected in accordance with the Board's inspection plan. These reports can be used for monitoring inspection activity to ensure all pharmacies and DME facilities are regularly inspected in order to protect public health and safety.

Increased Resources to Perform Inspections

Since the October 2013 audit, the Board has increased⁷ the number of pharmacy and DME facility inspectors from seven to 11. This increase in resources improves the Board's ability to regularly inspect pharmacies and DME facilities.

2. INACCURATE DATA IN THE INSPECTION DATABASE INCREASES THE RISK OF LATE OR MISSED INSPECTIONS

Data contained in the database that the North Carolina Board of Pharmacy (Board) uses to schedule and monitor inspections of pharmacies and DME facilities was found to be inaccurate and incomplete. Without reliable and accurate data in the inspection database, there is an increased risk that pharmacies and DME facilities are not inspected in accordance with the Board's inspection plan.

Inaccurate and Incomplete Data

Auditors sampled inspection forms and data from the 4,353 active permits in the Board's inspection database and noted inaccurate and incomplete fields for permit types and other fields that impact future inspection dates.

Incorrect Permit Types

Auditors found that 93 of 237 (39%)⁸ in-state pharmacies had inspection forms that did not agree with or lacked documentation to support the pharmacy's permit type as reflected in the inspection database.

Permit types only apply to in-state pharmacies and are given based upon risk. Pharmacies that are deemed riskier due to the services and procedures they perform⁹ should be inspected more often according to the Board's inspection plan.

⁷ The Board used a staffing methodology to determine its resource needs. Auditors reperformed the methodology to confirm the Board's staffing needs analysis.

⁸ 58 of 237 inspection forms did not agree to data within the inspection database and 35 of 237 lacked the documentation to support the pharmacy's permit type within the inspection database.

⁹ For example, sterile compounding pharmacies are considered the most risky because they physically make medicine that enters directly into the bloodstream or body tissue when consumed.

Missing and Inaccurate Database Fields

Auditors found that 16 of 281 (6%) facilities¹⁰ had inaccurate or missing database fields. Missing field types¹¹ included service type, sterile compounding percentage,¹² operating status, correction action notification, and next inspection dates.

Inaccurate Data Increases the Risk of Untimely or Missed Inspections

The inspection database is used by the inspectors for scheduling and performing their inspections. If the permit type or other information within the database is inaccurate, pharmacies and DME facilities are more likely to be inspected late or go completely uninspected.

Also, if there were violations from a previous inspection, the likelihood that a pharmacy or DME facility receives its 90-day follow-up inspection decreases. The 90-day follow-up inspection is mandated by the Board's inspection plan when certain violations occur.

Both past due inspections and the absence of 90-day follow-ups could expose the public to:

- Expired medications
- Mislabeled medications
- Untrained pharmacists and pharmacy staff
- Medication made with unsanitary or hazardous pharmacy equipment

Inaccurate Data is Primarily Due To Lack of Review and Training

There is no formal review of the data entered into the Board's inspection database. Although most data is entered by Board staff, some data such as "compounding type" is entered into the database by the pharmacy or DME facility representative from an online application during their permit renewal process.

However, no training is provided to pharmacies and DME facilities on how to update their permit data correctly. These factors directly contribute to the inaccurate or missing data fields noted above.

Best Practices Help Prevent Data Reliability Issues

Per the National State Auditor's Association's best practices for "Carrying out a State Regulatory Program," management should "evaluate the reliability of program data compiled and maintained by the agency."

In addition, the Committee on Sponsoring Organizations (COSO) states, "Inaccurate or incomplete data, and the information derived from such data, could result in potentially erroneous judgements, estimates or other management decisions."

¹⁰ Includes in-state pharmacies, out-of-state pharmacies, and DME facilities.

¹¹ Most of these fields can affect the next scheduled inspection date.

¹² The sterile compounding percentage represents the degree to which sterile compounding is performed. The greater the percentage, the more frequent sterile compounding is performed.

Other state's boards of pharmacy have a process for reviewing the quality of inspection data. Auditors surveyed state boards¹³ of pharmacy in Arizona, Georgia, Kentucky, Maryland, Oklahoma, and Tennessee and found that with the exception of Georgia, all had a management review process for data quality.

RECOMMENDATIONS

The Board should implement a formal review process to help ensure the accuracy and completeness of data in the inspection database.

The Board should train permit holders so that all permit holders can enter their permit data into the inspection database accurately and completely.

AGENCY RESPONSE

See page 8 for the Board's response to this finding.

¹³ Auditors selected state boards of pharmacy to survey based on (1) their proximity to North Carolina or (2) whether they operated independently instead of within the same department as other professional boards. The North Carolina Board of Pharmacy operates independently.



STATE AUDITOR'S RESPONSE

Government Auditing Standards require the Office of the State Auditor to provide additional explanation when an agency's response could potentially mislead the reader.

The Pharmacy Board (Board) states that, despite inaccurate and incomplete data within the Board's inspection database, inspectors performed the appropriate type of inspection at compounding pharmacies. Specifically, the Board states:

"Moreover, during each inspection, the Board inspectors performed their own assessment of the type of compounding services performed (if any), and then performed the appropriate inspection for that type of pharmacy practice. Therefore, the pharmacy was inspected, and the pharmacy was inspected to the standards required of, and dictated by, the particular compounding services the pharmacy performs."

However, auditors did not perform procedures to verify that the appropriate type of inspection was performed at compounding pharmacies. Therefore, this report provides no assurance that the proper inspections were performed.

Consequently, the readers of the report should not be misled into unwarranted reliance on the Board's statement that the appropriate inspection was performed at those compounding pharmacies.



RESPONSE FROM THE NORTH CAROLINA BOARD OF PHARMACY

Jack W. Campbell, IV
Executive Director

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November 22, 2016

Beth A. Wood, State Auditor
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Dear Ms. Wood:

On October 24, 2013, your office concluded that the Board of Pharmacy needed to improve and strengthen its program for inspecting pharmacies in North Carolina. Within one week of that recommendation, the Board launched a massive effort to ensure that it would inspect each and every North Carolina pharmacy that had not been recently inspected. Over a four-month period, Board staff inspected 1,353 pharmacies and device and medical equipment facilities. (In total, 3,467 inspections have occurred since November 2013). That effort ensured that, as changes in the inspection program were implemented, staff could be confident of baseline inspection dates and conditions of each pharmacy. This massive inspection blitz required intense effort by Board staff – particularly field investigation/inspection staff – often at substantial personal cost. To say that the staff went beyond the call of duty would be a gross understatement.

As this inspection blitz went forward, Board staff also developed, and the Board members approved, a formal risk-based inspection policy under which inspection frequency is keyed principally to whether a pharmacy performs prescription drug compounding services and, if so, what type. Inspection intervals range from annually to every four years, depending on the risk-based stratum into which a given facility falls. Initial implementation of the risk-based inspection intervals required a massive amount of data collection and input from some 2,800 pharmacies over a short period of time.

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Implementation of the more formal, risk-based inspection policy also required development of improved (and specialized) inspection forms and tools. As the program has moved forward, Board staff continually have updated inspection forms (including implementation of electronic forms and three major content revisions – with a fourth underway), database fields, and monitoring processes. This continuous improvement process goes on – the inspection program is not, and should not be, a static one. Moreover, the inspection forms and tools developed by the Board have been used as models by other states. Two Board staff have been leading resources on the development of national inspection form standards by the National Association of Boards of Pharmacy.

The Board has also grown inspection/investigations staff significantly. At the time of the 2013 report, the Board had seven (7) field staff devoted to inspections and investigations. In early 2014, that number grew to nine (9) field staff. In mid-2015, the Board implemented Team F.O.C.U.S., which divided the state into five geographical regions, each staffed by one investigator and one inspector, as well as added a floating inspector/investigator position to assist wherever needed, for a total of eleven (11) field staff. As well, staff have implemented rigorous (and continuous) training programs – both classroom- and field-based.

The Board appreciates your recognition of its successful efforts to develop, implement, and continuously improve its inspection program. The Board also appreciates that its operational and revenue independence allowed it to develop and implement this new inspection program quickly and efficiently.

Your report notes that inaccurate data in the inspection database can increase the risk of late or missed inspections. The Board agrees that accurate data is an integral component of a risk-based inspection program.

Two important contextual points bear mention here:

First, the principal concern identified is that the type of compounding services linked to a pharmacy in the database sometimes did not clearly match the compounding services identified on the inspection report form. In other words, these were not cases in which a pharmacy was not inspected. Moreover, during each inspection, the Board inspectors performed their own assessment of the type of compounding services performed (if any), and then performed the appropriate inspection for that type of pharmacy practice. Therefore, the pharmacy was inspected, and the pharmacy was inspected to the standards required of, and dictated by, the particular compounding services the pharmacy performs. As the forms have been revised, any inconsistencies in documenting those inspections have been remedied, as described below.

Second, the majority of potential, or perceived, mismatches identified by your office occurred during the first year of the revised inspection program's implementation. As noted above, the depth and breadth of that effort was enormous. Continuous improvement of policies and processes – and, in particular, continuous improvement of inspection forms – is reflected in the number of potential, or perceived, mismatches dropping significantly after that first year.

With respect to your specific recommendations:

1. The Board should implement a formal review process to help ensure the accuracy and completeness of data in the inspection database.

Agreed, and already done.

The Board has made numerous changes to ensure accurate reporting and data collection both on the front end of pharmacy registration and renewal, as well as during and after inspections. And the Board is in the process of making further programming and policy changes to strengthen that program.

Each year, every pharmacy permit is surveyed during permit renewal and required to report compounding services provided. A modified survey was implemented in October 2016 to limit unclear reporting whereby (a) a pharmacy might not select a risk-level for sterile compounding, or (b) a pharmacy performing only non-sterile compounding might have also selected an inapplicable sterile compounding risk level (therefore creating some inconsistency). In the modified survey, if, and only if, the pharmacy selects “sterile compounding,” the pharmacy is required to report the highest risk level performed, as defined by United States Pharmacopeia chapter <797>. The survey window prohibits a pharmacy from completing its annual permit renewal unless it completes the survey questions.

If a pharmacy has either added compounding services for the first time or has changed the risk level of sterile compounding services, then the pharmacy must contact the Board’s Director of Inspections and Investigations to schedule a compounding inspection. As a further improvement, by November 2017, the Board will implement a programming change to the database that will automatically generate a notification to inspection staff of a compounding service addition or change.

Moreover, the Board has improved documentation oversight to ensure that – when inspections are performed – the inspectors’ assessment of compounding performed is accurately reported and incorporated into the database. Each time a field inspector returns a completed inspection form, the Inspections and Investigations Coordinator verifies that the compounding services identified on the inspection form match the compounding services identified in the database, as well as reviews all data fields for the pharmacy for accuracy and completeness. If any mismatch (or omission) is identified, the coordinator corrects (or completes) the appropriate database field. This modified policy was implemented in May 2016. Board staff is working through the logistics of a policy to standardize notification of a discovered mismatch to a pharmacy and provide caution and instructions for future data reporting. A standardized notification policy will be implemented by April 2017.

A field was added to the inspections database in late 2014 that tracks a request for a corrective action plan from a pharmacy, as well as tracks whether the corrective action plan was received.

2. The Board should train permit holders so that all permit holders can enter their permit data into the inspection database accurately and completely.

Agree, and already done.

The Board has already provided additional training and information for permit holders. The Board also notes, however, that state and federal law, as well as the fundamental standards of the profession, already require all pharmacists to know the risk standards applicable to compounding.

In March 2015, Board staff published a document (available here: <http://www.ncbop.org/PDF/CompoundingRiskLevelsandCategoriesMar2015.pdf>) reminding pharmacists of the critical importance of correctly identifying compounding services provided and the appropriate risk level. That document also refers directly to United States Pharmacopeia chapter <797> risk level definitions and supplies examples.

In April 2015, the Board published an article in its quarterly newsletter (available here: <http://www.ncbop.org/Newsletters/Apr2015.pdf>) emphasizing the same things and referring to the March 2015 guidance document. As well, the April 2015 article emphasized that “[a]ccurate reporting of this information is crucial for at least two reasons. First, failure to provide accurate information in connection with seeking or renewing a permit is grounds to revoke or void a pharmacy permit (NCGS §90-85.38). Second, the Board’s risk-based inspection intervals are driven by the scope and type of service provided at a pharmacy, particularly compounding services.”

In October 2016, a link to the March 2015 Board staff added a link to this guidance document to the permit renewal compounding survey described above. Board staff will continue to link the guidance document (or subsequent versions) to the annual permit renewal compounding survey.

Likewise, in October 2016, Board staff added a link to this guidance document to the pharmacy permit application and to the pharmacy services questionnaire required of new applicants and of existing permit holders who change the compounding services provided outside of the permit renewal window.

Moreover, it is important to remember that, at the end of the day, pharmacists themselves bear responsibility for understanding the type and risk-levels of compounding services they provide. And both state and federal explicitly impose this responsibility. Revised compounding rules promulgated by the Board and effective January 1, 2015 not only codify that pharmacies must comply with United States Pharmacopeia chapters <795> and <797> (also required by federal law), but also that compounding pharmacies maintain a reference library that includes (either hard copy or electronically) United States Pharmacopeia standards. The rules also specify that the pharmacist-manager or pharmacist-manager’s designee pharmacist shall be knowledgeable in the specialized functions of preparing, labeling, and dispensing compounded drug preparations.

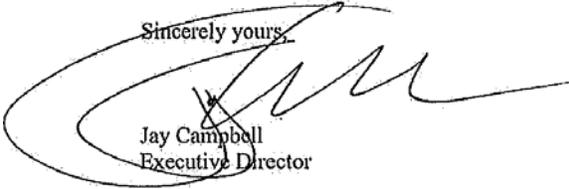
21 NCAC 46.2801. A pharmacist's failure to comply with these requirements would be a ground for potential discipline from the Board, federal action against the pharmacy, and criminal prosecution. Therefore, before pharmacists engage in compounding, they are already legally bound to be trained and competent in compounding risks, including identifying risk levels.

Finally, the pharmacy's own assessment of its compounding risk level is reviewed and corrected by the Board's field inspectors during their inspections. So, any initial misreporting of risk levels will be corrected by Board staff within the normal inspection rotation.

* * *

Thank you for the opportunity to respond. And I would be remiss not to express Board staff's appreciation to Denise Crowder and Shanté Scott for their friendly and professional work throughout.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Jay Campbell', is written over the typed name and title. The signature is fluid and cursive, with a large initial 'J' and 'C'.

Jay Campbell
Executive Director

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