STATE OF NEW HAMPSHIRE
BOARD OF PHARMACY
INSPECTIONS

PERFORMANCE AUDIT REPORT
MAY 2015

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To The Fiscal Committee Of The General Court:

We conducted a performance audit of Board of Pharmacy inspections to address the recommendation made to you by the joint Legislative Performance Audit and Oversight Committee. We conducted this audit in accordance with generally accepted government auditing standards. Those standards require we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. The evidence we obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

The purpose of the audit was to determine whether the Board of Pharmacy efficiently and effectively inspected facilities and practitioners that handled prescription medications and devices during State fiscal years 2013 and 2014.

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ABBREVIATIONS

Board	Board Of Pharmacy
DHHS	Department Of Health And Human Services
FDA	U.S. Food And Drug Administration
LRDD	Limited Retail Drug Distributor
NABP	National Association Of Boards Of Pharmacy
PIC	Pharmacist-In-Charge
SFY	State Fiscal Year

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EXECUTIVE SUMMARY

Our ability to assess the efficiency and effectiveness of Board of Pharmacy (Board) inspections was hampered by inadequate management controls and unreliable data. We found problems with policies, forms, administrative rules, and databases used to support inspections of facilities with prescription medications and devices such as retail pharmacies, wholesalers, hospitals, and health clinics. While management controls for inspections were less than ideal, we observed inspection personnel and reviewed inspection reports demonstrating inspections were performed proficiently, and inspectors were knowledgeable about the inspection process and requirements.

We found the Board should improve its operations by establishing goals and measurements, along with considering a risk-based approach to scheduling inspections. The inspection manual had not been updated since 1999 and computerized inspection templates had not been updated with new requirements since 2006. We also found databases used for inspections did not contain reliable data, were prone to data loss, and were not designed to track all individual pharmacists. As the Board continues readopting expired administrative rules it should specifically address issues with inspection procedures, forms, and fees.

The Board's inspection efforts were impacted by a reduction of Compliance Inspectors from 3.5 positions down to two, with the loss of one full-time and a part-time position at the conclusion of State fiscal year (SFY) 2011 due to budget cuts. This reduction in personnel, as well as additional action to address nationwide concerns over certain drug compounding facilities, contributed to not completing annual inspections for facilities and conducting fewer inspections of other health-related professionals. The Legislature subsequently reinstated funding for the cut positions, which were filled by July of 2014.

The Board generally inspected more types of facilities and more often than other northeast states. However, comparison with other states was complicated due to variation in the kinds of facilities and how often other boards of pharmacy conducted inspections. These variations also hindered ensuring out-of-State facilities, which may become licensed in New Hampshire, were held to the same inspection standards as in-State ones.

While not completed during the audit period, the Board's organizational structure was being revised by making the Executive Secretary's position responsible for all Board operations including, for the first time, inspections. When operationalized, the Board will have the opportunity to: 1) clarify the roles and responsibilities for overseeing inspections between the Chief Compliance Inspector and Executive Secretary, and 2) improve collecting, managing, and reporting inspection data.

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RECOMMENDATION SUMMARY

Observation Number	Page	Legislative Action Required?	Recommendations	Agency Response
1	13	No	Adopt procedural inspection rules for each type of licensee.	Concur
2	15	No	Update and periodically review compliance policy manual and provide training to inspectors in a timely manner.	Concur
3	17	No	Ensure inspection forms accurately include all requirements and inspectors receive training and written guidance on the forms. Enhance or replace the retail pharmacy inspection information system and work with the Department of Information Technology to determine whether the new licensing software will meet the Board's inspection needs.	Concur
4	20	No	Update the violation notice form and adopt into administrative rule. Consider whether the Board wants to limit its ability to discipline a licensee when a violation is issued.	Concur
5	21	No	Periodically review and, if necessary, adjust Board fees.	Concur
6	23	No	Establish a performance measurement system and compare goals to actual performance.	Concur
7	24	No	Establish a system to capture and report inspection activities; assess the inspection capabilities of the online licensing software; and collaborate with other boards receiving inspection services to identify practitioners who are in need of inspection.	Concur
8	26	No	Develop procedures to track violations related to individual pharmacists.	Concur
9	27	Yes	Establish procedures to ensure out-of-State licensees are inspected similar to in-State licensees and review statutory authority.	Concur In Part
10	30	No	Schedule inspections based on risk; work with other boards to update practitioners subject to Board inspection; identify agricultural, technical, and industrial users of prescription drugs; and report aggregate inspection results to the Board.	Concur

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BACKGROUND

Government Oversight Of Pharmaceuticals

Federal regulation of controlled drugs began in 1906 by prohibiting interstate commerce in misbranded and adulterated foods, drinks and drugs. In 1938 the federal Food and Drug Administration's (FDA) authority expanded to regulate drugs in several areas including requiring new drugs be shown as safe before marketing, and extending federal control to medical devices. Federal classification and regulation of controlled substances began in 1970 with the establishment of five schedules (or classes) of controlled substances based on their abuse potential, accepted medical uses, and safety when administered under medical supervision. The U.S. Attorney General, through the Drug Enforcement Administration, is required to register practitioners and pharmacies who dispense schedule II through V controlled substances, and who must maintain strict security and record-keeping for controlled drugs.

New Hampshire's Board of Pharmacy (Board), was established in 1875 to prevent persons engaged in retailing drugs, medicines, or chemicals used in compounding medicine; compounding prescriptions; and distributing medicine; from operating without a certificate of qualification and competency. The law also required such persons to obtain a certificate from the Board and allowed the Board to conduct examinations prior to issuing a certificate. Amendments in 1921 expanded the Board's responsibilities to include oversight for assistant pharmacists and to require drug stores to obtain a permit from the Board. The law also allowed the Board to recommend educational requirements and standards for certification. In 1963, the Board's responsibilities were further expanded to include inspections of licensees.

The Board's mission was "to promote, preserve, and protect the health, safety, and welfare of the citizens of New Hampshire by fostering the provision of quality pharmaceutical care." The Board did this by licensing, regulating, and "continuously monitor[ing] the practice of pharmacy in New Hampshire through the ongoing inspection of pharmacies throughout the [S]tate in order to ensure that the citizens of New Hampshire continue to receive the safe, quality pharmaceutical care they have come to expect." In addition to inspecting entities licensed by the Board, State law required the Board to provide inspection services to the Boards of Medicine, Veterinary Medicine, Podiatry, Optometry, Dental Examiners, and Nursing as it relates to the drug distribution system.

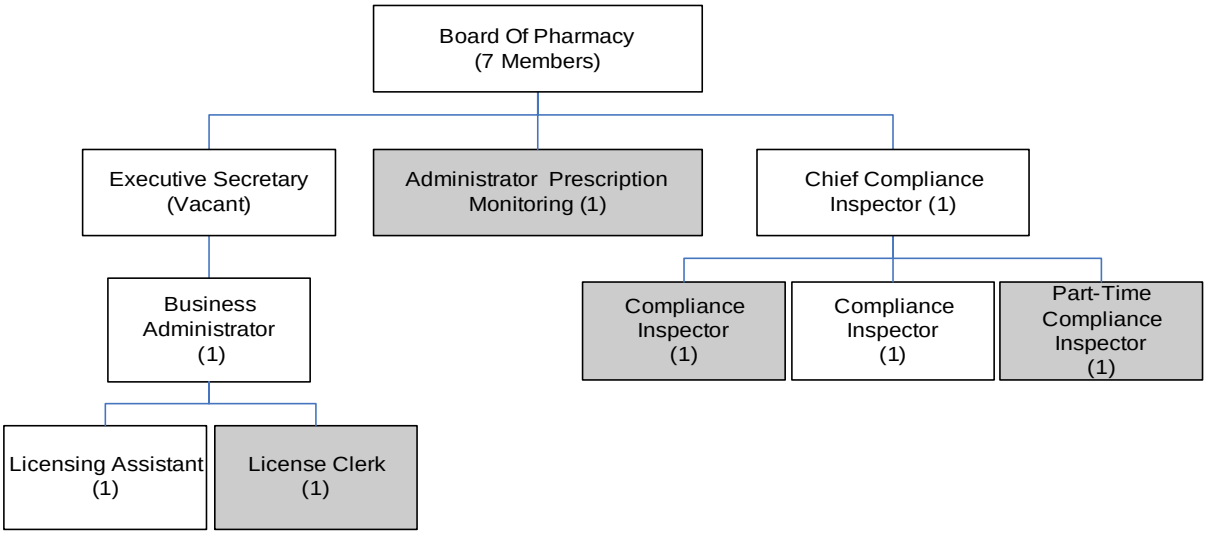
Board Organization

The Board was comprised of seven members each appointed by the Governor with the approval of the Executive Council to five-year terms. Six board members must be practicing pharmacists, one of which must be a full-time hospital pharmacist, and one public member who was not and had never been a member of the pharmaceutical industry. The Board was administratively attached to the Department of Health and Human Services (DHHS), which by mutual agreement was required to provide budgeting, recordkeeping, and related administrative and clerical assistance on a fee-for-service basis.

During State fiscal year (SFY) 2013 and the beginning of SFY 2014, the Board staff consisted of five positions including the Executive Secretary, the Business Administrator, the Chief Compliance Inspector, one Compliance Inspector, and a Licensing Assistant. In January 2014, the Board's staff was increased to eight, adding one full-time and one part-time inspector, as well as a Licensing Clerk. An Administrator for the new prescription monitoring program was also added. State law mandated the Board employ one person to serve as a full-time employee of the Board in the position of Executive Secretary; however, the position had been vacant since December 2013. The Executive Secretary position was reclassified in September 2014 to have expanded authority over all Board operations, including inspections. The Board's organization chart, as of June 30, 2014, is shown in Figure 1.

Figure 1

Board Of Pharmacy Organization Chart
As Of June 30, 2014



Notes: 1. The Executive Secretary position had been vacant since December 2013 and in the future will be responsible for all Board operations.
2. Boxes shaded in gray represent new positions as of January 2014.

Source: LBA analysis of Board information.

Since the summer of 2014, the Board had one full-time Chief Compliance Inspector, two full-time inspectors who were licensed pharmacists, and one part-time inspector who was a pharmacy technician. The inspectors who were licensed pharmacists not only conducted inspections, but also were responsible for investigating complaints. At times during our two-year audit period there were just two funded full-time inspector positions because of budget cuts. Inspections decreased from 694 in SFY 2012 to 416 and 499 in SFYs 2013 and 2014, respectively. On average during these three fiscal years, 213 in-State pharmacies received an annual inspection (100 less than those inspected in SFY 2011).

Licensing

The Board was required to establish a process for examining and issuing a license to pharmacists meeting Board requirements, as well as to qualified applicants already licensed in another state. State laws prohibited anyone from practicing pharmacy without first obtaining a license from the Board. As of the end of SFY 2014, the Board had issued licenses to over 2,500 pharmacists.

In addition to pharmacists, State laws required all pharmacies, manufacturers, distributors, wholesalers, and limited retail drug distributors (LRDD), be licensed by the Board. Specifically, the laws prohibited anyone from operating a pharmacy or manufacturing, distribution, or wholesale facility unless it was registered with the Board and had been issued a permit. Statutes also required registration and a permit for a mail-order pharmacy (i.e., out-of-State pharmacy) to ship, mail, or deliver prescription drugs into the State. At the end of SFY 2014, the Board had issued over 2,360 licenses and permits to these in-State and out-of-State entities.

State law also required pharmacy technicians and certified pharmacy technicians to register with the Board and work under the supervision of a licensed pharmacist. There were no licensing requirements in State law for pharmacy technicians, certified or otherwise. As shown in Table 1, the Board had 7,745 in- and out-of-State licensees and registrants at the end of June 2014.

Table 1

Licenses And Registrations Granted By The Board
As Of June 30, 2014

	In-State	Out-Of-State
Pharmacy Technician[1]	2,867	NA[2]
Pharmacist	2,516	NA[2]
Manufacturer, Wholesaler, Distributor	49	1,239
Retail Pharmacy	262	561
Hospital Pharmacy	35	NA[2]
LRDD - Medical Gas/Device Distributor	39	147
LRDD – Public Health And Methadone Clinic	30	NA[2]
Total Licensees And Registrants	**5,798**	**1,947**

Notes:
[1] Pharmacy technicians also included certified pharmacy technicians.
[2] Not applicable - the Board did not issue a license or registration to out-of-State pharmacy technicians, pharmacists, hospitals, or public health and methadone clinics.
Source: Unaudited Board data.

Inspections

State law required the Board adopt rules relative to procedures for inspecting its licensees. During the audit period, the Board established a schedule of annual routine inspections of its in-State licensees including retail pharmacies, institutional pharmacies (i.e., hospitals),

manufacturers, distributors, wholesalers, and LRDDs. Inspectors performed primary site inspections of new or relocated pharmacies, secondary inspections of pharmacy operations within 60 days of a primary inspection, and routine compliance inspections. Routine inspections were the types of inspections most often conducted by the Board. However, Board members and staff reported the Board had no authority over out-of-State entities and did not inspect pharmacies, manufacturers, wholesalers, or distributors mailing drugs to New Hampshire.

In addition to inspecting its own licensees, statute required the Board inspect prescription drug storage, labeling, distribution, and disposal by all physicians, veterinarians, dentists, advanced registered nurse practitioners, physician assistants, and clinics under contract with the DHHS, as well as agricultural, technical, or industrial users of prescription drugs. State law also required the Board provide inspectional services to the Boards of Podiatry and Optometry. During the audit period, the Board established a schedule of annual inspections for public health and methadone clinics and a schedule of every five years for other boards' licensees; however, it had never inspected technical, agricultural, or industrial users of prescription drugs.

At the end of the audit period, there were 415 in-State Board-licensed entities subject to inspection. While the Board established inspection schedules for all entities it was required to inspect, it did not meet these goals during the audit period. In SFY 2014, the Board inspected 312 Board-licensed entities, approximately 75 percent of those licensed in that fiscal year. The Board did not have a complete listing of practitioners subject to inspection, nor did the Board have a list of colleges, research facilities, or farms possessing prescription drugs and devices. Table 2 shows the number of inspections completed during SFYs 2013 and 2014.

While the Board was also responsible for inspecting pharmacists, its routine inspection process was focused on pharmacies and not individual pharmacists. Thus, while the Board captured the names of the pharmacists working in a pharmacy, there was no process in place to inspect the practices of each pharmacist licensed by the Board. Nor did the Board track whether all licensed pharmacists were part of a facility inspection. This same process was used for other boards' licensees, where inspectors conducted inspections of medical, dental, or veterinary practices, and not the individual practitioners.

Information Systems For Tracking Inspections

The Board's inspection forms were created using a variety of formats. Inspectors used a Microsoft Access database template to capture information while conducting retail inspections, while the other types of inspections were captured in Microsoft Word and Excel documents. The Board relied on two Access databases to track inspection data. Retail inspections were tracked in a database which was created in 2003 and modified in 2006. When conducting retail inspections, inspectors created a new record in the database by using an Access template to answer questions pertaining to requirements pharmacies must comply with. The information entered automatically populated data into fields in the database, allowing the Board to maintain a record of the pharmacy's level of compliance with each requirement during that inspection. The system was connected to the Board's licensing database to enable inspectors to verify the pharmacy, pharmacist, and pharmacy technician license numbers onsite. Information from inspector's

laptop and the master file were synchronized monthly, so they could review the pharmacy's compliance with each requirement from past inspections.

Table 2

Number Of Board Inspections Conducted
SFYs 2013 And 2014

Board-Licensed Entities	**2013**	**2014**
In-State Retail Pharmacy	209	222
In-State Hospital Pharmacy	30	27
In-State LRDD - Medical Gas/Device Distributor	4	10
In-State Manufacturer, Wholesaler, Distributor	2	24
In-State LRDD - Public Health And Methadone Clinics	12	29
In-State Pharmacist	0	0
Out-Of-State Entities	0	0
Subtotal	**257**	**312**
Other Entities And Practitioners Inspected		
Dentist	97	28
Veterinarian	22	51
Physician	19	68
Advanced Registered Nurse Practitioner	15	26
Physician's Assistant – Certified	6	12
Optometrist	0	2
Podiatrist	0	0
Agricultural Users	0	0
Technical Users	0	0
Industrial Users	0	0
Subtotal	**159**	**187**
Total Inspections	**416**	**499**

Source: Unaudited Board data.

The Board also used an Access database created in 1998, to track basic inspection information for other types of inspections including manufacturers, wholesalers, distributors, LRDDs, and practitioners. The system contained information such as the licensee name, address, type of facility, date of last inspection, whether violations were issued, and the inspector's notes about the licensee. However, unlike the retail inspection database, it did not contain data about each entity's level of compliance with each inspection requirement as the inspection forms for these types of inspections were created in Word and Excel, rather than in Access.

Other States' Inspection Practices

According to a 2013 Congressional study,[1] "While some states perform routine surprise in-person inspections, other states rely on scheduled announced inspections, while still others primarily rely in whole or in part on pharmacy self-inspections. In a self-inspection, a pharmacy submits responses to a questionnaire on its compliance with laws and regulations. In some states, inspections are driven primarily by the receipt of complaints that warrant an investigation into pharmacy activities." Additionally, there is no formal mechanism for states to know about the quality of out-of-state pharmacies.

We found variations in inspection practices when we contacted pharmacy compliance representatives of six northeast states. Overall, New Hampshire's Board was responsible for inspecting the most types of facilities and practitioners, and at the greatest frequency compared to other northeast states. Table 3 shows the facility types inspected annually by the Board and whether they were inspected by these other states. Unlike New Hampshire's Board, none of the other states' boards inspected healthcare practitioners.

Table 3

Scope Of Six Northeast States
Pharmacy Inspection Programs

Type Of Facility Or Entity	Number Of States And Frequency Of Their Routine Inspections				
	Annual	Biennial	Every Four Years	Every Six Years	Not Inspected
Retail Pharmacy	3	2	1		
Hospital Pharmacy[1]	3	1		1	1
Wholesaler[2]	1	2			3
Manufacturer[2]	1	1			4
Medical Equipment Provider	1				5
Public Health Clinic	1				5
Methadone Clinic	1				5

Note: [1] Three states performed inspections of the hospital pharmacy with the Department of Public Health only if the pharmacy dispensed to the public. Otherwise, hospitals were only inspected by the Department of Public Health.
[2] Pharmacy inspectors in one state were responsible for conducting inspections for wholesalers and manufacturers, but did not conduct routine inspections.
Source: Summary of LBA contact with other states.

The six northeast states reported having between one to ten compliance inspectors with three states' inspectors also performing investigations. Four states required inspectors to have a

[1] "State of Disarray: How States' Inability to Oversee Compounding Pharmacies Puts Public Health At Risk." Written by Staff of Congressman Edward Markey, April 15, 2013

pharmacist license; although two states did not require a pharmacist license, one required inspectors to have either a pharmacist or medical background. All of the states' pharmacy inspectors were responsible for routine inspections of retail pharmacies; however, three states did not have a separate stricter inspection process for compounding pharmacies. While there were no mandatory self-inspections, two states encouraged an optional supplemental self-inspection for in-state retail pharmacies. None of the states performed out-of-state inspections. A majority of states reported performing unannounced inspections when applicable.

Addressing Compounding Concerns

Pharmacy compounding is the process by which a pharmacist combines or alters ingredients to create a drug tailored to the medical needs of an individual. Compounding may also require sterile preparation in which specific equipment, environment, and greater care must be used. Government oversight of large-scale compounding facilities became an issue in 2012. A compounding facility in Massachusetts was identified as manufacturing a tainted preservative-free injectable steroid, which was responsible for over 60 deaths and hundreds becoming seriously ill with fungal meningitis across 20 states. There was no requirement for compounding pharmacies to register with the FDA, which was responsible for the oversight of drug manufacturers who are required to follow good manufacturing practices. Additionally, the 2013 Congressional study found "that most states are incapable of assuring the safety of compounded drugs that are prepared using the riskiest sterile processes or that are shipped into their state from an out-of-state pharmacy."

These serious deficiencies refocused the efforts of many state pharmacy boards to reevaluate inspection practices of sterile and non-sterile compounding pharmacies, including New Hampshire's Board. New Hampshire's inspectors were trained on sterile compounding and began using a new inspection form developed by national experts for the Massachusetts Board of Pharmacy following the 2012 tragedy.

Prior Financial Audit

In our *Board of Pharmacy Financial Audit Report For The Six Months Ended December 31, 2008*, we issued several observations identifying deficiencies in management oversight, policies and procedures, and frequency of inspections. We followed-up on six of the 19 observations relevant to inspections and found none had been completely resolved as shown in Appendix C.

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POLICIES AND PROCEDURES

Management controls provide reasonable assurance an organization achieves its objectives of efficient and effective operations, reliable internal and external reporting, and compliance with applicable laws and regulations. Controls span all aspects of an organization's operations, improve accountability, minimize operational problems, and must be continually assessed and updated by management to reflect changes in the operating environment. Controls encompass the methods, policies and procedures used to fulfill the mission, plans, goals, and objectives of an entity and management is responsible for developing the detailed policies and procedures to operationalize these controls.

The Board lacked policies and procedures in several areas which would be beneficial to guiding its inspection activity. The inspection manual utilized by Compliance Inspectors, last updated in 1999, was outdated and did not reflect inspection practices used by inspectors during State fiscal years (SFY) 2013 and 2014. Even though statutes required the Board to adopt rules outlining procedures to implement a specific statute, the Board lacked administrative rules outlining inspection procedures for each of the entities it was responsible for inspecting, as well as for the violation form issued to licensees found in violation of pharmacy regulations. To exacerbate the issue, the forms used by inspectors when conducting inspections did not include all requirements outlined in statutes and administrative rule, potentially leading to inconsistent inspection practices and documentation among inspectors.

Observation No. 1

Adopt Rules For Inspecting Licensees

State law gave the Board broad power to inspect its licensees, allowing inspectors and Board members "free access during business hours to all places where drugs, medicines, poisons or hypodermic devices are held, stored, or offered for sale and to all records of sale and disposition of drugs." The Board was also statutorily required to adopt administrative rules for inspection procedures. We found Board rules generally lacked inspection procedures. As shown in Table 4, we found inconsistent inspection rules for the various types of inspections conducted on licensees.

Table 4

Inspection Rules For Board Licensees

Type Of Licensed Facility	Types Of Inspections Conducted By The Board			Administrative Rule Language[2]
	Opening[1]	Closing	Routine	
Retail Pharmacies	Yes	Yes	Yes	Rules require inspections for the opening and closing of retail pharmacies, but no mention of routine inspections.
Drug Manufacturers Or Wholesalers	Yes	No	Yes	"Inspections shall be performed by the board's inspectors and be conducted at the request of the board." "Inspections shall be conducted during normal business hours, and notification of inspections shall be given no less than 48 hours in advance."
Limited Retail Drug Distributors	Yes	No	Yes	No mention of the types of inspections, however, dispensing records "shall be open to inspection by the pharmacy board and its agents."
Institutions	Yes	Yes	Yes	"Members of the board and/or their agents shall inspect the pharmacy, drug room/medication room and all areas or departments of the facility where drugs are stored, manufactured, compounded, dispensed or distributed…." However, there is no mention of types of inspection.
Nuclear/ Radiologic Pharmacy[3]	Yes	Yes	Yes	No mention of procedural rules for inspections, except that "[c]opies of the bureau of radiological health inspection reports shall be available at the pharmacy for board inspection."
Compound Pharmacies	Yes	Yes	Yes	No mention of procedural rules for inspections.
Long Term Care Pharmacies	Yes	Yes	Yes	No mention of procedural rules for inspections.
Home Infusion Pharmacies	Yes	Yes	Yes	No mention of procedural rules for inspections.

Notes: [1] Included a second inspection after opening and, if needed, follow-ups.
[2] Many rules in this table were expired or were interim rules due to expire in 2015.
[3] There were no nuclear pharmacies located in New Hampshire during the audit period.
Source: Board administrative rules and the Chief Compliance Inspector.

According to the *New Hampshire Drafting And Procedures Manual For Administrative Rules*, a rule should be specific enough to avoid the need for verbal clarifications or interpretations, which is known as "oral rulemaking." At a minimum, the inspection procedure rules for the different types of licensees should be comparable in scope and detail so Board staff and licensees understand under what circumstances the Board may inspect a regulated facility. The following examples demonstrate the inconsistency in the rules.

- All the facilities received an inspection prior to opening; however, only retail pharmacy rules mentioned it specifically.
- Except for drug manufacturers or wholesalers, it was not clear if other facilities' inspections should be unannounced (which is considered a best practice) or announced.
- Retail pharmacy rules specifically mention inspections for opening and closing a pharmacy, but were silent on routine inspections. No rules specifically addressed the practice of routine inspections, even though the Board recommended conducting them annually.
- Because only drug manufacturers or wholesalers rules stated inspections shall be performed "at the request of the board," the Board could easily change the criteria for initiating inspections, thereby risking oral rulemaking.

Recommendation:

We recommend the Board adopt similar kinds of procedural inspection rules for each type of licensee when updating its administrative rules.

Auditee Response:

We concur. The Board will adopt procedural inspection rules for each type of license or permit when updating its administrative rules.

Observation No. 2

Update Compliance Investigator Policy Manual

Compliance Inspectors used an outdated policy manual which lacked comprehensive policies and procedures for conducting inspections, issuing violations, and identifying potential conflicts of interest. It also contained examples of inspection documentation with confidential information. While new inspectors received on-the-job training from their colleagues and supervisor, some procedures were not in writing, which could lead to deviations in interpreting and applying standardized inspection forms and unwritten policies.

Revising Policy Manual

The *Compliance Investigator Policy Manual* (*Manual*) was last revised in 1999. The Chief Compliance Inspector reported beginning to update the *Manual* following the 2008 LBA financial audit of the Board, but had not completed the process. Changes in law and rules since 1999 were not addressed in the *Manual* such as inspections of compounding facilities, wholesalers, and manufacturers. While Board policy decisions were relayed to staff through the chief inspector, they generally were not formally written. Some outdated sections included:

- citing modified or expired administrative rules;
- instructions on how to use obsolete technology;
- specifications for issuing a discontinued noncompliance violation; and
- procedures for calculating costs of inspections.

Without established policies and procedures and training to emphasize significant activities like conducting inspections of licensees, management could not easily hold staff accountable for deviations from Board standards. Nor could the Board members easily hold management accountable for deviation from these standards. Ultimately, the lack of adequate written policies and procedures increased the risk of operating an inefficient and ineffective regulatory program designed to protect the public.

Issuing Violations

There was no written guidance for issuing violations, with the exception of one policy for checking pharmacists' monitoring of patient chronic conditions. The administrative rule which was based on federal statute, required "[t]he pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent, and record, any known… [c]hronic conditions or disease states of the patient.…" Our review of a non-statistical sample of 51 retail inspection reports from SFYs 2013 and 2014, found chronic condition monitoring was the most common deficiency, with eight instances of repeat deficiencies cited, yet no violations were issued. The policy outlined the process for an inspector to check for chronic condition compliance and issue a violation for a repeat finding. Reportedly, the Board instructed inspectors to cease issuing violations for this deficiency in 2011. The administrative rule expired in 2013, but was still being used to guide inspections.

Inspectors had discretion when issuing violations and reported they generally issued them for repeat deficiencies and for first-time deficiencies with potential risk to public safety or statutory noncompliance. As part of a complete inspection process, policies should establish standard criteria for types of violations that may occur and when corrective action should take place. Standardized procedures for conducting inspections help ensure uniform treatment of licensees and timely compliance in correcting problems. Insufficient training and guidance for issuing violations poses the risk licensees would receive inconsistent inspections and violations thereby indirectly facilitating inconsequential compliance.

Handling Conflicts Of Interest

The Board lacked written policies requiring inspectors to disclose any actual or perceived impairment they may have in carrying out their duties. Policy and training regarding potential conflicts of interest is important for avoiding biased treatment of licensees. With the return of two inspector positions in SFY 2014, the chief inspector reported taking steps to mitigate the risk of conflict of interest by having inspectors rotate inspections in the future. Additionally, inspectors reported they would notify management of any perceived conflicts of interest. However, on one occasion we observed an inspector performing an inspection at the inspector's former employer, where one employee was a former intern who had been hired by the inspector. Another inspector reported performing an inspection at their family physician's office. Both cases may raise conflict of interest concerns; however, management should determine what level of risk it is willing to accept.

Recommendations:

We recommend the Board update its compliance policy manual by:

- **including policies and procedures regarding performing inspections, issuing violations, and potential conflicts of interest;**
- **removing outdated policies and references to expired administrative rules; and**
- **redacting confidential information.**

We further recommend the Board periodically review the *Manual*, as well as formally document and communicate any changes in writing, and provide training to inspectors in a timely manner.

Auditee Response:

We concur. The Board will work on updating the Compliance Investigator Manual as it develops rules for inspections. The Board will also make sure to develop policies on the issuance of violations and guidelines to address potential conflicts of interest. Although the policy manual is an internal document we will be careful not to include any confidential information.

Observation No. 3

Ensure Inspection Forms Reflect All Statutory And Administrative Rule Requirements

The Board's inspection forms did not reflect all requirements in statutes and administrative rules. While the inspection forms for hospitals; manufacturers, wholesalers, and distributors; sterile and non-sterile compounding pharmacies; limited retail drug distributors; and public health clinics included the majority of statutory or administrative rule requirements, the retail inspection forms were missing many requirements outlined in statute or administrative rule. By not including all requirements on the inspection forms, the Board risks inconsistent inspections and cannot ensure

pharmacies are in compliance with all requirements. Additionally, we found some citations contained in inspection forms were not accurate.

Retail Inspections

Inspectors used an Access database to record and track retail pharmacy inspections. During an inspection, inspectors entered data into an electronic template which was connected to a table in the Access database. The retail pharmacy inspection database and accompanying template, last modified in 2006, had not been updated since. According to the inspectors, the Board could not add new or delete obsolete criteria in the inspection template as no one at the office had the expertise to modify the Access database and template. In July 2015, the Board plans to transition to online licensing software which reportedly may include inspection capabilities. However, Board staff and Board members were not fully familiar with its capabilities, nor had Board and Department of Information Technology personnel worked to determine whether the online licensing software would accommodate the Board's inspection needs. Inspectors acknowledged there were outdated requirements on the inspection form, as well as new requirements which should be on the form but were not. Instead, inspectors relied on their memory to determine which requirements not included in the form needed to be reviewed.

The retail pharmacy inspection template did not incorporate 11 broad categories required by statute or administrative rules, consisting of 26 individual requirements. For example the form did not address:

- seven requirements regarding the sale of hypodermic syringes,
- five requirements regarding pharmacist administration of vaccines,
- four requirements regarding electronic prescriptions,
- two requirements regarding oral prescriptions, and
- two requirements regarding prescription labels.

Although the retail inspection template was missing these requirements, we found inspectors reviewed some of these requirements for compliance during inspections we observed. However, inspectors did not consistently document these reviews, nor was there a policy requiring them to do so.

Other Inspection Forms

We found the inspection forms used for other licensed entities, most of which were updated in May 2014, were in compliance with the majority of requirements in statutes and administrative rules. However, the following requirements were not included in the respective inspection forms.

- Institutional pharmacy (hospitals) inspection form did not address one requirement to have a designated area for storing flammable or caustic materials.
- Methadone clinic inspection form did not address maintenance of dispensing records for four years, keeping drugs in a well-lit and ventilated space, or ensuring drugs are kept at an adequate temperature.

- Limited retail drug distributor inspection form did not address the requirement to keep drugs at an adequate temperature and ensuring drugs are stored in lockable areas to prevent unauthorized entry.
- Public health clinic inspection form did not address a requirement to maintain dispensing records for four years, keeping drugs in a well-lit and ventilated space, or ensuring drugs are kept at an adequate temperature.

Inaccurate Citations In Inspection Forms

Some inspection forms included citations to statutes, administrative rules, and federal laws while others did not. While most inspection forms contained accurate citations, we found the inspection form for manufacturer/wholesaler contained the following inaccurate citations:

- "Returned goods" is cited as Ph 710.11 but the 710 series discusses administrative fines and only contains two sections. Administrative rules section Ph 309 outlines standards of practice for manufacturers, wholesalers, and distributors and returned goods are discussed in Ph 309.10.
- "Recalls" is cited as Ph 710.09, but the 710 series only contains two sections. Administrative rules section Ph 309 outlines standards of practice for manufacturers, wholesalers, and distributors and handling recalls are discussed in Ph 309.11.
- "Adequate: lighting, ventilation, sanitation/space, and storage" is cited as Ph 309.05; however, this section discusses suitable size of the facility, ensuring it is commercially zoned, and notifying law enforcement of the facility's presence. Ph 309.04 discusses storage conditions including "proper lighting, ventilation, temperature, sanitation, humidity, equipment, and security conditions."

Recommendations:

We recommend the Board:

- **ensure its inspection forms include all requirements outlined in statute and administrative rule,**
- **ensure citations contained in inspection forms are accurate, and**
- **provide written guidance and training for interpreting and using the inspection forms in a consistent manner.**

Further, prior to implementing the online licensing software, we recommend the Board and the Department of Information Technology work together to determine whether the software will meet the Board's needs for supporting inspections. If not, the Board should seek to enhance or replace its retail pharmacy inspection information system using other means.

Auditee Response:

We concur. We concur that the citations that are contained on our inspection forms need to be accurate. As we are actively working on getting our rules updated and there are plans for us to move to on-line licensing which does include an inspection module we plan to review all inspection forms. That review will include making sure that our citations are correct. We will ensure that inspection forms include all requirements and will work towards all forms being used in a consistent manner.

Observation No. 4

Violation Form Should Be In Administrative Rule

The Board did not update the *Violation Notice* form and include it in administrative rules. Inspectors used the document to cite noncompliance of licensees, which then required the recipient to return the *Violation Notice* to the Board with a corrective action plan within a time period set by the inspector. Because the form required the recipient to provide information to the Board, State law required the form be established in rule. State law also stipulated forms may be adopted by an agency by incorporating the actual form by reference or by setting forth the requirements of the form in rules. While the Board was addressing expired rules, the *Violation Notice* was never included.

The *Violation Notice* retained the previous address of the Board. One inspector was observed neglecting to inform the licensee of the address change upon issuing a violation. It also contained language restricting the Board's authority to pursue disciplinary action after an initial violation. While the Board viewed inspectors as primarily educators rather than enforcers, some situations may require further investigation from the Board. For example, the Board wanted to discipline a licensee following the review of an initial violation; however, the Department of Justice, Administrative Prosecution Unit found the Board could not take any disciplinary action in this case. The *Violation Notice* stated, "unless the conditions… are corrected and a written report detailing the conditions is submitted to the Board… further action may be taken." As a result, no disciplinary action could take place if an initial violation was given and the recipient reacted in a timely manner.

Recommendations:

We recommend the Board update the *Violation Notice* and promulgate administrative rules to adopt the updated form.

The Board should review whether it wants to limit its ability to discipline a licensee when an initial violation is given to the licensee.

Auditee Response:

We concur. We will include the violation notice in the rules we develop on procedural inspections. The issue with limiting the Board's ability to discipline based upon an initial violation has already been resolved. After the limitation was discovered towards the end of calendar year 2014, the Board reviewed the matter with legal counsel. Based on advice from counsel, the violation notices were amended in the following way;

"Notice is hereby given that unless the conditions noted above are corrected and a written report detailing the conditions is submitted to the Board of Pharmacy, Compliance Division on or before _____, further action may be taken."

Was replaced with the following language:

"Notice is hereby given that you must correct the above conditions and submit a written report detailing the conditions to the Board of Pharmacy, Compliance Division on or before _____. Further action may be taken in this matter."

Observation No. 5

Ensure Board Fees Are Reasonable

Board licensees were charged fees to ensure Board operating and State overhead costs were paid for by the direct recipients of its services. Fees were set by the Board and adopted in administrative rule. We found Board revenues from fees consistently exceeded amounts required by law.

Excessive Revenue Collection

The Board collected over $1.2 million in excess revenue over the past five SFYs. The Legislature placed a footnote to the operating budget for boards administratively attached to the Department of Health and Human Services (DHHS) that required boards and commissions to establish fees for examining applicants, applications for a license or registration, publications for which they sell, or other programs for which they were specifically authorized to charge a fee. These fees must recover the full cost of the program, including the cost of support and administrative services provided by other agencies, or 125 percent of the direct cost of the board, whichever is greater. According to calculations by the DHHS, the Board collected more than the requisite 125 percent in fees in each of the past five years as shown in Table 5.

Table 5

Excess Revenue In SFYs 2010-2014

	2010	2011	2012[1]	2013[1]	2014	Total
Percent Of Revenues To Expenditures	168	152	170	186	172	
Excess Revenues Over 125 Percent Threshold	$ 228,435	156,467	256,157	323,460	291,212	1,255,731

Note: [1] Two inspector positions were lost with no corresponding reduction in revenue.
Source: Unaudited DHHS data.

The Board was aware of this issue when it wrote in its budget submission for the 2014-2015 biennium budget manual, "The Board of Pharmacy is a 125% agency and earns revenue through licensing fees ***well in excess of 125% of its expenses*** and excess revenues, after Board operating expenses, are turned over to the General Fund at the close of each fiscal year." [emphasis added] In collecting revenue in excess of the requisite 125 percent, the Board may have overcharged its licensees for the cost of administering the Board.

Budget reductions can be ordered as part of the budget process or after the budget has been approved. Fees, however, were established in administrative rule; thereby making it more troublesome to change because of the perceived challenge of the rulemaking process.

Board Licensees Paying For Inspections Of Other Professionals

The Board was statutorily required to provide inspectional services to the Boards of Medicine, Podiatry, Veterinary Medicine, Optometry, Dental Examiners, and Nursing. Starting in SFY 2014, these boards were no longer required to enter into agreements with the Board of Pharmacy and pay for inspections. As a result, the Board of Pharmacy collected revenue only from its license fees to cover its expenditures, including for inspections of other health care practitioners.

Recommendation:

The Board should periodically review and, if necessary, adjust its fees to ensure it is charging a fair amount to administer the Board.

Auditee Response:

We concur. The Board agrees that we have been above 125 percent for the last 5 years. However, this is often a result of Executive Orders that freeze purchases and out of state travel. The Board has tried to maintain a responsible budget and charge reasonable fees that allow us to meet our needs. At times we have been unable to replace cars that should be replaced, unable to attend out of state conferences and cancel the services of consultants to aid with rule writing, all things that we planned and budgeted for.

BOARD OPERATIONS

A performance measurement system allows efficient and effective management by assessing whether an agency's activities are achieving its mission and producing desired results. Performance measurement ties activities to goals supporting the agency's mission, compares actual performance to pre-established targets, allows agencies to identify their strengths and weaknesses, and actively monitors performance over time.

The Board had not established a performance measurement system to demonstrate, or aid in determining, whether inspection activity was helping it achieve its mission. The lack of formal goals and objectives, reliable data, and periodic analysis made measurement problematic. Reliable information is necessary to help an agency identify if it is meeting its goals, where strengths and weaknesses exist, and how operations could be improved. Without such a system, there was no assurance practices such as: not tracking inspections and violations issued to individual pharmacists, inspecting only in-State licensees, and requiring annual routine inspections of all in-State licensed entities, allowed the Board to appropriately focus on areas of higher public risk.

Observation No. 6

Establish Performance Goals And Measurements

The Board lacked a system to measure inspection performance against goals and objectives. Additionally, the Board did not analyze inspection data to ensure resources were utilized efficiently and effectively. Instead, the Board received basic inspection output data to remain apprised of inspections. A performance measurement system should include goals and objectives linked to a clear mission, as well as relevant measures to compare against actual performance.

While the Board established a schedule of annual inspections for all of its licensees and inspections of other boards' licensees every three to five years, there were no clear connections between these expectations and day-to-day activities. The Chief Compliance Inspector provided monthly lists of forthcoming inspections to each Compliance Inspector, which were based on the date of the licensee's previous inspection. Monthly reports to the chief inspector from inspectors outlined activities and the number of inspections completed, but did not include inspection results such as the number of licensees who were in compliance with all requirements, the number or type of issues found during inspections, the type of violations issued, or whether these issues resulted in further action against the licensee. Comparing this information to established goals could help inspectors and the Board better target inspections, as well as allow the Board to monitor opportunities to improve licensee compliance with statutory or other requirements. For instance, tracking and comparing the percent of licensees in compliance with specific statutory or other requirements over several years could help the Board determine whether inspections should occur more frequently, less frequently, or remain the same.

Additionally, while the Board counts the number of inspections conducted and violations issued, it did not measure cost per inspection. Determining how much time it takes to conduct inspections of each type of facility (including preparation, travel, onsite work, and follow-up) could help the Board to assess the efficiency of the inspection process.

Recommendation:

We recommend the Board establish an inspection performance measurement system by improving its utilization of data collected during the inspection process, as well as develop and compare goals to actual performance in order to improve the effectiveness and efficiency of inspections.

Auditee Response:

We concur. The Board agrees that establishing performance measures will be beneficial to improve the effectiveness and efficiency of inspections.

Observation No. 7

Improve Reliability Of Agency Inspection Data

The Board lacked a complete, accurate, and reliable inspection database. In addition, inspectors did not receive formal training or written guidance to effectively use the database. Inspectional activities cannot be efficiently and effectively monitored without reliable data for management to make informed decisions and evaluate the agency's performance in achieving key objectives and addressing risk.

Prior Finding

In our 2008 LBA financial audit, we recommended the Board establish a system to capture and report its inspectional activities sufficient to effectively monitor and manage those activities to reasonably ensure it is utilizing its inspectional resources in an efficient and effective manner. The Board concurred with our finding, stating the Department of Information Technology was in the process of replacing the antiquated software with new licensing software, which included inspectional applications. The Board reportedly experienced problems implementing the new software, causing the Board to revert to its antiquated database. The Board continued to rely on Microsoft Access, Excel, and Word files to capture inspectional activity, and to record results in two Access databases which were created in 1998 and 2003. We found the databases still contained numerous deficiencies which were not addressed.

Continued Weakness

The Board lacked written policies and procedures, program documentation, and training which put its data collection at risk for errors, omissions, and losses. Consequently, there was an indeterminate amount of lost inspection data regarding nurse practitioners and eight months of

retail inspections. The chief inspector could not specify the cause for the data loss or when it occurred, but cited possible errors in performing data updates and system queries. Over time, the chief inspector tried to mitigate the risk of erasing data by performing all updates to the database, limiting inspector access, and creating a backup.

Additionally, inspectors reported difficulty with locating and maintaining updated data for licensed practitioners within the State. The Board recommended other boards' licensees receive an inspection every three to five years. However, we found the database was missing inspection data for 1,845 practitioners. The chief inspector speculated the entries were either never updated or the practitioners had never been inspected.

Our review of a non-statistical sample of 51 SFY 2013 retail inspection reports found other concerns regarding the reliability of the database, including:

- eight of 51 (16 percent) inspections contained at least one duplicate entry;
- 12 of 51 (24 percent) paper reports were missing a corresponding electronic entry; and
- 20 of 39 (51 percent) applicable electronic entries lacked either appropriate notation of a repeat deficiency, additional handwritten notes, or had other minor field omissions.

Online Licensing Software

During the audit period, the administratively attached Department of Health and Human Services boards were instructed to transition to an updated version of the online licensing software by calendar year 2016, which again reportedly included inspection capabilities. The Board of Pharmacy was not familiar with the details regarding the capabilities, compatibility, training, and application of the online software. It was not known if the functionality of the new software would replace the need for the aforementioned databases.

Recommendations:

We recommend the Board:

- **establish a system to capture and report its inspectional activities sufficient to effectively monitor and manage those activities to reasonably ensure it is utilizing its inspectional resources in an efficient and effective manner;**
- **assess the inspection capabilities of the online licensing software, prior to implementation, to determine the best course of action in order to meet the needs of the inspection process, as well as provide formal training and properly maintain whichever programs the Board deems appropriate; and**
- **collaborate with other boards receiving inspection services to establish a process to effectively and efficiently identify practitioners who have been inspected and those who are in need of inspection.**

Auditee Response:

We concur. The Board agrees that having a reliable system to track inspectional activities is important. Additionally, meeting with DoIT and researching other inspectional software options is important to make sure we end up with a system that meets our needs is beneficial. Working collaboratively with the other Boards receiving inspectional services from us to identify practitioners in need of inspection is also important to making sure we meet our goals.

Observation No. 8

Establish A Process To Track Violations Related To Individual Pharmacists

The Board did not have a process to identify whether the approximately 2,500 pharmacists licensed to practice pharmacy in New Hampshire at the end of the audit period had been inspected, nor did it have a process to track violations issued to a specific pharmacist if one was issued during a pharmacy inspection. As a result, the Board could not ensure all pharmacists underwent an inspection, nor could it ensure problems with individual pharmacists were proactively identified and corrected in a timely manner.

State law required the Board to adopt administrative rules relative to procedures for inspecting its licensees. Statutes required a person to be licensed in order to practice pharmacy in New Hampshire; therefore, pharmacists were considered licensees of the Board and should be subject to inspection requirements. However, the Board's inspection process was primarily facility-based and not focused on individual pharmacists. While inspectors ensured all pharmacists working at a pharmacy were licensed, there was no mechanism to track which of the approximately 2,500 pharmacists had been reviewed and which had not. According to the Board, individual pharmacists were in essence "inspected" when the pharmacy where they were employed was inspected. However, we found violations issued during the course of an inspection, even if traceable to an individual pharmacist, were usually addressed to the pharmacist-in-charge (PIC) and not to individual pharmacists working under their supervision. Without a process to track inspections and violations issued to individual pharmacists, the Board risked being unable to detect and identify pharmacists who may require remedial or corrective action.

The Board was also not made aware of the types of violations issued to its licensees or which licensees received violations. Information such as the violation type, types of deficiencies identified during inspections, and pharmacies which were issued a violation were not shared with the Board, hindering it from proactively identifying areas where it can direct remedial or corrective actions. According to Board members, the focus on the PIC was appropriate as State law placed the responsibility for pharmacy operations on the PIC and the Board could identify issues with individual pharmacists' practices if the pharmacist was the subject of a complaint.

We note inspectors were also responsible for conducting inspections of practitioners licensed by other regulatory boards (e.g., physicians, veterinarians, and dentists). If the inspector issued a violation, the board licensing the practitioner received a letter outlining the nature of the

violation, ensuring the licensing board was made aware a violation had been issued. However, the Board did not have a similar process for tracking violations issued to its own licensees.

Recommendation:

We recommend the Board develop procedures to track violations related to individual pharmacists.

Auditee Response:

We concur. We agree that we should be able to track all violations. Violations are issued to the individual responsible at the identified location. Board rules outline that the Pharmacist-In-Charge (PIC) is responsible for the practice of pharmacy at the store where he/she has agreed to be the PIC. We will look into the feasibility of identifying the individual pharmacist responsible for the actions that led to a violation being issued and determine if this could be done.

Individual Pharmacists have been "inspected" each year during the initial license and renewal process. During the initial license period applicants are screened to make sure they meet all of the requirements for licensure. Additionally, during the renewal period they are screened to make sure they meet the requirements for renewal. Each year 10 – 20 percent of pharmacists that have renewed their license are audited to verify they met the continuing education requirement that was sworn to under penalty of perjury on the renewal application.

Observation No. 9

Ensure Out-Of-State Licensees Are Inspected Similarly To In-State Licensees

The Board did not have a process to ensure its over 1,947 out-of-State licensees received inspections similar to those it conducted of New Hampshire-based entities. State law required the Board to adopt rules relative to procedures for inspecting its licensees. According to the Board, it was advised by the Joint Legislative Committee on Administrative Rules legal staff that out-of-State entities, such as mail-order pharmacies (including those shipping compounded medications into the State), manufacturers, wholesalers, and distributors, were outside of the Board's jurisdiction and not subject to Board inspection procedures. However, statutes and administrative rules appeared to place licensed out-of-State entities within the jurisdiction of the Board; thereby establishing a requirement for the Board to adopt in administrative rule, procedures for ensuring these entities were inspected regardless of where domiciled.

Requiring inspections for out-of-state licensees is a practice commonly recognized by the National Association of Boards of Pharmacy (NABP). The NABP's *Model State Pharmacy Act And Model Rules Of The NABP* (August 2014) suggested nonresident (i.e., out-of-state) pharmacy inspections should be performed by the pharmacy board of the domiciliary state if that board's "inspection is substantially equivalent to inspection in this State." Of four other states' inspection reports we reviewed, we found the content included many requirements similar to New Hampshire. However, we found processes for some of the northeast states we contacted

were less stringent than New Hampshire's inspection processes. The NABP was in the process of compiling a uniform inspection format which states could adopt, providing greater consistency in inspections among the states. In January 2015, the NABP released a blueprint for sterile compounding inspections.

Submitting Inspection Reports With License Applications

The Board required mail-order pharmacies to submit a copy of an inspection report conducted within the previous 18 months when applying for, or renewing, a license. However, it only required out-of-State manufacturers, distributors, and wholesalers to submit their "most recent" inspection report when applying for a license, without any limitation on the date of the most recent inspection.

Frequency Of Inspections

New Hampshire established a schedule of annual inspections of in-State licensees; however, we found some northeast states we contacted did not conduct annual inspections and did not inspect certain types of facilities inspected in New Hampshire.

- One northeast state with nine pharmacies and 17 manufacturers or distributors licensed to send products into New Hampshire reported conducting inspections of its in-state retail pharmacies every four years and did not have a routine inspection schedule for manufacturers.
- One northeast state with seven pharmacies and four manufacturers or distributors licensed in New Hampshire conducted its inspections every two years.
- Another northeast state with 95 manufacturers or distributors licensed in New Hampshire reported it did not conduct inspections of manufacturers or distributors domiciled in its state.
- Another state reported it did not conduct inspections on manufacturers, wholesalers, or distributors as there were none domiciled in that state. However we found seven manufacturers or distributors reporting they were domiciled in that state and holding licenses in New Hampshire as of January 2015.

Sterile And Non-Sterile Compounding Inspections

New Hampshire Board inspectors used three separate inspection formats depending on whether a pharmacy performed sterile compounding, non-sterile compounding, or if the pharmacy was not engaged in compounding. If a pharmacy engaged in all three activities, all three inspection formats were used. The retail pharmacy inspection format reviewed general pharmacy operations including general facility requirements, pharmacy security, and security over controlled and non-controlled drugs; while the non-sterile compounding inspection formats included a review of 12 elements pertaining to the compounding environment, 11 quality control elements, and 16 elements pertaining to compounding procedures. The sterile compounding inspection format included 36 quality control elements, 50 elements pertaining to the compounding environment, 23 pertaining to compounding procedures, and an additional 18 elements pertaining to engineering controls.

Three northeast states we surveyed reported using the same process to inspect pharmacies which performed compounding as they used for pharmacies which did not compound products. These states combined had 55 pharmacies licensed to send products into the State. The Board's tracking systems were unable to easily identify which out-of-State pharmacies or manufacturers compounded products to be shipped into New Hampshire, so we were unable to determine how many of these pharmacies compound products. However, a review of information in the Board's licensing database showed at least nine pharmacies licensed in New Hampshire may perform some compounding.

Recommendations:

We recommend the Board establish procedures to ensure out-of-State licensees are inspected similar to in-State licensees.

We also recommend the Legislature consider whether existing laws give the Board adequate authority to regulate out-of-State entities.

Auditee Response:

We concur in part. The Board agrees that better oversight is necessary to ensure non-resident pharmacies (mail-order pharmacies) are following New Hampshire laws and rules when doing business in NH. Due to statutory constraints non-resident licensees need only have a license in good standing in their domiciled state to qualify for a license in NH (RSA 318:37 II(b)). The expectation is they will follow all laws and rules in their home state and NH Inspectors would not be qualified to judge whether another state's requirements are being met. In NH the pharmacist in charge (PIC) is responsible for making sure all laws and rules are complied with. Two years ago the Board began to address the need for more oversight by amending the Ph 900 rules regarding out of state requirements. RSA 318:37 II (c) allows the Board to request information from the applicant. The Board drafted rules that would require the PIC in a non-resident pharmacy be licensed in NH which would give the Board access to a responsible party at each location who would be familiar with NH laws and rules and whom the Board could have redress to if an issue arose. We also began to require inspection reports obtained within 18 months of licensure or renewal, GAP analysis, equipment testing, etc. be submitted to the Board for review before a license would be granted. At the JLCAR hearing on these proposed rules we were challenged and lost our request for the PIC requirement on the basis of not having the statutory authority to add this requirement. We were successful in implementing the other requirements and now use those as a basis for issuing or renewing a license. We also have HB 141 working its way through the system which would give the Board broader rule-making authority to accomplish these types of changes. The Board currently reviews each of these licenses on an individual basis before renewing a license. This was not done during the period of time this audit was reviewing.

Observation No. 10

Consider A Risk-Based Inspection Schedule

The Board established a schedule of annual routine inspections of in-State retail pharmacies, hospital pharmacies, manufacturers, distributors, wholesalers, limited retail drug distributors, and public health and methadone clinics, as well as a schedule of every three to five years for other boards' licensees. However, the schedule did not consider, nor did it allow, the flexibility to prioritize inspections using a risk-based approach.

While Board members received a monthly report showing the number of inspections conducted and violations issued during the prior month, it was not made aware of the types of violations and deficiencies found during inspections. Without detailed information on the types of violations issued or deficiencies identified, the Board was not kept apprised of problems, potential risks, or other trends in the pharmacy industry, nor could it use this information to improve the inspection process.

Using a risk-based approach to scheduling is considered a better practice for regulatory agencies, and would allow the Board to focus more resources and effort to facilities and practitioners who pose a greater risk to public safety.

Inspections For Other Entities

In addition to inspecting its own licensees, statute required the Board inspect prescription drug storage, labeling, distribution, and disposal practices of all physicians, veterinarians, dentists, advanced registered nurse practitioners, physician assistants, and clinics under contract with the Department of Health and Human Services, as well as agricultural, technical, or industrial users of prescription drugs. These include public health and methadone clinics, research laboratories, colleges and universities providing technical training (e.g., nursing schools), and farmers using prescription medications to treat livestock. State law also required the Board provide inspectional services to the Boards of Podiatry and Optometry.

At the end of the audit period, there were approximately 385 in-State Board-licensed entities, 22 public health clinics, and eight methadone clinics subject to inspection. While the Board updated its list of practitioners as it came across them during routine inspections of medical, dental, and veterinary practices, it did not have a complete listing of practitioners subject to inspection or have procedures for obtaining such information. Nor did the Board have a list of colleges, research facilities, or farms possessing prescription drugs and devices. As a result, the Board had never inspected technical, agricultural, or industrial users of prescription drugs.

The number of entities required to be inspected, combined with the Board's focus on annual routine pharmacy inspections did not provide flexibility for higher risk entities to be inspected more than once per year. For example, entities were required to respond with written corrective actions in response to inspector-issued violations arising from routine annual inspections. However, there was no formal follow-up process between annual routine inspections to ensure violations were actually rectified. Entities with inspector-identified areas needing improvement

generally were not inspected again until at least a year later, increasing the risk deficiencies could continue without being corrected, as we observed during a retail pharmacy inspection. Similarly, other boards' licensees who received routine inspections every three to five years could pose a greater risk as inspectors may not check to see if a violation or deficiency has been corrected until up to five years later.

Flexibility In Scheduling Inspections Lacking

Board members and staff we interviewed stated the annual inspection cycle for some types of facilities is appropriate, but the Board could benefit from more flexibility in scheduling inspections. For example, there may be opportunities to leverage some inspections conducted by federal agencies of some licensed entities. In the past, when the Board employed more inspectors than it did during the majority of the audit period, the Board's requirement for inspecting licensed entities varied. For instance, the Board established an annual inspection cycle for hospitals, but requested retail pharmacies be inspected twice a year. A self-inspection retail form was used when Board staffing was not adequate to meet the goal of two onsite inspections. The cycle was changed to eliminate the second yearly inspection, which negated the need for the self-inspection. Other northeast states' boards of pharmacy conducted inspections ranging from once a year to once every four years for retail pharmacies. The NABP's model rules suggested routine inspection of retail pharmacies be conducted at least once every two years and once a year for facilities that compound sterile pharmaceuticals.

Recommendations:

We recommend the Board:

- **establish policies and procedures for scheduling and performing inspections to best respond to areas of higher public risk;**
- **work with other boards to identify and regularly update its list of practitioners subject to inspection;**
- **develop a process for identifying and compiling a list of agricultural, technical, and industrial users of prescription drugs; and**
- **establish policies and procedures for formally reviewing, monitoring, and communicating aggregate results of inspections to Board members so information which could potentially be used to improve the inspection process are available.**

Auditee Response:

We concur. As the Board develops rules for inspection and updates the Compliance Policy Manual in accordance with the rules, the Board will also look at a risk based inspection schedule. Also, as policy and procedures are updated and performance measures are established as recommended in Observation No. 6, the Board will work on establishing policies to communicate aggregate inspection results to the Board so information can be used to improve the inspection process. We will work with the other Boards to identify practitioners that are subject to inspection. The Board will also look into the feasibility of identifying who the

agricultural, technical, and industrial users of prescription drugs are so that they can be inspected.

APPENDIX A
OBJECTIVE, SCOPE, AND METHODOLOGY

Objective And Scope

In April 2014, the Fiscal Committee of the General Court approved a joint Legislative Performance Audit and Oversight Committee recommendation to conduct a performance audit of inspections conducted by the Board of Pharmacy (Board). Our entrance conference with the Board was in October 2014. Our audit sought to answer the following question:

Did the Board efficiently and effectively inspect facilities and practitioners that handle pharmaceuticals during State fiscal years (SFY) 2013 and 2014?

This audit focused on the Board inspection activities of licensed pharmaceutical operations and professions and not on other Board functions such as licensing or investigations.

Methodology

To gain an understanding of operations and legal requirements, management, the internal control environment, and procedures for Board inspections, we performed the following steps:

- Reviewed relevant State laws and administrative rules, the Board's organization charts, policy documents, data, job descriptions, forms, and website.
- Compared inspection forms with legal requirements.
- Reviewed similar audits from the federal government and other states, congressional report on states' oversight of compounding, and a national survey of pharmacy law.
- Reviewed industry standards, inspections reports from other states, and model rules for boards of pharmacy.
- Inquired about inspections in six northeast states through telephone contacts with pharmacy compliance inspectors.
- Interviewed Board members, Compliance Inspectors, and Department of Health and Human Services personnel.
- Observed inspections conducted by all of the Board inspectors.
- Sought opinions from regulatory boards and associations representing practitioners receiving inspections from the Board.

Review Of Inspection Files

We reviewed a judgmental sample of 121 inspection reports to determine whether: 1) inspections conformed to Board operating procedures, 2) inspection forms were completed, and 3) violations were addressed. Some facilities we reviewed received more than one inspection during our audit period; we included all inspections for that facility occurring during our audit period in our sample. Additionally, some facilities were subjected to more than one type of inspection. We included each type of inspection in our sample. For instance, a hospital pharmacy which

compounded medication for patients (e.g., a hospital oncology department) would receive both an inspection of overall hospital pharmacy operations, as well as an inspection of its compounding facility. This hospital would be included in both our hospital pharmacy sample and our compounding pharmacy sample. Our sample of inspection reports included:

- fifty-one reports on 33 retail pharmacies, including five newly opened pharmacies;
- five wholesalers, distributors, and manufacturers;
- six hospitals;
- six public health clinics;
- ten compounding pharmacies; and
- forty three non-Board licensed facilities with 93 practitioners (e.g., physicians, dentists, and veterinarians).

The reports were checked for completeness, repeat deficiencies, and if applicable, issuance of violations, responses, and follow-up actions. Because we used a non-statistical sample, results cannot be projected to the entire population of inspection files.

Data Reliability

We assessed the reliability of Board inspection databases as part of our file review and determined we could not rely on the data for audit purposes.

APPENDIX B
AGENCY RESPONSE TO AUDIT

STATE OF NEW HAMPSHIRE
BOARD OF PHARMACY
121 South Fruit Street
Concord, NH 03301-2412
Phone: 603-271-2350 | Fax: 603-271-2856

Board Members
Charles J. Fanaras, R.Ph. - President
Robert J. Stout, R.Ph. - Vice President
Helen C. Pervanas, PharmD, R.Ph - Secretary
Michael D. Bullek, R.Ph. - Treasurer
John R. Genovese, R.Ph. - Member
Gary J. Merchant, R.Ph., M.B.A. - Member
Heather C. Shamburger - Public Member

Board Staff
Margaret A. Clifford, R.Ph. — *Chief Compliance Investigator*
Robert D. Elder, R.Ph. — *Compliance Investigator*
James. M. Queenan, R.Ph. — *Compliance Investigator*
Brenda J. Langis — *Licensing Assistant*
Jason R. Richard — *Business Administrator*
Paula L. Smykil — *License Clerk*

Website: www.nh.gov/pharmacy
E-Mail: pharmacy.board@nh.gov

March 18, 2015

Dear Fiscal Committee Members,

I just wanted to take a few moments to comment on the recently completed audit of the Compliance Unit at the Board of Pharmacy. I was appointed to the Board in September 2012 and this was the first audit that I have been a part of since my appointment.

The audit team appeared before the Board in early winter to explain their task and how they would execute the audit. Throughout the process the communication was excellent and they solicited comments from the entire Board staff and all the Commissioners. I personally met with Jay and Paige for almost 3 hours to discuss many of their findings and they gave consideration to my thoughts both as a Commissioner and also how my interactions were with Compliance during my 40 years in community practice. I found the debate to be thought-provoking, informative and a great learning experience. I hope that I was able to educate them as well to the many changing challenges we face today.

The Board recently received the waiver to hire an Executive Secretary. This position has been vacant for 15 months and this position is crucial to the success of the Board both with its license base as well as in the legislative arena. We are anxious to have this position filled and positively address the many great ideas uncovered during this audit.

We had our exit interview with the audit team today at their office. Four of the Commissioners were present and as through this entire process we discussed the report in its entirety and made a few modest adjustments. As I have seen through the entire process the auditors were willing to listen, compromise and suggest mutually agreeable solutions to a few minor details.

I wanted to compliment the audit team on the way they conducted the entire process. When the audit was announced I was skeptical of the motives for the audit. At the end of the audit I was clearly wrong in my perception. The team was thorough and fair. Many of the findings we completely agree on and other recommendations they made were well thought out and appreciated.

Sincerely,

Robert J Stout, RPh
Vice President

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STATE OF NEW HAMPSHIRE
BOARD OF PHARMACY
INSPECTIONS

APPENDIX C
STATUS OF PRIOR AUDIT FINDINGS

The following is a summary of the status of observations applicable to this performance audit found in the *Board of Pharmacy Financial Audit Report For The Six Months Ended December 31, 2008*. A copy of the prior audit can be obtained from the Office of Legislative Budget Assistant, Audit Division, 107 North Main Street, State House Room 102, Concord, NH 03301-4906 or online at our website http://www.gencourt.state.nh.us/LBA/audit.aspx.

Status Key

Fully Resolved	● ● ●
Substantially Resolved	● ● ○
Partially Resolved	● ○ ○
Unresolved	○ ○ ○

No.	Title	Status
1.	Organizational Structure Should Be Clarified	● ● ○
7.	Scope Of Inspectional Efforts Should Be Reviewed	○ ○ ○
8	System To Capture And Report Inspectional Activity Should Be Established	○ ○ ○
12.	Policies And Procedures For Promoting The Licensing Of Out-Of-State Entities Should Be Established	● ○ ○
17.	Board Administrative Rules Should Be Reviewed	● ● ○
19.	Biennial Reports Should Be Filed	● ○ ○

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