STATE OF NEW HAMPSHIRE
PHARMACY BOARD
CONTROLLED DRUG PRESCRIPTION
HEALTH AND SAFETY PROGRAM

PERFORMANCE AUDIT REPORT
DECEMBER 2017

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To The Fiscal Committee Of The General Court:

We conducted a performance audit of the Pharmacy Board's Controlled Drug Prescription Health and Safety Program, commonly called the Prescription Drug Monitoring Program or PDMP, to address a requirement of State law that we "conduct a performance audit of the program on or before December 31, 2017 for the use of the speaker of the house of representatives, the president of the senate, and the governor, in evaluating the effectiveness of the program… including but not limited to changes in the number and type of drug-related deaths, the number of instances of drug abuse, and the number of instances of overprescribing." 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 objectives.

The purpose of the audit was to determine how effective the PDMP was through State fiscal year 2017.

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December 2017

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PHARMACY BOARD
CONTROLLED DRUG PRESCRIPTION HEALTH AND SAFETY PROGRAM

TABLE OF CONTENTS

Page

LIST OF FIGURES

ABBREVIATIONS AND GLOSSARY OF TERMS

Abuse	The use of controlled drugs solely for their stimulant, depressant, or hallucinogenic effect and not as a therapeutic agent recommended by a practitioner in the course of medical treatment.
Act	*Controlled Drug Act* (RSA 318-B)
2008 audit	*Board of Pharmacy Financial Audit Report For The Six Months Ended December 31, 2008*, June 2009
2015 audit	*Board of Pharmacy Inspections Performance Audit Report*, May 2015
Board	Pharmacy Board
Commission	Governor's Commission On Alcohol And Drug Abuse Prevention, Intervention, And Treatment
Controlled Drug	Any drug or substance categorized into one of five schedules by the federal Drug Enforcement Administration based on their potential for abuse or addiction, and scheduled according to State law and rules adopted by the Department of Health and Human Services. • schedule I, listing substances with high potential for abuse and lacking accepted medical use or safe medical supervision (e.g., heroin); • schedule II, listing substances with accepted medical use and high potential for abuse and dependence (e.g., cocaine, fentanyl, amphetamine); • schedule III, listing substances with accepted medical use and low to moderate potential for abuse and dependence (e.g., low-dose codeine, anabolic steroids); • schedule IV, listing substances with accepted medical use and low potential for abuse (e.g., diazepam, alprazolam); and • schedule V, listing substances with accepted medical use, and the least potential for abuse (e.g., cough preparations with low-dose codeine). Controlled drugs are a subset of prescription drugs and of drugs and substances generally.
Council	Controlled Drug Prescription Health And Safety Program Advisory Council
CY	Calendar Year
DEA	U.S. Drug Enforcement Administration
DHHS	Department Of Health And Human Services
Dispenser	A person lawfully authorized to deliver a schedule II through IV controlled drug.
Doctor Shopping	An unlawful act in which an individual seeks controlled drugs or prescriptions for controlled drugs from multiple prescribers or dispensers for abuse or diversion.
DoIT	Department Of Information Technology

ABBREVIATIONS AND GLOSSARY OF TERMS (CONTINUED)

DOJ	Department Of Justice
Drug	Articles or components that are: recognized in an official formulary of medicines that may be prescribed; intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; and intended to affect the structure or any function of the body. Often used interchangeably with substance but under State law is a subset of substance. All drugs are substances, but not all substances are drugs.
Memorandum	*Attorney General's Memorandum On New Hampshire's Right-to-Know Law, RSA 91-A*
NIU	Narcotics And Investigations Unit
OCME	Office Of The Chief Medical Examiner
OPLC	Office Of Professional Licensure And Certification
PDMP	Prescription Drug Monitoring Program
Prescriber	A person lawfully authorized to prescribe a schedule II through IV controlled drug.
Prescription	An oral, written, facsimile, or electronically transmitted order for any controlled drug or preparation issued by a licensed practitioner to be compounded and dispensed by a pharmacist and delivered to a patient for a medicinal or therapeutic purpose arising from a practitioner-patient relationship.
Prescription Drug	A drug delivered pursuant to a prescription. A subset of drugs, generally, and broader in meaning than a controlled drug.
SFY	State Fiscal Year
Substance	Something deemed harmful and usually subject to restriction, such as alcohol or drugs whose use is illicit. Broader in meaning than drug, prescription drug, or controlled drug.

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STATE OF NEW HAMPSHIRE
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EXECUTIVE SUMMARY

The Controlled Drug Prescription Health and Safety Program, commonly called the Prescription Drug Monitoring Program (PDMP), was established in June 2012 to help address the abuse, misuse, and diversion of controlled drugs. We found the PDMP remained at an initial stage of maturity through State fiscal year (SFY) 2017, due to inadequate planning and implementation. The Pharmacy Board (Board), the agency responsible for the PDMP, lacked a strategy to guide the PDMP from implementation, through full and complete operationalization, to achieving optimization. The Controlled Drug Prescription Health and Safety Program Advisory Council (Council) was intended to assist the Board with implementing and operating the PDMP. However, the Council never developed the core criteria necessary for programmatic effect to be realized, including criteria for reviewing PDMP data, reporting matters for further investigation, and notifying practitioners of concerns. Furthermore, the Council did not collect data on user satisfaction, impact on prescribing patterns, impact of referrals, or other relevant measures of PDMP outcomes and impact.

Neither body examined expected PDMP outcomes and effectiveness measures framed in State law for validity or practicality. Had relevant research and data been reviewed, the Board would likely have found: 1) expected outcomes and effectiveness measures in State law were inconsistently demonstrated by empirical research to be valid expectations of the PDMP and 2) complex measurement systems were required to quantify specific PDMP effects. Subsequently, the Board could have pursued legislative changes to focus the PDMP on viable outcomes using practical measures. Thereupon, the Board could have built systems to measure outputs and performance at the process level and aggregated performance into an overall programmatic effect. Through SFY 2017, we found no empirically-demonstrated PDMP outcomes or effects.

The systems and subsystems necessary for effective operations were either mis-oriented, poorly structured, or altogether absent, and significant management controls were not implemented. The PDMP was implemented without relevant data collection, reporting mechanisms and cycles, or formats necessary to effectively communicate PDMP operation and performance internally and externally. Basic definitions, criteria, and thresholds could have facilitated performance measurement but were not developed. Basic program intent was compromised by the lack of criteria and quantified thresholds, which were instrumental to understanding PDMP effectiveness in identifying cases of potential abuse, misuse, or violation of professional standards.

PDMP-related functions included registration, waivers, extensions, uploading, querying, criteria and thresholds indicating potential issues and related reporting, staffing, inspections, investigations, sanctions and discipline, education and training, and complaints. Each constituted relevant management data streams the Board could have utilized to systematically understand and refine PDMP operations. None were consistently tracked, nor was progress made towards achieving outcomes envisioned in State law. Through SFY 2017, the correct number of practitioners required to register with the PDMP was not established. Responsibility for disciplining noncompliance was distributed to individual regulatory boards, and there were no indications Board staff, the Council, or the Board attempted to measure compliance or systematically work with regulatory boards to enforce requirements holistically.

PDMP data was incomplete and of unknown quality, the extent of which were never established. A system to control and improve the quality of data was never created, even though erroneous and incomplete data could nullify the PDMP's potential value and prevent accurate measurement of some outputs and outcomes. Furthermore, the large volume of PDMP data essentially went unanalyzed and had not been systematically used to create knowledge of PDMP outcomes and effectiveness. Alone, unanalyzed PDMP data could not demonstrate any outcome or effect. However, the Board relied primarily on inconsistent and irregular reporting of raw output data and anecdotal information on outcomes, which were often based on arbitrary federal thresholds. The Board never translated any of this data into outcomes or effectiveness-related expectations of the PDMP articulated in State law. Without appropriate context or analysis, the Board's reports left consumers to infer the data demonstrated something relevant to the PDMP, when other factors likely had some effect on observed changes in outputs. To actually develop an analysis of the PDMP's effect, Board staff would likely need additional analytical capabilities, as well as to obtain and analyze output and outcome data from several State and law enforcement agencies in combination with raw PDMP data and anecdotal survey information.

The roles and responsibilities of PDMP stakeholders, especially those related to enforcement, were ill-defined, and few efforts were made to provide clarity. Integration across regulatory boards overseeing practitioners subject to PDMP registration and utilization requirements was inadequate, bordering on nonexistent. The value and utility of the PDMP was undermined by the lack of a functioning system of controls to ensure the efforts of all regulatory boards with PDMP responsibilities were integrated to achieve outcomes. The Board also did not formally clarify confusion surrounding when and how law enforcement officials could access or receive PDMP information, formally clarify who met and did not meet the definition of law enforcement, or reconcile the prohibition on direct law enforcement access to the PDMP database with the level of access necessary to achieve certain outcomes. These inadequacies contributed to limited enforcement of PDMP requirements through SFY 2017, which inhibited the achievement of statutorily-intended outcomes related to controlled drug abuse, misuse, diversion, and prescribing practices.

The Board did not include PDMP compliance in its inspection practices or consistently use PDMP data to target enforcement activities. The Board lacked systematic management control in numerous administrative areas, failing to establish a clear organizational structure, establish a records management program, or resolve prior audit findings. Some prior audit findings remained unresolved for more than nine years, and 19 of the 20 prior findings we reviewed remained unaddressed. Noncompliance with the *Financial Interest* law, the *Administrative Procedure Act*, and the Right-to-Know law was substantial, jeopardizing accountability, rendering certain Board actions and every Council action subject to legal challenge, and subjecting PDMP registrants to requirements without statutory or regulatory basis.

Importantly, the implementation and operation of the PDMP was also reportedly inhibited by staffing turnover, organizational turbulence, frequent changes in underpinning laws, and funding constraints. Addressing these limitations as well as rationalizing outcomes the PDMP could reasonably be expected to achieve within the statutory and regulatory framework, developing a coherent strategy and multi-year plan to structure PDMP development, exercising oversight, and ensuring plan execution could facilitate PDMP maturation and optimization. Eventually, PDMP effects might be quantifiable and outcomes realized.

STATE OF NEW HAMPSHIRE
PHARMACY BOARD
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RECOMMENDATION SUMMARY

Observation Number	Page	Legislative Action Required?	Recommendations	Agency Response
1	19	No	The Pharmacy Board (Board) develop definitions, criteria, and thresholds to validate relevant indicators of Prescription Drug Monitoring Program (PDMP) effectiveness; implement and refine an evidence-based approach to assess validated PDMP outcomes; develop, implement, and refine a system to empirically demonstrate PDMP outcomes; include components related to monitoring and assessing in the strategic plan; and clarify how the PDMP can be reasonably expected to affect validated outcomes, and when outcomes and effects will be expected.	Board: Concur
2	24	No	The Board formally establish doctor shopping as a PDMP outcome; select relevant and measureable outcome indicators; qualify outcomes so the PDMP is not expected to achieve unreasonable outcomes; develop standard educational materials for prescribers and dispensers on potential doctor shopping; provide initial and ongoing training and education to prescribers and dispensers; develop, implement, and refine routine reporting mechanisms through which prescribers and dispensers can report potential doctor shopping or overprescribing for further investigation; and develop methods to mitigate unintended consequences.	Board: Concur
3	30	Yes	The Board select relevant and measureable outcome indicators; qualify outcomes so the PDMP is not expected to achieve unreasonable outcomes; determine whether available data from other State agencies is amenable, or could be amenable, to assessing PDMP effectiveness; develop agreements with relevant State agencies to obtain necessary data; determine whether soliciting patient feedback is feasible and	Board: Concur

Observation Number	Page	Legislative Action Required?	Recommendations	Agency Response
3 (Continued)			cost-effective; and develop a process to connect survey results with data analysis. If the Board is unable to obtain data from other State agencies or obtain patient feedback, it should either seek legislative changes to eliminate outcomes or further qualify outcomes.	
4	38	Yes	The Board consider seeking legislative changes to eliminate the statutory outcomes of patient mortality and the number of drug deaths, and limit outcomes related to prescription drug diversion to those more plausible outcomes and practical measures and improve the detection of diversion by caretakers and individuals picking up another's prescriptions.	Board: Concur
5	48	No	The Board develop a holistic, multi-year strategy to first fully implement the PDMP and then move it towards optimization; formalize a risk-based strategy and targets, goals, performance measures, and objectives; evaluate the strategy's near-term and long-term effectiveness; include key stakeholders; assess the current contracts and Board strategic needs before potential vendor migration must occur to ensure the terms and conditions of each contract fully support attaining PDMP outcomes; and revalidate the data analytics contract with amended dates for deliverables reflecting anticipated completion of tasks.	Board: Concur
6	52	No	The Board develop and establish a performance management system; define goals, objectives, targets, and measures to evaluate effectiveness at the process, output, and outcome levels; incorporate multiple data sources into analyses; develop performance measures; routinely administer comprehensive surveys; and include performance management in its strategic plan.	Board: Concur

Observation Number	Page	Legislative Action Required?	Recommendations	Agency Response
7	56	No	The Board develop, implement, and refine criteria and thresholds defining abuse, misuse, diversion, and violation of professional standards; revise administrative rules to set quantified criteria and thresholds; discontinue issuing unsolicited reports to practitioners and regulatory boards until criteria and thresholds have been defined and adopted; provide necessary reports to regulatory boards for further investigation; and include criteria and threshold development in its strategic plan.	Board: Concur
8	59	Yes	The Board develop rules to structure and regulate the system it expects to use to address potential doctor shopping; base the threshold on statute; timely notify practitioners who may be involved in prescribing for a doctor shopper; timely provide reports to regulatory boards on practitioners identified as taking part in possible doctor shopping; track indicators of potential doctor shopping and monitor trends; regularly report on enforcement and related outcomes; discontinue ad hoc enforcement; clarify law enforcement access to PDMP information; include a doctor shopping component in its strategic plan; and, should it formally conclude the current statutory doctor-shopping threshold is outmoded or obsolete, develop an appropriate threshold and seek legislative changes to adopt it in statute. We also recommend the Board consider seeking legislative changes to clarify whether the Controlled Drug Prescription Health and Safety Program Advisory Council (Council) is to develop criteria for notifying practitioners of individuals under their care that are potentially engaged in inappropriately obtaining controlled drugs from multiple practitioners or dispensers.	Board: Concur

Observation Number	Page	Legislative Action Required?	Recommendations	Agency Response
9	63	No	The Board establish, refine, codify, and use concrete, observable, and objective measures that clearly represent PDMP performance to describe relevant inputs, processes, outputs, and outcomes; standardize periodic reporting cycles, and the format and content of reports; adopt the system in rule; and include in the strategic plan a component addressing information management.	Board: Concur
10	67	No	The Board develop policy and procedure to ensure compliance with external reporting requirements; improve sharing of non-confidential PDMP-related performance and outcome data; and include an external reporting and communications element in its strategy. Office of Professional Licensure and Certification (OPLC) management timely file the Board's biennial operations reports with the Governor and Council.	Board: Concur OPLC: Concur
11	69	Yes	The Board develop PDMP educational materials for regulatory board members; provide initial and ongoing training and education to regulatory boards; seek clarification on the classification of Board compliance inspectors and their ability to access PDMP information; incorporate oversight and enforcement requirements in rules; and include monitoring and enforcing compliance components in its strategy. We also recommend the Board clarify the enforcement authorities under its purview via rulemaking, and seek clarification from the Legislature on those outside its purview.	Board: Concur
12	75	Yes	The Board remediate the conditions leading to prior inspection management-related audit findings; establish a system to capture and report inspection activities; assess the inspection capabilities of the latest online licensing software before implementation;	Board: Concur

Observation Number	Page	Legislative Action Required?	Recommendations	Agency Response
12 (continued)			collaborate with other regulatory boards receiving inspection services to establish a process to effectively and efficiently identify all practitioners subject to Board inspection authority; fully incorporate PDMP compliance into inspection policies, procedures, and violation notices; determine if additional Legislative changes are needed to complete incorporation of PDMP compliance into inspection practices and seek necessary Legislative changes; incorporate naturopaths into inspection policies and procedures, pursue agreement with the Naturopathic Board of Examiners establishing inspection protocols, determine if additional Legislative changes are needed to complete incorporation of naturopaths into inspection practices, and seek necessary Legislative changes; track and analyze resources dedicated to inspections and investigations for other boards; and include an inspection management element in its strategy. We further recommend the Board, once it establishes a system to concretely determine the actual costs it incurs providing inspection, investigation, and other services to other regulatory boards, seek appropriate legislation to allocate those costs to each board.	
13	81	Yes	The Board develop, implement, and refine oversight mechanisms to ensure the other regulatory boards follow up on potential noncompliance; develop, implement, and refine routine reporting mechanisms for other regulatory boards to provide basic data on investigation and disciplinary outcomes; adopt oversight and reporting mechanisms in rule; establish procedures to ensure effective communication; and include a regulatory board integration component in its strategy.	Board: Concur

Observation Number	Page	Legislative Action Required?	Recommendations	Agency Response
13 (Continued)			We also recommend the Board pursue legislative changes to fully incorporate all regulatory boards whose licensees are subject to the PDMP and the Board's inspection activities.	
14	86	Yes	The Board include a law enforcement-related component in its strategy; develop, implement, and refine routine law enforcement outcome reporting mechanisms; include law enforcement effectiveness information in its annual report; develop law enforcement educational materials; ensure PDMP users are aware of the requirements and limitations related to law enforcement access; seek clarification on its investigative and enforcement authority related to crimes stemming from patient misconduct; adopt related administrative rules; and pursue legislative changes to law enforcement access to PDMP information necessary to achieve legislatively-envisioned outcomes.	Board: Concur In Part
15	92	No	The Board develop and implement a system to definitively establish the number of authorized users required and not required to register with the PDMP; formalize the designee registration process; ensure individuals required to register are, while those not eligible are removed from the PDMP; work with other regulatory boards to develop and implement a system to ensure changes to the number of authorized prescribers or licensees are reported timely, delegates are registered and de-registered timely, and undelegated use of the PDMP is identified and violations sanctioned; develop and implement a system to ensure registration compliance is enforced by other regulatory boards and compliance data are reported to the Board; and include in its strategy and plans a component related to registration management functions.	Board: Concur

Observation Number	Page	Legislative Action Required?	Recommendations	Agency Response
16	98	No	The Board define utilization outputs and outcomes, establish long-term goals and objectives, and near-term targets; limit the definition of "query" to actual queries of prescription histories to help ensure accurate data are analyzed and reported; devise and implement a system to obtain utilization data from regulatory boards; regularly survey PDMP registrants; address dispenser extension rules to ensure they accurately reflect statute; track extension compliance; remove zero reporting from submission data and ensure prescribers who identify as dispensers are included in submission data; and include utilization management elements in its strategy.	Board: Concur In Part
17	105	Yes	The Board determine what degree of quality PDMP data must achieve; develop, implement, and refine rules, policies, and procedures designed to achieve quality and timeliness standards; assess PDMP data quality and timeliness; enforce relevant requirements; ensure disclosures of PDMP data and information are appropriately qualified to convey limitations; assess structural limitations creating gaps in PDMP data and seek necessary legislative changes to create a sufficiently complete database; and include a data quality component in its strategy.	Board: Concur
18	110	No	The Board develop, implement, and refine a system to routinely assess the adequacy of third-party controls over State data; develop, implement, and refine a system to identify and monitor breaches of confidentiality by authorized and unauthorized users of the system, and track their resolution; develop, implement, and refine a system to ensure ineligible users of the system are removed timely; develop and adopt policies and procedures regarding the development of metadata and the de-identification, release, maintenance, and	Board: Concur OPLC: Concur

Observation Number	Page	Legislative Action Required?	Recommendations	Agency Response
18 (continued)			purging of information; ensure vendors are required to regularly provide public attestations on the adequacy of their confidentiality and security controls; and include in its strategy and plans components related to monitoring and assessing PDMP security and confidentiality. OPLC management supervise, coordinate, and assist the Board with rulemaking and assist the Board with maintaining the confidentiality of PDMP information, documents, and files.	
19	118	No	The Board promulgate rules detailing its organizational structure, formal and informal procedures, the course and methods of operations, and the apportionment of roles and responsibilities; ensure the Council fulfills its statutory and regulatory obligations; ensure ongoing surveillance of rule validity, related requirements, and statutory changes to avoid future noncompliance; timely remediate audit findings; and clarify the terms and conditions of its relationship, and the relationship of the Council, to the OPLC. OPLC management supervise, coordinate, and assist the Board with rule development and provide the Board and Council necessary administrative, clerical, and business processing support.	Board: Concur OPLC: Concur
20	122	No	The Board develop policy and procedure to ensure consistent and ongoing Board and Council compliance with the Right-to-Know law; ensure members receive relevant information on their duties and responsibilities as public servants; develop orientation materials for new members; ensure at least key officers of both bodies regularly attend the Department of Justice administrative law workshop; periodically	Board: Concur In Part

Observation Number	Page	Legislative Action Required?	Recommendations	Agency Response
20 (continued)			review both bodies' compliance with law and policy; and secure needed administrative, clerical, and business processing assistance. OPLC management provide the Board and Council necessary administrative, clerical, and business processing assistance to promote compliance with the Right-to-Know law.	OPLC: Concur
21	125	No	The Board comply with State law and only hold regular meetings with a quorum of eligible members physically present; develop, implement, and refine policy and procedure to ensure meetings comply with law and members are eligible to serve, and review past meeting minutes for quorum issues and seek legal counsel to determine how to ratify prior actions taken in meetings without a quorum.	Board: Concur In Part
22	127	No	The Board develop, implement, and refine policies and procedures to ensure the Council complies with law and members are both eligible to serve and the Council only holds meetings with a quorum of eligible members physically present; review past Council meeting minutes for quorum issues; and seek legal counsel to determine how to ratify prior Council actions taken in meetings without a quorum. The Board may also consider limiting the number of meetings members may miss before requesting removal and replacement by the appointing authority.	Board: Concur
23	130	No	Board and Council members comply with the requirements of the *Financial Disclosure* statute and timely complete annual statements; the Board develop, implement, and refine policy and procedure to ensure ongoing compliance; periodically review compliance; and annually submit an organizational chart of all Board and	Board: Concur

Observation Number	Page	Legislative Action Required?	Recommendations	Agency Response
23 (continued)			Council members required to file statements to the Secretary of State. OPLC management develop policy and procedures to help ensure supported regulatory bodies, including the Board and Council, receive necessary administrative and clerical support to comply with the *Financial Disclosure* statute.	OPLC: Concur
24	132	No	The Board ensure rules reflect underpinning statutes and encompass all professions subject to PDMP requirements; define relevant terms; contain all forms; ensure any requirements intended to be binding upon anyone other than the Board are adopted in rule; dispense with *Zero Report* requirements; ensure form and rule deficiencies identified in prior audits are timely remedied; and obtain necessary assistance from the OPLC. OPLC management supervise, coordinate, and assist the Board with rulemaking.	Board: Concur OPLC: Concur
25	137	No	The Board develop a records management system; control public and nonpublic records; ensure Board and Council records contain adequate and proper documentation of Board and Council policies, decisions, procedures, and transactions; seek and obtain necessary OPLC assistance; and include a related element in its strategy. OPLC management assist the Board and Council with recordkeeping and management requirements.	Board: Concur OPLC: Concur
26	140	No	The Board develop, validate, and implement policy and procedures to ensure audit recommendations are timely resolved, incorporate processes into its strategy and plans, review new and prior observations to prioritize their importance, estimate the work required to adequately address new and prior observations, develop realistic	Board: Concur In Part

Observation Number	Page	Legislative Action Required?	Recommendations	Agency Response
26 (Continued)			plans and a schedule to make needed changes, and formally and holistically integrate risk management into its strategy, plans, operations, policies, procedures, and other activities.	OPLC: Concur In Part

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EFFECTIVENESS

National-level data indicated dispensing and use of controlled drugs substantially increased each year beginning in the 1990s until calendar year (CY) 2010, with the prescribing of controlled drugs declining thereafter through at least CY 2015. Controlled drugs constituted a subset of prescription drugs and were federally scheduled by the Drug Enforcement Administration (DEA) based on medical use, potential for abuse, and probability of use resulting in dependence. To prescribe controlled drugs in New Hampshire, medical practitioners had to be authorized by the State and obtain a federal DEA registration associated with their practice in the State.

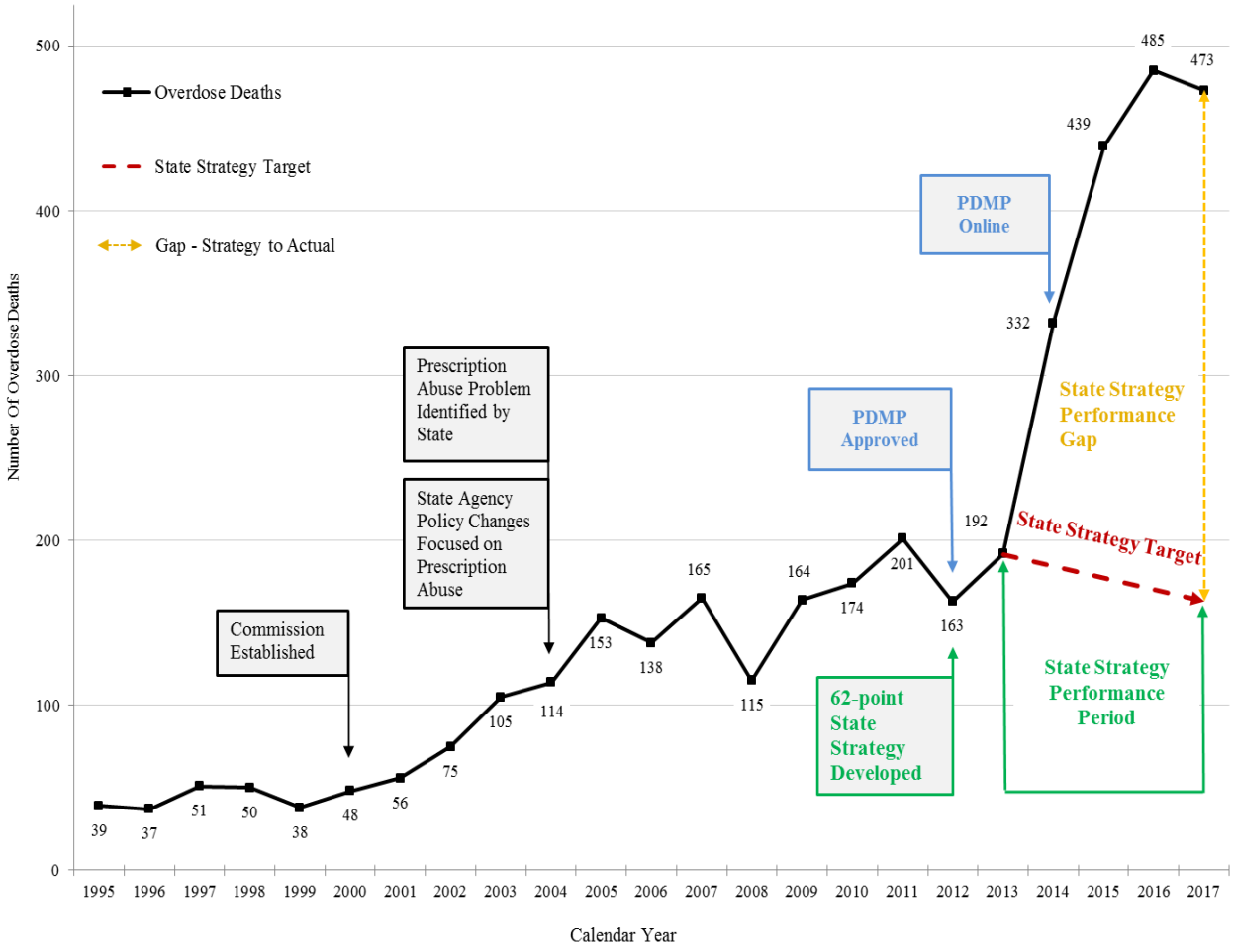
As depicted in Figure 1, overdose deaths in New Hampshire have been increasing since at least CY 1995. The illicit use of prescription drugs has increasingly contributed to the number of overdose deaths at least since CY 2004. Recently, most overdose deaths were opioid-related. Prescription synthetic opioids were originally thought to be less addictive, yet still effective for treating pain, becoming preferred among practitioners. Milligram per person use of opioid prescriptions continually increased until CY 2010. Nationally, increased deaths paralleled increased prescribing. Although national data indicated the prescribing of synthetic opioids decreased after CY 2010, deaths attributed to controlled drugs continued to rise, as did the use of and deaths attributed to illicit substances, such as heroin. As a result, opioid-related emergency department visits increased significantly, and overdoses became one of the leading causes of injury mortality and morbidity in the United States, reportedly affecting costs associated with healthcare, the criminal justice system, and lost productivity. National-level forecasts suggested opioid-related deaths would continue to increase, potentially for several years, without differentiating between licit and illicit opiates. Similar State-level longitudinal analyses and comparisons have not been published.

Initiating The Prescription Drug Monitoring Program

After approximately a decade of consideration, the State established the Controlled Drug Prescription Health and Safety Program, more commonly called the Prescription Drug Monitoring Program (PDMP), in June 2012. The PDMP was to help address the abuse, misuse, and diversion of controlled drugs in federal DEA schedules II, III, and IV, which led to deaths and unnecessary visits to health care practitioners and hospital emergency rooms. Statute required anyone authorized to prescribe a schedule II through schedule IV controlled drug, such as medical doctors, pharmacists, and any "other person licensed or otherwise permitted to prescribe, dispense, or administer a controlled drug in the course of licensed professional practice," to register with the PDMP. This requirement principally affected licensees of eight regulatory boards: the boards of Dentistry, Medicine, Nursing, Registration in Optometry, Registration in Podiatry, Veterinary Medicine, the Pharmacy Board (Board), and the Naturopathic Board of Examiners. Practitioners were required by Board rule to be registered no later than June 30, 2015.

Figure 1

Overdose Deaths[1], CY 1995 Through CY 2016 With CY 2017 Projection, Major Milestones, And State Strategy Target[2], Performance Period, And Performance Gap



Notes:

1. Overdose death data were obtained from the Office of the Chief Medical Examiner (OCME) and contained limitations as discussed in Appendix A.
2. The State strategy target was LBA-estimated and based on the State's strategy developed by the Governor's Commission on Alcohol and Drug Abuse Prevention Intervention and Treatment (Commission) to reduce drug-related deaths by 15 percent for between CY 2013 and CY 2017 the period covered by the strategy.

Source: LBA analysis of unaudited OCME data.

The PDMP's creation also followed the CY 2012 development of the State's strategy by the Commission, which included at least 62 discreet elements to address drug-related deaths. The strategy recognized no single solution to the crisis existed, but implementing a PDMP was one of the elements expected to address prevention. Reflective of federally-stated goals, the strategy contemplated: 1) reducing deaths and 2) non-medical use of prescription drugs by 15 percent over a five-year period running through CY 2017, and increasing the percentage of individuals

with substance use disorders receiving treatment with no specified target. The goal to reduce deaths appeared to be unrealized, as illustrated by the projected gap between drug-related deaths reported or projected by the OCME and the State strategy target trend depicted in Figure 1.

The PDMP was expected to be operational and provide evidence of effect to avoid sun-setting. However, the Commission's strategy did not ascribe a discreet, quantifiable outcome expectation to the PDMP, there was no articulation of the run-in time the PDMP would have before effects were identifiable, and there was no holistic PDMP outcome measurement system envisioned. Neither did the strategy ascribe quantifiable outcome expectations, run-in times, or structure holistic measurement systems for the other 61-odd elements of the State's strategy. The strategy did include a five-year goal, which might inferentially be the run-in time for the aggregate effects of each strategy element. Each element might be implemented contemporaneously with outcomes realized, or unrealized, at some undefined future date, with no way to disaggregate effective elements from under-performing elements. Consequently, innumerable confounding variables may have existed, limiting objective determination about what outcomes were expected to be attributable to the State's PDMP, and by when.

Prescription monitoring programs nationally differed in design and intent, since each was implemented in a unique environment. However, none appeared to have discernable quantifiable outcome expectations, run-in times, or holistic outcome measurement systems. Analyses of programs nationally were limited and identified mixed outcomes, with more research into program effectiveness generally recommended. As in New Hampshire, programs nationally were likely implemented in the context of other efforts aimed at affecting substance abuse, and controlling the effect of these variables was generally not accounted for in these analyses. Consequently, innumerable confounding variables may have existed in any or all of the research conducted nationally, limiting their value in objectively determining which outcomes were attributable to a prescription monitoring program in a particular environment.

The PDMP was included in the *Controlled Drug Act* (*Act*) and was amended by six subsequent chapter laws through the 2016 session, with two additional amendments adopted during the 2017 session. Certain statutory amendments were purportedly intended to better align the State's PDMP with "best practice." Notably, the outcome-like components of State law, such as changes in the number and type of drug deaths, were *not* amended.

Outcomes and Effectiveness Measures

Controlled drugs could place patients at risk for overdose, side effects, increased effect when combined with alcohol or other substances, or developing patterns of drug abuse. The PDMP was intended to provide prescribers and dispensers a means to identify and address these problems. State law established several interrelated outcomes and effectiveness measures. By providing secure access to information on patients' controlled drug prescription histories, the PDMP was expected to:

- create a greater sense of safety, security, and comfort in the healthcare practitioner-patient relationship when controlled drugs were prescribed, but State law provided no explicit effectiveness measures or potential indicators for this outcome;

- help practitioners provide better care to patients with legitimate needs for controlled drugs and improve medical treatment, but State law provided no explicit effectiveness measures or potential indicators for this outcome although effectiveness could be evaluated, in part, by changes in the number of instances of overprescribing;

- identify health practitioners fraudulently prescribing controlled drugs and adding to prescription drug abuse, with effectiveness evaluated, in part, by changes in the number of instances of overprescribing;

- reduce patient morbidity, or the rate of disease, associated with controlled drugs, with effectiveness evaluated, in part, by changes in the number of instances of drug abuse and changes in the number of instances of overprescribing; and

- reduce patient mortality, or the rate of death, associated with controlled drugs with effectiveness evaluated, in part, by changes in the number and types of drug deaths.

Although prescription drug diversion, the redirection of prescription drugs to illegitimate purposes, was not an explicitly-established PDMP outcome, State law acknowledged: 1) diversion was a significant problem,and 2) practitioners were challenged to discern between patients with a legitimate need for pain treatment and "doctor shoppers" seeking controlled drug prescriptions for their own addiction or for diversion. The Board and its staff established diversion as a PDMP outcome through informal goals and objectives, asserting the PDMP would combat the illicit trade in, and reduce the diversion of, controlled drugs. Associated behaviors included prescription drug theft, fraud, and forgery; unlawfully selling, dispensing, or possessing with intent to sell or dispense controlled drugs; and doctor shopping.

We assessed the extent to which it was plausible for the PDMP to measure progress towards, and ultimately achieve, each of these outcomes and the appropriateness of related effectiveness measures. Because PDMP data alone could not demonstrate an outcome or effect, we examined other State agencies' data including:

- OCME overdose death data,
- Bureau of Emergency Medical Services data on naloxone administrations,
- Division of Public Health Services data on emergency department encounters,
- Bureau of Drug and Alcohol Service data on treatment admissions,
- Forensic Laboratory data on drug analyses, and
- Narcotic and Investigations Unit data on substance seizures.

No State agency dataset we present was created with the intention of demonstrating a PDMP outcome, and their use for such a purpose was limited in many respects. We present excerpts from the various datasets as the best available data to provide context only, and not to demonstrate a PDMP outcome.

PDMP Maturity

The audit period encompassed the initiation of the PDMP, planning for and execution of implementation, and operation of the PDMP for two-and-a-half years. The audit period was amenable to application of a maturity model to assess progress the Board made towards optimizing the PDMP and constituent elements. The model consists of five maturity levels, from least to most mature:

1. Level 1 – Initial
2. Level 2 – Repeatable
3. Level 3 – Integrated
4. Level 4 – Managed
5. Level 5 – Optimized

Additional information on the model is contained in Appendix A.

We established the maturity level of various components of the PDMP to assist the Legislature, the Board, the Controlled Drug Prescription Health and Safety Program Advisory Council (Council), and the public in assessing the work needed to optimize the PDMP. Overall, the State's PDMP was at an ***initial*** stage of maturity through State fiscal year (SFY) 2017.

Observation No. 1

Improve Focus On Outcomes And Effectiveness Measures

PDMP effectiveness was at an initial stage of maturity. Despite expressed concerns about the ability of the PDMP to achieve certain statutorily intended outcomes, the Board had not formally reviewed the appropriateness of the intended outcomes and effectiveness measures contained in State law or informally adopted by Board staff. The lack of clearly defined and achievable outcomes, a performance measurement system to demonstrate effect, and integration with other regulatory boards and State agencies inhibited measuring or reporting on effectiveness. These inadequacies contributed to ineffective PDMP implementation and prevented the Board from demonstrating PDMP effectiveness or providing accountability to stakeholders and the public.

The PDMP was unable to achieve its intended outcomes through SFY 2017, as influencing or achieving program outcomes could take months or even years to occur, once stable and mature operations were in place. Ongoing changes to the statutory environment, and a control structure ill-prepared to respond to such changes, hindered the ability of the PDMP to achieve stable and mature operations. Consequently, Board and Council members, as well as Board staff, reported the PDMP was still being implemented in late SFY 2017, almost three years after dispensers began uploading PDMP information and prescriber registration commenced.

We administered surveys to the 50 members of the non-pharmacy regulatory boards with licensees subject to PDMP requirements, of whom 32 (64.0 percent) responded, and to the 21 members of the Board and the Council, of whom 18 (85.7 percent) responded. A majority expressed concerns with:

- monitoring PDMP effectiveness (13 Board and Council members, or 72.2 percent; and 20 non-pharmacy regulatory board members, or 62.5 percent), and
- collecting and preparing relevant information and analyses of outcomes and impact (13 Board and Council members, or 72.2 percent).

The complete results of our survey of Board and Council members are included in Appendix D, and the results of our survey of members of other regulatory boards are included in Appendix E.

Board Actions

The Board was required to report annually on PDMP effectiveness, which included progress towards achieving statutorily-intended outcomes. The Council was required to develop criteria for reviewing PDMP information, and the Board was required to adopt Council-generated criteria in rule. The Council was also required to collect information on PDMP outcomes and impact, including user satisfaction, impact on prescribing patterns, impact on referrals to regulatory boards, and other relevant measures, such as those related to outcomes framed in State law. However, the Council and the Board appeared to engage in few discussions related to these tasks. The Council reviewed and discussed potential indicators of morbidity and mortality in March 2016, but took no further action to select appropriate indicators or measure outcomes. Board reports contained no empirical evidence demonstrating PDMP effectiveness, and basic tasks needed to move towards evaluation were incomplete.

Through October 2017, the Board did not:

- produce sufficient information and analysis to demonstrate PDMP effectiveness related to intended outcomes;
- establish a causal relationship between the PDMP and any intended outcomes or effectiveness measures;
- consider how to isolate PDMP-specific effects or best measure effectiveness;
- develop a timeline indicating by when changes in PDMP outcomes or effectiveness measures should be observed and achieved;
- adopt or develop and operationalize relevant definitions or identify relevant indicators based on Council-generated criteria and thresholds related to intended outcomes and effectiveness measures;
- establish baseline performance to permit measurement of change and assist in determining whether the PDMP contributed to, or was associated with, changes;
- attempt to systematically obtain relevant information from other State agencies to help demonstrate effectiveness, as we discuss in Observation No. 3 and elsewhere;
- consider and account for the extent to which PDMP data quality may prove problematic when measuring effectiveness; or

- seek legislative changes either to ensure outcomes were reasonable, given the PDMP's focus on schedule II through IV controlled drugs, and opioids in particular, or to limit outcomes to those empirically demonstrated to be most reasonable for the PDMP to achieve.

Neither did the Board seek legislative changes to include diversion as a PDMP outcome, despite informally adopting it as one, nor had it incorporated diversion as an outcome via Board rules.

Impracticalities In Developing Evaluation Framework

There was a lack of robust, integrated data management and evaluation, complicating or rendering impossible Board monitoring and reporting on PDMP effectiveness. Board staff reported in early SFY 2018 that the PDMP software did not permit reports on certain indicators of fraudulent prescribing or overprescribing, and the first aggregated PDMP dataset for analysis was received only in March 2017. Other State agency data, potentially useful for assessing PDMP effectiveness, was not collected with the purpose of informing PDMP effectiveness, requiring additional information or analysis to make it suitable for use in PDMP evaluations. Similar and significant challenges were faced by the Commission when attempting to develop a framework to assess the effectiveness of the State's strategy. Furthermore, although the PDMP could reportedly affect intended outcomes only when a high percentage of prescribers and dispensers complied with registration and utilization requirements, instances of noncompliance could not be quantified, and enforcement was not pursued during the audit period.

Additionally, there was no agreed-upon definition of PDMP effectiveness. Stakeholders often disagreed on how to define outcomes and measures. Although input was needed from other stakeholders in order to define and measure outcomes, Board staff indicated non-pharmacy regulatory boards provided insufficient direction and guidance to identify health practitioners fraudulently prescribing controlled drugs and adding to prescription drug abuse. Board staff first sought to obtain feedback from the other regulatory boards in May 2017 as to what constituted potential violations of law, such as overprescribing, and breaches of professional standards, such as improper prescribing, although no resolution was reached through October 2017. Stakeholders also disagreed on whether, or how, each outcome was reasonable to achieve. Some intended outcomes were reasonable to expect the PDMP to achieve in the short-term, after operations have been stable for a short time; others were reasonable to achieve only in the long-term; and still others were not reasonable to expect the PDMP to ever achieve. None of these complexities had been resolved by the Board.

The influence of other known and unknown external factors on statutorily-intended outcomes also complicated effectiveness measurement. Stakeholders familiar with the PDMP indicated the program was only one component of the larger strategy affecting outcomes related to overdose deaths and substance abuse. In addition to other State interventions, such as promoting safe prescribing practices, naloxone availability, and educational campaigns, factors found to influence prescribing, prescription use, drug abuse, and overdose deaths included individual patient characteristics; federal, local, and private sector interventions; and prescriber and dispenser actions. Consequently, changes in data purportedly representing intended PDMP outcomes could actually represent the combined effects of the PDMP and other known and

unknown external factors. Creating a sufficiently comprehensive framework to measure each intended outcome and then ascribing changes directly to the PDMP would be difficult at best, as such a framework will likely omit important factors affecting these outcomes. Establishing a cause and effect relationship between intended outcomes and the PDMP would also be difficult, if not impossible in some cases. Creating a system to measure the PDMP's specific contribution to each outcome was likely incalculably complex and had never previously been developed.

Given difficulties in attaining stable and mature PDMP operations, as well as significant limitations in monitoring and analyzing PDMP information on outputs and outcomes, it was likely impractical for the Board to have developed an evaluation framework during the audit period.

Plausibility Of Intended PDMP Outcomes And Effectiveness Measures

Intended outcomes and effectiveness measures spanned a continuum from plausible to somewhat plausible to less plausible. Plausibility was based on available evidence and determined by the ability of the Board to: 1) develop specific and measurable indicators, 2) collect and analyze necessary evidence, and 3) reasonably attribute changes in outcomes specifically to the PDMP.

- *Plausible* outcomes included improved patient care and treatment and changes in prescribing practice and doctor shopping. The Board should be able to measure effect through analyses of current PDMP information, regulatory board and law enforcement investigations, and surveys of PDMP-registered prescribers and dispensers.

- *Somewhat plausible* outcomes included improved practitioner-patient relationships; changes in patient morbidity, drug abuse, and the type of drug deaths; and select indicators of diversion, including fraudulent prescribing and forged or altered prescriptions. The Board may be able to measure effect by selecting specific and valid indictors and analyzing information currently collected by other State agencies, linked with analyses of current PDMP information, regulatory board and law enforcement investigations, and surveys of PDMP-registered prescribers and dispensers.

- *Less plausible* outcomes included patient mortality, changes in the number of drug deaths, and select indicators of diversion, including diversion committed in dispensaries, in transit to or from dispensaries, or in patients' homes. It was unlikely that the Board would be able to measure effect given the limitations in data collected by the PDMP and other State agencies and the difficulty in demonstrating a causal relationship.

Recommendations:

We recommend the Board:

- **develop definitions, criteria, and thresholds to validate relevant indicators of PDMP effectiveness and incorporate them into administrative rule;**
- **implement and refine an evidence-based approach to assess validated PDMP outcomes;**
- **develop, implement, and refine a system to empirically demonstrate PDMP outcomes related to each validated outcome;**
- **include components related to monitoring and assessing PDMP effectiveness relative to each validated outcome in its strategy and plans, including a timeline with milestones spanning initial development through final validation and implementation to help mature the program; and**
- **clarify how the PDMP can be reasonably expected to affect validated outcomes, and when outcomes and effects will be expected.**

Board Response:

We concur.

The Board will work with the Council and other relevant State stakeholders to: (1) develop definitions, criteria, and thresholds to validate relevant indicators of PDMP effectiveness, and (2) implement an evidence-based approach to assess PDMP outcomes. This will include the following key strategic elements: assessment, capacity building, planning, implementation, evaluation/monitoring, sustainability, and cultural competency. These components will be referenced from initial development through final validation to assist the Board in maturing the PDMP. Lastly, the Board will clarify how and when the PDMP will reasonably be expected to have validated outcomes.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Strategic plan draft	*July 2018*
Monitoring and assessing PDMP effectiveness	*March 2019*
All policy and procedure development identified	*Ongoing/2 years, with 3 months interval updates*

Plausibility

Observations No. 2, No. 3, and No. 4 that follow provide detailed information on the plausibility of each intended PDMP outcome and effectiveness measure intended primarily for the use of the Board, the Council, and Board staff. These observations include recommendations that address specific deficiencies preventing the development of an evaluation framework and the measurement and evaluation of outcomes and measures.

The next section, entitled *Implementation and Operation*, provides detailed information and recommendations related to PDMP strategy, planning, performance measurement, and other aspects of implementation and operation.

Observation No. 2

Improve Assessment And Measurement Of Plausible Outcomes And Effectiveness Measures

Stakeholders generally agreed the PDMP could have reasonably been expected to:

- help practitioners provide better care and medical treatment,
- change the number of instances of overprescribing, and
- reduce doctor shopping.

However, Board staff expressed concerns the PDMP might *not* help practitioners provide better care and medical treatment, because some practitioners may use PDMP information for this purpose, while others may punitively remove patients from their care. Punitive use of PDMP information by practitioners was one of an unknown number of unintended consequences related to the implementation and use of the PDMP.

Stakeholders inconsistently agreed whether the PDMP's influence on these outcomes would be direct or indirect and whether its influence would be observable in the short- or long-term. No research or empirical or anecdotal evidence clearly demonstrated or compelled the conclusion that these were reasonable outcomes for prescription monitoring programs nationally or in the State. Nonetheless, it was *plausible* the PDMP may affect these outcomes and for the Board to measure that effect through analysis of PDMP data and surveys of PDMP-registered prescribers and dispensers.

Neither the Board nor the Council rationalized disparate opinions or conducted a systematic review of available research and data in order to identify a practical means to measure these outcomes and isolate PDMP-specific effects. We identified several factors hindering the development of an evaluation framework for these outcomes.

Lack Of External Empirical Evidence

A limited amount of research evaluated prescription monitoring programs' effectiveness in achieving these outcomes, and research did not always examine the outcomes and effectiveness measures envisioned for the State's PDMP. Research on prescribing examined changes in the number, quantity, or amount of prescriptions over time, but did not determine whether such changes reflected a positive or negative shift in the appropriateness of prescribing. Available research was methodologically limited, and research evaluating patient care and treatment relied on anecdotal evidence. These limitations, combined with differences in methodology and analytical approaches, contributed to mixed conclusions about prescription monitoring programs' effectiveness in changing prescribing and reducing doctor shopping.

Known and unknown external factors may also have contributed to variation in conclusions. Changes in patient care and treatment, prescribing, and doctor shopping may be affected by individual patient characteristics, such as chronic pain conditions or age, and by interventions such as prescribing guidelines. When asked about changes in their licensees' prescribing habits, six of 10 (60.0 percent) non-pharmacy regulatory board members responding to our 2017 survey attributed changes in their licensees' prescribing habits to the presence of prescribing rules, greater awareness of overprescribing concerns, an increase in board investigations, and their disciplinary actions, while four of 10 (40.0 percent) attributed changes to the PDMP.

Insufficient Empirical Data And Analysis To Assess Effectiveness

If definitions, criteria, and thresholds to measure and assess these outcomes were established, PDMP information could presumably identify indicators of patient care and treatment, overprescribing, and doctor shopping and could have readily permitted evaluating changes over time. Before prescriber registration began, the PDMP collected six months of prescription data. These data could have been used to establish a baseline of prescribing behavior and doctor shopping, but no baselines were created.

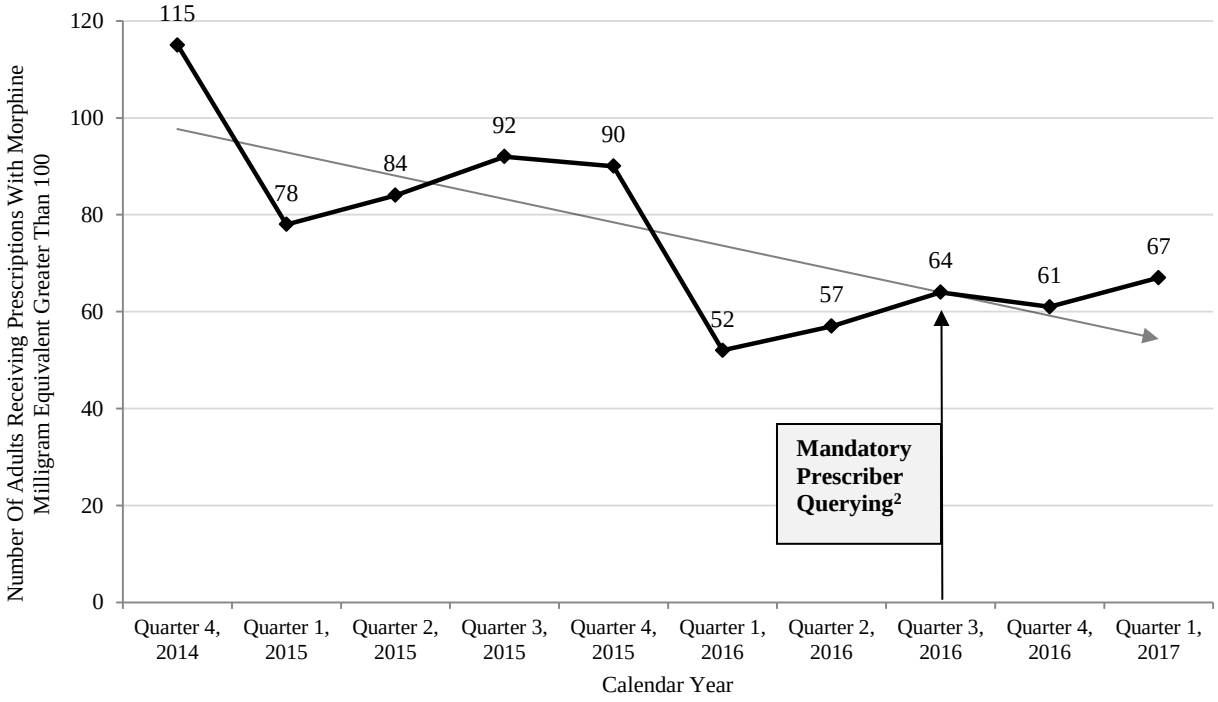
Board staff used PDMP information to identify potential indicators of overprescribing, such as the number of prescriptions written for the top five controlled drugs dispensed in the State and the quantity and number of days' supply dispensed, and prescribers writing and dispensers filling the most prescriptions. Board staff provided this output information to the regulatory boards and the Council but did not include it in annual PDMP reports or federal grant reports. Additional potential indicators of overprescribing, also federally-required metrics reported in periodic PDMP and quarterly federal grant reports, are shown in Figure 2, depicting unaudited PDMP information on the number of adults filling painkiller prescriptions with a morphine equivalent of 100 milligrams or greater per day and Figure 3, depicting unaudited PDMP information on the number of patients exceeding the threshold of five prescribers and five dispensing locations within three months.

As presented in the cautionary notes in Figures 2 and 3, PDMP data are currently not reliable. Additional indicators that could be derived from PDMP information, such as overlapping prescriptions or a high number, frequency, or duration of prescriptions per patient, might also have been used to evaluate effects on patient care and treatment or prescribing, but were not.

Board staff never analyzed the output information it did publish and translate it into a PDMP effect on better patient care and treatment, overprescribing, or doctor shopping. Neither were PMDP data placed into context, as other factors likely affected the observed changes in outputs. For example, unaudited federal data indicated the amount of opioids prescribed nationwide peaked in CY 2010 and then decreased at least through CY 2015, mirroring unaudited PDMP information showing a downward trend in the number of opioid prescriptions in the State.

Figure 2

Adults Receiving Painkiller Prescriptions With A Morphine Milligram Equivalent Greater Than 100[1], Fourth Quarter, CY 2014 Through First Quarter, CY 2017



Notes:

1. PDMP data were limited as described in Observation No. 17 and Appendix A.
2. Mandatory prescriber querying went into effect during September 2016 when registered prescribers were generally required to query the PDMP when initially prescribing a schedule II through IV opioid and at least twice per year afterwards. Querying requirements changed over time as discussed in Observation No. 16.

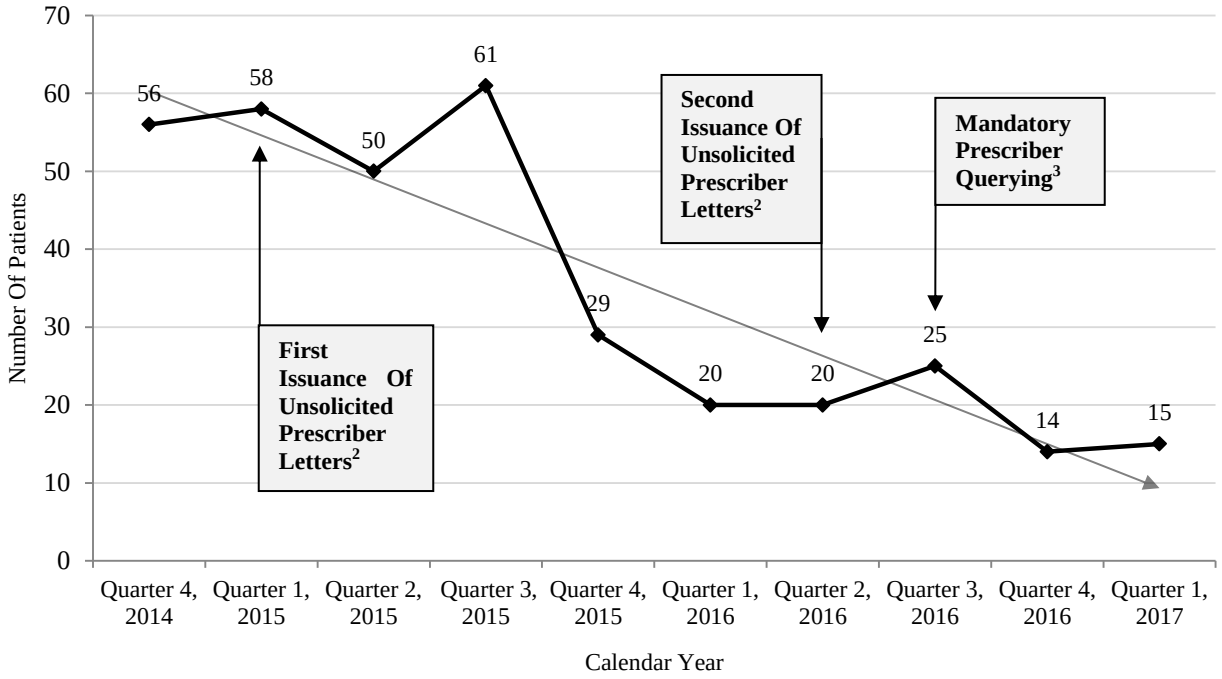
Source: LBA analysis of unaudited PDMP information.

Insufficient Evidence And Analysis To Assess Effectiveness

Stakeholders indicated evaluation of prescribers' and dispensers' use of PDMP information to affect patient care and treatment relied on anecdotal evidence. Board staff indicated they tracked relevant information through the Council's surveys of registered prescribers in CY 2016 and registered dispensers in CY 2017, which were also potential mechanisms to collect information on the effect of the PDMP on overprescribing and doctor shopping. The survey results alone did not indicate whether prescribers purposefully and appropriately reduced overprescribing as a result of viewing PDMP information, however, and Board staff never translated anecdotal output information into analysis of the PDMP's effect on better care and treatment, overprescribing, or doctor shopping.

Figure 3

Number Of Patients Exceeding Threshold Of Five Prescribers And Five Dispensing Locations In Three Months[1], Fourth Quarter, CY 2014 Through First Quarter, CY 2017



Notes:

1. PDMP data were limited as described in Observation No. 17 and Appendix A.
2. Unsolicited prescriber letters were first issued in April 2015 regarding patients obtaining schedule II through IV controlled drug prescriptions from multiple prescribers and dispensers. Letters were issued once more in the second quarter of CY 2016. Inconsistencies with the registration process raised questions as to whether all registrants actually received the letters as discussed in Observation No. 8.
3. Mandatory querying went into effect during September 2016 when registered prescribers were generally required to query the PDMP when initially prescribing a schedule II through IV opioid and at least twice per year afterwards. Querying requirements changed over time as discussed in Observation No. 16.

Source: LBA analysis of unaudited PDMP information.

The surveys directly asked about only one PDMP outcome, doctor shopping, and asked indirectly about potential indicators of patient care and treatment, prescribing, and doctor shopping, as well as related actions. In responding, a majority of the 2,679 prescribers and the 392 dispensers who responded agreed the PDMP was a useful tool:

- to help prevent doctor shopping (1,980 prescribers, or 73.9 percent, and 319 dispensers, or 81.4 percent);

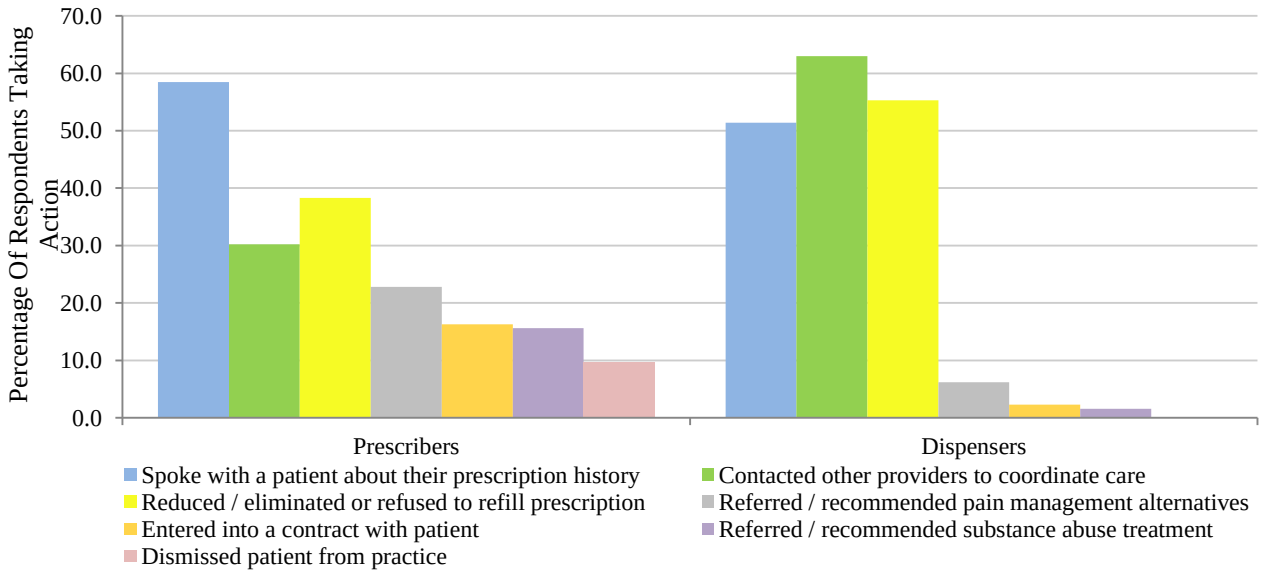
- when making prescribing decisions (1,765 prescribers, or 65.9 percent, and 274 dispensers, or 69.9 percent); and
- for communicating patient information between providers and dispensers (1,943 prescribers, or 72.5 percent, and 319 dispensers, or 81.4 percent).

Survey results also indicated 1,360 of 2,666 prescribers (51.0 percent) believed their controlled drug prescribing behaviors were more closely monitored as a result of the PDMP.

Prescribers and dispensers could reportedly use PDMP information and patient histories to directly provide better care and medical treatment and change their prescribing by: 1) identifying potentially dangerous medication interactions, 2) assessing whether patients followed pain contracts, 3) determining when to switch pain patients to a non-opioid regime, 4) discussing care with patients, and 5) coordinating care with other practitioners. Figure 4 summarizes actions survey respondents reported taking after receiving PDMP patient histories, although the results in and of themselves do not demonstrate whether such actions contributed to improvements in the quality of care or treatment or positive changes in prescribing practices. For example, the surveys did not solicit information as to why prescribers eliminated prescriptions for patients, dispensers refused to fill prescriptions for patients, or prescribers dismissed patients from their practice. Additionally, no mechanisms existed to determine the magnitude of potential doctor shopping, such as the number of patients or prescriptions involved, or PDMP registrants' success at preventing doctor shopping, such as whether patients were able to obtain and fill prescriptions from other prescribers or dispensers.

Figure 4

Prescriber And Dispenser Actions Taken After Reviewing PDMP Reports



Note: Council survey data were limited, as described in Appendix A.

Source: LBA analysis of unaudited Council survey data.

Survey results also indicated a potential lack of positive effect on patient care and treatment. Over one-half of prescribers (1,510 of 2,613, or 57.8 percent) indicated the PDMP had no effect on helping patients manage their conditions. Survey results also indicated potential unintended consequences, such as: 1) reduced prescribing resulting from the referral of all patients needing an opioid or other controlled drug prescription to specialists or other prescribers, or 2) a decision to stop prescribing any controlled drugs. However, without a mechanism in place to assess holistically the reasons for changes in prescribing practices, no conclusions could be drawn as to the validity of these concerns.

Recommendations:

We recommend the Board:

- **formally establish reducing opportunities for doctor shopping of schedule II through IV controlled drugs as a PDMP outcome;**
- **select relevant and measureable indicators of patient care and treatment and overprescribing related to schedule II through IV controlled drugs;**
- **qualify overprescribing-related and doctor shopping-related outcomes, such as limiting them to opioids specifically, so the PDMP is not expected to achieve unreasonable outcomes;**
- **develop standard educational materials for prescribers and dispensers on indicators of doctor shopping, and when and how to report potential doctor shopping to Board staff or law enforcement;**
- **provide initial and ongoing training and education to prescribers and dispensers on doctor shopping, patient care and treatment, and prescribing;**
- **develop, implement, and refine routine reporting mechanisms through which prescribers and dispensers can report potential doctor shopping or overprescribing to Board staff for further investigation; and**
- **identify, and develop methods to mitigate, unintended consequences.**

Board Response:

We concur.

The Board, after recommendation from the Council, will establish a measurable threshold for doctor shopping as an outcome. Thereafter, this threshold level will capture indicators of doctor shopping and notification letters with reports will be issued to prescribers through the PDMP system.

The Board will coordinate with the other regulatory boards to determine what qualifies as "over prescribing." The Board will work with the new database management vendor to determine if there is an existing mechanism to capture this type of report or if something would have to be developed. Development of a new report could be considered an enhancement to the system and may require additional funding.

The Council will develop, and the Board will approve, standard educational materials and training for practitioners on indicators of doctor shopping, patient care, treatment, and prescribing and when and how to report to regulatory board staff for further investigation.

These practices and procedures will assist the Board in mitigating unintended consequences.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Provider training materials	*June 2018*
Defined statute changes	*July 2018*
Refine and develop doctor shopping outcome	*September 2018*
Administrative rules changes as defined	*September 2018*
All policy and procedures development	*See Observation No. 1*

Observation No. 3

Improve Assessment And Measurement Of Somewhat Plausible Outcomes And Effectiveness Measures

Stakeholders generally agreed the PDMP could have reasonably been expected to:

- create a greater sense of safety, security, and comfort in the practitioner-patient relationship;
- reduce patient morbidity;
- change the number of instances of drug abuse;
- change the type of drug deaths; and
- reduce the diversion of drugs.

However, Board staff reported anecdotes indicating the PDMP was *not* achieving a greater sense of safety, security, and comfort for practitioners, as some registrants were purportedly uncomfortable using the PDMP and thought its use took time away from medical practice.

Additionally, some stakeholders noted the types of deaths expected to be affected by the PDMP should be restricted either to controlled drugs or to controlled opioids, due to the limited scope of the PDMP and related regulatory board rules on prescribing and querying requirements. Other stakeholders expressed concerns that illicit substance abuse would *increase* due to a decrease in the prescription drug supply and an increase in cost of purchasing prescription drugs illicitly. A potential increase in illicit substance abuse was one of an unknown number of unintended consequences related to the implementation and use of the PDMP.

Stakeholders inconsistently agreed whether the PDMP's influence on these outcomes would be direct or indirect and whether its influence would be observable in the short- or long-term. No research or empirical or anecdotal evidence clearly demonstrated or compelled the conclusion that these were reasonable outcomes for prescription monitoring programs nationally or in the State. Nonetheless, it was *somewhat plausible* the PDMP may affect these outcomes and the Board could measure that effect through analysis of PDMP data, surveys of PDMP-registered

prescribers and dispensers, and data from other State agencies. Developing such a framework would be complex, however. For example, Board staff and some stakeholders indicated changes may indirectly be derived if the PDMP contributed to safe prescribing practices, better patient care, and a reduction in the overall drug supply, which might then contribute to lower addiction rates and behaviors associated with abuse and subsequently result in lower prescription death rates. Measuring such effects would require robust data collection and analysis, as well as the integration of data from other State agencies.

Neither the Board nor the Council rationalized disparate opinions or conducted a systematic review of available research and data in order to identify a practical means to measure these outcomes and isolate PDMP-specific effects. We identified many factors hindering the development of an evaluation framework for these outcomes.

Lack Of External Empirical Evidence

No research examined the relationship between prescription monitoring programs and practitioner-patient relationships or diversion generally, and no evidence nationally or from other states provided insight into the validity of these outcomes for the State's PDMP.

Research evaluating prescription monitoring programs' effects on morbidity and substance abuse generally examined outcomes related to substance treatment admissions, while research evaluating effectiveness related to mortality examined accidental and intentional overdose deaths caused by illicit and licit substances. However, research was limited methodologically, such as through the failure to distinguish between abuse of licit and illicit forms of prescription drugs. These limitations, combined with differences in methodology and analytical approaches, contributed to mixed conclusions, variously finding associations between prescription monitoring programs and 1) reductions, 2) increases, or 3) no change at all in substance treatment admissions, doctor-shopping behavior, and the types of overdose deaths.

Known and unknown external factors may have contributed to variation in conclusions. Changes in morbidity, abuse, and the types of overdose deaths may be affected by individual patient characteristics, such as employment status; environmental conditions, such as the availability of prescription drugs or reformulations intended to decrease the potential for abuse; and other interventions, such as the availability of substance abuse treatment or naloxone.

Insufficient Empirical Data And Analysis To Assess Effectiveness

PDMP Information

If definitions, criteria, and thresholds to measure and assess these outcomes were established, PDMP information could presumably identify some indicators of patient morbidity, controlled drug abuse, diversion, and fraudulent prescribing and could have permitted evaluating changes over time, with integration of data from other sources. Before prescriber registration began, the PDMP collected six months of prescription data. These data could have been used to establish a baseline of some indicators of patient morbidity and controlled drug abuse, but no baselines were created.

The PDMP did not collect information useful in identifying outcomes related to the changes in the type of drug deaths or the safety, security, and comfort of practitioner-patient relationships. Board staff and stakeholders variously asserted PDMP information could be used to identify indicators of potential:

- controlled drug misuse;
- controlled drug abuse, such as high dosages;
- doctor shopping, such as obtaining prescriptions from multiple doctors and pharmacies; and
- controlled drug diversion and fraudulent prescribing, such as prescriptions written on stolen prescription pads and altered prescriptions for higher dosages or amounts.

However, misuse was never formally defined in this context. Board staff tracked a limited amount of information on these indicators, primarily federally-required metrics that were reported in the Board's periodic PDMP and quarterly federal grant reports. Additional indicators, such as overlapping prescriptions, early prescription refills, or a high number, frequency, or duration of prescriptions per patient, might also have been used to evaluate effects on morbidity, abuse, and doctor shopping behavior and could have been derived from PDMP information, but were not. Board staff never analyzed the output information it did publish or translate it into a PDMP effect on morbidity, abuse, or diversion. Neither were PMDP data placed into context, as other factors likely affected the observed changes in PDMP outputs.

Diversion Of Non-opioid Controlled Drugs

Board staff expressed concerns about the use of PDMP data to detect and reduce diversion of non-opioid controlled drugs, particularly of stimulants such as amphetamine or methamphetamine, due to limits in querying requirements. Unaudited PDMP information indicated that while doses dispensed of schedule II opioids decreased between the fourth quarter of CY 2014 and the first quarter of CY 2017, doses of schedule II and III sedatives and schedule II stimulants increased. A contemporaneous change in the types of prescription drugs being diverted, from schedule II opioids to other drugs, including stimulants, was reportedly observable in State Police Narcotics and Investigations Unit (NIU) cases. Unaudited federal data indicated similar trends in reported nonmedical use of stimulants and overdose deaths caused by benzodiazepines, a class of sedative. To track and address a wider range of controlled drug diversion, Board staff indicated mandatory PDMP utilization requirements should be extended beyond opioids. However, no further discussion appeared to occur, nor was action taken, in support of legislative changes to the PDMP.

Data From Other State Agencies

To develop a framework for analysis of the PDMP's effect on morbidity, abuse, type of drug deaths, and select diversion indicators, PDMP output information would need to be connected with output information from other State agencies; outcome data from non-pharmacy regulatory boards on disciplinary actions related to prescribing practices, and data from law enforcement agencies on patient-related investigations. Bureau of Drug and Alcohol Services, Division of Public Health Services, Bureau of Emergency Medical Services, and OCME data were being

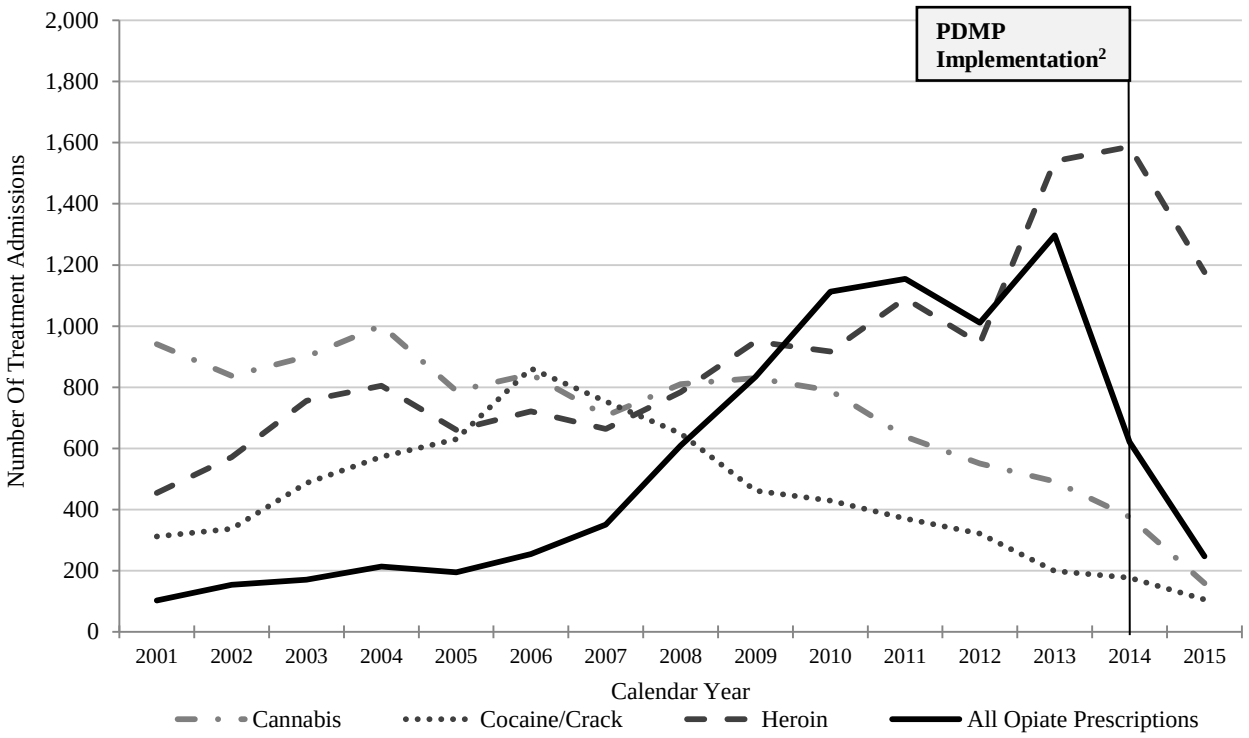
used to provide information on morbidity, substance abuse, and overdose deaths in New Hampshire. This information was compiled and reported by the Information and Analysis Center's Drug Monitoring Initiative and the Commission. Potential indicators of morbidity, substance abuse, and the type of overdose deaths are shown in:

- Figure 5, depicting unaudited substance abuse treatment admissions data,
- Figure 6, depicting unaudited drug-related emergency department encounters,
- Figure 7, depicting unaudited naloxone administrations, and
- Figure 8, depicting unaudited overdose death data on the cause of deaths.

As presented in the cautionary notes in the Figures, these data are currently not reliable for the purpose of measuring PDMP outcomes.

Figure 5

Substance Abuse Treatment Admissions, By Primary Substance Of Use At Admission[1], CY 2001 Through CY 2015



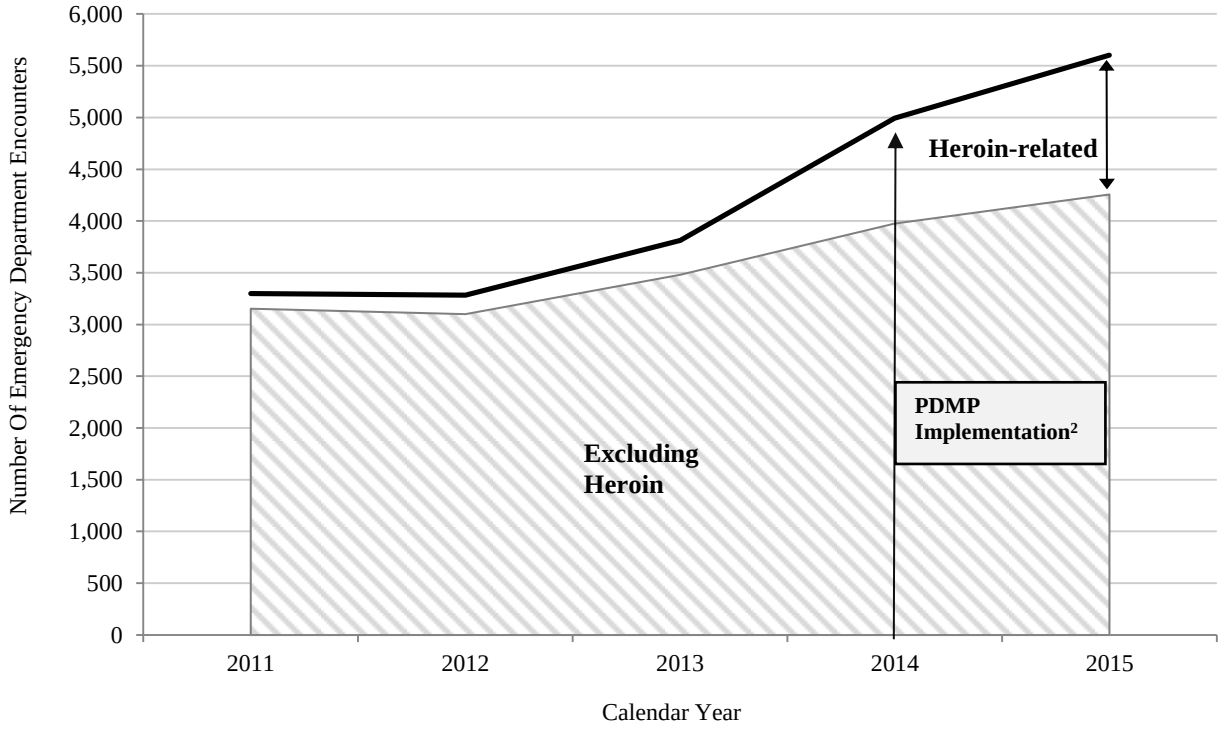
Notes:

1. Bureau of Drug and Alcohol Services data were limited as described in Appendix A.
2. PDMP implementation occurred during mid- to late CY 2014 once the software became operational. Dispensers began registering and uploading data between August and October 2014 while prescribers began registering in October 2014 as discussed in Observations No. 15 and No. 16.

Source: LBA analysis of unaudited Bureau of Drug and Alcohol Services data.

Figure 6

Opioid-related Emergency Department Encounters[1], CY 2011 Through CY 2015



Notes:

1. Division of Public Health Services data were limited, as described in Appendix A.
2. PDMP implementation occurred during mid- to late CY 2014 once the software became operational. Dispensers began registering and uploading data between August and October 2014, while prescribers began registering in October 2014, as discussed in Observations No. 15 and No. 16.

Source: LBA analysis of unaudited Division of Public Health Services data.

Data from other State agencies needed to be placed into context, as other factors besides the PDMP likely affected observed changes in outputs. Depicted trends indicated changes to each potential indicator occurred prior to PDMP implementation. Additionally, unaudited federal data on substance abuse treatment admissions, emergency department visits, and the type of overdose deaths reflected trends similar to those seen in State data.

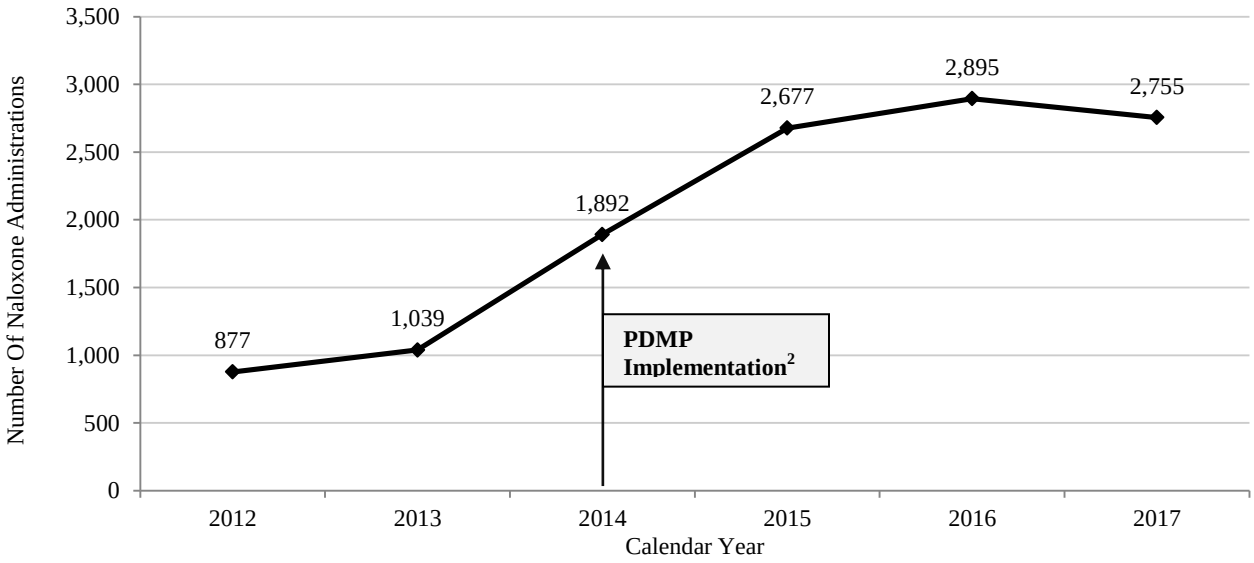
Insufficient Anecdotal Evidence And Analysis To Assess Effectiveness

The Council's surveys were potential mechanisms to collect anecdotal information on the PDMP's effect on practitioner-patient relationships, morbidity, controlled drug abuse, and fraudulent prescribing or forged and altered prescriptions. Survey results alone did not indicate whether the PDMP had an effect on these outcomes, however, and Board staff never translated anecdotal output information into analysis of the PDMP's effect on practitioner-patient relationships, morbidity, abuse, and select indicators of diversion. Further, no comparable mechanism existed through which the Board could solicit patients' perspectives on changes in

their relationships with practitioners. Doing so would be difficult given statutory confidentiality protections.

Figure 7

Naloxone Administrations[1], CY 2012 Through CY 2016, With CY 2017 Projections



Notes:

1. Bureau of Emergency Medical Services data were limited as described in Appendix A.
2. PDMP implementation occurred during mid- to late CY 2014 once the software became operational. Dispensers began registering and uploading data between August and October 2014 while prescribers began registering in October 2014 as discussed in Observations No. 15 and No. 16.

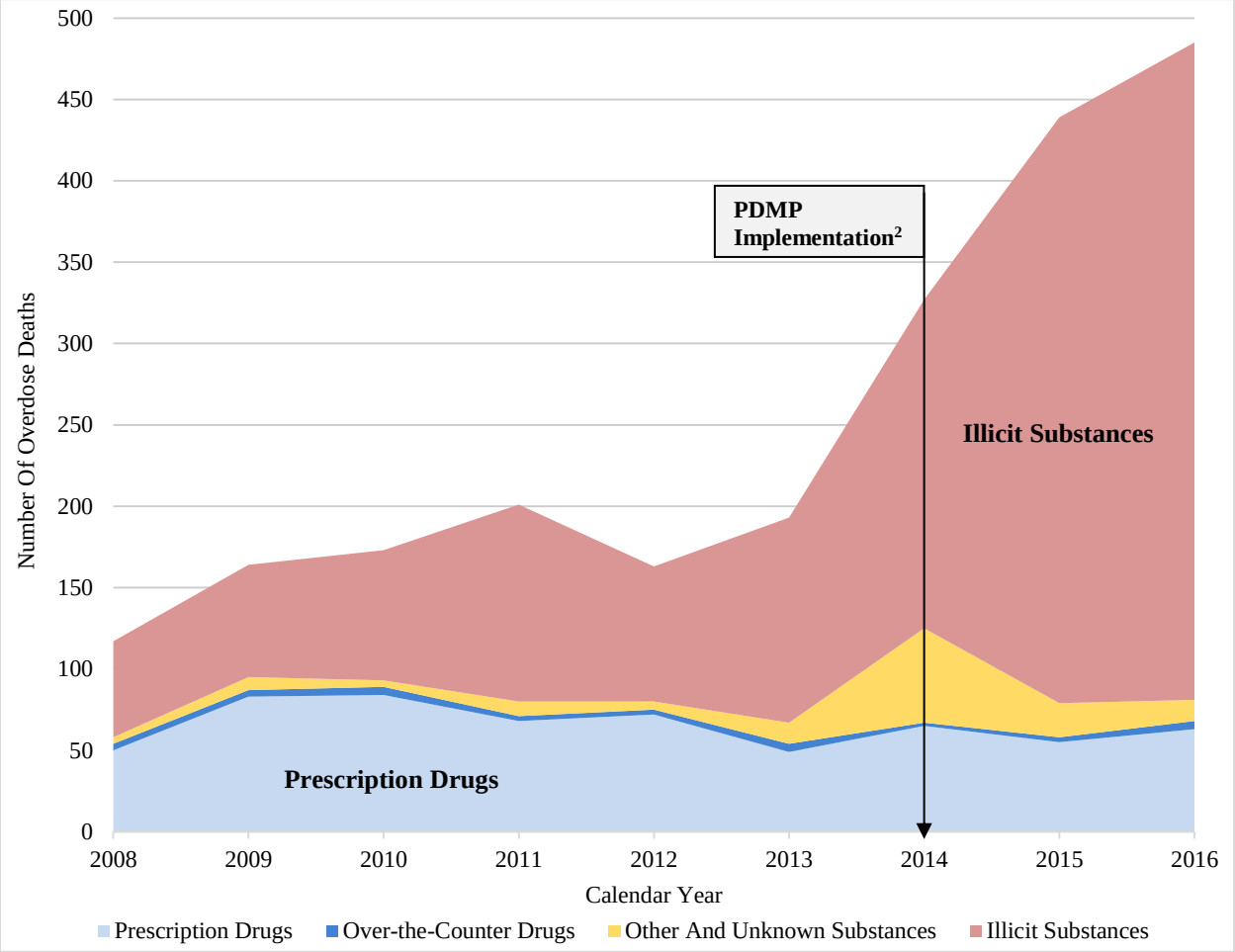
Source: LBA analysis of unaudited Bureau of Emergency Medical Services data.

The Council's surveys of prescribers and dispensers asked about prescription drug *misuse*, not *abuse*, although misuse could be a potential indicator of abuse, morbidity, and practitioner-patient relationships. A majority of prescribers (1,956 of 2,679, 73.0 percent) and dispensers (309 of 392, 78.8 percent) agreed the PDMP was a useful tool for helping to reduce prescription drug misuse. Importantly, however, misuse was never formally defined for the purposes of the survey.

One Board member noted prescribers and dispensers might feel more comfortable that patients were seeking prescriptions for legitimate medical use after querying PDMP information. When asked about actions taken in the past year as a result of viewing patient history reports through the PDMP, 579 of 1,224 (47.3 percent) prescribers and 137 of 257 (53.3 percent) dispensers confirmed a patient *was* misusing prescriptions, while 853 (69.7 percent) prescribers and 184 (71.6 percent) dispensers confirmed a patient *was not* misusing prescriptions. However, the survey did not ask about resulting changes in these relationships from practitioners' perspectives.

Figure 8

Overdose Deaths, By Contributing Substance[1], CY 2008 Through CY 2016



Notes:

1. OCME data were limited as described in Appendix A.
2. PDMP implementation occurred during mid- to late CY 2014 once the software became operational. Dispensers began registering and uploading data between August and October 2014 while prescribers began registering in October 2014 as discussed in Observations No. 15 and No. 16.

Source: LBA analysis of unaudited OCME overdose death data.

The Council's prescriber survey indicated some prescribers shared concerns the PDMP was not contributing to a greater sense of safety, security, and comfort in practitioner-patient relationships. However, without a mechanism in place to assess holistically the quality of all practitioner-patient relationships encompassed by the PDMP, no conclusions could be drawn as to the validity of these concerns.

The Council's surveys did not contain any questions that would permit Board staff to determine whether fraudulent prescribing and forged or altered prescriptions were being identified or to assess whether changes in these behaviors were occurring. Although respondents reported refusing to fill prescriptions or dismissing patients from their practice after viewing PDMP information, the survey results alone did not indicate whether such actions were taken as a result of identifying fraudulent, forged, or altered prescriptions or for other reasons, and whether such actions were successful in preventing patients from obtaining or filling these prescriptions at other dispensaries.

Recommendations:

We recommend the Board:

- **rationalize opinions and evidence to select relevant and measureable indicators of practitioner-patient relationships involving controlled drugs, patient morbidity related to controlled drugs, abuse and opportunities for abuse of controlled drugs, and opportunities for diversion of controlled drugs, including fraudulent prescribing and forged or altered prescriptions, for schedules II through IV controlled drugs;**
- **qualify outcomes related to patient morbidity, abuse and opportunities for abuse, the type of deaths, and opportunities for diversion related to schedule II through IV controlled drugs, such as limiting to opioids specifically, so the PDMP is not expected to achieve unreasonable outcomes;**
- **determine whether available data from other State agencies is amenable, or could be amenable, to assessing PDMP effectiveness on patient morbidity, abuse and opportunities for abuse, the type of deaths, opportunities for fraudulent prescribing, or opportunities for filling forged and altered prescriptions related to schedule II through IV controlled drugs;**
- **develop agreements with relevant State agencies to obtain necessary data on a routine basis;**
- **determine whether a mechanism to solicit patient feedback on changes in practitioner-patient relationships is feasible and cost effective;**
- **develop a process to connect survey results with analysis of PDMP data and data from other State agencies, where necessary; and**
- **develop methods to mitigate unintended consequences.**

If the Board is unable to obtain necessary and amenable data from other State agencies to conduct its evaluations, it should either seek legislative changes to eliminate unmeasurable outcomes or further qualify outcomes to those it can measure with available data.

If the Board is unable to obtain patient feedback on changes in practitioner-patient relationships, it should either seek legislative changes to eliminate the statutory outcome or further qualify the outcome, such as limiting it to changes from the perspective of PDMP-registered prescribers and dispensers.

Board Response:

We concur.

The Board will review its rulemaking authority and, where authority is inadequate, will seek legislative changes to authorize the integration of PDMP data with other State agencies' data to quantify outcomes relative for patient morbidity, drug abuse, diversion and fraudulent prescriptions, types of deaths by drugs, or any mechanism to solicit patient feedback, the Board will consider recommendations for legislative changes to eliminate the statutory outcomes of patient mortality and the number of drug deaths and will work with other State agencies to obtain necessary data to assess PDMP effectiveness on a routine basis.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Administrative rules changes and development	*July 2018*
All policy and procedures development	*See Observation No. 1*

Observation No. 4

Refine Or Eliminate Less Plausible Outcomes And Effectiveness Measures

Stakeholders generally agreed the PDMP could have reasonably been expected to:

- reduce mortality,
- change the number of drug deaths, and
- reduce the diversion of controlled drugs.

Some stakeholders noted mortality outcomes and the number of drug deaths affected by the PDMP should be restricted either to controlled drugs or to controlled opioids due to the limited scope of the PDMP and related regulatory board rules on prescribing and querying requirements. Other stakeholders expressed concerns that illicit overdose deaths would *increase* due to a decrease in the prescription drug supply and increase in cost of purchasing prescription drugs illicitly. A potential increase in the number of overdose deaths caused by illicit substances was one of an unknown number of unintended consequences related to the implementation and use of the PDMP.

Stakeholders inconsistently agreed whether the PDMP's influence on these outcomes would be direct or indirect but generally agreed its influence would be in the long-term. No research or empirical or anecdotal evidence clearly demonstrated or compelled the conclusion that these were reasonable outcomes for prescription monitoring programs nationally or in the State. Given the indirect nature of the relationships, it was *less plausible* the PDMP may have a measurable effect on these outcomes, and given the significant complexity in developing a framework to isolate PDMP-specific effects and obtaining sufficient and relevant data, it was also less plausible that the Board would be able to measure an effect at all.

Neither the Board nor the Council rationalized disparate opinions or conducted a systematic review of available research and data in order to identify a practical means to measure these outcomes and isolate PDMP-specific effects. No efforts were made to limit these outcomes to those most reasonable to expect of the PDMP, and Board staff acknowledged patient mortality was not a formalized outcome. We identified a substantial number of factors hindering the development of an evaluation framework for these outcomes.

Lack Of External Empirical Evidence

No research examined the relationship between prescription monitoring programs and diversion generally, and no evidence nationally or from other states provided insight into the validity of this outcome for the State's PDMP.

Research evaluating the effectiveness of prescription monitoring programs related to mortality and the number of overdose deaths examined accidental and intentional overdose deaths caused by illicit and licit substances. However, research was limited methodologically, such as through the failure to distinguish between abuse of licit and illicit forms of prescription drugs. These limitations, combined with differences in methodology and analytic approaches, contributed to mixed conclusions, variously finding associations between prescription monitoring programs and 1) reductions, 2) increases, and 3) no change in the number of overdose deaths.

Known and unknown external factors may have also contributed to variation in conclusions. Changes in mortality and the number of overdose deaths may be affected by individual patient characteristics and risk factors, such as behaviors indicative of prescription drug abuse and diversion, as well as environmental factors and State interventions, including a shift from prescription drug abuse to illicit substance use generally and the implementation of prescription drug take back events and educational campaigns, which were thought to increase public awareness.

Insufficient Empirical Data And Analysis To Assess Effectiveness

PDMP information could not be used to directly identify indicators of mortality, the number of drug deaths, or certain types of diversion, including diversion committed in dispensaries or in transit to or from dispensaries. It was possible PDMP data collection could be expanded to identify a wider array of controlled drug diversion, but such effort would likely require significant changes to State law and PDMP software.

Diversion Of Prescriptions By Caretakers

Council members expressed concerns about the ability of the PDMP to detect diversion committed by caretakers, such as parents picking up prescriptions for their children or by families of elderly patients. Members questioned whether practitioners could query a caretaker's prescription history and came to the conclusion such action was not permitted by statute. State law also did not require dispensers to upload information on who picked up a filled prescription. Members considered the possibility of seeking legislative changes to improve the ability of the PDMP to detect diversion in these instances and decided more research and conversation at the

Council level would be necessary. However, no discussions appeared to occur during subsequent Council meetings to resolve concerns or pursue legislative changes.

Diversion Of Prescriptions Filled For Animals

Council members also expressed concerns about the ability of the PDMP to detect and reduce diversion committed by people picking up prescriptions for animals. Members of the Board of Veterinary Medicine noted a number of ways in which diversion of animal prescriptions might go undetected, asserting duplicate records may exist for individual animals because animals have no unique tracking number and instead, records may be entered under multiple owners or caretakers or multiple names for the same animal. Duplicate prescriptions might then be written and filled without being tracked, affecting PDMP data quality and identification of diversion. Council members considered the possibility of seeking legislative changes to record information on the person who picked up animal prescriptions, but no further discussions appeared to occur during subsequent Council meetings to pursue legislative changes. Council members generally agreed veterinarians should be required to query the PDMP for their animal patient, but not for the human owner, due to the complexity. Veterinarians became exempt from querying requirements in SFY 2018.

Data From Other State Agencies

To develop an analysis of the PDMP's effect on mortality and the number of drug deaths, Board staff would likely need to obtain and analyze information from the OCME on outputs and outcomes related to use of PDMP data during drug death investigations. OCME data on mortality and the number of overdose deaths was compiled and reported by the OCME, the Information and Analysis Center's Drug Monitoring Initiative, and the Commission.

To develop an analysis of the PDMP's effect on select indicators of diversion, Board staff would likely need to obtain and analyze output and outcome data from several State agencies and law enforcement agencies generally, including the Department of Justice's Medicaid Fraud Control Unit, the NIU, and the State Police Forensic Lab; the Pharmacy Board's compliance unit; and non-pharmacy regulatory boards' investigations and disciplinary actions. However, no comprehensive dataset on prescription drug diversion had been compiled.

Potential indicators of mortality, the number of overdose deaths, and certain types of diversion are shown in:

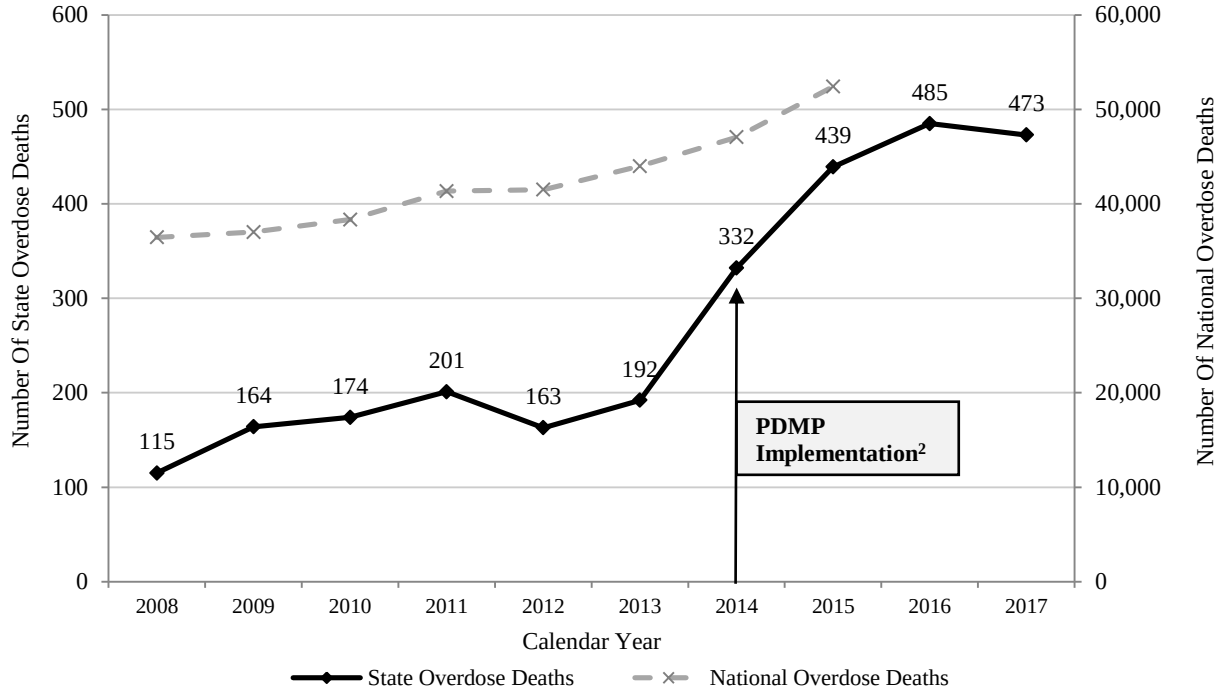
- Figure 9, depicting unaudited overdose death data,
- Figure 10, depicting unaudited Board data on pharmacy controlled drug losses,
- Figure 11, depicting unaudited State Police Forensic Lab analysis, and
- Figure 12, depicting NIU licit and illicit substance seizures.

Data from other State agencies needed to be placed into context, as other factors besides the PDMP likely affected observed changes in outputs. For example, the trends indicated changes to each potential indicator occurred prior to PDMP implementation. Additionally, unaudited federal

data on the number and type of overdose deaths reflected trends similar to those seen in State data.

Figure 9

National And State Overdose Deaths[1], CY 2008 Through CY 2016, With CY 2017 Projection



Notes:

1. OCME and Centers for Disease Control and Prevention data were limited as described in Appendix A.
2. PDMP implementation occurred during mid- to late-CY 2014 once the software became operational. Dispensers began registering and uploading data between August and October 2014 while prescribers began registering in October 2014 as discussed in Observations No. 15 and No. 16.

Source: LBA analysis of unaudited U.S. Centers for Disease Control and Prevention and OCME overdose death data.

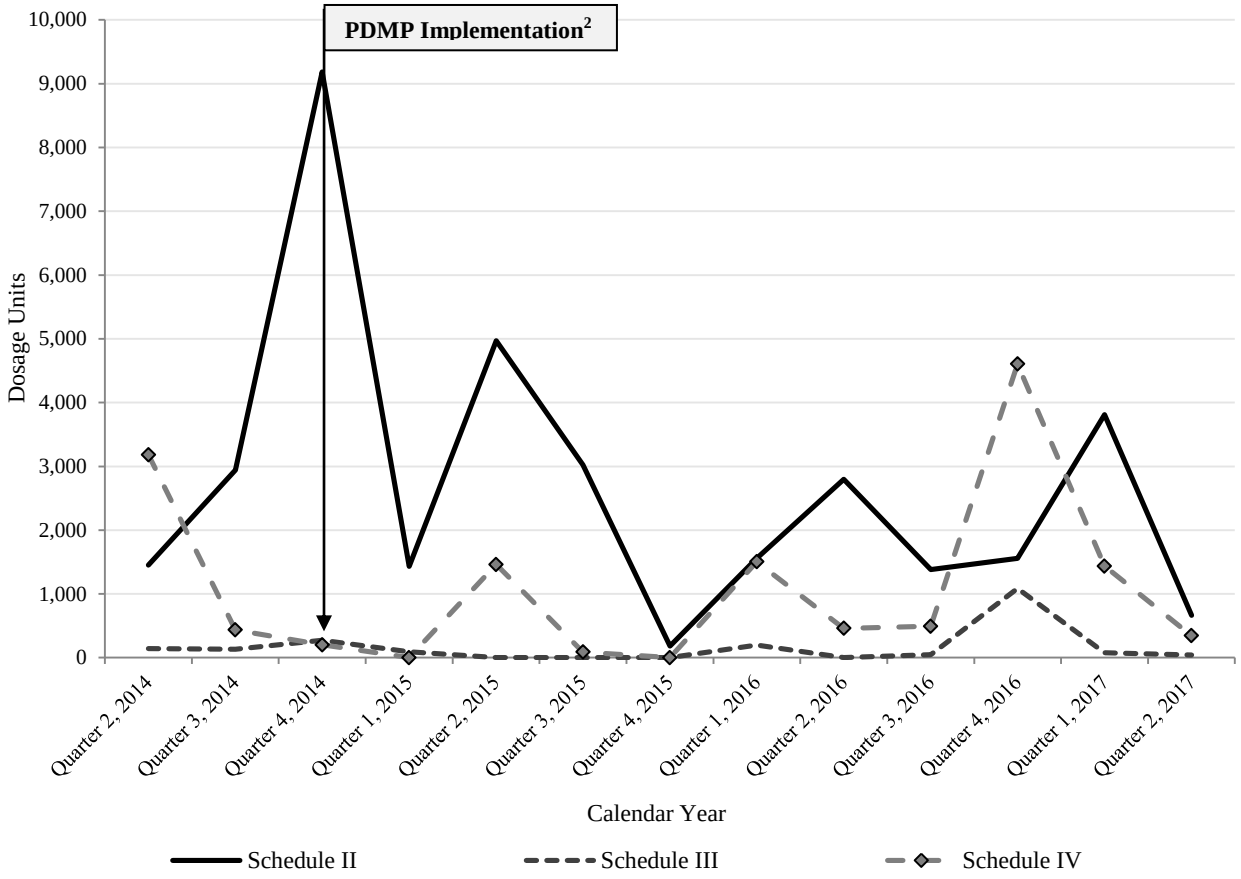
Insufficient Anecdotal Evidence And Analysis To Assess Effectiveness

Although 1,790 of 2,679 prescribers (66.8 percent) and 296 of 392 dispensers (75.5 percent) responding to the Council's surveys agreed the PDMP was a useful tool to help prevent drug diversion generally, no detailed questions were asked about specific types of diversion. The survey results alone did not indicate whether the PDMP had an effect on diversion, and Board staff never translated anecdotal output information into analysis of the PDMP's effect on select indicators of diversion. Council surveys did not include any questions about patient mortality or

the number of drug deaths, and it is unlikely such information would help demonstrate a conclusive relationship between the PDMP and these outcomes.

Figure 10

Board Data On Pharmacy Controlled Drug Diversion, By Schedule[1], Second Quarter, CY 2014 Through Second Quarter, CY 2017



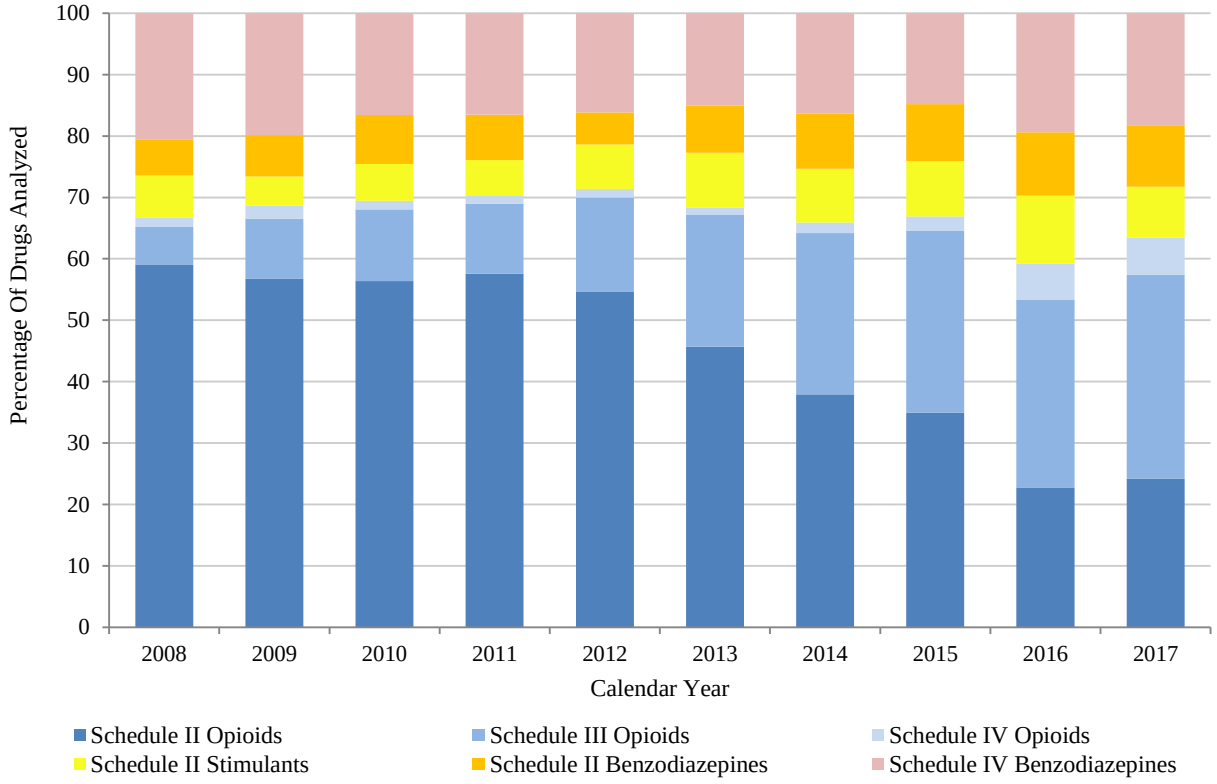
Notes:

1. Board data were limited, as described in Appendix A.
2. PDMP implementation occurred during mid- to late CY 2014 once the software became operational. Dispensers began registering and uploading data between August and October 2014, while prescribers began registering in October 2014, as discussed in Observations No. 15 and No. 16.

Source: LBA analysis of unaudited Board data.

Figure 11

Percentage Of Drugs Analyzed Annually By The State Police Forensic Lab, By Schedule And Type[1], CY 2008 Through CY 2017[2]



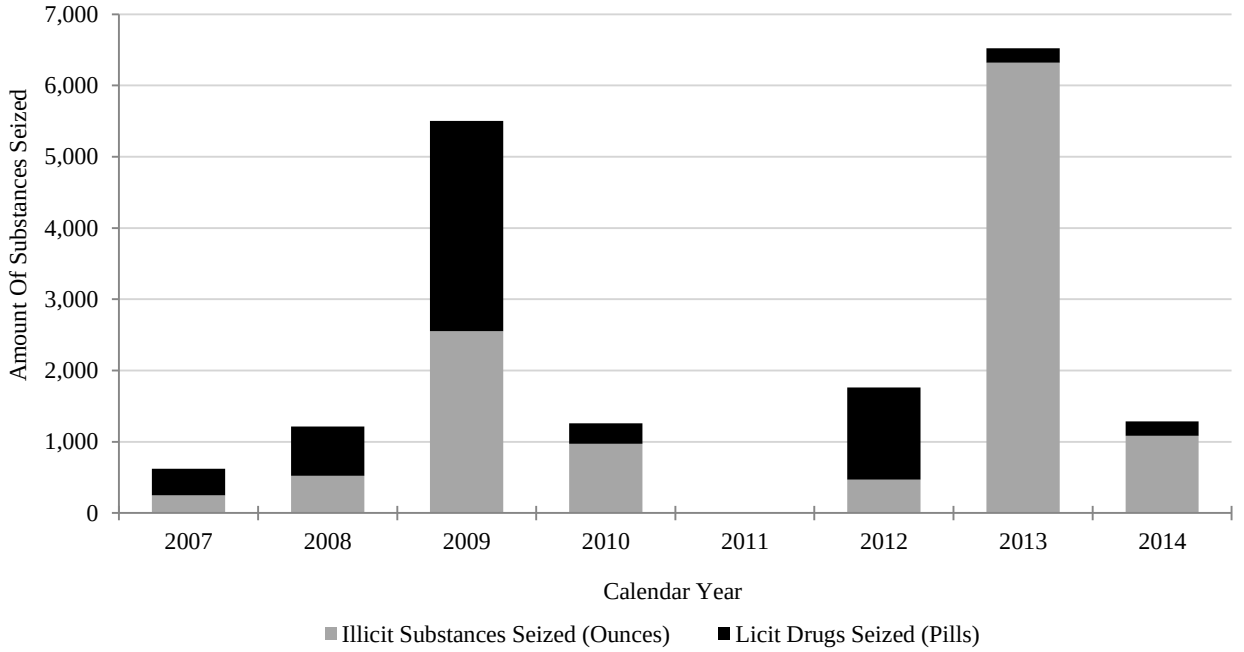
Notes:

1. State Police Forensic Laboratory data were limited as described in Appendix A.
2. PDMP implementation occurred during mid- to late CY 2014 once the software became operational. Dispensers began registering and uploading data between August and October 2014 while prescribers began registering in October 2014 as discussed in Observations No. 15 and No. 16.

Source: LBA analysis of unaudited State Police Forensic Laboratory data.

Figure 12

Amount Of Licit And Illicit Substances Seized In NIU Cases, CY 2007 Through CY 2014



Note: NIU data were limited, as described in Appendix A.

Source: LBA analysis of unaudited NIU data.

Recommendations:

We recommend the Board consider seeking legislative changes to:

- **eliminate the statutory outcomes of patient mortality and the number of drug deaths,**
- **limit outcomes related to diversion of schedule II through IV controlled drugs to more plausible outcomes and practical measures, and**
- **improve the ability of the PDMP to detect diversion of schedule II through IV controlled drugs by caretakers and individuals picking up another's prescriptions.**

Board Response:

We concur.

The Board will review and consider recommendations for legislative changes to eliminate the statutory outcomes of patient mortality and the number of drug deaths and will work to limit PDMP outcomes related to drug diversion to more plausible outcomes and practical measures.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Administrative rules changes and development	*See Observation No. 3*
All policy and procedures development	*See Observation No. 1*

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IMPLEMENTATION AND OPERATION

The Pharmacy Board (Board) was the State agency responsible for Prescription Drug Monitoring Program (PDMP) implementation and operation. A 14-member Controlled Drug Prescription Health and Safety Program Advisory Council (Council) was created to:

- assist and advise the Board with PDMP development, implementation, and operation**;**
- assist the Board in adopting and revising rules to implement the program;
- develop criteria for reviewing prescribing and dispensing information;
- develop criteria for reporting matters to the applicable health care regulatory board for further investigation;
- develop criteria for notifying practitioners who are engaged in obtaining controlled drugs from multiple prescribers or dispensers; and
- collect information on the outcomes and impact of the PDMP including satisfaction of users of the PDMP, impact on prescribing patterns, impact on referrals to regulatory boards, and other relevant measures.

For administrative support, the Board was administratively attached to the Department of Health and Human Services (DHHS), Office of Professional Licensure through State fiscal year (SFY) 2015 and assigned to the Office of Professional Licensure And Certification (OPLC) thereafter. Before Board staff dedicated to the PDMP were hired, the Council performed PDMP administration, such as grant writing and contract-related tasks, and Board staff played a role as well.

Planning And Strategy

Board staff developed informal goals and objectives with substantial commonality with provisions of State law. These informal goals and objectives were not clearly adopted by the Board. PDMP materials stated the PDMP's purpose was to enhance patient care, curtail the misuse and abuse of controlled drugs, combat the illicit trade in and the diversion of controlled drugs, and enable access to prescription information by practitioners, dispensers, and other authorized individuals and agencies. The PDMP was to provide a complete picture of a patient's controlled drug use so prescribers and pharmacists could properly manage the patient's treatment, including referral to substance abuse treatment services when needed. Informal goals included:

- providing prescribers and dispensers with a tool to improve clinical decision making and patient care in managing patients' health and prescriptions,
- promoting public health and safety through the prevention and treatment of misuse and abuse of controlled drugs, and
- assisting in the reduction of the diversion of controlled drugs.

Purported benefits included:

- providing comprehensive patient controlled substance prescription records;
- reviewing prescribing history reports for possible abuse or diversion;
- monitoring prescribing and dispensing trends to reduce abuse and overdose;
- facilitating coordination of care among health care providers;
- encouraging collaborative provider-pharmacist relationships to improve patient care;
- providing feedback to prescribers on their prescribing trends;
- providing information on patients' prescription histories and compliance with prescription orders;
- alerting providers to patients whose total prescription use for a given time period exceeds pre-determined threshold levels;
- identifying patients who can benefit from early assessment, treatment, and rehabilitation for drug misuse and addiction; and
- reducing unnecessary prescriptions leading to fewer diverted, now illicit, drugs being available.

Observation No. 5

Formalize A Risk-based PDMP Strategy And Plans

The Board's PDMP-related strategy and planning were at an initial stage of maturity. The Board had implemented and operated the PDMP since its inception without a strategy or overarching plans. The PDMP remained in implementation through SFY 2017, due in part to the lack of established and well-understood strategic goals and objectives to help move the PDMP through implementation and towards optimization. There were no formal PDMP-related risk management policies, procedures, or practices, which were essential for developing risk-based strategies and plans. Lack of formal planning contributed to ineffective PDMP implementation.

The Board was responsible for: 1) developing a mission, strategic plan, goals, and objectives and 2) establishing an effective control structure comprised of the methods, policies, and procedures to efficiently fulfill plans and achieve goals, objectives, and targets. Since calendar year (CY) 2008, we have commented on the Board's lack of formal plans, goals, and objectives. The Board did not begin preliminary development of a PDMP strategic plan, mission, goals, objectives, or targets until May 2017, with high-level, early concept draft documents produced in August 2017.

Governor's Commission On Alcohol And Drug Abuse Prevention, Intervention, And Treatment (Commission)'s Strategy

When applying for PDMP-related grants, Board staff reported referring to the Commission's five-year strategy published in CY 2012 for guidance. The strategy was intended to reduce the misuse of alcohol and other substances, as well as promote recovery, by focusing on alcohol, marijuana, and prescription drug misuse and underserved persons with substance use and mental health disorders. However, the strategy only covered CY 2013 through CY 2017, and the PDMP was one of at least 62 elements intended to reduce substance misuse. The strategy's connection

to the PDMP was limited further by the understanding the PDMP was not then fully established and was potentially temporary because the original legislation contained a prospective repeal, ending the PDMP after three years, in September 2015.

The Commission's strategy envisioned no specific PDMP outcomes and neither the Board nor the Council nor Board staff adopted the State strategy's five-year goal of a 15 percent reduction in drug abuse, which could have aligned PDMP goals with the State's strategy. Further, the strategy was not updated after the prospective repeal of the PDMP was eliminated in June 2013, further limiting the utility of the CY 2012 strategy as strategic guidance for the PDMP and emphasizing the need for the Board to develop its own strategic plan. The State strategy was reportedly under revision and the revised strategy was pending release as of October 2017.

Extent Of Board And Council Strategy Development And Planning

State law provided the Board and the Council with a framework of PDMP outcomes and tasks to guide and facilitate the development of a strategy, plans, a mission, goals, objectives, and targets. Informal goals were included in periodic public Board reports, Board staff reports to the Board and the Council, and PDMP informational materials and presentations. Many of these informal goals were largely consistent with those established for the PMDP in State law, while others were ministerial, were focused on software changes, or went beyond the framework established in State law. All similarly lacked detailed implementation and operational plans, objective means to quantify progress, timelines for achieving outcomes, and demonstration of effect. Council members intermittently discussed the Council's role in the PDMP over the years since its establishment in June 2012, but no mission, goals, objectives, or targets were ever formalized, validated, or pursued, as discussed in Observations No. 1 through No. 4 and No. 6.

As late as September 2017, the Board described the PDMP as still in implementation and reported ongoing concerns regarding PDMP expectations among the Council, the Legislature, and the OPLC, in the absence of a formal cohesive strategy. The Board and Council recognized the need for strategic planning and, in late SFY 2017, began the process to formalize a strategic plan with a mission, a vision statement, goals, and objectives. However, a timeline for implementation with major milestones had yet to be developed as of November 2017.

Vendor Contract Planning

A formal plan with major milestones for the initial PDMP software implementation was developed by the original database management vendor, and plans were drafted by the new database management vendor and third-party data analytics vendor covering time-limited delivery of services, but no reporting on plan execution was evident. Consequently, the Board was reportedly concerned with the way the PDMP was implemented, asserting the database was incomplete, not all required licensees were registered with the PDMP, and resources were limited to ensure structured oversight.

The Board's contract with the new database management vendor was approved through January 30, 2019, while the third-party data analytics vendor contract was valid through October 2017, without any objective measure of adequacy or identified need to change the contracts' terms and

conditions to better achieve outcomes. Reportedly, the Board was planning to seek additional reporting capabilities with the new database management vendor in SFY 2018. Additionally, the third-party data analytics vendor estimated milestones beyond the October 2017 date, but the Board did not re-evaluate or amend the agreement to reflect anticipated completion dates prior to the contract becoming invalid.

Recommendations:

We recommend the Board:

- **develop a holistic, multi-year strategy to first fully implement the PDMP and then move it towards optimization;**
- **formalize a risk-based strategy, with milestones, targets, goals, performance measures, and objectives;**
- **evaluate the strategy's near-term and long-term effectiveness by reviewing and updating the strategy routinely;**
- **include key stakeholders throughout the process;**
- **assess the current contracts and Board strategic needs before potential vendor migration must occur to ensure the terms and conditions of each contract fully support attaining PDMP outcomes; and**
- **revalidate the data analytics contract with amended dates for deliverables reflecting anticipated completion of tasks.**

Board Response:

We concur.

The Board will work with the Council and other relevant State stakeholders to develop a holistic multi-year strategic plan guided by the following key strategic elements: assessment, capacity building, planning, implementation, evaluation/monitoring, sustainability, and cultural competency. This plan will formalize risk-based strategies, goals, objectives, performance measures, and targets. Through its evaluation and monitoring component, this plan will also structure evaluation of near- and long-term effectiveness and provide information permitting the Board to update strategies routinely.

The Board will review current contracts and dates and the Board's strategic needs to ensure terms and conditions of each contract are fully met and support attaining PDMP outcomes, especially in anticipation of any vendor changes.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Integration with compliance inspection processes	*January 2018*
Reporting functions identified with vendor	*April 2018*
Statute changes to legislature	*July 2018*
Strategic plan draft	*July 2018*
Rule writing on changes	*October 2018*
Data analysis-trends/2yr data	*December 2018*
Implement statute changes	*January 2019*
Refine data analysis-vendor funding issue	*January 2019*
Verification statute and rules change	*March 2019*
Implementation of strategic plan	*July 2019*
Obtain additional personnel, including two pharmacy inspectors and one data analyst	*July 2019*
All policy and procedures development	*See Observation No. 1*

Measuring Performance

In September 2012, the Council developed an evaluation plan that envisioned developing an approach to measure progress towards short- and long-term output and outcomes based goals. The plan was never implemented. Initial activities were expected to document: 1) progress towards developmental and operational goals and 2) process measures, such as enrollment, utilization, reporting, and user satisfaction. The plan specified four long-term goals:

- reducing patient morbidity and mortality associated with controlled drugs,
- assisting practitioners with discerning between patients in need of legitimate pain treatment and patients seeking controlled drug for their own addiction or for diversion,
- helping identify practitioners who were fraudulently prescribing controlled drugs, adding to prescription drug abuse, and
- creating a greater sense of safety, security, and comfort in the practitioner-patient relationship.

While the PDMP database contained a substantial amount of data, there was no inherent value in it. Data must be translated into relevant, useful information. Analysis could show trends over time. However, systemic analysis of PDMP data and report development was only initiated in the fall of 2016 and not completed through the audit period. The data analytics vendor created the first draft product in the first quarter of SFY 2018, but this was only a proof-of-concept undertaking, as it was provided on a one-time basis. Institutionalizing data analytics was viewed as a priority but was contingent upon the receipt of federal grant funding and the hiring of a Board data analyst dedicated to the PDMP. The State applied for, but did not receive, applicable federal grant funding in early SFY 2018.

Observation No. 6

Create A Performance Measurement System

The Board's performance measurement system was at an initial stage of maturity. The Board's ability to monitor and report on PDMP effectiveness and other Board operations was hindered by the lack of a formal performance measurement system. The large volume of PDMP data collected since CY 2014 essentially went unanalyzed and was never systematically used to create knowledge or improve understanding of PDMP outcomes and effectiveness.

Defining goals and objectives and identifying what data to collect to measure progress on reaching those goals and objectives enables assessment of how efficiently and effectively services operate. Continuous monitoring allows management to make adjustments to deficient areas. We have recommended the Board develop measureable performance standards for inspections since at least 2008, but recommendations remained unaddressed. Monitoring and reporting on PDMP achievements, including outputs and outcomes, was ad hoc and inconsistent and done without the guidance of a strategic plan. In lieu of a formal performance measurement system supporting a strategic plan, the Board relied primarily on inconsistent and irregular reporting of outputs and anecdotal information on outcomes, and often based on arbitrary federal thresholds. Additionally, reporting was often unclear, associating trends in PDMP data with desired programmatic outcomes. However, reports never *demonstrated* any association, correlation, or causation existed between the data and desired outcomes. Consequently, the Board was unable to provide public accountability for PDMP effectiveness, or strategically manage the PDMP and other subdivisions of Board operations.

Council Evaluations

Strategic and other plans should identify what data to track to assess outcomes and other performance measures, such as goals, objectives, targets, service quality, and processes. The Council was obligated to collect information on PDMP outcomes and impacts, including: 1) user satisfaction, 2) impact on prescribing patterns, 3) impact on referrals to regulatory boards, and 4) other relevant measures. In September 2012, the Council developed, but never implemented, an evaluation framework based on expected outcomes articulated in State law. Furthermore, neither the Council nor the Board had plans or developed a holistic reporting and data collection system to assess overall PDMP performance or performance of constituent parts of the PDMP.

Instead, limited data collection of anecdotal outcomes occurred through two Council-administered surveys of PDMP-registered prescribers in CY 2016 and dispensers in CY 2017. Only summary results were provided from the dispenser survey, and both surveys were optional, producing low response rates of an estimated 23 percent of PDMP-registered prescribers and 16 percent of PDMP-registered dispensers. The Council included specific questions regarding prescribing and dispensing habits, PDMP utilization, and general usefulness of the PDMP. However, user satisfaction and other potential relevant measures were not direct survey inquiries and were obtained only if a respondent chose to provide relevant comments. The ad hoc collection of satisfaction and other information limited: 1) the surveys' utility in collecting statutorily-required information and 2) the efficiency of potential survey analysis. Additionally,

routine follow-up surveys to prescribers and dispensers did not occur, supplemental evaluations integrating other available data were not undertaken, and referrals to other regulatory boards were ad hoc and not tracked, as discussed in Observations No. 1 through No. 4, No. 13, and No. 16. This compromised longitudinal analysis of potential changes in PDMP performance.

Board-reported Outputs

Ongoing monitoring and reporting of PDMP performance was fundamental to performance measurement. Effective measures rely on accurate data, must be observable, and address a variety of areas including inputs, outputs, process, and outcomes. As discussed in Observations No. 10 and No. 16, several formal PDMP reports were required of the Board, including annual effectiveness reports and quarterly federal grant reports. Board staff also provided periodic reports to the Board and the Council. However, overall reporting by the Board was ad hoc and inconsistent, and while outputs required for federal reporting measures were included in other reports at times, the data was unreliable and no reports contained, nor did the Board develop, additional outputs or measures beyond the arbitrary federal metrics. Comparative assessments of the available outputs to analyze progress towards PDMP outcomes were not completed by the Board. Accurately reporting on effectiveness was impossible without defined goals, targets, and objectives, additional measures, reliable data, and analyses.

Furthermore, outputs were quantitative measures of activity, such as the number of users or the number of prescriptions uploaded, while outcomes were the results achieved from those outputs, such as percentage of users compliant with querying requirements and changes in prescribing habits. PDMP collection and reporting activities focused on outputs and never translated any measures into outcomes or characterized effectiveness-related expectations of the PDMP articulated in State law.

Vendor Contracts

The original PDMP database management service contract was approved in June 2014 and assumed by a new vendor in December 2016. Dispensers could submit required information beginning in September 2014, and prescribers received access and the ability to query in October 2014. Since July 2015, State law permitted the Board to use and release information and reports based on aggregated, de-identified PDMP data for analysis, research, and education.

However, contractually-required reports were limited to pre-established standard formats developed by the database management vendor, which Board staff indicated were not consistently delivered, did not meet all user needs, and contained data errors at times. Standard reports were useful for retrieving outputs necessary for federal grant reporting. However, the Board did not seek additional reporting and data validation capabilities from the original database management vendor, which would have assisted in analysis and evaluation. Reportedly, Board staff wanted to seek additional reporting capabilities with the new database management vendor in SFY 2018.

Board staff indicated PDMP data was primarily reviewed in response to inquiries, and staff lacked the capacity to effectively evaluate outcomes in a systematic manner. In late SFY 2016,

Board staff submitted a proposal to obtain data analytic services from a third-party vendor, at no cost to the Board, to assist with:

- acquiring a data dictionary and report templates,
- coordinating and sharing formatted report templates with benchmark reporting,
- soliciting feedback from stakeholders to identify analytical needs,
- drafting report templates to be included in the 2016 annual PDMP report,
- implementing data analysis and reporting,
- reviewing and revising report templates, and
- identifying a distribution process for additional PDMP reports to stakeholders.

The Board entered into a one-year, sole-source agreement with the data analytics vendor in October 2016. The partnership with the vendor focused on de-identifying data and delivering outputs through standard reports. It was not focused on developing other relevant measures, distilling relevant performance information from the PDMP database, or undertaking evaluations to assess outcomes. While the data analytics vendor reportedly assisted with the 2016 annual report and developed a data dictionary, other tasks were not accomplished timely and were not anticipated to be completed until December 2017 or later.

Other Data Resources

The Board did not utilize other potential data resources to assess PDMP outcomes. Several entities collected relevant statewide data before and after the PDMP was established, data which could have aided in: 1) providing context for PDMP data and trends, 2) monitoring statewide trends affecting PDMP management and operation, and 3) evaluating PDMP outcomes. While Council members indicated they were aware of these data resources and expressed interest in utilizing them, acquiring usable data and performing analyses never progressed beyond discussions. Also, the Council periodically reviewed national trends developed and published by federal agencies; however, associating or correlating national trends to the State's PDMP-related trends could not be interpreted as demonstrating a State-specific outcome.

Prior Audits

Our *Board of Pharmacy Financial Audit Report For The Six Months Ended December 31, 2008* (2008 audit) and *Board of Pharmacy Inspections Performance Audit Report* issued in May 2015 (2015 audit) noted the Board informally monitored inspections by occasionally reviewing staff inspection reports, lacked a system to measure inspection performance against goals and objectives, and did not analyze inspection data to ensure resources were utilized efficiently and effectively. We recommended the Board establish an inspection performance measurement system and develop and compare goals to actual performance to improve efficiency and effectiveness. The Board concurred. As discussed in Observations No. 12 and No. 26, the Board failed to develop formal policies and procedures to monitor Board operations, establish a system to capture inspection activity, collect data for analysis, or develop goals and objectives to measure performance. Furthermore, PDMP compliance was not integrated into Board inspection processes during the audit period.

Appendix G contains a summary of the status for each prior audit observation we examined during the course of this audit.

Recommendations:

We recommend the Board:

- **develop and establish a performance measurement system with defined goals, objectives, targets, and measures to efficiently and effectively evaluate Board operations and PDMP effectiveness at the process, output, and outcome levels;**
- **collaborate with other statewide entities to incorporate multiple data resources into Council and Board analyses and assessments of PDMP processes, outputs, and outcomes;**
- **develop performance measures and routinely administer comprehensive surveys related to statutorily-specified areas for monitoring and evaluation, as well as relevant outputs and processes; and**
- **include performance measurement in the development of its strategy and plans.**

Board Response:

We concur.

As discussed above, the Board will develop and establish a performance measurement system with defined goals, objectives targets, and measures.

The Board will identify appropriate stakeholders and seek collaboration to incorporate multiple data resources into analyses and assessments of PDMP processes, outputs, and outcomes. This will take additional analytical resources (e.g., software, staffing or contracted services) to incorporate this data with PDMP data, unless stakeholders offer services in-kind to assist with this merging of data.

The Board will review the statutorily specified areas and, as defined in the strategic plan, routinely administer surveys in specified areas for monitoring and evaluation. Finally, the Board will include performance measurement in the strategic plan.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
As part of draft strategic plan timeline	*July 2018*
Survey development – Council	*September 2018*
All policy and procedures development	*See Observation No. 1*

Observation No. 7

Establish Criteria And Thresholds

The Board's oversight of criteria and threshold development essential to PDMP operation was at an initial stage of maturity. The lack of quantified criteria and thresholds to objectively identify cases of potential abuse, diversion, or violation of professional standards undermined PDMP effectiveness, as related Board and Council statutory obligations remained unfulfilled.

The Board was required to design and establish the PDMP; promulgate rules defining the criteria for: 1) reviewing prescribing and dispensing information, 2) reporting to regulatory boards with jurisdiction to further investigate matters, 3) notifying practitioners of patients engaged in obtaining controlled drugs from multiple practitioners or dispensers, and 4) any other measure necessary to implement the PDMP; and annually report on PDMP effectiveness. The Council was required to assist the Board with: 1) implementing and operating the PDMP and 2) adopting and revising related rules. The Council was also required to develop the review, reporting, and notification criteria to be included in Board rules and collect outcome and impact information.

Eighteen of 21 Board and Council members (85.7 percent) responded to our June 2017 survey. Member responses indicated a lack of clarity regarding which entities they understood to be responsible for developing relevant criteria to evaluate the PDMP, as indicated by the following results:

- 16 (88.9 percent) reported the Council was responsible,
- 13 (72.2 percent) reported the Board was responsible,
- 13 (72.2 percent) reported Board staff dedicated to the PDMP were responsible,
- six (33.3 percent) reported other regulatory boards were responsible, and
- four (22.2 percent) reported the PDMP database management vendor was responsible.

The complete results of our survey of Board and Council members are included in Appendix D.

The Council recognized its statutory responsibility to develop criteria and thresholds at its first meeting in July 2012 and during at least five other meetings through CY 2015. Elements of its statutory responsibilities, such as developing criteria and thresholds, notifying other regulatory boards of noncompliance, and specifying report data, were discussed at meetings since the inception of the Council through the audit period. However, criteria discussions never matured, and criteria and thresholds remained undeveloped. Reportedly, the Council intended to revisit the topic of criteria and thresholds again during its September 2017 meeting, but this discussion did not appear to occur.

While Board rules required the database management vendor to collect and monitor PDMP information, the rules lacked any specificity to effectuate core PDMP monitoring thresholds. Rules required the PDMP database management vendor to review and evaluate PDMP information "to identify behavior that suggests possible drug abuse, misuse, or diversion, or possible violations of law or breaches of professional standards," without setting thresholds indicative of abuse, misuse, diversion, or violation of professional standards or developing

relevant definitions. Rules did include nine patient-related and eight prescriber- and dispenser-related factors for the vendor to consider at a minimum, again without quantifying any of the factors.

Further, we found:

- The statutory threshold for doctor shopping was not observed, and arbitrary federal grant reporting measures were substituted in the absence of duly adopted Board-set criteria and thresholds, as we discuss in Observation No. 8. These federal grant measures were also found in periodic public reports, as we discuss in Observation No. 10, and in reports to the Board, Council, and other regulatory boards, as we discuss in Observations No. 9 and No. 13, potentially creating a false impression of PDMP effect.

- Absence of statutorily-required Board and Council threshold standards left stakeholders to determine their own criteria and thresholds.

- The PDMP Program Manager had to divert focus from other implementation activities to engage other regulatory boards to solicit individual board threshold preferences based on individual professions' scopes of practice, to no effect through SFY 2017.

- The PDMP was statutorily required to review information for indications of abuse or misuse of schedule II through IV controlled drugs and to notify the responsible prescriber of any instances where they may have been involved. Other than doctor shopping as we discuss in Observation No. 8, unsolicited reporting to prescribers and pharmacies was to begin in SFY 2016 but was delayed to SFY 2017. Through early SFY 2018, the types of reports that would be available to PDMP users were still not determined, and unsolicited reporting was not occurring on a regular basis. Instead, regulatory boards were inconsistently notified of instances that may have required further investigation based not on duly adopted Board standards and definitions codified in rules, but instead on arbitrary federal grant reporting criteria.

- The PDMP was statutorily required to notify regulatory boards and provide information necessary for an investigation when there was reasonable cause to believe a violation of law or breach of professional standards may have occurred. Without established criteria and thresholds, regulatory boards were unable to objectively take appropriate notification and disciplinary action against licensees, such as alerting licensees of PDMP noncompliance or possible doctor shopping indicators, even if notifications from the PDMP were received.

Recommendations:

We recommend the Board comply with State law and:

- **in the near-term, work with the Council to develop, implement, and refine criteria and thresholds defining abuse, misuse, diversion, and violation of professional standards;**
- **revise administrative rules to set quantified criteria and thresholds on potential controlled drug abuse, misuse, or diversion, as well as breaches of professional standards;**
- **discontinue issuing unsolicited reports to practitioners and their regulating board until criteria and thresholds have been defined and adopted in rule;**
- **provide regulatory boards necessary reports and instructions to ensure recommendations for further investigation are received timely; and**
- **include in its strategy and plans a component addressing criteria and threshold development.**

Board Response:

We concur.

The Board will work with the Council and other regulatory boards to develop, implement, and refine criteria and thresholds defining abuse, misuse, diversion, and violation of professional standards. The Board will also revise administrative rules to set quantified criteria and thresholds on potential drug abuse, misuse, or diversion, as well as breaches of professional standards.

The Board has only issued alerts on patients who have seen multiple providers or pharmacies. This threshold has already been defined, and the PDMP software is ready and automatically identifies individuals exceeding the threshold. The Board will work to define other criteria and thresholds and, based on those definitions and the new database management vendor's capacity, will work on reporting mechanisms to notify practitioners and other regulatory boards. The Board will include addressing criteria and threshold development in the strategic plan.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Rules developed concerning reporting functions	*June 2018*
Rules development reporting cycles, content, and format	*June 2018*
Rules development diversion criteria in administrative rules	*June 2018*
All policy and procedures development	*See Observation No. 1*

Observation No. 8

Establish A System To Address Potential Doctor Shopping

The Board's system to identify instances of potential doctor shopping indicated in PDMP data was at an initial stage of maturity. The system to address doctor shopping envisioned in statute included criteria developed by the Council and adopted into Board rules, routine analysis of PDMP data for indications of improper prescribing, routine reporting to cognizant regulatory boards for follow up investigation and enforcement, and evaluation of process and PDMP effectiveness. None of these elements were formalized, undermining achievement of a fundamental, though informal, PDMP goal.

Criteria Unadopted

Doctor shopping was an unlawful act generally defined as an individual seeking, from multiple prescribers, prescriptions for controlled drugs for the recipient's own abuse or diversion. Doctor shopping was purportedly a substantial means of diverting prescription drugs to illicit use, although no definitive data describing the magnitude of the problem in New Hampshire existed. Minimizing diversion via doctor shopping was nonetheless an informal PDMP goal.

State law provided it was:

> unlawful for any person to knowingly acquire, obtain possession of or attempt to acquire or obtain possession of a controlled drug by misrepresentation, fraud, forgery, deception or subterfuge. This prohibition includes the situation in which a person independently consults 2 or more practitioners for treatment solely to obtain additional controlled drugs or prescriptions for controlled drugs.

This effectively defined the statutory doctor shopping threshold for an individual as improperly obtaining any controlled drugs from two or more practitioners and one or more dispensing locations. Alternatively, the contract with the State's original PDMP database management vendor defined the threshold as obtaining schedule II, III, or IV controlled drugs from six practitioners and six pharmacies within three months.

Regardless, the Board did not apply the statutory or contractual thresholds when analyzing PDMP data for patients, instead using arbitrary federal thresholds derived from federal grant reporting requirements and focusing on the first two:

- five prescribers and five dispensing locations,
- ten prescribers and ten dispensing locations, and
- 15 prescribers and 15 dispensing locations.

We asked members of the regulatory boards responsible for overseeing practitioners subject to the PDMP which threshold their board used as an indication doctor shopping may be occurring. Twenty-nine responded to specific options we provided and:

- 11 (37.9 percent) reported they did not know what the threshold was,
- seven (24.1 percent) reported there was no current threshold,
- seven (24.1 percent) reported consulting two or more practitioners was the threshold, and
- four (13.8 percent) reported consulting three prescribers and three dispensers was the threshold.

Three respondents provided other responses, without specifying a threshold. None reported a threshold of five, six, ten, or 15 prescribers and dispensing locations.

The results of our survey of other regulatory boards are in Appendix E.

Board and Council members and Board staff reported a belief the statutory threshold of seeking prescriptions from two or more practitioners was dated, likely too low, and impossible to operationalize. Discussions related to updating and amending the threshold were underway in early SFY 2018.

Ad Hoc Enforcement

Contemplated with the initiation of the PDMP in CY 2012 was issuing to prescribers unsolicited reports on patients obtaining schedule II through IV controlled drug prescriptions from multiple prescribers and dispensers. Federal grant report data published by the State indicated that, during the ten quarters covered, one unsolicited report was issued in the fourth quarter of CY 2016. However, Board staff also reportedly issued unsolicited "education letters" twice based on the grant reporting criteria of five prescribers and dispensing locations. In one instance, records indicated Board staff sent letters to at least 111 prescribers in a two-month period. In the second instance, 61 individuals were purportedly over the grant-based threshold, but Board records did not specify the number of PDMP registrants receiving letters. Inconsistencies with the registration process in effect at the time raised questions as to whether registrants actually received the reports. The ability of Board staff to continue sending letters ended with changes resulting from the migration to the new PDMP database management vendor, with no timeline for resumption.

While the Board had approved the education letter's format, the underpinning criteria were not described in Board rules, there was no regulating policy or procedure, and the Board did not appear to provide approval for issuing the letters. Instead, the Council adopted the arbitrary federal grant threshold for use to identify those to be contacted by Board staff for involvement in potential doctor shopping. This action appeared to be outside the Council's statutory advisory authority.

As we discuss in Observations No. 7, No. 9, and No. 13, consistent reporting to other regulatory boards did not occur, and as we discuss in Observation No. 14, clarity on law enforcement use of PDMP data and information, including access to information indicating potential doctor shopping, was not achieved. There were no indications information on potential doctor shopping was provided to law enforcement, and it was not clear how many, if any, reports related to doctor shopping were provided to regulatory boards for action.

Tracking Outputs And Outcomes

Output tracking of instances of potential doctor shopping occurred pursuant to federal grant requirements. Periodic reports provided to satisfy federal grant requirements indicated the number of individuals exceeding the arbitrary federal grant threshold of:

- *five* prescribers and *five* dispensing locations decreased by 73.2 percent across ten quarters, from 56 individuals during the fourth quarter of CY 2014 to 15 individuals in the first quarter of CY 2017, and

- *ten* prescribers and *ten* dispensing locations decreased from two individuals in the fourth quarter of CY 2014 to zero in each of the remaining nine quarters.

Neither were reports on the number of individuals exceeding the statutory or contractual thresholds ever produced nor were outcome measures related to the effect that unsolicited "educational reports" or reports to regulatory boards had on doctor shopping developed.

Conflicting Statutory Language On Criteria And Rule

Statute appeared to contain inconsistencies regarding the Council developing and the Board adopting rules for criteria related to doctor shopping. Statute provided:

- the Council must "[d]evelop criteria for notifying *practitioners who are engaged* in obtaining controlled substances from multiple prescribers or dispensers" [emphasis added] but

- also provided the Board must adopt certain rules including, "[t]he criteria for notifying practitioners *of individuals that are engaged* in obtaining controlled substances from multiple practitioners or dispensers." [emphasis added]

Statute pertaining to the Council omitted references to patients or persons in the care of practitioners, which led to the risk of misinterpreting the law and conflicting with eventual rule. The discrepancy was known to the Council and brought to the Board's attention during its September 2017 meeting.

Recommendations:

We recommend the Board:

- **promulgate administrative rules to structure and regulate the system it expects to use to address potential doctor shopping, based on the State's statutory threshold;**
- **timely notify practitioners who may be involved in prescribing for a doctor shopper;**
- **timely provide reports to regulatory boards on practitioners identified as being involved in possible doctor shopping;**

- **track indicators of potential doctor shopping based on the State's statutory threshold, routinely monitor doctor shopping trends, and regularly report on enforcement and related outcomes;**
- **discontinue the use of "education letters" until the supporting criteria, rules, processes, and procedures are finalized;**
- **clarify law enforcement access to PDMP information on potential doctor shopping; and**
- **include in its strategy and plans a component related to doctor shopping threshold revisions, rule promulgation, policy and procedure development, reporting, and outcomes tracking.**

Should the Board formally conclude the current statutory threshold defining doctor shopping is outmoded or obsolete, we recommend the Board elicit an appropriate threshold from the Council and relevant stakeholders, and seek legislative changes to adopt the new threshold in statute.

We also recommend the Board consider seeking legislative changes to clarify whether the Council is to develop criteria for notifying practitioners of individuals under their care that are potentially engaged in inappropriately obtaining controlled drugs from multiple practitioners or dispensers.

Board Response:

We concur.

The Board will develop rules concerning doctor shopping thresholds, monitoring trends and outcomes based on national best practices. Since the current State threshold definition for doctor shopping is not appropriate for current practice, the Board will seek legislative changes to adopt a new threshold in statute and rule.

The Board will develop policy and procedures concerning provider notification of doctor shopping through an automated push report generated by the new database management vendor's software that will alert a prescriber when a patient has exceed the defined threshold of multiple providers and multiple pharmacies.

While the Board sees the benefit of tracking potential doctor shopping, it believes doing so would require system/analysis development to identify those prescribers who are participating in doctor shopping. This requirement would either require a work order quote from the new database management vendor or result in costs for software to build internal capacity.

The Board believes that "education letters" that inform providers of issues and trends in respective practice settings may be a valuable tool for both licensees and other agencies. The Board will develop a policy and procedure for process of notification and work the timing of the education letters into the strategic plan since the education letters/alerts outside of the doctor shopping letters are considered an "enhancement" to our system and will require additional funding for the program to fully implement.

The Board agrees that its strategic plan will include all required information. This will include obtaining statutory change to doctor shopping threshold.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
All policy and procedures development	*See Observation No. 1*

Information Management, Knowledge Management, And Reporting

Reportedly, it took from CY 2012 through CY 2016 just to "ramp-up" the PDMP, leaving little time to develop required reports and underlying analytics. Since June 2012, the Board was required to annually report to the Oversight Committee on Health and Human Services on the PDMP's effectiveness. Board staff reportedly provided monthly reports to different regulatory boards and the Council, which included PDMP outputs. The PDMP software could provide standard reports and supported custom reporting.

Board staff also reported data required by the terms of the federal grants the Board received for the PDMP. The requirements contained output measures. Juxtaposition of raw data without appropriate context left consumers of PDMP data to infer the data demonstrated something relevant to the effectiveness of the PDMP, when this might not have been the case.

Observation No. 9

Improve Knowledge And Internal Information Management

The Board's information management practices and procedures facilitating PDMP-related knowledge management were at an initial stage of maturity. Internal communications facilitate performance of key tasks, evaluating performance and results, achieving objectives, and managing risk through informed Board oversight. The lack of a strategy and implementing plan, discussed in Observation No. 5, likely contributed to the lack of focus on creating a thorough, well-structured system to internally manage information. We have noted issues with Board information and knowledge management in our 2008 and 2015 audits, which remained unaddressed. The PDMP was implemented without relevant data collection activities, reporting mechanisms and cycles, and formats necessary to effectively communicate PDMP operation and performance internally. Further, basic data the Board could have utilized to systematically understand and refine PDMP operations were inconsistently collected. Data related to process and output metrics specified in State law, as well as intended outcomes, were similarly not tracked.

Information Requirements

State law framed expected outcomes, as discussed in Observation No. 1, and staff-developed goals and objectives augmented the provisions of State law, as discussed in Observation No. 5. Additional PDMP-related functions included registration, waivers, extensions, uploading, querying, criteria and thresholds indicating potential issues and related reporting, staffing, inspections, investigations, sanctions and discipline, education and training, and complaints.

Each constituted relevant management data streams the Board could have utilized to understand and refine PDMP operation. In CY 2012, the Council developed, but never implemented, an evaluation framework based on expected outcomes articulated in State law. Since the PDMP's implementation, there has been no standardized, holistic reporting and data collection system, or relevant formats detailing each aspect of PDMP operation and performance to help assess overall PDMP performance. Neither the Board nor the Council fully defined relevant inputs, processes, outputs, or outcomes.

Instead, quarterly reports were generated to summarize certain PDMP data into outputs to satisfy federal grant requirements. Federal grant threshold standards were arbitrary in nature, which resulted in the Board relying on the same arbitrary standards for programmatic purposes. In October 2016, the Board entered into an agreement with a third-party data analytics vendor focused largely on developing an external reporting system, which was expected to conclude by early October 2017. While updates on progress were intermittently contained in Board minutes, these milestones did not appear to be timely accomplished, and completion was not expected until December 2017 or later.

The Board and the Council also relied upon output reports developed by the original database management vendor to identify trends in PDMP data. However, identifying desired reports took time, there was no set cycle or format for Board and Council distribution, and reporting appeared ad hoc to address specific Board or Council questions.

PDMP Reports To The Board

According to Board minutes, formal PDMP programmatic reporting to the Board during public session expanded over time, from minimal in CY 2012 to routine by the end of the audit period in June 2017. Public minutes contained varying levels of detail, and supplemental reports addressing PDMP operations and specific aspects of PDMP activity were intermittently provided to the Board. The reports at times quantified PDMP activity, such as:

- registrant use of the interstate querying function,
- queries by profession,
- uploading waivers requested and approved,
- registrants not uploading as required, and
- registrant data compliance.

Nonpublic reports principally focused on ministerial matters, such as staffing, and PDMP functions, such as registration or data compliance processes, but lacked PDMP outputs or outcomes. One did discuss a specific case of an unlawful release of data, and another contained PDMP data prepared for a third-party. After the audit period, we noted discussions of substantive outcome-related information took place.

PDMP Reports To The Council And Council Reports To The Board

The Council received regular updates from Board staff on various aspects of PDMP implementation and operation. Board staff also provided the first analysis of PDMP data from

the data analytics vendor to the Council in July 2017. The vendor's analysis was for demonstration purposes and was not based on systemic data requirements to meet Board, Council, or other regulatory board needs.

As noted in Observation No. 19, the Board and the Council were not integrated, and interactions were limited. No regular, structured Council reporting to the Board was established. No formal apportionment of data and information collection responsibilities was established between the Board and Council; neither were the information requirements for each body set. The Council did not fully operationalize its obligation to collect information on the outcomes and impact of the PDMP, including user satisfaction, impact on prescribing patterns, impact on referrals to regulatory boards, and other relevant measures, which limited its ability to fully meet its obligation to assist the Board with designing, establishing, implementing, and operating the PDMP. As of August 2017, preliminary efforts were underway to schedule a meeting with a Council subcommittee and other relevant parties to determine which types of reports and research questions stakeholders were interested in receiving.

PDMP Reports To Other Regulatory Boards

The database management vendor was required to report relevant information to regulatory boards to be used: 1) for further investigation of potential violations of law or breaches of professional standards and 2) when a failure to report the dispensing of a schedule II through IV controlled drug might conceal potential diversion. Underpinning criteria were to be developed by the Council and adopted in Board rule. However, the PDMP was implemented without a structure to provide information needed by regulatory boards to enforce provisions of the PDMP affecting their licensees and operationalize the PDMP as intended. No standard report formats were identified. Routine reporting of potential noncompliance by the licensees of other regulatory boards did not occur. Substantive prescribing-related reports, such as registration and utilization reports, top prescribers for all schedules, top prescribers by schedule, top opioid prescribers, registration and reporting compliance reports, and error and correction reports, were not finalized during the audit period.

Information And Knowledge Management Component Of Strategy

Without a guiding strategy, disciplining plans, and definitions of effectiveness as discussed in Observations No. 1 through No. 5, establishing a useful information management system focused on salient data was likely problematic. Board staff reported inadequate capability of the PDMP software itself, and staffing limitations also hampered internal reporting. Board staff reported sending the new database management vendor a list of desired reports, available for an additional, one-time estimated fee $100,000 and annual maintenance fees of $20,000. These reports were, however, standard software-based reports that were not: 1) customized based on criteria and thresholds established to meet State legislative outcomes, 2) developed through a process eliciting individual regulatory board needs, or 3) 3) validated by the Board through the rule-making process.

Recommendations:

We recommend the Board:

- **establish, refine, and use concrete, observable, and objective measures that clearly represent PDMP performance and are uninfluenced by external factors to describe relevant inputs, processes, outputs, and outcomes that are directly linked to validated outputs and outcomes framed in State law and in the Board's strategy;**
- **standardize periodic reporting cycles, and the format and content of reports between the Board, the Council, and other regulatory boards to: 1) ensure each receives necessary information to permit regulatory boards to enforce PDMP requirements, 2) permit the Council to collect performance information, and 3) allow the Board to evaluate PDMP operations and outcomes;**
- **adopt the system in rule; and**
- **include in its strategy and plans a component addressing information management.**

Board Response:

We concur.

The Board will develop: (1) rules and policy concerning reporting functions to the Pharmacy Board and other regulatory boards based on statutory requirements; (2) rules and policy on information management and procedures for performance, operations, and outcomes; and (3) a timeline for data management, reporting functions, and outcomes as part of the strategic plan, including staffing, analysis, and computer upgrades needed to meet statutory requirements.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Information management included as part of strategic plan draft	*See Observation No. 5*
Standardization of reporting	*See Observation No. 7*
Required rules development	*July 2018*
All policy and procedures development	*See Observation No. 1*

Observation No. 10

Improve External Reporting And Communications

The Board's external reporting function was at an initial stage of maturity. The Board inconsistently complied with external reporting requirements, lacking adequate management controls, such as an external communications strategy and related policies and procedures, to ensure reporting requirements were met. Board compliance with statutory and regulatory requirements is a fundamental expectation. Publically communicating performance facilitates achieving objectives and managing risk, enables oversight, and underpins transparency.

Biennial Reports

The Board was required to publish a biennial report by December 1 of each odd calendar year. The Board's biennial report should have summarized its operations and included administrative, personnel, membership, and organizational information; outlined Board functions and major accomplishments; summarized fiscal data; and listed relevant legislation passed during the biennium covered. The Board was required to retain a copy on file in their office as a public document, post the report to the State's transparency website, and provide hardcopies to the State Library and several other recipients. Beginning in SFY 2016, the OPLC became responsible for the Board's administrative, clerical, and business processes and was required to file the Board's biennial report with the Governor and Council.

Beginning with our 2008 audit, we identified inadequacies related to the Board's biennial reporting practices. We recommended the Board ensure it prepared and submitted required biennial reports. The Board concurred. However, our 2015 audit illustrated the resolution of our 2008 financial audit's recommendations was incomplete. We found noncompliance continued through SFY 2017 with no biennial reports on Board operations completed, published, or distributed since CY 2008.

Annual PDMP Effectiveness Reports

Between June 2012 and July 2015, the Board was required to annually report on PDMP effectiveness to the Oversight Committee on Health and Human Services. Starting in July 2015, the Board was required to also provide the annual effectiveness report to the President of the Senate, the Speaker of the House of Representatives, the Governor, and Senate and House committees with policy jurisdiction. Subsequently, annual effectiveness reports were also required to include the number of practitioners registered, the percentage of practitioners using the PDMP, and a comparison of results and progress based on the use of the PDMP.

The Board could not produce evidence that annual effectiveness reports for SFYs 2013 or 2014 were published. Two reports, one covering SFY 2015 and the second covering October 2015 through September 2016, and one semi-annual report, covering July 2015 through December 2015, were created. The report covering the period through September 2016 may have been presented to the Oversight Committee on Health and Human Services. None contained an addressee or clear transmittal to any external body, nor did the reports describe PDMP effectiveness. Instead, the reports contained tabulated and graphed aggregated surveillance data

on registrations, utilization, prescriptions, and dispensing, which appeared responsive to the requirement to include the number of practitioners registered and the percentage of practitioners using the PDMP.

Audit Follow-up Reports

The Board was required to develop and publish a remedial action plan within 30 days of the release the 2015 audit on inspection practices. The report was to identify remedial actions the Board would take in response to the audit, as well as any actions required of the Legislature, the Governor and Council, or others. The Board was thereafter required to report semi-annually on its progress in responding to the 2015 audit. The Board published only an undated initial plan, never publishing any subsequent periodic progress reports.

Other PDMP-related Documents

Beyond complying with reporting requirements, the Board should have also established open and effective communications with stakeholders, including the public, to facilitate oversight and transparency. However, periodic non-confidential PDMP-related reports, containing certain PDMP outputs, and Council meeting minutes, plans, and other materials, were not generally available, limiting the opportunity for public oversight and understanding of the PDMP and its mission, goals, objectives, and performance.

Recommendations:

We recommend the Board:

- **develop policy and procedure designed to ensure compliance with external reporting requirements;**
- **improve sharing of non-confidential PDMP-related performance and outcome data to provide greater transparency for the Legislature, stakeholders, and the public; and**
- **include in its strategy and plans an external reporting and communications element.**

We recommend the OPLC timely file the Board's biennial operations reports with the Governor and Council.

Board Response:

We concur.

The Board will develop policy and procedures concerning external reporting requirements in conjunction with the OPLC, will develop policy and procedures concerning transparency of data and reporting such data to required entities within the scope of the statutes, and will develop policy and procedures to address outcomes and PDMP performance measurement.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
External reporting requirement included in strategic plan draft	*See Observation No. 5*
All policy and procedures development	*See Observation No. 1*

OPLC Response:

We concur.

The OPLC will be creating an annual report detailing the operations of the agency and the boards, commissions, and councils we support. The one annual report will be shared with the boards and filed with the Governor and Executive Council. We will seek legislation to amend current statutes of annual and biennial reports for each board, commission, and council, replacing them with the submission of one annual report by the OPLC.

Compliance With Board Administrative Requirements

The Board had a duty to enforce statutory requirements and was empowered to investigate misconduct by its licensees or any other matter governed by *Pharmacists and Pharmacies* and the *Controlled Drug Act (Act)*. This included the PDMP, a component of the *Act*. The Board employed professional and para-professional staff involved in inspections, investigations, drug losses, diversion reporting, controlled drug destruction requests, questions about State pharmacy laws and rules, and all other issues related to the inspection and investigative functions of the Board. The Board could provide investigative information to law enforcement or health licensing agencies, in accordance with specific statutory requirements or pursuant to a court order. Whether this authority applied to investigative materials derived from the PDMP was not clarified through SFY 2017, and PDMP-specific requirements were not integrated into compliance and inspection protocols. The Board reportedly self-limited PDMP-related responsibilities to the individuals and facilities it licensed but possibly had broader enforcement authority.

Observation No. 11

Clarify And Improve Board Enforcement

The Board's enforcement of PDMP requirements under its purview was at an initial stage of maturity. The Board did not:

- begin conducting investigations initiated with PDMP information until the fourth quarter of SFY 2017;
- formally clarify its own enforcement authorities and responsibilities or those of other entities responsible for overseeing and ensuring compliance with PDMP requirements;
- formally clarify the ability of its or other boards' compliance inspectors to access PDMP information;

- conduct sufficient education and outreach for entities responsible for monitoring or enforcing PDMP requirements, including law enforcement officials and non-pharmacy regulatory boards;
- develop a strategy and plans related to monitoring and enforcement of PDMP compliance;
- integrate non-pharmacy regulatory boards into monitoring and enforcement processes;
- develop rules, policy, or procedure necessary to structure and operate PDMP monitoring and enforcement systems; or
- oversee PDMP monitoring and enforcement requirements to evaluate outcomes, and report on PDMP effectiveness.

These inadequacies contributed to limited enforcement of PDMP requirements through SFY 2017, which inhibited the achievement of formal statutory outcomes and informal PDMP goals.

Distributed Responsibilities

The Board never formally defined the boundaries between enforcement entities, nor did it structure how those entities were to interoperate. Statute distributed PDMP-related enforcement authorities to various entities, as we discuss in Observations No. 13 and No. 14. Seven of the eight regulatory boards that oversaw professions required to register with the PDMP, including the Board, were responsible for enforcing compliance with registration, querying, and confidentiality and security requirements, as well as prescriber and dispenser conduct, through penalties and disciplinary actions. The Board was also responsible for enforcing compliance with requirements for dispensers to upload accurate PDMP information and not conceal a pattern of diversion by failing to upload, by issuing warning letters, applying penalties, and taking other disciplinary actions. As we discuss in Observation No. 13, the Board also held enforcement authority against those knowingly accessing, altering, destroying, or disclosing PDMP information or attempting to obtain PDMP information by fraud, deceit, misrepresentation, or subterfuge, and had held primary enforcement authority over querying requirements. Law enforcement was partially responsible for enforcing PDMP requirements, including potential crimes committed by prescribers, dispensers, and patients, through fines and imprisonment. Finally, the Board was responsible for annually reporting on the effectiveness of the entirety of the PDMP, including compliance with requirements and achievement of legislatively-intended outcomes.

The State's PDMP was expected to affect controlled drug diversion, abuse, and misuse, including, reducing patient morbidity associated with controlled drugs, affecting the number of instances of controlled drug abuse, and helping identify patients potentially engaged in doctor shopping or controlled drug misuse, abuse, or diversion. Additionally, the PDMP was expected to identify practitioners who were fraudulently prescribing controlled drugs and to affect overprescribing.

PDMP effectiveness rested, in part, on prescriber and dispenser adherence to requirements to register with, upload accurate data to, and query the PDMP, as well as adherence to regulatory board conduct standards, such as those related to prescribing practices. Without a holistic system

of controls in place to monitor and enforce compliance with requirements, PDMP effectiveness was compromised. Prescribers, dispensers, Board staff, and other enforcement entities were constrained in their ability to use PDMP information to detect behaviors indicative of controlled drug abuse, misuse, or diversion, such as doctor shopping, noncompliance with pain contracts, or use of fraudulent prescriptions. These constraints limited the extent to which such behaviors could have been addressed through preventative measures or treatment. Furthermore, noncompliance limited the ability of Board staff and other enforcement entities to detect misconduct on the part of prescribers or dispensers contributing to controlled drug abuse, misuse, or diversion.

Board's Overall Responsibility For Enforcement

Ultimately, the Board held overall responsibility for the PDMP, its operations, and reporting on its effectiveness. The Board held authority to enforce the *Act*, which encompassed the entirety of the PDMP's statutory framework. The Board also held responsibility for PDMP-related oversight of other entities to which statute distributed PDMP enforcement authorities and for enforcement of related requirements.

However, Board and Council members appeared to be unclear as to their responsibility for overall PDMP oversight and enforcement, and the relationship between the responsible regulatory boards was never formalized. Council members indicated the Council was unable to advise non-pharmacy regulatory boards as to how to use information provided by the PDMP, such as top prescriber reports, to ensure compliance with PDMP requirements. Board members indicated the Board could *generally* advise non-pharmacy regulatory boards but not take further action. Board staff indicated they did not believe they could systematically review PDMP information for potential breaches of professional standards or violations of law, unless such information was uncovered during the course of a specific regulatory board request for information. Some uncertainty was expressed by Board members as to whether statute allowed the Board to become involved in enforcement under certain circumstances against non-pharmacy licensees who were required to use the PDMP but was not formally clarified by the Board. Nonetheless, the Board, with its responsibility for overall enforcement of the *Act*, had the authority to fine *any person* who violated the *Act* a minimum of $350 for a first offense and $500 for a second or subsequent offense.

Insufficient Education And Outreach

Although enforcement authorities were assigned in statute, entities with enforcement authority reported an inconsistent understanding of their own roles and responsibilities, or the roles and responsibilities of others, which: 1) contributed to limited enforcement of requirements related to prescriber and patient misconduct and 2) hindered potential PDMP effectiveness in affecting controlled drug abuse, misuse, and diversion. As we discuss in Observation No. 13, regulatory board members inconsistently reported an accurate understanding of which entities were responsible for monitoring and enforcing various PDMP requirements. This confusion was shared by law enforcement officials and Board and Council members. Education and outreach efforts appeared to have limited success in conveying relevant information to enforcing entities:

- As we discuss in Observation No. 14, many law enforcement officials were unfamiliar with the PDMP itself or on the process by which they could obtain PDMP information for use in investigations, which was seen as a barrier to accessing PDMP information.

- As we discuss in Observation No. 13, non-pharmacy regulatory board members were unaware of many PDMP requirements and were often unaware of the authority of their own boards to regulate licensees' PDMP use. Non-pharmacy regulatory boards were not systematically involved in monitoring or enforcing compliance of their licensees with PDMP requirements.

Insufficient Clarity In Statute And Rules

Ten of 18 Board and Council members (55.6 percent) and 20 of 32 non-pharmacy regulatory board members (62.5 percent) expressed concerns about the extent to which enforcement responsibilities and authorities were clearly defined in State law or administrative rule. Stakeholders also expressed confusion regarding specific enforcement responsibilities and authorities, including when and how law enforcement officials could access or receive PDMP information, and who met or did not meet the definition of law enforcement.

Numerous stakeholders expressed confusion about the classification of the Board's compliance inspectors and whether they were considered to be law enforcement. The perceived inability of Board compliance inspectors to access PDMP information during the course of compliance inspections was seen by some State stakeholders as hindering PDMP compliance enforcement. Despite Board and Council members and Board staff recognizing confusion, the Board had not formally clarified the role of compliance inspectors through administrative rules or sought statutory changes, nor was it in the process of seeking clarification. If compliance inspectors were considered to be law enforcement, they would have to obtain a court order or search warrant to access PDMP information. However, statute authorized providing PDMP information to regulatory boards, pursuant to their official duties and responsibilities, which, for the Board, included investigation of possible misconduct by licensees and overarching responsibility to enforce PDMP requirements. The Board had an obligation to design and establish the PDMP and promulgate necessary rules to clarify operation of the PDMP.

Insufficient Monitoring And Enforcement

Without an adequate foundation to oversee and enforce the compliance of prescribers, dispensers, and patients with PDMP and professional conduct requirements, Board enforcement efforts were limited. Most Board and Council members and non-pharmacy regulatory board members expressed concerns with monitoring and enforcing specific PDMP requirements and prescriber, dispenser, and patient conduct. Further:

- The Board had not developed objectives, performance measures, or other mechanisms to implement and ensure systematic monitoring and enforcement of PDMP requirements, including tracking outputs or outcomes from monitoring and enforcement efforts of the Board, non-pharmacy regulatory boards, and law

enforcement. Consequently, the Board was reliant on ad hoc reports from stakeholders, including prescribers, to identify instances of noncompliance, rather than on systematic and clearly defined processes.

- The Board did not fully integrate non-pharmacy regulatory boards into the operation of the PDMP or into processes to monitor or enforce licensee compliance with PDMP requirements. Non-pharmacy regulatory boards reported minimal monitoring and enforcement action related to PDMP noncompliance through SFY 2017. In lieu of consistent reporting on licensee compliance with PDMP requirements, Board staff intermittently provided certain non-pharmacy regulatory boards with monthly reports on the prescribers writing the most prescriptions. Some non-pharmacy regulatory board staff were unsure how such information could be used. Board staff indicated the new PDMP software will have the ability to send unsolicited reports to the regulatory boards, although the ability to implement unsolicited reports relies on the yet-to-be-developed criteria and thresholds.

- The Board did not fully integrate law enforcement into processes to monitor or enforce licensee compliance with PDMP requirements, specifically those related to patient misconduct, such as doctor shopping, as we discuss in Observations No. 8 and No. 14. In lieu of law enforcement involvement, Board staff sent notifications only to prescribers and dispensers of patients who were potentially doctor shopping, which was a statutory requirement.

- Although Council and Board members discussed the idea of monitoring compliance through Board inspections as early as January 2015, the Board did not incorporate PDMP compliance into its inspection practices through SFY 2017, as we discuss in Observation No. 12, and only one Board investigation relied upon PDMP information during this timeframe. In early SFY 2018, PDMP information was increasingly used not only to support Board investigations, but also to initiate investigations in a manner originally intended. Board staff reported working on efforts to better integrate the PDMP into compliance processes.

- The Board appeared to relinquish some of its oversight and enforcement responsibilities to varying degrees, such as over delegate compliance and data confidentiality and security requirements, as we discuss in Observations No. 15 and No. 18, despite being aware of instances in which breaches of compliance occurred.

Reliance On Prescribers And Dispensers To Identify Diversion And Enforce Compliance

Board staff and Board and Council members appeared to defer detection of controlled drug diversion and doctor shoppers to individual prescribers and dispensers, as well as related enforcement to some extent. Prescribers and dispensers were expected to identify potential doctor shoppers and those seeking to divert controlled drugs through PDMP information, despite limited querying requirements for prescribers and none for dispensers. However, the Board did not appear to provide PDMP registrants with necessary information or training to identify

behaviors indicative of diversion or doctor shopping, which the Council had discussed providing through a web-based tutorial as early as February 2016.

Prescribers and dispensers were also expected to take actions to mitigate or prevent such behavior by patients, including, but not limited to, refusing to dispense or renew prescriptions. However, no information was systematically collected by Board staff on these outputs, and such information alone, without analysis by Board staff, would not have determined whether such actions were successful in preventing controlled drug diversion or doctor shopping, or whether patients were able to obtain controlled drugs from other prescribers or dispensers. The Board also provided no guidance as to when and how to report instances of suspected diversion or doctor shopping to Board staff or law enforcement.

Enforcement of controlled drug diversion and doctor shopping by prescribers and dispensers could fundamentally transform practitioners' relationships with their patients. Law enforcement would appear to be the more appropriate enforcement authority to handle investigations and cases of possible diversion and doctor shopping, as discussed in Observation No. 14.

Recommendations:

We recommend the Board:

- **develop standard educational materials for regulatory board members on the PDMP generally, as well as individual boards' monitoring and enforcement responsibilities and authorities;**
- **provide initial and ongoing training and education to regulatory boards;**
- **seek clarification from its Department of Justice (DOJ) attorney on the classification of Board compliance inspectors and their ability to access PDMP information;**
- **incorporate oversight and enforcement requirements in rules; and**
- **include in its strategy and plans components related to monitoring and enforcing compliance with PDMP requirements.**

We also recommend the Board clarify the enforcement authorities under its purview via rulemaking and seek clarification from the Legislature on those outside its purview.

Board Response:

We concur.

The Board will develop policy and procedures concerning education materials for regulatory boards and the Council as part of the member manuals (discussed in other parts of this response). The Board will clarify enforcement of PDMP responsibilities with other regulatory boards through rules and policy and procedure development. This is already in development.

As discussed in other observation responses, a training program for regulatory boards will be developed.

In April 2017, the Board clarified investigator responsibilities with the DOJ as it related to PDMP data access and use.

The Board will develop rules concerning enforcement and oversight of the PDMP, and will include monitoring and enforcing compliance in the strategic plan.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Standard regulatory board materials	*Completed September 2017*
Council and Board materials	*March 2018*
All policy and procedures development	*See Observation No. 1*

Observation No. 12

Improve Inspection Practices

The Board's legacy inspection practices were at a repeatable stage of maturity, while inspection practices specifically related to PDMP requirements were at an initial stage. The Board: 1) failed to remediate inspection management-related deficiencies identified initially in our 2008 audit and again during our 2015 audit, 2) had not incorporated PDMP compliance or naturopaths into inspection practices, and 3) did not track inspection and investigative resources dedicated to other regulatory boards whose licensees were subject to Board and PDMP regulation. These inadequacies contributed to ineffective PDMP implementation.

Prior Recommendations Unremediated

During our 2008 audit, we found significant deficiencies with the Board's inspections practices, which continued through our 2015 audit and remained unremediated through the end of the current audit period.

Inspection Management

During our 2008 audit, we found Board inspection management procedures did not result in a balanced inspection effort, and the Board lacked a complete inventory of establishments subject to inspection. The Board concurred with our recommendations that it review inspection efforts to focus on risks and establish policies and procedures on: 1) scheduling and performing inspections, 2) updating lists of facilities subject to inspection, and 3) formally reviewing, monitoring, and communicating inspection results.

During our 2015 audit, we found the Board had not resolved the deficiencies identified during the 2008 audit. We issued ten observations addressing elements of Board inspections, further recommending the Board collaborate with other regulatory boards receiving inspection services to establish a process to effectively and efficiently identify practitioners subject to Board inspection. The Board concurred and stated it would work with other boards to obtain necessary practitioner data and address prior recommendations.

During SFY 2017, the Board reported it: 1) had revised, but had not yet implemented inspection policy and procedure, 2) collaborated with other boards to identify all licensees subject to Board inspections, and 3) established policies and procedures to maintain and update a list of practitioners subject to inspection. This list, coincidentally, could have aided PDMP registration processes.

Capturing And Reporting Inspection Activity

During our 2008 audit, we found the Board did not maintain a system to capture and report sufficient data on its inspection activities to allow for efficient and effective management, monitoring, and reporting. We recommended the Board establish such a system to help it effectively monitor and manage inspections and ensure inspection resources were used efficiently and effectively. The Board concurred, reporting it was working with the Department of Information Technology (DoIT) to acquire licensing software with inspection management and data collection capabilities to remedy the identified deficiencies.

During our 2015 audit, we found our recommendations unaddressed. The Board stated the licensing software intended to address inspection management issues raised in 2008 was incapable of meeting Board needs. Furthermore, the same antiquated and deficient databases and related processes used before the 2008 audit were still in use. However, new online licensing software supported by the DoIT purportedly had inspection management and data capabilities and was expected to address inadequacies. We reissued the prior recommendations, such as recommending the Board establish a system to capture and report inspection activities. We further recommended the Board assess the inspection management capabilities of the new online licensing software prior to implementation, to determine the best course of action to meet the needs of the inspection process and to properly maintain whichever software the Board deemed appropriate. The Board concurred with the recommendation and stated it would research other inspection management software and meet with the DoIT to ensure the future system met the Board's needs.

In CY 2017, the Board was still using the antiquated inspection management databases which were agreed nine years ago to be deficient. Reportedly, the Board did not migrate to the online licensing software as planned in CY 2015 due to implementation failures, and no alternative options had been developed. The migration, delayed until August 2017, would have reportedly allowed the Board to access demographic data for all practitioners and licensees subject to inspection, as well as incorporate inspection reports. However, there were no formal implementation plans or timelines, and while the Board began testing the licensing software's relevant features, it was awaiting confirmation from the DoIT that inspection reports would be added by October 2017. Once more, a timeline for implementation, developing policies and procedures, and locating practitioners subject to inspection remained dependent on purported features of an untested and only anticipated licensing software solution. The Board planned to return to its former antiquated databases should the new software not meet its inspection management needs.

Inspection Practices Not Comprehensive

The Board had the authority to inspect: 1) all places where drugs were held, stored, or offered for sale and 2) all records on the sale and disposition of drugs. The Board was also responsible for operating the PDMP and enforcing certain areas of noncompliance, such as practitioners failing to submit required information or concealing patterns of diversion. However, neither PDMP compliance nor naturopaths were integrated into Board inspection procedures, and the Naturopathic Board of Examiners was omitted from statute requiring the Board provide inspection services to other regulatory boards, even though the Board was statutorily authorized to inspect naturopaths' facilities.

PDMP Compliance Excluded

Anyone authorized to prescribe or dispense schedule II through IV controlled drugs in the State was required to register with the PDMP and submit information as specified in statute and rule. As we discuss in Observation No. 13, statute distributed responsibility for aspects of PDMP oversight and enforcement to seven of the eight regulatory boards that oversaw professions required to register with the PDMP. However, the Board did not incorporate PDMP compliance into its inspection practices to identify noncompliance and refer matters to the appropriate licensing board, nor did it include PDMP noncompliance on violation notices it issued.

Instead, reporting was ad hoc and Board staff relied on requests for information from regulatory boards, law enforcement, or other stakeholders authorized in statute to receive PDMP information to disclose potential instances of PDMP noncompliance. The Board reported statute and rules did not allow PDMP data to be included in inspection activities; however, statute did not prohibit the Board from incorporating aspects of PDMP compliance into its inspection practices, such as having the prescriber or dispenser provide verification they were registered with the PDMP. Furthermore, the Board was the primary or secondary enforcement authority for many PDMP requirements, as we discuss in Observation No. 11.

In September 2017, the Board reported it had incorporated some aspects of PDMP compliance into inspection forms and practices that were awaiting Board approval, but policies and violation notice updates remained in draft form. In addition to not having a system to locate all licensees subject to inspection, regardless of PDMP requirements, the Board's monitoring capabilities and effectiveness were further limited by not having PDMP compliance incorporated fully into inspection practices, policies, and procedures.

Naturopaths Excluded

During our *Naturopathic Board of Examiners Performance Audit Report*, issued in April 2017, we found naturopaths had authority to prescribe and dispense prescription drugs from the naturopathic formulary. While naturopath's offices needed to comply with federal and State regulations, there were no inspections or other assurances of compliance. The Naturopathic Board of Examiners had no interactions with other regulatory authorities to effectuate inspections, and did not have the information needed to assess the scope of the potential requirement. We recommended the Naturopathic Board of Examiners consider an agreement

with the Pharmacy Board to develop an inspection protocol, and seek legislation to include naturopaths within the scope of the Board's authority to inspect and regulate the storage, labeling, distribution, and disposal of prescription drugs, effectively bringing this aspect of regulating naturopaths up to par with other practitioners in the State. In May 2017, the Board reported it had not begun the process to incorporate naturopaths into the inspection system, citing an update to the naturopathic formulary would need to occur to allow for prescribing medications not considered "natural," and then policy and procedures would follow. On May 4, 2017, the Naturopathic Board of Examiners adopted rules effective May 17, 2017, containing a new naturopathic formulary listing controlled drugs, as did the prior formulary adopted in CY 2009. As of September 2017, Pharmacy Board rules were reportedly under development and incorporating naturopaths into inspection protocols was pending.

Inspection And Investigation Services Not Quantified

Board licensees may have disproportionately borne the cost of inspection and investigative services related to prescription drugs and PDMP compliance provided to other regulatory boards' licensees; however, the amount of resources dedicated to other boards' inspections and investigations was not tracked. Prior to July 2013, statute required the Board to enter into agreements with six regulatory boards to compensate the Board for inspections, but the agreement and compensation provisions for services rendered were later removed, and additional budget cuts were requested of the Board. To compensate for these reported budget constraints, the Board raised pharmacy and pharmacist application fees.

As we discuss in Observation No. 26, we have commented on Board fee-setting practices since our 2008 audit. We recommended in our 2015 audit that the Board address its fee structure to ensure licensees were charged a fair amount to administer the Board and establish an inspection performance measurement system to improve the effectiveness and efficiency of inspections. However, the Board reported continuing to collect revenue in excess of 125 percent of its direct costs, by nearly $1.2 million in SFY 2016 alone; did not develop a performance measurement system; and did not quantify activity-related costs. The Board reported increased investigative and managerial demands with the incorporation of the PDMP into its enforcement systems. The Board contemplated raising licensee fees again to sustain funding for the PDMP, which increased members' concerns that the pharmacy profession would bear a disproportionate burden. While current and proposed funding indicated inspections and parts of the PDMP were subsidized through pharmacy-related license fees, the Board did not track actual resources and time dedicated toward inspections and investigations, including services rendered to other boards, to establish costs of regulating the profession of pharmacy versus costs associated with services provided to others. This limited the Board's ability to clearly quantify what could be considered an equitable cost-sharing model.

Recommendations:

We recommend the Board:

- **timely remediate the conditions leading to prior inspection management-related audit findings;**

- **establish a system to capture and report inspection activities sufficient to effectively monitor and manage those activities and reasonably ensure inspection resources are used efficiently and effectively;**
- **assess the inspection capabilities of the latest online licensing software before implementation to determine the course of action best meeting the needs of the inspection process and properly maintain whichever software the Board deems necessary;**
- **collaborate with other regulatory boards receiving inspection services to establish a process to effectively and efficiently identify all practitioners subject to Board inspection authority;**
- **fully incorporate PDMP compliance into inspection policies, procedures, and violation notices, and revise administrative rules as necessary;**
- **determine if additional Legislative changes are needed to complete incorporation of PDMP compliance into inspection practices, and seek necessary Legislative changes;**
- **fully incorporate naturopaths into inspection policies and procedures, pursue agreement with the Naturopathic Board of Examiners establishing inspection protocols, determine if additional Legislative changes are needed to complete incorporation of naturopaths into inspection practices, and seek necessary Legislative changes;**
- **track and analyze resources dedicated to inspections and investigations for other boards to determine needed resources and the most equitable model to share PDMP costs; and**
- **include in its strategy and plans an inspection management element.**

We further recommend the Board, once it establishes a system to concretely determine the actual costs it incurs providing inspection, investigation, and other services to other regulatory boards, seek appropriate legislation to allocate those costs to each board.

Board Response:

We concur.

A timeline to address audit concerns on prior and current audit findings has been developed and outcomes will be reported to the Department of Administrative Services at required intervals. For the past eight years, a resolution to prior audit issues was in development but it never materialized, forcing the Board to continue using available inspections database management software, developed internally, to meet the needs of an increasing inspection load as well as usual compliance and diversion activities.

The Board is currently working towards implementation of inspection activities. Pertinent data from inspection reports will be entered into the system by hand, and newly updated inspection reports will be scanned into individual provider, licensee, pharmacy permit holder, and pharmacist files. This information will be available in the aggregate for the compliance unit before they inspect facilities.

The current system does not allow for aggregating data from the entire inspection report. Though this does not conform to recommendations from the LBA audit, software will be developed to allow real time access to all inspection data for pharmacy permit holders and pharmacists.

The Board will recommend that other regulatory boards require a DEA registration number and the place of practice for each licensee as part of their registration process that would download into the MyLicense Online licensing software, which the Board can now access.

PDMP compliance has been integrated into the Board's compliance unit. Policy and procedures, inspection forms, "report cards" and Violation Notices *have been developed to include the PDMP in normal function of the Board office in both compliance and licensing.*

The Board administrator has been in contact with the Naturopathic Board of Examiners to start the process of adding them to inspection protocols. Inspections of this type of provider will require specialized training, as a majority of scope of practice does not involve Food and Drug Administration approved prescription therapies and outside the scope of practice for pharmacy inspectors.

The Board will track expenses associated with inspections for other medical boards through the recently updated MyLicense Online software and develop a proposal to share costs associated with inspections. The Board continues to develop a proposal on PDMP funding that is discussed elsewhere in this report. The Board will also track time involved in inspecting and investigating pharmacy and PDMP issues that arise. The Board notes that current staffing levels are insufficient to handle all increased inspection duties with the development and update of site inspections, PDMP verifications, license review of manufacturer and compounding pharmacies, naturopaths, and other duties of the Board's office.

Board inspections will include a PDMP "report card" on individual pharmacy information for verification and compliance. Outcomes will be developed on specific compliance and diversion issues for report to both regulatory boards and providers and dispensers.

The Board will establish a system through the MyLicense Online software that will add a cost to each investigation and inspection for all regulatory boards. Once this has been established, policy and procedure will be updated.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Real time inspection information development	*January 2020*
Naturopath integration into inspection practices	*January 2019*
All audit recommendations from 2015-ongoing	*December 2019*
Policy and procedure manual reference update in draft	*September 2017*
All policy and procedures development	*See Observation No. 1*

Compliance With Other Regulatory Board Requirements

Primary enforcement authority over mal-prescribing practitioners was distributed, resting with regulatory boards responsible for overseeing individual professions. Reportedly, instances of overprescribing were identified, and mal-performing prescribers were disciplined. Whether these changes were attributable to the PDMP was not established, nor was any context provided to demonstrate whether these anecdotes represented the norm or a change.

Generating reports on mal-performing practitioners was based on regulatory boards' criteria and upon other boards' requests, constituting a reactive data "pull" approach to compliance. Proactive data "push" approaches were purportedly more effective and appeared to be required by statute. If Board staff identified something of concern in PDMP data, they should then "push" out the information to another regulatory board without solicitation. This was not accomplished systematically. Further complicating enforcement was the lack of established criteria for analysis of PDMP data and reporting. Also, other indications of noncompliance reportedly existed, such as prescribers prescribing controlled drugs without being registered, but were not investigated due to limited PDMP resources.

The Board retained primary oversight of pharmacist and dispenser compliance and could conduct inspections of facilities operated by any authorized prescriber that prescribed or possessed controlled drugs and report noncompliance to the responsible regulatory board. Data limitations, primarily other regulatory board data, compromised the completeness of the Board's knowledge of other professions' facilities subject to inspection.

Observation No. 13

Improve Integration With Other Responsible Regulatory Boards

The Board's system to ensure the efforts of all regulatory boards with PDMP responsibilities were integrated to achieve PDMP outcomes was at an initial stage of maturity. The lack of a functioning system of controls and routine regulatory board interactions undermined the value and utility of the PDMP and limited its effectiveness.

Distributed Responsibilities

The Board was responsible for PDMP operation and overall effectiveness. However, statute distributed responsibility for aspects of PDMP oversight and enforcement to seven of the eight regulatory boards that oversaw professions required to register with the PDMP, the: 1) Board of Dental Examiners, 2) Board of Medicine, 3) Board of Nursing, 4) Board of Registration in Optometry, 5) Board of Registration in Podiatry, 6) Board of Veterinary Medicine, and 7) Pharmacy Board.

The Board was responsible for developing a system of registration, and all prescribers and dispensers authorized to prescribe or dispense schedule II through IV controlled drugs within the State were required to register with the PDMP. As we discuss in Observation No. 11, the Board was responsible for enforcing requirements related to registration and submitting accurate PDMP

information, as well as imposing certain penalties. Dispensers and prescribers who had not registered with the PDMP were subject to penalties and discipline established by their regulatory board. Additional statutory provisions subjected registrants to regulatory board discipline and penalties, including:

- engaging in the prescribing or dispensing of schedule II through IV controlled drugs without registering with the PDMP,
- knowingly disclosing PDMP information to unauthorized persons, or
- using PDMP information in an unauthorized manner.

Knowingly accessing, altering, destroying, or disclosing PDMP information except as authorized and attempting to obtain PDMP information by fraud, deceit, misrepresentation, or subterfuge, were felonies over which only the Board, with its overarching responsibility to enforce the *Act* and ability to access PDMP information, could exert oversight and enforcement authority.

When mandatory PDMP querying requirements for prescribing schedule II through IV opioids were first implemented via statute in September 2016, the Board was also responsible for primary oversight and enforcement. However, the initial statutory requirements were repealed, effective in January 2017, and the non-pharmacy regulatory boards were required to promulgate administrative rules detailing when and how the regulated professions were to use the PDMP when prescribing schedule II through IV opioids. Once each regulatory board adopted final rules regulating the use of the PDMP when prescribing opioids, and the statutory requirement was repealed, the non-pharmacy regulatory boards became primarily responsible for enforcement of utilization requirements related to opioid prescribing. While the Boards of Nursing, Medicine, and Dental Examiners timely finalized administrative rules as required, the Board of Registration in Podiatry and Naturopathic Board of Examiners finalized administrative rules after the date set in statute, and licensees of the Board of Veterinary Medicine became exempt from these query requirements in SFY 2018 through legislation. The Board of Registration in Optometry did not adopt relevant rules and appeared to be left without a mechanism to enforce PDMP utilization compliance and take disciplinary action when necessary.

Inadequate And Inconsistent Understanding

We administered surveys to the 50 members of the non-pharmacy regulatory boards, of whom 32 (64.0 percent) responded, and to the 21 members of the Board and Council, of whom 18 (85.7 percent) responded. Despite the statutory assignment of enforcement authorities, survey results demonstrated an inconsistent understanding of who was responsible for enforcing various aspects of the PDMP. For example, members could choose multiple entities to indicate their understanding of who was responsible for enforcing PDMP querying requirements, which is outlined in Table 1.

Additionally, practitioners engaging in the prescribing or dispensing of controlled drugs, without having registered with the PDMP, were subject to discipline by their respective licensing board. However, we found 23 of 32 respondents (71.9 percent) to the non-pharmacy regulatory board survey indicated they did not know whether all of their board's eligible licensees required to register were actually registered, and 25 (78.1 percent) indicated they did not know if licensees

were using the PDMP as required. Methods to identify prescribing non-registrants were not implemented, as we discuss in Observation No. 11.

Table 1

Regulatory Board And Council Members' Views On PDMP Querying Enforcement

Entity Responsible	Non-pharmacy Regulatory Board Members	Pharmacy Board And Council Members
Licensee's regulatory board	17 (53.1%)	13 (72.2%)
Pharmacy Board	15 (46.9%)	13 (72.2%)
Board staff	9 (28.1%)	11 (61.1%)
Council	8 (25.0%)	2 (11.1%)
PDMP vendor	6 (18.8%)	1 (5.6%)
Unsure/Do not know	3 (9.4%)	0 (0.0%)
Other	0 (0.0%)	1 (5.6%)

Source: LBA analysis of results from our surveys of Board and Council members and of non-pharmacy regulatory board members.

As we discuss in Observation No. 7, non-pharmacy regulatory boards inconsistently received notification of licensee noncompliance with PDMP-related requirements from the Board. Further, and as we discuss in Observation No. 9, the Board inconsistently reported to other regulatory boards information on potentially noncompliant licensees who had been identified using PDMP data. Eleven of 32 non-pharmacy regulatory board members (34.4 percent) reported their board had not received *any* notifications of PDMP noncompliance by licensees through the end of SFY 2017, while 17 (53.1 percent) did not know if their regulatory board received any notifications. Only four members (12.5 percent) reported their board had received at least one notification since the PDMP's inception. Without receiving consistent notification, regulatory boards were unable to take appropriate actions against licensees' noncompliance. Only three respondents (9.4 percent) indicated disciplinary action against a licensee occurred, of which only one respondent stated their regulatory board made Board staff or the Board aware of the disciplinary action. Reporting the outcomes of disciplinary matters back to the Board would facilitate assessment of PDMP outputs and help assess outcomes and impacts, data the Council was required to collect.

Integration Mechanisms

The PDMP was implemented before a system to coordinate regulatory boards' activities had been developed, and consequently, ad hoc interactions ensued. The Board and its staff acknowledged communication and collaboration obstacles existed with certain regulatory boards. Board staff reported intermittently contacting other regulatory boards or their staff and noted additional outreach was likely necessary to: 1) ensure follow up on PDMP reports of potential practitioner noncompliance and 2) facilitate other boards' understanding of their disciplinary and enforcement authority.

As we discuss in Observation No. 19, the Board and the Council were inadequately integrated. Refining the responsibilities and roles of the Council was neither internally resolved nor formalized, as we discuss in Observation No. 7. Even though five regulatory boards appointed members to the Council to represent their professions, non-pharmacy regulatory board survey results indicated respondents were unaware of both fundamental PDMP requirements and their respective board's authority to regulate licensees' use of the PDMP. Additionally, 27 of 32 respondents (84.4 percent) reported they had never heard of the Council or knew only of its existence. The single respondent who reported familiarity with the Council and indicated it had a clear role in overseeing the PDMP was a member of both the Council and a regulatory board. Separately, a second non-pharmacy regulatory board member who was also on the Council, asserted being familiar with the Council and that it had a clear role. Other regulatory board members separately indicated their knowledge of the Council was minimal and its role was unclear. This left a detrimental programmatic gap between the Council, which was responsible for at least: 1) developing criteria for thresholds and reporting matters to regulatory boards for further investigation, 2) collecting information on PDMP outcomes and impacts, and 3) advising the Board on PDMP implementation and operation, and the regulatory boards responsible for overseeing and enforcing certain requirements upon their licensed professions, and instrumental in reporting results and outcomes.

Naturopathic Board Of Examiners

While naturopaths were subject to the PDMP since its inception in June 2012 and explicitly added to the definition of a practitioner in January 2017, naturopaths had yet to be incorporated into the Board's inspection activities as we discuss in Observation No. 12, and the Naturopathic Board of Examiners was excluded from key elements of PDMP oversight and enforcement.

The Naturopathic Board of Examiners was omitted from the statute permitting PDMP information, including indicators of licensees' possible fraudulent conduct, to be provided to regulatory boards if requests were pursuant to official board duties. The Naturopathic Board of Examiners was unable to request PDMP information if it had concerns regarding licensee noncompliance, limiting that board's ability to perform investigations and hindering the PDMP's effectiveness. This omission appeared to conflict with the statutory requirement for the PDMP to provide appropriate regulatory boards with information necessary for an investigation when there was reasonable cause to believe a violation of law or breach of professional standards occurred.

The Naturopathic Board of Examiners was one of three regulatory boards whose licensees were subject to PDMP requirements without representation on the Council, excluding them from processes developing statutorily-required and essential PDMP components and from receiving periodic PDMP updates from Board staff. The PDMP could not assess outcomes and be effective without full integration of all regulatory boards and their prescribing practitioners regulated by the PDMP.

Recommendations:

We recommend the Board:

- **develop, implement, and refine oversight mechanisms to ensure the other regulatory boards follow up on PDMP-generated reports of potential noncompliance;**
- **develop, implement, and refine routine reporting mechanisms through which the other regulatory boards can provide the Council and Board basic data on investigation and disciplinary outcomes based on PDMP-generated reports of potential noncompliance;**
- **adopt the oversight and reporting mechanisms in administrative rule;**
- **establish procedures to ensure effective communication between Council members and represented stakeholders; and**
- **include in its strategy and plans a component related to regulatory board integration.**

We also recommend the Board pursue legislative changes to fully incorporate all regulatory boards whose licensees are subject to the PDMP and the Board's inspection activities.

Board Response:

We concur.

While the Board does not believe it currently has regulatory authority over other board's actions, the Board will continue to collaborate with other regulatory boards to facilitate consistency. The Board will develop rules and policy and procedures for reporting mechanisms of specified data to respective regulatory boards and follow-up on board actions in reference to outcomes. Finally, the Board will develop policy and procedures on communications for Council members to report PDMP information back to the respective boards and appointing authorities they represent.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Will be included in strategic plan draft	*See Observation No. 5*
All policy and procedures development	*See Observation No. 1*

Compliance With Law

The PDMP was reported to be primarily a quality of care tool, not a law enforcement tool. State law prohibited law enforcement officials from directly accessing the PDMP but permitted the PDMP to provide data on "a case-by-case basis for the purpose of investigation and prosecution of a criminal offense when presented with a court order based on probable cause." Board rules also permitted law enforcement access to PDMP information with a search warrant signed by a judge. The court order or search warrant was to be presented to a Board representative

designated to receive such orders, who would notify the PDMP Program Manager to provide the requested information. Reportedly, without a subpoena, law enforcement could not receive information from the PDMP indicating controlled drug diversion, and other regulatory boards could not provide law enforcement any PDMP information used during licensee investigations.

However, limits on law enforcement access appeared inconsistent with aspects of the statutory intent of the PDMP. The PDMP was expected to systematically affect controlled drug abuse, fraudulent prescribing, controlled drug diversion, and doctor shopping, behaviors which not only presented a public health and safety issue, but also inherently involved unlawful acts.

The diversion of controlled drugs to illicit purposes was a public health and safety issue. Drugs were diverted in numerous ways, such as by theft, forgery, and counterfeiting of prescriptions; illicit sales of prescriptions and drugs; fraudulent activities victimizing prescribers, dispensers, and patients; and indiscriminate prescribing practices by dishonest, disabled, or deceived prescribers or by prescribers who were dated in their practices. A number of State entities potentially had responsibility for investigating controlled drug diversion, doctor shopping, and prescriber and dispenser misconduct. The DOJ's Drug Task Force conducted criminal drug investigations and tracked information on the number of cases, arrests, and amount of prescription and illicit substances seized or purchased. The DOJ's Medicaid Fraud Control Unit conducted investigations associated with the Medicaid program, such as controlled drug diversion by medical professionals, and tracked information on the number of convictions. Additionally, the Board required pharmacists-in-charge to report prescription drug diversion, including information on the type of diversion, the drugs diverted and their purchase value, and whether any official prescription drug order forms were stolen. Law enforcement agencies, including the State Police NIU, also investigated related crimes. No aggregate law enforcement data appeared to have been generated, however, limiting empirical definition of the scope and nature of diversion and other related crimes in the State.

Observation No. 14

Clarify And Improve Law Enforcement Access To The PDMP

The State's system regulating law enforcement agencies' access to PDMP information was at an initial stage of maturity. The Board did not:

- formally clarify confusion surrounding when and how law enforcement officials could access or receive PDMP information,
- formally clarify who met and did not meet the definition of law enforcement,
- reconcile the prohibition on direct law enforcement access with the level of access necessary to achieve certain PDMP outcomes,
- develop objectives or performance measures associated with law enforcement use of PDMP information, or
- create processes to track outcomes associated with law enforcement use of PDMP information.

These inadequacies contributed to ineffective PDMP implementation and undermined PDMP effectiveness.

Insufficient Knowledge

Law enforcement officials reportedly used the process to access PDMP information only two or three times through June 2017, due to their unfamiliarity with the PDMP and requirements to access PDMP information. Fifty-one of 224 local, county, and State law enforcement officials (22.8 percent) responded to our 2017 survey. They variously responded to specific questions related to the PDMP:

- 19 of 48 respondents (39.6 percent) were unfamiliar with the PDMP,
- 24 of 42 respondents (57.1 percent) were unfamiliar with the process to access PDMP information, and
- unfamiliarity with the process to access PDMP information was cited by 14 of 21 respondents (66.7 percent) as a reason their agencies had not attempted to obtain access to PDMP information.

The complete results of our survey of law enforcement officials are contained in Appendix F.

The Council informally agreed, as early as July 2014, that the PDMP should conduct outreach with law enforcement on topics including the restrictions on accessing PDMP information and the process to request information. The contract with the original PDMP database management vendor also specified the database management vendor must create online tutorials and training for law enforcement users. However, no objectives were established as to which law enforcement officials should receive training or by when, and no policies and procedures were developed to govern and track initial and ongoing education and outreach efforts. Although it did not appear the database management vendor ever developed or implemented law enforcement trainings, Board staff ultimately conducted a few presentations, reaching at least 72 law enforcement officials, although it did not appear presentations placed emphasis on the process by which law enforcement officials could access PDMP information. As a result, not all law enforcement officials received relevant information, and 26 of 45 respondents (57.8 percent) to our survey thought PDMP outreach and educational efforts were either not at all, or only somewhat, successful.

There was also at least one instance where law enforcement obtained, but then returned, PDMP information without going through the required process. Unauthorized access undermined statutory security and confidentiality requirements. As discussed in Observation No. 18, the PDMP lacked processes to detect unauthorized access to PDMP information, including access by law enforcement officials. Education and outreach to PDMP users and others with the ability to obtain PDMP information may have also insufficiently addressed law enforcement access requirements.

Unclear Process

Nine of 18 law enforcement officials (50.0 percent) responding to our survey and reporting they were familiar with the process to access PDMP information indicated it was only somewhat, or not at all, easy to understand and interpret. There also appeared to be confusion among Board and Council members and Board staff as to: 1) when law enforcement could access information, 2) how they could access information, 3) whether the PDMP or regulatory boards could share PDMP information if possible unlawful or criminal activity was discovered, and 4) whether regulatory board compliance investigators were considered to be law enforcement agents and were subject to the same restrictions on accessing PDMP information, as we discuss in Observation No. 11.

Board staff did not believe they could provide law enforcement with PDMP information they used to identify potential offenders, such as doctor shoppers, without receiving a court order or search warrant. Board staff believed, but had not formally clarified, they would have to undertake their own investigation, develop sufficient evidence to substantiate potential wrongdoing identified in PDMP information, and then turn the non-PDMP evidence over to law enforcement. Existing policies, procedures, and administrative rules inadequately clarified law enforcement information sharing. Although no formal resolution existed through June 2017, Board staff were in the process of seeking clarification from Board counsel, the DOJ, and counsel for other regulatory boards whose licensees were subject to the PDMP.

Relationship to PDMP Effectiveness

Limited law enforcement access and involvement reportedly hindered achievement of PDMP outcomes. The PDMP was to reduce patient morbidity associated with controlled drugs, affect the number of instances of drug abuse, and help identify patients potentially engaged in doctor shopping or in prescription drug misuse and abuse or diversion. The unlawful behavior defined in the *Act* included:

- doctor shopping, where someone independently consulted two or more practitioners for treatment solely to obtain additional controlled drugs or prescriptions for controlled drugs;
- obtaining a controlled drug by fraud, deceit, misrepresentation, or subterfuge;
- obtaining a controlled drug by the forgery or alteration of a prescription; and
- making or uttering a false or forged prescription.

PDMP information was reportedly useful for investigations related to potential patient misconduct, which may have served as a means by which the PDMP was able to affect controlled drug diversion, including doctor shopping; fraudulent prescribing; and controlled drug abuse.

Enforcement Authority

The *Act*, encompassing the PDMP, imposed a duty to enforce on the Board, all peace officers, and all county attorneys. Although the *Act* appeared to provide for Board enforcement of

unlawful acts stemming from patient misconduct, the Board itself was primarily intended to oversee the pharmacy profession. The Board was neither structured nor originally intended to carry out law enforcement activities against patients.

State law appeared to permit both law enforcement and Board investigations related to patient misconduct and provided for the imposition of fines against those committing unlawful acts specified in the *Act* or imprisonment. Although the Board began pursuing investigations into potential patient misconduct, such as doctor shopping, in early SFY 2018, it was not taking enforcement action against patients. Nonetheless, unclarity persisted. Twelve of 18 Board and Council members (66.7 percent) and 32 of 41 law enforcement officials (78.0 percent) responding to our surveys indicated enforcement resulting from patient misconduct was the responsibility of law enforcement agencies. Seven Board and Council members (38.9 percent) and seven law enforcement officials (17.1 percent) indicated enforcement over patient misconduct was the responsibility of the Board.

Law enforcement would appear to be the more appropriate enforcement authority to handle investigations and cases of possible patient misconduct. Although the Board does have enforcement authority specific to its regulatory responsibilities, extending its enforcement authority to patients would appear to be inappropriate and duplicative of the authority already provided to law enforcement and would fundamentally alter the role of the Board. PDMP users, the Board, and other regulatory boards should be able to identify indications of crimes stemming from patient misconduct and report them to law enforcement agencies, which are both structured and intended to investigate and handle cases related to the public.

Objectives And Planning

No objectives on the desired level of law enforcement access in order to facilitate PDMP effectiveness were established, and there were reported differences of opinion as to whether limited law enforcement access positively or negatively affected PDMP effectiveness. However, 17 of the 42 law enforcement officials (40.5 percent) responding to our survey indicated a lack of direct law enforcement access to PDMP information had a moderate to significant negative effect on their agency's investigations. Board staff also expressed concerns about limited law enforcement access.

Some jurisdictions provided broader prescription monitoring programs access to law enforcement than New Hampshire. Techniques included unsolicited reports to law enforcement agencies or prosecutors, use of administrative subpoenas, and unsolicited reports on high-risk patients to law enforcement under certain circumstances. Purported benefits included increased efficiency of law enforcement investigations, lower investigative costs, and improved prescription monitoring program effectiveness through early access to information or access without a subpoena or warrant.

Outcome Tracking

Finally, there did not appear to be a process in place to track or report on outcomes from law enforcement investigations, and there were no associated performance measures, further limiting

the ability of the Board to assess PDMP performance and effectiveness. Board staff reported output measures on the number of law enforcement requests for PDMP information, but no outcome measures on the progress and results of associated investigations existed.

Recommendations:

We recommend the Board:

- **develop, implement, and refine routine reporting mechanisms through which law enforcement officials can provide the Council and Board basic data on investigative outcomes based on PDMP information to support comprehensive PDMP performance and outcome measurement reporting;**
- **include in its annual report information on the effectiveness of the law enforcement community's use of PDMP information and its effects on PDMP outcomes;**
- **develop standard educational materials for law enforcement officials on accessing PDMP information, identify which law enforcement officials should receive training, develop a timeline for providing training and educational materials to law enforcement officials, and provide ongoing training and education;**
- **ensure PDMP users and others with access to PDMP information are aware of the requirements and limitations related to law enforcement access;**
- **seek clarification on its investigative and enforcement authority related to crimes stemming from patient misconduct so there is only one interpretation as to which entities are responsible for enforcement of potential patient-related misconduct and pursue necessary legislative changes;**
- **adopt administrative rules implementing the Board's enforcement authority; and**
- **include a law enforcement-related component in the PDMP's strategy and plans.**

We also recommend the Board pursue legislative changes to law enforcement access to PDMP data and information necessary to achieve legislatively-envisioned outcomes, incorporating revised outcomes limited to those outcomes the PDMP can be reasonably expected to achieve, and clarify law enforcement access through administrative rules.

Board Response:

We concur in part.

Any issues with increasing integration of law enforcement to the PDMP program has been well documented in past legislative discussions and will need to be addressed at that level. The Board does not agree that it is responsible for increasing additional law enforcement access.

The Board will develop a process and policy to collect information on effectiveness of data provided to law enforcement, regulatory boards, and the medical examiner's office as part of their investigations. This data will be included in future annual reports.

The Board will develop an outreach program to better educate law enforcement on the use of the PDMP program and its integration into the Board of Pharmacy investigative process.

The Board will ensure as part of the education information provided to all regulatory boards that all licensed practitioners are aware of the requirements and limitations law enforcement officials have to PDMP information and their access. The Board does not believe that its compliance investigators have enforcement authority over individuals.

The Board will seek out clarification from legal counsel as to the investigative and enforcement authority of the Board related to crimes stemming from patient misconduct.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Develop training program for law enforcement	*September 2018*
Administrative rules concerning Board enforcement authority	*July 2018*
All policy and procedures development	*See Observation No. 1*

LBA Rejoinder:

We did not recommend the Board alone change law enforcement access to the PDMP. We recommended it validate PDMP outcomes and seek necessary legislative changes to facilitate achieving those outcomes. If the Board has determined law enforcement-related outcomes are invalid, it should seek legislative changes to expunge those expectations from law.

PDMP Design

To implement the PDMP, the State entered into a five-year contract with a third-party database management vendor for web-based proprietary software to: 1) maintain a confidential database collecting and storing prescribing and dispensing data and 2) facilitate analysis and reporting of information on the prescribing, dispensing, and use of selected controlled drugs. The original contract was approved by the Governor and Council on June 18, 2014. The software underpinning the PDMP permitted access to patients' controlled drug prescription records, multi-state sharing of patients' controlled drug prescription records, prescribing history reports, and prescribing and dispensing trends. Dispensers first uploaded the preceding six months of prescribing data, starting in September 2014. The PDMP went live in October 2014, allowing prescribers to register. Interstate data sharing, reporting, and evaluation enhancements were subsequently introduced. The original database management vendor also provided technical assistance to users. Following the acquisition of the State's original PDMP database management vendor by another entity, migration to new software occurred early in SFY 2018, and a second implementation essentially took place. The migration required manual registrations for both prescribers and dispensers. Ensuring all prescribers and dispensers were re-registered remained a concern prior to and throughout the migration process.

To meet statutory reporting requirements, the Board engaged a data analytics vendor via a confidentiality agreement in October 2016. The data analytics vendor was to provide analytic

support and assist with PDMP evaluation, including drafting reporting templates and working with the database management vendor and Board staff to implement analysis and reporting.

Statute required the Board promulgate rules necessary to implement the PDMP generally. Statute also specifically required rules on: 1) registration and waiver criteria, 2) criteria for reviewing prescribing and dispensing information, 3) criteria for reporting matters for investigation to regulatory boards, 4) criteria for notifying prescribers of individuals engaged in obtaining controlled drugs from multiple practitioners or dispensers, and 5) the content and format of required forms. Other regulatory boards were also required to adopt rules related to opioid prescribing and their professions' relationship to the PDMP.

Registration

The scope of the PDMP encompassed all registrants, both prescribers and dispensers, and the regulatory boards overseeing them. *Dispensers* were persons lawfully authorized to deliver a schedule II through IV controlled drug but excluded: 1) licensed hospital pharmacies dispensing for in-hospital administration, 2) practitioners and other authorized persons who administered schedule II through IV drugs, and 3) wholesale distributors. *Prescribers* were practitioners or other authorized persons who prescribed schedule II through IV controlled drugs and included physicians, physician assistants, podiatrists, veterinarians, naturopaths, dentists, optometrists, and advanced practice registered nurses. Prescribers and dispensers were required to register by June 30, 2015, or they could use a delegate to register for them. Delegates were appointed in writing by a prescriber or dispenser and delegated the task of retrieving PDMP information for specific patients. Some registration exemptions existed, such as dispensers dispensing less than a 48-hour supply of a schedule II through IV controlled drug from a hospital emergency department.

Observation No. 15

Improve Registration Management

The Board's controls over registration management was at an initial stage of maturity. Registration management included various functions, such as registering prescribers and dispensers, managing delegates, de-registration, compliance, enforcement, working with other regulatory Boards, and contract oversight. The Board did not implement a holistic system to sufficiently manage practitioners or dispensers and their delegates and ensure: 1) all individuals required to register were registered; 2) those ineligible or no longer eligible to register were de-registered; or 3) enforcement of noncompliance with registration requirements was carried out. The Board lacked a strategy and plans and did not develop goals or objectives related to monitoring registration, such as the percentage of practitioners authorized to prescribe or dispense schedule II through IV controlled drugs within the State who should be registered and by when. The Board did not effectively collaborate with other regulatory boards to ensure PDMP requirements were implemented timely and necessary data were collected in order to operate the PDMP effectively, as discussed in Observation No. 13. Registration management was further hindered due to insufficient contract oversight of the database management vendor and insufficient enforcement of registration requirements, resulting in erroneous or missing

information in the PDMP database; difficulties with password management; and difficulties receiving adequate reports from the database management vendor.

Registrant Management

Registration of prescribers, dispensers, and delegates was reportedly the primary focus of Board staff through SFY 2017. Dispensing pharmacies began registering in August 2014 and uploading data to the PDMP in September 2014. By mid-September 2014, non-pharmacy dispensers began registering with the PDMP and uploading data. Licensed providers and pharmacists began registering in October 2014, and eligible practitioners were required to register no later than June 30, 2015. Each pharmacy was also required to register and report the federal Drug Enforcement Administration (DEA) numbers of its uploaders.

Regulatory boards were required by Board rules to submit licensee information necessary to implement the PDMP. However, not all regulatory boards consistently collected the necessary licensee information, such as DEA registration numbers specifically linked to New Hampshire, which were reportedly necessary to finalize a licensee's PDMP registration. Registrations were approved manually by Board staff. While automated registration was preferred, manual registration was reportedly necessary due to both the lack of information from regulatory boards and the original database management vendor's processes. Manual registration initially produced some backlog through at least July 2015, and although registrations were reportedly approved daily by the end of the audit period, the migration to new PDMP software in July 2017 and continued use of manual registration reportedly resulted in re-registration backlogs that persisted through at least August 2017.

No assurance was obtained that all practitioners required to register with the PDMP were in fact registered. To determine whether eligible prescribers were registered, Board staff relied on PDMP information to intermittently identify unregistered prescribers prescribing schedule II through IV controlled drugs. Without other regulatory boards tracking which of their licensees possessed DEA numbers associated with New Hampshire, determining what percentage of those required to register were *actually* registered was impossible. Non-pharmacy regulatory boards, which were responsible for enforcing compliance of their licensees, were asked by the Board as late as September 2017 to update their administrative rules and licensing forms with necessary requirements to permit the Board to monitor the PDMP and enforce registration requirements.

Additionally: 1) many individuals already registered with the PDMP lacked DEA registration numbers, indicating de-activation was required; 2) no formal system existed to ensure the other regulatory boards were enforcing registration requirements when notified of noncompliance by the Board; and 3) the Board did not establish a formal system to monitor either the number of noncompliance referrals sent to other regulatory boards or their actions against noncompliant practitioners. We surveyed the 50 members of regulatory boards whose licensees were regulated by the PDMP, of whom only one of 32 respondents (3.1 percent) indicated their board had received notification of registration noncompliance from Board staff through July 2017. The same survey also showed 23 of 32 respondents (71.9 percent) did not know whether all of their board's licensees required to register with the PDMP were *actually* registered. However, the

Board began issuing fines to noncompliant pharmacies in early SFY 2018, and a compliance plan was reportedly approved by the Board to ensure proper registration.

Statutory language in the original legislation was broad and appeared to include naturopaths. However, the Board did not initially recognize naturopaths as needing to register with the PDMP because they were not specifically mentioned in statute. State law explicitly added naturopaths to the definition of prescriber, effective January 1, 2017. However, as of June 2017, there were delays registering naturopaths, reportedly due to limitations in the original database management vendor's software. The new database management vendor was expected to remedy the deficiency.

Delegate Registration

State law permitted *designees* of prescribers and dispensers to access the PDMP. While *delegates* were neither provided for in State law nor equated with designees in Board rules, rules stipulated that, to enable the timely and efficient delivery of care for a patient, a prescriber or dispenser registered with the PDMP could delegate the task of retrieving PDMP information for a specific patient. The task could be delegated to an individual working under the direction and supervision of the registered prescriber or dispenser, provided that written authorization documentation was provided to Board staff. Board rules did not provide further information on the process that would be followed to approve delegates. In practice, however, requests were reviewed by Board staff, who verified information and approved delegate accounts. The delegate then needed to notify their sponsoring prescriber or dispenser, known as a master account holder, to link the two accounts. The delegate would be unable to query the PDMP until their account was linked with that of the master account holder. Master account holders were required to submit a list of all their delegates, keep the list up to date, and "unlink" delegates who left their employment.

The Board effectively transferred the management of delegates to master account holders. No mechanisms existed to verify delegate registration or de-registration, except potentially by routine compliance inspections conducted by the Board. Although the Board incorporated PDMP compliance as part of their inspections beginning in SFY 2018, delegate compliance was not included. Complicating enforcement of delegate compliance was the fact not all delegates were licensees of a regulatory board, although the Board retained primary enforcement authority over these delegates and had the authority to fine any person who violated the *Act*, as we discuss in Observation No. 11.

De-registration

De-registration of former delegates and ineligible users was another component of registrant management. Individual practitioners held responsibility for de-registering delegates. Practitioners were to be de-registered from the PDMP after the Board was notified by a regulatory board that a practitioner was no longer licensed. However, incomplete information submitted by other regulatory boards likely hindered de-registration. We requested information related to the timely de-registration of registrants, but relevant data had not been collected. To an unknown extent, issues with inappropriately registered prescribers or dispensers necessitated retroactive removal of some registrants, which may have affected accurate quantification of

registrant data. Accounts without DEA registration numbers associated with New Hampshire would also need to be de-activated; however, some practitioners may not have known their DEA numbers needed to be linked with the State to register with the PDMP. The renewal process was also reported to be problematic. Reportedly, Board staff had requested regulatory boards send information on new licensees, renewals, inactive licensees, and suspended licensees on a monthly basis. This occurred inconsistently. Only two regulatory boards provided automated data submissions on licensees to the Board. However, data only included current licensees, and if a registrant had not renewed their license or moved out of state, the database management vendor would be unable to timely de-register those individuals.

Waivers And Extensions

Practitioners could avail themselves of exemptions from registration, waivers from uploading requirements, and extensions from timely uploading requirements. Board staff developed: 1) approval processes; 2) related requirements, such as annual renewal or submission of supporting documents; and 3) related forms requiring self-certification. Controls over these processes were ad hoc. For example, independent verification by Board staff of claims made on forms was not evident. Further, data were systematically tracked. While we requested data pertaining to waiver requests and extensions, the Board lacked comprehensive data, so we could not systematically determine when waivers were received by the Board, when registrants were notified they needed to submit substantiating documentation, or for how long requests for substantiating documentation had been pending. Though 181 waivers had been approved between December 2016 and August 2017, a system to monitor these items did not exist. Issues with the extension and waiver request forms are discussed further in Observation No. 24.

Registration Data

We requested registrant data from the PDMP's inception through June 30, 2017. We received six registration reports, which covered various months between April 2015 and June 2016. Data showed a 73.4 percent increase (from 5,833 to 10,117) in the number of registrants, excluding delegates, who had activated their accounts between April 2015 and April 2016. Registrant data, excluding delegates, showed a 15.1 percent increase (from 11,420 to 13,139) between April 2015 and April 2016 in the number of total registrants, meaning PDMP accounts had been created but the individual had not logged in to finalize their accounts. It was not likely the State had acquired such a substantial number of new practitioners between April 2015 and April 2016. Rather, it was more likely eligible registrants had not registered by the mandated June 30, 2015 registration date. This was consistent with estimates indicating fewer than half of eligible registrants had actually registered and finalized their accounts by April 2015. Figures included within the database management vendor's contract estimated 14,327 eligible registrants from all licensing boards in CY 2014, compared with 5,833 registrants who had finalized PDMP accounts by April 2015.

In addition to difficulties registering practitioners, registration data submitted to the Board also contained a significant number of errors. For example, as of June 2016:

- 1,850 of 15,109 accounts (12.2 percent) were created with blank birth dates,

- 305 accounts (2.0 percent) contained irrational birth dates,
- 193 accounts (1.3 percent) lacked the state issuing the registrant's license, and
- 2,258 accounts (14.9 percent) were created without complete address information.

More importantly, 5,529 practitioner accounts (36.6 percent) did not include DEA numbers. Out of 2,549 registered pharmacists, 2,082 (81.7 percent) did not include DEA numbers. We also identified instances of practitioners who were registered but likely should not have been, such as those retired, not practicing, or not employed in New Hampshire.

Enforcement

The Board held overall responsibility for enforcing requirements related to registration and imposing certain penalties. Additionally, eligible practitioners who had not registered with the PDMP were subject to penalties and disciplinary actions established by their regulatory board. Enforcement against noncompliant practitioners did not occur during the audit period. The Board's management of data quality likely hindered enforcement of PDMP requirements, as discussed in Observation No. 17. As discussed in Observations No. 9 and No. 10, the Board lacked mechanisms to manage and fully utilize PDMP information and a system to manage information internally. Without definitive data on prescribers, dispensers, and delegates, the Board's ability to accurately measure performance and effectiveness, gauge compliance, conduct enforcement activities, notify other boards of noncompliance, and ensure the enforcement of PDMP requirements conducted by other regulatory boards was limited.

Recommendations:

We recommend the Board:

- **develop and implement a system to definitively establish the number of authorized prescribers, dispensers, and delegates who are required to register with the PDMP or not, and ensure individuals required to register are, while those not eligible are removed from the PDMP to accurately reflect the true PDMP registrant population;**
- **formalize the process by which designees are approved for PDMP accounts and linked to master account holders;**
- **work with other regulatory boards to develop and implement a system to ensure changes to the number of authorized prescribers or licensees are reported timely, delegates are registered and de-registered timely, and undelegated use of the PDMP is identified and violations sanctioned;**
- **develop and implement a system to ensure registration compliance is enforced by other regulatory boards and compliance data are reported to the Board;**
- **amend or promulgate administrative rules as necessary; and**
- **include in its strategy and plans a component related to all registration management functions.**

Board Response:

We concur.

The Board acknowledges that issues existed regarding registration management and notes that these issues were exacerbated by the transfer of ownership of the vendor. Nevertheless the Board is working to automate the registration process in conjunction with the implementation of MyLicense Online for licensing registration for all regulatory boards. Our inability to collect all required information from regulatory boards slows down the registration process. We need to search for required data and enter it by hand. The Board will recommend a State-level DEA registration-like controlled drug license as a way to ensure compliance.

The Board will develop a policy in concert with the other regulatory boards for identifying undelegated use of the PDMP and sanctioning violations. Furthermore, the Board will develop a policy and procedure that will give limited access to a licensing agent from each regulatory board to access the PDMP software to check on the registration status of licensees.

The Board will include, as part of the PDMP strategic plan, a component related to all functions related to registration management, including milestones related to achieving compliance.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Will be included in strategic plan development	*See Observation No. 5*
Statutory change for a State controlled substance license	*September 2019*
All policy and procedures development	*See Observation No. 1*

PDMP Utilization

The PDMP could achieve intended outcomes only if all registrants consistently used it. The PDMP was established to help practitioners provide better care to patients in need of schedule II through IV controlled drugs and to identify health practitioners contributing to prescription drug abuse by fraudulently prescribing these drugs. PDMP registrants could reportedly use the system to identify prescriptions with potentially dangerous drug combinations; identify indicators of patient doctor shopping, controlled drug abuse, or controlled drug addiction; monitor patient compliance with prescription directions; and identify fraudulent prescriptions.

Statute required dispensers to submit information on each schedule II through IV controlled drug dispensed. Initially, dispensers were required to submit specified data to the PDMP within seven days of dispensing. Effective September 2016, daily data submission was required, unless a waiver was approved. Use by prescribers was initially encouraged, but not required. Legislative changes mandated use starting September 1, 2016, when prescribers were required to query the PDMP during the initial prescribing of a schedule II through IV controlled opioid and review PDMP information periodically during the course of patient treatment. Effective August 15, 2017, veterinarians were excluded from the definition of practitioners subject to the PDMP requirement for querying patient controlled drug history when prescribing PDMP-covered

controlled drugs. Veterinarians were still required to upload dispensing data and could query the PDMP if registered.

Observation No. 16

Improve Management Of PDMP Utilization

The Board's management of PDMP utilization was at an initial stage of maturity. The PDMP: 1) was implemented without a statutory obligation for registrants to utilize it for established purposes, 2) set other utilization requirements without clear underlying statute or rule, and 3) lacked a control structure establishing goals and objectives to assess performance and enforce compliance. These deficiencies contributed to ineffective PDMP implementation and a lack of clear, quantifiable outcomes derived from PDMP utilization to date.

Utilization Requirements

While registration requirements were established in statute effective June 2012, prescribers and dispensers could not access and query the PDMP until fall 2014, when the PDMP was initially implemented. Dispensers were statutorily required to submit specific information regarding each schedule II through IV controlled drug dispensed, but prescribers were not required to query the PDMP database under any circumstance until September 2016, when statute implemented limited querying requirements related to opioid prescribing. However, querying the PDMP prior to dispensing any controlled drugs remained optional for dispensers.

Prescribers

Beginning in September 2016, statutory prescriber requirements included querying the PDMP when initially prescribing a schedule II through IV opioid and at least twice per year thereafter, unless the drug was administered in a health care setting or the prescription was for a supply of less than thirty days to treat acute pain. Effective in January 2017, registrants were no longer required by statute to query the PDMP when prescribing opioids. Individual regulatory boards overseeing prescribers were required to implement opioid prescribing rules for their licensees. Statute required boards' rules remove the exemption to query the PDMP when treating acute pain. Rules were also to exempt querying only: 1) when administering medications to patients in a healthcare setting, 2) when unable to access the PDMP due to technical issues, or 3) if querying in an emergency department would materially delay patient care. However, as we discuss in Observation No. 13, two boards finalized administrative rules after the date set in statute; one board did not adopt relevant rules, which appeared to leave it without the ability to enforce PDMP utilization compliance; and the Board of Veterinary Medicine became exempt from these rulemaking requirements in SFY 2018.

Primary enforcement authority migrated to individual regulatory boards whose licensees were subject to the PDMP. Although the Board was no longer responsible for primary utilization enforcement, it retained responsibility for overall PDMP enforcement, as discussed in Observation No. 11, and was therefore still responsible for overseeing and ensuring compliance with and enforcement of utilization requirements.

To solicit feedback about the PDMP, the Council administered a survey to PDMP-registered prescribers from late June 2016 through August 2016, before the statutory querying requirements went into effect. The Council reported receiving 2,915 responses, for an estimated response rate of 23.0 percent. Results indicated 1,250 of the responding prescribers (42.9 percent) had not queried the PDMP to review a patient's controlled drug history within the prior year, while 364 prescribers (12.5 percent) did not know whether they had queried. Prescribers cited several reasons for not querying the PDMP, including not knowing they could query, accessing the PDMP was too time-consuming, not finding PDMP information useful, and rarely or never prescribing controlled drugs. While administering surveys could be an effective assessment tool to solicit testimonial evidence on PDMP utilization, routine follow-up surveys, data analysis, and performance measurement processes were required to fully understand and assess PDMP utilization. Board staff never published final survey results, a follow-up survey to prescribers did not occur following the advent of statutorily-required querying to identify potential effects of PDMP reforms, and supplemental evaluations to assess prescriber utilization were never implemented, which limited survey effectiveness and left utilization assessments to rely upon anecdotal evidence.

Dispensers

Effective June 2012, dispensers were required to submit schedule II through IV controlled drug information within seven days from the date a prescription was dispensed. Dispenser data submission began in September 2014. Dispensers unable to submit information within the required timeframe could seek an extension for up to ten additional days if there was good cause. However, Board rules were not explicit as to what constituted good cause, appearing to leave the decision to grant an extension to the sole discretion of the PDMP Program Manager. Dispensers unable to submit information electronically due to financial hardship could seek a waiver from the Board but still had to submit information within the required timeframe by an alternate method. However, Board rules were not explicit as to what constituted a financial hardship or how such a hardship would be assessed, appearing to leave the decision to grant a waiver to the sole discretion of the PDMP Program Manager. Consequently, PDMP registrants were left without a clear interpretation of binding regulations related to extensions or waivers. Effective, sufficient rules should explicitly implement and interpret statutes enforced and administered by the Board.

Effective September 2016, legislation increased the submission frequency to daily, by the close of business on the next business day from the date the prescription was dispensed. Veterinarians were legislatively exempt from the increased submission frequency and retained the seven day submission requirement. The Board was to be notified if a dispenser failed to submit the information within the extended timeframe. However, the Board did not track or measure timeliness of submissions for registrants granted extensions, potentially hindering compliance enforcement and resulting in the Board being unable to use timeliness as a measurement to assess utilization. Additionally, rules for submitting information timely and granting extensions were not updated to reflect statutory changes increasing submission frequency.

As we discuss in Observation No. 24, dispensers who were not exempt from submission requirements were required to submit a *Zero Report* when no schedule II through IV controlled

drugs were dispensed in a given day within the statutorily required timeline. However, the Board's requirement appeared to conflict with statute and rules, which only required submission of controlled drugs *dispensed*, not the lack thereof. Data depicting instances of dispenser submissions appeared to include *Zero Reports*, potentially inflating dispenser submissions and inaccurately reflecting outputs related to statutory compliance, making data and periodically-reported figures unreliable.

The Council surveyed PDMP-registered dispensers from June 2017 through August 2017 to which 446 dispensers reportedly responded, for an estimated response rate of 16 percent. Raw survey data was not provided, but summary results showed 294 of the 446 respondents (65.9 percent) had used the PDMP within the prior year to optionally query a patient's history. However, the Council administered only one survey to dispensers, the survey produced a low response rate, and supplemental evaluation activities were not implemented, limiting the validity of survey-based testimonial evidence and limiting effective assessment of dispenser utilization.

Lack Of Control Structure

The Board lacked adequate controls over PDMP utilization, compromising PDMP effectiveness. Minimally, a control structure should include documented policies and procedures; tracking of achievements and comparing them to plans, goals, and objectives to measure performance; conducting checks of data to ensure accuracy; and evaluating control activities to determine effectiveness. However, as we discuss in:

- Observations No. 12 and No. 15, the Board did not have policies or procedures to identify and maintain a list of practitioners subject to inspection, which could have aided in PDMP registration processes and assessing utilization;
- Observations No. 1 through No. 4, No. 6, No. 9, and No. 13, the Board lacked a performance management system, standards to measure effectiveness, or data collection and knowledge management systems; and
- Observation No. 17, the Board did not quantify PDMP data reliability and lacked a system of controls to ensure sufficient reliability was achieved and maintained.

Performance Measures

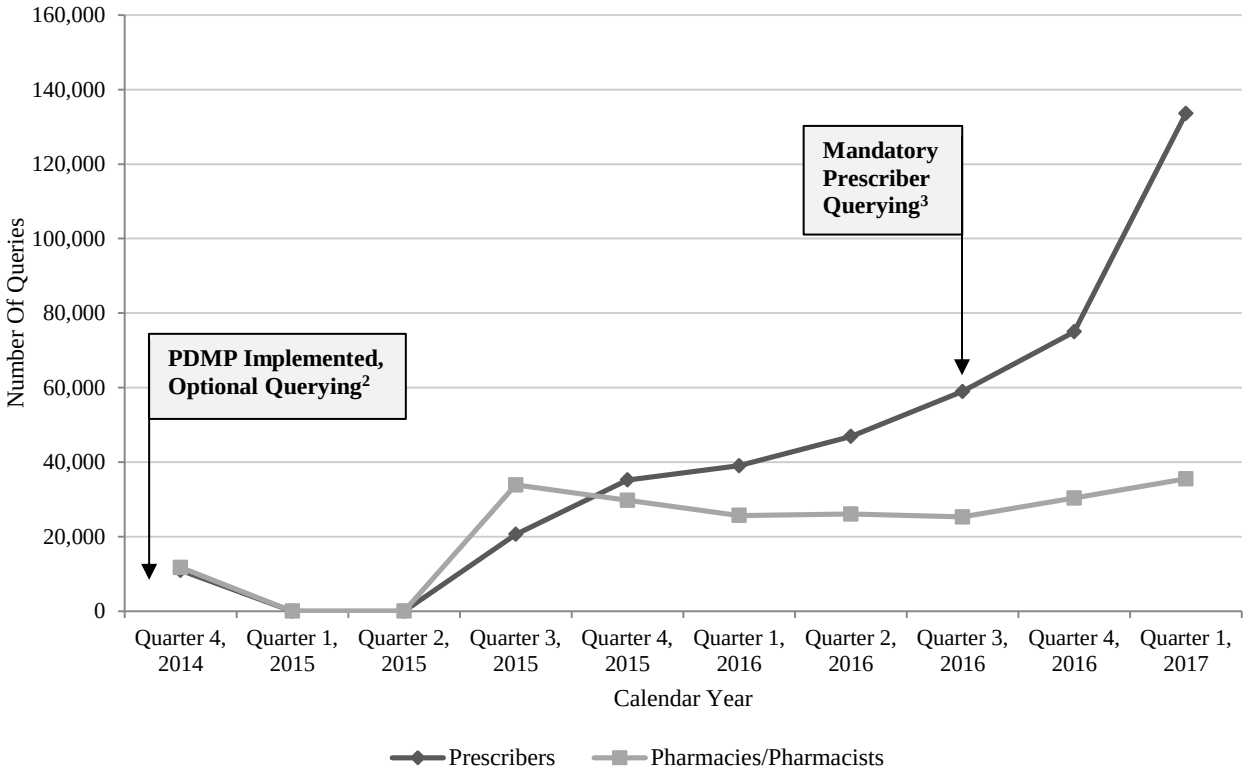
While certain utilization outputs were tracked to satisfy federal grant reporting requirements, the Board lacked performance standards; PDMP data was not collected, analyzed, monitored, or evaluated; and outcomes were not quantified to measure whether PDMP utilization was effective.

The two outputs related to utilization contained in quarterly federal grant reports provided the number of instances in which prescribers and pharmacists and pharmacies solicited reports from the PDMP. Outputs reported for federal grant purposes indicated utilization significantly increased after legislation in September 2016 required prescribers query the PDMP database, while optional querying for dispensers remained consistent as shown in Figure 13.

We requested upload and querying data from the PDMP's inception through June 30, 2017. We received 20 reports on practitioner querying, which included varying levels of detail and covered various timeframes between December 2015 and June 2016. While the *number of instances* in which registrants queried the PDMP appeared to increase, unaudited PDMP data between August 2016 and June 2017 indicated the *number of PDMP-registrants* querying the PDMP from month-to-month was only a small portion of all registrants, as shown in Figure 14. The unaudited data also appeared to indicate the increasing trend only continued a pre-mandate trend. Additionally, while unaudited data indicated a similar increase in instances of querying when the statute mandating querying became effective, we were unable to reconcile instances of querying reported in the quarterly federal reports with instances of querying in the unaudited data provided.

Figure 13

Number of PDMP Queries[1],
Fourth Quarter, CY 2014 Through First Quarter, CY 2017



Notes:

1. PDMP data were limited as described in Observation No. 17 and Appendix A.
2. Dispensers could first register for the PDMP between August and October 2014 and prescribers could first register for the PDMP in October 2014. Initially there were no requirements for either prescribers or dispensers to query the PDMP when prescribing or dispensing any controlled drugs.
3. Effective September 2016 statute mandated prescribers to query the PDMP under certain circumstances when prescribing a schedule II through IV opioid.

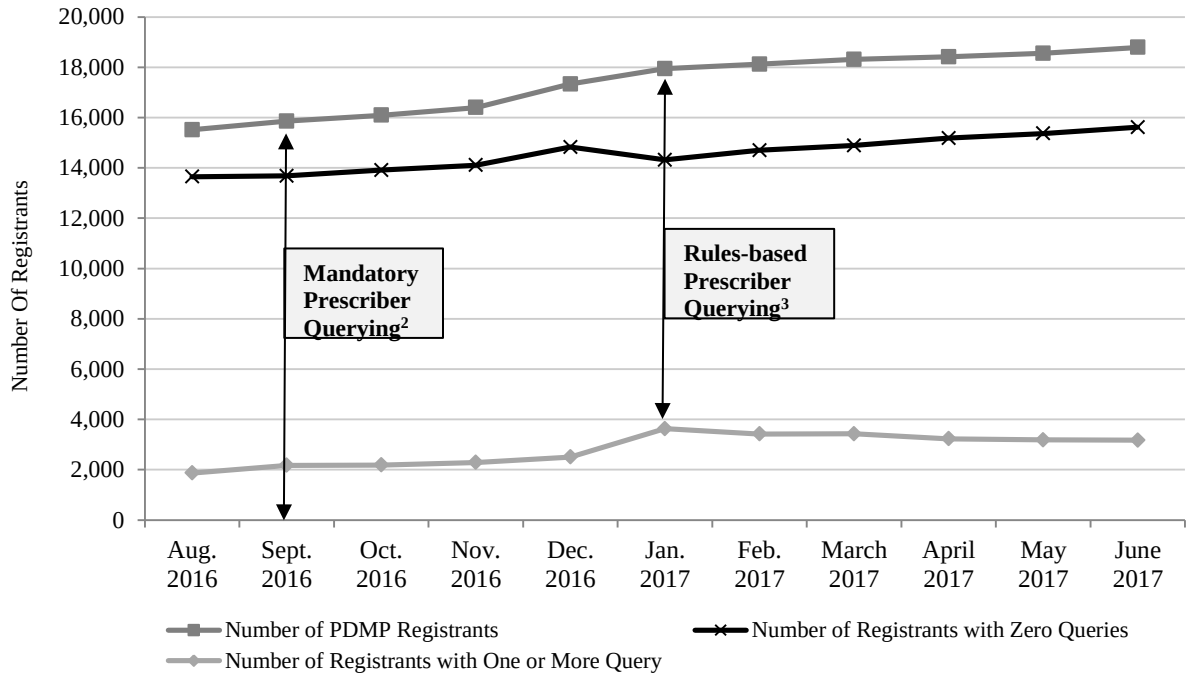
Source: LBA analysis of unaudited PDMP information.

Board staff included utilization outputs, such as the number of practitioners querying the PDMP and the percentage of practitioners registered and utilizing the PDMP, in the periodic reports it published. However:

- these presentations likely overstated utilization, because the data used in the periodic reports were not limited to querying a patient's history but also included any modifications to practitioners' accounts, such as changing a password or profile;
- the dispenser output provided in the federal grant reporting was limited, omitting non-pharmacists and non-pharmacy dispensers, such as veterinarians, emergency room physicians, and other prescribing practitioners who also dispensed;
- the population of those required to register with and utilize the PDMP was unknown to the Board, making it impossible to accurately compare registrant use of the PDMP to the number of practitioners actually required to utilize the PDMP; and
- the data simply depicted outputs, and there was no analysis demonstrating what effect, or outcomes, utilization had.

Figure 14

Number Of PDMP Queries[1] By Month, June 2016 Through August 2017



Notes:

1. PDMP data were limited as described in Observation No. 17 and Appendix A.
2. Effective September 2016 statute mandated prescribers to query the PDMP under certain circumstances when prescribing a schedule II through IV opioid.
3. Effective January 2017 the statutory mandate to query was replaced with a requirement for individual regulatory boards to develop rules-based requirements on querying.

Source: LBA analysis of unaudited PDMP information.

Data Controls

Board staff reported audit capabilities within the PDMP, such as reviewing: 1) the name of a prescriber, 2) when a query was performed and for which patient, or 3) whether a delegate accessed the PDMP on behalf of a prescriber. In addition to data deficiencies we discuss in Observation No. 17, Board staff indicated there were concerns regarding querying access and accessing PDMP data. For example, some delegates serving multiple practitioners, reportedly queried on behalf of the wrong practitioner and negatively affecting individual practitioners' compliance with querying mandates. Further, Board staff review of data occurred inconsistently and only upon request.

Reportedly, Board staff were awaiting input from the Board and other regulatory boards to determine whether it would be useful to provide the boards with utilization reports and send notices to licensees stating they would be subject to random auditing. However, primary utilization enforcement authority had been transferred to these entities, making utilization reports and auditing necessary to carry out enforcement. Additionally, some prescribers anecdotally indicated they modified their prescribing habits to avoid having to comply with requirements to utilize the PDMP, thereby negating the purpose of the PDMP and further compromising the reliability of output and outcome analyses solely reliant upon PDMP data.

Recommendations:

We recommend the Board:

- **collaborate with the Council to define utilization outputs and outcomes, establish long-term goals and objectives, and near-term targets for the PDMP to help achieve its statutory purpose;**
- **limit the definition of "query" to actual queries of patient histories and disaggregate instances of PDMP use not applicable to the final definition to help ensure accurate data are analyzed and reported;**
- **devise and implement a system to obtain utilization data from regulatory boards, ensure regular surveys are administered to all PDMP registrants, and implement supplemental evaluation activities to corroborate PDMP data and accurately analyze and assess utilization;**
- **address dispenser extension rules to ensure they accurately reflect statute and begin tracking compliance as a form of measurement and adopt or revise other rules as required;**
- **remove zero reporting from submission data and ensure prescribers who also identify as dispensers are included in submission data to accurately assess dispenser utilization; and**
- **include in its strategy and plans a component addressing utilization management.**

Board Response:

We concur in part.

Practitioner registration with the PDMP was always a mandate, and the use of the PDMP was voluntary until recently. The Board does not agree that utilization management is a legislative expectation of the Board or any of the regulatory boards. In fact, it is still voluntary for practitioners to review the PDMP when writing a prescription for any controlled drug other than opioids. If the Board were required to monitor utilization for the current mandate on opioid utilization by prescribing practitioners, it would require significant analytic resources to either work with the new databased management vendor or to purchase analytic software and support for analytic staff.

The Board agrees that "querying" will need to be defined in rules.

As previously stated, other regulatory board data requirements will require legislation to develop a DEA registry in their licensing system for the other boards to fully determine which of their licensees are required to register with the PDMP. The Board will continue to work with the other regulatory boards, DoIT and the new database management vendor to set up the automated registration system and provide a licensing agent in each regulatory board limited access to the system to validate licensee registration in 'real time' as opposed to waiting on monthly reports. The Board will continue to work with the other regulatory boards to facilitate the administration of regular surveys to assist in corroborating PDMP data.

The Board will review with the new database management vendor to ensure that the data given to users can de-aggregate zero reporting from actual data submission; however, a 'zero report' is a requirement that aids the program in assessing compliance with uploading compliance against failure to upload during a period of time, which is also an important compliance measure of the law. Zero reports do not impact or are seen by the query users. It is simply a compliance tool.

The Board will include in its timeline current data elements available and will develop measurable objectives based on current capacities and adjust if/when those capacities change.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Will be included in strategic plan draft	*See Observation No. 5*
All policy and procedures development	*See Observation No. 1*

LBA Rejoinder:

In responding to our survey, most Board members reported awareness of the Board's statutory responsibilities for enforcement, as five of seven Board members indicated the Board was responsible for enforcing utilization requirements and six of seven indicated other regulatory boards were responsible.

The PDMP cannot achieve any outcome without registrants using it. Suggesting measuring such a fundamental activity as utilization is not necessary because State law does not explicitly require it appears shortsighted – compromising the utility of the PDMP and undermining the reason for its existence.

Data Quality

The PDMP was wholly reliant upon information technology to effectively carry out its mission and achieve its outcomes. The Board contracted with a database management vendor to provide the PDMP software and database management services. The DoIT supported procurement and contract oversight, approving the Board's service contract. It was not evident the Board, the Council, or Board staff ever examined technology or other controls over PDMP data. Board staff acknowledged data limitations affected the completeness and accuracy of PDMP data. Further, until July 2015, individual prescription data that were not indicative of controlled drug abuse or diversion had to be expunged from the PDMP database after six months, which limited longitudinal analyses.

Observation No. 17

Improve Management Of Data Quality And Timeliness

The Board's management of PDMP data quality and timeliness was at an initial stage of maturity. The Board did not: 1) quantify PDMP data quality, 2) implement a system of controls to understand data quality or ensure sufficient quality was achieved and maintained, or 3) establish a threshold specifying what degree of quality was sufficient. The Board also did not develop and implement controls over timeliness factors. The successful implementation and operation of a database was crucial for the PDMP to obtain desired results. PDMP data could be used for patient care decisions, administrative and criminal sanctions, Office of the Chief Medical Examiner (OCME) overdose death investigations, and analyses supporting policy formulation. Consequently, data accuracy was of paramount importance, as erroneous and incomplete data could nullify the potential value of the PDMP.

PDMP data quality encompassed validity, reliability, accuracy, and completeness, as well as timeliness. Unless operating under an extension, dispensers were required to submit 17 data elements for each schedule II through IV controlled drug dispensed. Uploading was to occur within seven days of the controlled drug being dispensed through September 2016, when daily uploading became a requirement. The database management vendor was required to perform checks to ensure data were accurate, complete, and submitted timely. The vendor was to notify individual dispensers who failed to submit data or who submitted reports with no data. The vendor was also to notify the Board of these noncompliant dispensers and was to report to the Board weekly on dispensers not uploading any information. The vendor-provided error reports sent to noncompliant dispensers detailed minor and serious errors in uploaded data. Records containing fatal errors could not be uploaded to the PDMP database and were treated as a non-submission if not corrected and re-submitted. By rule, dispensers were provided seven days to

remedy errors, although this timeframe was expected to change to 72 hours. Board staff could also obtain on-demand data quality queries as required.

Database management vendor reports were submitted to the Board regularly but were delayed at times or were substantively unsatisfactory. Enforcement against noncompliant dispensers did not occur during the audit period.

Degree Of Quality Not Established

The PDMP database contained errors, gaps, and duplicate records for the same patient or the same prescription. Records missing prescribers' federal DEA registration numbers, patients' first or last names, or patients' birth dates had "fatal errors" and could not be uploaded to the database. Records with invalid prescriber DEA numbers, National Drug Codes, or patients' birth dates were considered "serious errors," and only a limited number of records containing these errors could be uploaded. Consequently, patients' records may have been missing from the PDMP database or may have included incorrect data. Unbeknownst to health care practitioners, they may have been viewing only a partial report regarding their patients' prescription histories. Questionable reliability was known to the Board and the Council and was disclosed by disclaimers contained in certain documentation provided to registrants and in periodic public reports. These disclaimers disavowed the accuracy, completeness, and adequacy of data; disclaimed liability for errors and omissions; advised users to verify PDMP data before any clinical decisions were made or actions were taken; and acknowledged data screening efforts did not identify and correct all errors.

The PDMP's database quality was never quantified by the Board or others. No systematic review of data quality and timeliness factors was undertaken by the Board or others. Board staff reported some difficulties tracking errors and corrections. Nonetheless, some isolated examinations of compliance by Board staff were conducted intermittently after October 2014 and indicated certain registrants inconsistently uploaded data, submitted incomplete data, and did not upload data timely. Examples of errors we identified included:

- One unaudited CY 2016 upload accuracy report depicting one month's uploading errors for 49 registrants indicated ten (20.4 percent) had no correct uploads that month, and while 97.0 percent of the prescriptions uploaded were reportedly correct, the report was of questionable completeness and accuracy.

- Unaudited error data encompassing late December 2016 through late June 2017 indicated prescription errors persisted through SFY 2017, ranging from 47 errors to over 40,000 errors month-to-month and from one error to over 79,000 errors by individual uploaders.

- A limited unaudited data set indicated at least 150 erroneous transactions occurred in a five-month period through late April 2017, although the context for the 150 errors was not stated.

- One unaudited monthly query report listing nearly 5,400 querying prescribers: 1) was missing prescribers' agency names (11.3 percent), the prescribers' phone number (4.5 percent), and the prescribers' address (11.8 percent); 2) contained irrational date data for password resets (2.2 percent), irrational birth date data (3.8 percent),and unknown birth dates (4.5 percent); 3) missing a user name (one); 4) contained 192 bogus entries for telephone numbers; 5) contained test and other non-prescriber accounts; and 6) contained other data consistency issues.

- Unaudited registration data taken intermittently from April 2015 through June 2016 lacked data in several fields, including some birth dates, agency names, addresses, licensing states, phone numbers, and cities. To a lesser extent, other issues existed in the registrant data, such as irrational birth dates and addresses. Irrational and blank birth date counts are contained in Table 2. Importantly, the data indicated a reduction in irrational and blank birth dates over time.

Table 2

Irrational And Blank Registrant Birth Dates In PDMP Data,
April 2015 Through June 2016

April 2015	June 2015	January 2016	February 2016	April 2016	June 2016
6,029	4,539	2,428	2,417	2,397	2,155

Note: PDMP data were limited, as described in Observation No. 17 and Appendix A.

Source: LBA analysis of unaudited PDMP data.

The original contract for database management services required the vendor to validate that data submissions met accuracy and completeness thresholds established by the Board. The original database management vendor asserted the PDMP software used internal data checks and validation to ensure data complied with Board standards. However, no standards were set and the software permitted entry of irrational data or blank fields. There were no indications changes to the software were made or contemplated to better control data entry.

The Board was provided information on data quality at least as far back as April 2015, and Board staff acknowledged data limitations affected the completeness and accuracy of PDMP data. Quality issues also reportedly limited Board requests for PDMP reports, as the Board knew they could not rely on the accuracy and reliability of PDMP data. We asked non-pharmacy regulatory board members responding to our 2017 survey whether they had concerns about data accuracy and reliability, and:

- 15 of 32 (46.9 percent) reported not having any concerns,
- one (3.1 percent) reported concerns that were fully mitigated,
- seven (21.9 percent) reported having concerns that were somewhat mitigated, and
- nine (28.1 percent) reported having concerns that were not at all mitigated.

Some regulatory board members noted that data entry errors occurred commonly, and data quality affected the reliability of registration numbers, among other reported outputs.

Data Quality Control System Not Implemented

The Board lacked data quality- and timeliness-related policies and procedures. Draft procedures to control and improve data quality were incomplete and unimplemented, with the initiation date yet-to-be-determined. These procedures did not address timeliness factors. Initial indication of compliance reporting related to data quality was provided to the Council, then the Board, in January 2015. Implementing a compliance program was set as a goal for SFY 2017. In November 2016, Board staff started developing procedures and requirements intended to improve data quality, with implementation scheduled for June 2017. Implementation was delayed until after vendor migration and remained inoperative through September 2017, despite a reported objective to have quality data by January 2018.

The draft procedures and requirements included error thresholds with connections to compliance enforcement action by the Board. Inadequate reporting was defined in the draft plan as a dispenser who, within 30 days: 1) was late uploading by three days or more or 2) had fatal or serious errors not fixed timely. The draft plan contemplated issuing an "inadequate letter" on the first offense. If inadequate reporting occurred for more than two months, the Board's compliance staff would be notified to follow up with the dispenser. If corrections were not made after the Board's compliance staff visited the dispenser, the dispenser would be reported to the Board and any other regulatory board with disciplinary jurisdiction.

Board rules did not reflect these thresholds, procedures, and penalties, and the proposal differed from statute, which provided failure to submit required information or knowingly submitting incorrect information was immediately subject to a warning letter, and individuals were to be provided an opportunity to correct the failure. Subsequent failure to correct or resubmit required information subjected the individual to discipline by the Board.

Structural Issues

PDMP data were structurally incomplete. Not all dispensers were required by statute to use the PDMP. Consequently, the PDMP excluded relevant data from: 1) licensed hospital pharmacies dispensing less than a 48-hour supply of a schedule II through IV controlled drug from a hospital emergency department or dispensing a schedule II through IV controlled drug for in-hospital administration; 2) practitioners, or other authorized persons who administered schedule II through IV controlled drugs; 3) wholesale distributors of schedule II through IV controlled drugs and analogs; 4) prescribers dispensing less than a 48-hour supply of a schedule II through IV controlled drugs from a hospital emergency department to a patient; or 5) veterinarians dispensing less than a 48-hour supply of schedule II through IV controlled drugs to a patient. The PDMP also did not collect data on controlled drugs dispensed from opioid addiction treatment programs due to federal confidentiality requirements. The process to integrate federal prescribers began in May 2016, and their full integration was indeterminate. Finally, interstate data sharing did not start on time, delayed from September 1, 2016 until October 7, 2016.

From implementation in October 2014 through November 2015, the PDMP retained prescription data after six months only if the patient's prescription history met a threshold indicating potential concern, as we discuss in Observation No. 8. Deleting this data likely limited the utility of the PDMP for identifying potential abuse. Beginning in November 2015, data could be kept for three years. Board staff considered data submitted after April or May 2015 to be complete.

Recommendations:

We recommend the Board:

- **determine what degree of quality PDMP data must achieve;**
- **develop, implement, and refine rules, policies, and procedures designed to achieve quality and timeliness standards including the contemplated quality control system, and broaden it to include other quality and timeliness requirements;**
- **assess PDMP data quality and timeliness on an ongoing basis and enforce relevant requirements intended to achieve data quality and timeliness standards;**
- **ensure disclosure of PDMP data are appropriately qualified to convey limitations to all users, and until quality and timeliness are reasonably assured, PDMP data should likely be viewed to contain only *indicators* of potential issues or matters of concern, and not be viewed as definitive without corroborating, reliable, third-party evidence;**
- **assess structural limitations creating gaps in PDMP data and seek necessary legislative changes to create a sufficiently complete database to include dispensing activities that would reasonably improve the usefulness of the PDMP; and**
- **include data quality component in its strategy and plans.**

Board Response:

We concur.

The Board realizes that it cannot leave the monitoring of the compliance and integrity of PDMP data to only the database management vendor as once assumed. The Board will assess and determine a degree of quality the PDMP data must achieve and put it into policy. The Board will also assess PDMP data quality and timeliness on an ongoing basis and enforce relevant requirements. A process for this has already been developed and is anticipated to be launched early in CY 2018.

Each printed report has a disclaimer regarding data, reminding practitioners that there could be incomplete data and they should not make decisions solely on what they view in a patient's PDMP controlled drug prescription history report. The Board will include this in practitioner training and outreach as well.

The Board will assess structural limitations that may be creating gaps in PDMP data and seek any necessary legislative changes to create a sufficiently complete database to include dispensing activities that would improve the usefulness of the PDMP.

Finally, the Board will include in the strategic plan goals, objectives, and a timeline for data quality and timeliness.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Will be included in strategic plan draft	*See Observation No. 5*
All policy and procedures development	*See Observation No. 1*

Security And Confidentiality

Security and confidentiality were statutory requirements. The original database management vendor-provided website was proffered as secure, transmissions were reportedly encrypted, and contractual controls were to be reviewed periodically by the State. The data analytics vendor had no corresponding control construct in its agreement with the Board. It was not evident the controls over security and confidentiality were examined, and no metrics in these areas were evident. Functional oversight of security and confidentiality controls over the database management vendors may have been delegated by Board staff to the DoIT, but the DoIT did not accept such delegation.

Observation No. 18

Improve Management Of Security And Confidentiality

The Board's ability to monitor security and confidentiality of PDMP information was at an initial stage of maturity. The Board lacked comprehensive rules, policies, and procedures to adequately ensure the security and confidentiality of PDMP data and information. Consequently, no system was implemented to monitor breaches of security and confidentiality by those with access or ensure ongoing security and confidentiality was being assured by the database management or analytics vendors. The Board did not engage in ongoing oversight and lacked a relevant strategy and plans. Due to: 1) confidentiality restrictions related to relevant controls at the current database management vendor and 2) a lack of contractual obligations requiring the vendor to publicly provide assurances, relevant controls over the security and confidentiality of the database itself, and of the processes surrounding the database, were unauditable.

Data security and confidentiality were central statutory expectations of the PDMP. Management should actively monitor an entity's control system and establish clear objectives to identify risk and define risk tolerances. The Board was: 1) required to ensure the PDMP complied with all State and federal Health Insurance Portability and Accountability Act privacy and security laws and regulations, 2) required to establish and maintain procedures to ensure the privacy and confidentiality of PDMP information, 3) authorized by statute to release aggregated or otherwise de-identified PDMP data, and 4) required to adopt rules necessary to implement the PDMP. However, the Board lacked relevant rules, policies, and procedures and Board involvement was

limited. Directly monitoring security and confidentiality was likely beyond the capability of the Board and its staff. Security and confidentiality responsibilities were shared between the Board, its vendors, the DoIT, and individual registrants. After July 1, 2015, the OPLC was also responsible for providing assistance and supervision to the Board regarding rulemaking and for maintaining the confidentiality of information, documents, and files.

Board Controls Over Vendors

The Board originally entered into a PDMP database management contract in June 2014. The Board entered into a separate agreement for data analytics services more than two years later, in October 2016, to help support PDMP reporting and evaluation. Both vendors had access to PDMP data and were contractually obligated to maintain security, confidentiality, and data integrity. While statute authorized the Board to contract with a third-party vendor to implement the PDMP, the Board retained responsibility for PDMP effectiveness; ensuring statutory requirements were met through rules, policies and procedures; and contract oversight. Third-party attestation on the adequacy and effectiveness of vendors' technology-related controls was a common way to obtain some degree of assurance that vendors were properly safeguarding State data. While State data contained in the PDMP was confidential and not subject to disclosure under the Right-to-Know law, the Board was responsible for providing public assurances the systems securing those data operated effectively. Reporting on the technical elements of the PDMP's data security, which could expose vulnerabilities, was likely inappropriate. However, the Board should have provided public assurances of adequate oversight of its contracts and attested to its vendors' compliance with State standards and contractual requirements.

Database Management Vendors

The DoIT assisted the Board with developing the original request for proposal and procuring PDMP database management services in 2014. The original database management vendor was acquired by another entity, which assumed the State's PDMP database management contract in December 2016. We requested from Board staff and the DoIT verification of statutory and contractual compliance related to the security and confidentiality of PDMP data and services by the vendors. We were informed production of those materials for the current vendor would require non-disclosure agreements because the reports were proprietary information. Furthermore, similar attestations by the *original* vendor were not provided to or obtained by the DoIT or Board staff. Reports attesting to the *new* vendor's security and confidentiality controls over PDMP data and services were only provided to the DoIT in July 2017. This resulted in a period of more than two years where the vendor's obligations to ensure the security and confidentiality of PDMP data went unverified by the DoIT, the Board, or Board staff, and, since July 2015, by the OPLC.

Although Board rules inadequately reflected statutory requirements regarding security and confidentiality, provisions in the database management contract, if properly implemented, appeared sufficient to satisfy DoIT requirements, since the DoIT approved the contract. For example, the contract required a physically secure data center, secure hosting, disaster recovery, data encryption, only authorized users accessed the system, and vendor testing and strengthening to prevent critical security flaws in the application. Additionally, the contract provided for State

verification of vendor compliance with contractual obligations, such as providing security testing results and attesting to the security of the software to the DoIT before the PDMP became operational. Testing results were to then be reviewed and accepted by the DoIT. The State also had the option of performing random security audits and vulnerability testing of the vendor's hosting infrastructure and the application. However, neither the Board nor the DoIT were provided security testing results from the original vendor, and no random security audits or vulnerability assessments were conducted by the DoIT for either the original or new vendor. Testing results and related reports were reportedly provided by the new vendor to the DoIT, but we did not review them due to purported confidentiality restrictions imposed by the vendor. Further, reports provided to the DoIT by the new vendor were not shared with the Board or its staff. Neither the contract nor the agreement required ongoing security and confidentiality reporting to the State, as assurances provided by the new vendor were a one-time requirement.

Data Analytics Vendor

In contrast to the Board's contract with the PDMP database vendor, the sole-source agreement with the data analytics vendor was not a standard State contract. The data analytics vendor agreement had no security and confidentiality provisions, and no assurances or reviews were contemplated. The data analytics vendor was reportedly provided access to raw PDMP data to assist in de-identification and limited access to the PDMP database. The DoIT and the DOJ reportedly reviewed the agreement before the Board finalized the contract. Relevant provisions in the contract with the PDMP analytics vendor focused on the scope of work, unauthorized dissemination and divulging of PDMP data, and the vendor's obligation to report breaches of confidentiality to the Board. The vendor had no formal guidance on de-identifying PDMP data, since no rules, policies, or procedures had been adopted by the Board.

Board Confidentiality And Security Controls Over Authorized Users

The Board had not established a system to identify and track the timely resolution of breaches of confidentiality by authorized users. During the audit period, one breach of security and confidentiality of PDMP data was documented. The violation was self-reported by the registrant, rather than identified through systematic monitoring by the Board and involved a registrant providing PDMP information to law enforcement. The compromised documentation was reportedly recovered by the Board. Additionally, requests by law enforcement to access the PDMP were reportedly limited to two or three subpoenas from the DOJ and the DEA. However, according to our 2017 survey of law enforcement personnel, 12 of 46 (26.1 percent) respondents reported their agency had used PDMP information for investigations, including respondents representing local, county, and State law enforcement agencies. We did not resolve this discrepancy.

The use of delegates by practitioners also posed potential confidentiality issues. State law permitted *designees* of prescribers and dispensers to access the PDMP, but as we discuss in Observation No. 15, *delegates* were neither provided for in State law nor equated with designees in Board rules. However, Board rules required delegate appointments be made in writing and subjected delegates to statutory penalties. In practice, delegates had to be sponsored by a prescriber or dispenser, were required to register with the PDMP, and had to utilize the PDMP

from their own account to query patient prescription data. Board rules did not reflect these requirements. Further, undelegated use of PDMP data reportedly occurred, such as unregistered administrative assistants querying patients on behalf of a prescriber or dispenser. However, no system was in place to systematically identify, monitor, and resolve violations. No audits of user queries were conducted unless requested for investigation by a regulatory board whose licensees were subject to the PDMP. Complicating enforcement was the fact not all delegates were licensees of a regulatory board, although the Board retained primary enforcement authority over these delegates and had the authority to fine any person who violated the *Act*, as we discuss in Observation No. 11. However, the Board had not created a system or rules, policy, and procedures to implement this authority.

The de-registration process reportedly occurred when regulatory boards provided Board staff notice a registrant was no longer licensed. We requested information related to the timely de-registration of registrants identified as being ineligible to access the PDMP from the time they became ineligible, to the time ineligibility was identified, and to the time when their access was revoked. Documentation demonstrating timely de-registration of practitioners or their delegates no longer eligible to access the PDMP were not collected. De-registration relied on regulatory boards providing adequate information to the Pharmacy Board, and the vendor subsequently removing access to the PDMP timely. However, other regulatory boards reportedly did not consistently collect and report necessary data, which hindered Board identification of registrants no longer practicing in, or no longer possessing a DEA registration associated with the State. New vendor and Board systems purportedly would automate registration and de-registration.

Purging Data And Retaining Metadata Or De-identified Data

Initially, PDMP information was to be deleted within six months of the date the initial prescription was dispensed, unless it met the level established to suggest possible drug abuse or diversion had occurred. The PDMP database was reportedly purged and resulted in some data gaps between March 2014 and April or May 2015. Effective January 21, 2016, information had to be purged within three years after an initial prescription was dispensed if the information did not suggest possible drug abuse or diversion. Throughout, deletion of all other information after three years was required. No rules, policies, or procedures were formalized to address the loss of PDMP data and information due to purging requirements. Through early SFY 2018, the issue of purging data had yet to be discussed with the new vendor.

Neither were rules, policies, or procedures to develop metadata or de-identified data sets from PDMP prescription data developed. Metadata included descriptive PDMP data in general, such as the aggregate number of prescribers or the average age of those receiving prescription opioids, while omitting personally identifiable information. Since July 2015, the Board was authorized to use and release aggregated or otherwise de-identified PDMP information and reports.

OPLC Role

The OPLC was required to provide guidance and assistance to the Board regarding rulemaking and to ensure the confidentiality of information, documents, and files. The OPLC did not appear to have provided meaningful support to the Board's confidentiality and security efforts. Board

rules did not reflect statute with respect to PDMP confidentiality and security. As legislative changes occurred, Board rules were not updated to align with statute.

Recommendations:

We recommend the Board:

- **develop, implement, and refine a system to routinely assess the adequacy of third-party controls over State data;**
- **develop, implement, and refine a system to identify and monitor breaches of confidentiality by authorized and unauthorized users of the system, and track their resolution;**
- **develop, implement, and refine a system to ensure ineligible users of the system are removed timely;**
- **develop and adopt policies and procedures regarding the development of metadata and the de-identification, release, maintenance, and purging of PDMP data and information;**
- **ensure vendors are required to regularly provide public attestations on the adequacy of their confidentiality and security controls; and**
- **include in its strategy and plans components related to monitoring and assessing PDMP security and confidentiality.**

We recommend the OPLC supervise, coordinate, and assist the Board with rulemaking and assist the Board with maintaining the confidentiality of PDMP information, documents, and files.

Board Response:

We concur.

The Board will work with the DoIT to develop and implement a system that will routinely assess the adequacy of third-party controls over State data, and that will monitor breaches of confidentiality by authorized and unauthorized users of the system, and track their resolution.

The Board will: 1) work with the DoIT and the new database management vendor to refine a system to ensure ineligible users of the PDMP are removed timely and 2) ensure all vendors are required to regularly provide public attestations on the adequacy of their confidentiality and security controls.

The Board will develop and adopt policies and procedures regarding the development of metadata and the de-identification, release, maintenance, and purging of PDMP data.

These responses will be part of the developmental timeline of the PDMP strategic plan.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Will be included in strategic plan draft	*See Observation No. 5*
All policy and procedures development	*See Observation No. 1*

OPLC Response:

We concur.

OPLC strives to provide all boards, commissions, and councils under its administration sufficient rulemaking oversight and assistance in maintaining confidentiality of information gathered. OPLC will work with the Board and the Council in furtherance of that statutory mandate, to ensure that rules are updated as needed in a timely manner, and that confidentiality and security efforts are adequately supported.

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GENERAL MANAGEMENT CONTROL

Management control: 1) includes the plans, policies, methods, and procedures adopted to meet a mission, goals, and objectives; 2) includes processes for planning, organizing, directing, and controlling program operations; 3) encompasses systems for measuring, reporting, and monitoring program performance; 4) helps safeguard assets; and 5) can prevent and detect errors, fraud, abuse, and noncompliance with provisions of laws and regulations. Systematized management controls can increase the likelihood the Pharmacy Board (Board) will attain effective and efficient operations. Effective operations achieve intended results; efficient operations achieve intended results and minimize waste. Ineffective or unintegrated controls undermine management control effectiveness. Effective management control includes oversight and periodic review.

Integration Of Supporting Agencies

The Controlled Drug Prescription Health and Safety Program Advisory Council (Council) was created along with the Prescription Drug Monitoring Program (PDMP) in calendar year (CY) 2012. The Council initially consisted of 13 members, but membership was later increased to 14, including:

- a Board of Medicine-appointed representative;
- a Pharmacy Board-appointed representative;
- a Board of Dental Examiners-appointed representative;
- a Board of Nursing-appointed representative;
- a Board of Veterinary Medicine-appointed representative;
- the Attorney General, or designee;
- the Commissioner of the Department of Health and Human Services (DHHS), or designee;
- a New Hampshire Medical Society-appointed representative;
- a New Hampshire Dental Society-appointed representative;
- a New Hampshire Association of Chiefs of Police-appointed representative;
- a representative of a retail pharmacy, appointed jointly by the New Hampshire Pharmacists Association, the New Hampshire Independent Pharmacy Association, and the New Hampshire Association of Chain Drug Stores;
- two public members appointed by the Governor's Commission on Alcohol and Drug Abuse Prevention, Treatment, and Recovery (Commission), one of whom may be a member of the Commission; and
- a New Hampshire Hospital Association-appointed representative.

The Board consisted of seven Governor and Council-appointed members, including six practicing pharmacists and one public member. The Board was administratively attached to the DHHS through State fiscal year (SFY) 2015. DHHS provided budgeting, recordkeeping, and related administrative and clerical assistance on a fee-for-service basis. On a cost allocation basis, provided support included budgeting, recordkeeping, and related administrative and

clerical assistance. The Board's powers, duties, functions and responsibilities; budget submission; and reporting were independent of DHHS. Available for PDMP operations was one administrator, who also oversaw other Board operations, the PDMP Program Manager, and an administrative assistant. Other Board staff also supported PDMP development, the Council and working groups, grants, and requests for proposals before dedicated staff were hired.

Beginning in SFY 2016, the Board became a component of the Division of Health Professions, one of three divisions within the newly-created Office of Professional Licensure and Certification (OPLC). The OPLC, created in July 2015 as a stand-alone agency, derived from the former Joint Board of Licensure and Certification, a separate organizational entity that functioned within the Department of State, and the DHHS, Office of Professional Licensure. The OPLC was responsible for Board administration and day-to-day operations, while the Board maintained responsibility for regulating and overseeing the practice of pharmacy. Administrative support from the OPLC included assistance with processing licenses; corresponding with the public; supervising, coordinating, and assisting with the rulemaking process; recordkeeping; and accounting. OPLC services were a cost to the Board and to be reimbursed by licensing fees. The Board also received legal assistance from a Department of Justice (DOJ) attorney and assistance with administrative rules from an OPLC attorney. Migrating Board administration from DHHS, Office of Professional Licensure to the OPLC occurred during the audit period. Board managerial staff reportedly underwent substantial change, and significant vacancies reportedly existed during the audit period.

Observation No. 19

Clarify And Formalize Organizational Structure

The Board's controls related to its organizational structure, operations, and procedures related to the PDMP were at an initial stage of maturity. The Board did not establish a clear organizational structure or lines of reporting, define the general course and methods of Board and Council operations, describe formal and informal Board and Council procedures, or adopt related administrative rules. The Board operated under expired organizational rules since CY 2013 and did not resolve the conditions that led to prior audit findings related to its organizational structure. Since the inception of the PDMP, the relationship between the Board, the Council, and supporting administrative units was never formalized. These inadequacies contributed to ineffective PDMP implementation.

Inadequate Board-Council Relationship

We found the Board and the Council had limited direct contact and an unstructured relationship, with the bodies principally relying upon the PDMP Program Manager or other Board staff to pass along PDMP information. Articulation of roles and responsibilities and their division between the Board and the Council never occurred, which led to ongoing and inadequate clarity about the role of the Council and the Board's oversight responsibility. A memorandum of understanding between the two bodies was contemplated, and the Council drafted role-related recommendations in CY 2013 and submitted them for the Board's consideration in CY 2014. However, there was no clear effect on the relationship through at least August 2017, and the two bodies remained unintegrated.

Our 2017 survey of the 21 members of the Board and Council amplified the lack of clarity. When asked:

- whether anyone reviewed State law for expected PDMP outcomes, six of the 19 members responding (31.6 percent) replied yes, three (15.8 percent) replied no, and ten (52.6 percent) replied they did not know;
- how clear the Board's oversight role was, five of the 18 members responding (27.8 percent) replied the Board's role was clear, eight (44.4 percent) replied it was somewhat clear, four (22.2 percent) replied it was not at all clear, and one (5.6 percent) replied they did not know; and
- how clear the Council's oversight role was, seven of the 18 members responding (38.9 percent) replied the Council's role was clear, seven (38.9 percent) replied it was somewhat clear, and four (22.2 percent) replied it was not at all clear.

The complete results of our survey of Board and Council members are included in Appendix D.

Absent adequate direction, guidance, and apportionment of responsibility, the Council took the lead on several aspects of PDMP implementation, including soliciting and selecting a vendor, initiating staff hiring, drafting rules, seeking legislative changes and contacting stakeholders, drafting and submitting budgets, and publicizing PDMP information. The Council sometimes took action without clear Board direction or approval and, at other times, clearly without Board involvement. Statutory obligations underpinning PDMP operation, including developing criteria for reviewing prescribing and dispensing information, reporting matters to regulatory boards for further investigation, and notifying practitioners of potential doctor shoppers under their care, were unfulfilled, as we discuss in Observations No. 7 and No. 8. Board expectations related to the Council's obligation to collect information on PDMP outcomes and impact, including user satisfaction, PDMP impact on prescribing patterns, the impact of referrals to regulatory boards, and other relevant outcome measures, were never articulated, as we discuss in Observation No. 9.

The lack of synergy between the two bodies subsequently led to an intervention by the DOJ in CY 2015, which attempted to set a foundation for the bodies' interactions. This effort was reportedly unsuccessful, but we did observe the Council's Chair attend one Board meeting in September 2017, which was expected to continue.

Lack Of Rules

The Board was required to adopt organizational rules, rules describing its general course and methods of operations, rules related to public access, and rules describing formal and informal procedures. Organizational rules only expire if the governing statute is amended, rendering then-existing rules inaccurate. In such cases, the Board must commence rulemaking to amend organizational rules no later than 90 days after the effective date of the law rendering rules inaccurate. Inaccurate rules expire one year after the effective date of the law rendering the rules inaccurate.

With implementation of the PDMP in June 2012, the Council was created and became a component of the Board intended to assist it with PDMP implementation and operation. Board

rules never incorporated the Council or related procedures and practices. Neither were the PDMP and its staff included within the Board's procedures and practices. Moreover, the Council itself lacked formal practices and procedures, such as those structuring meetings or how the public could contact the Council or provide input. The Board operated with expired organizational and procedural rules since June 2013.

Since our *Board of Pharmacy Financial Audit Report For The Six Months Ended December 31, 2008* (2008 audit), we identified inadequacies related to the Board's organizational structure. We found: 1) the Board's organizational structure did not support and promote controlled operations and 2) a lack of clarity in the lines of authority, responsibility, and flow of information. We recommended the Board establish an organizational structure to promote the achievement of Board objectives and clearly establish and define lines of authority, responsibility, and flow of information to promote efficient and effective Board operations. Our *Board Of Pharmacy Inspections Performance Audit Report* issued in May 2015 (2015 audit) illustrated the lack of the Council within the Board's structure and that the resolution of our 2008 audit's recommendations was incomplete. Since July 1, 2015, the OPLC was responsible for supervising, coordinating, and assisting the Board with rulemaking.

Relationship With Administrative Support Elements

The relationship the Board and the Council had with the OPLC was unstructured beyond the provisions of the OPLC's statutory obligations. Many areas of Board and Council noncompliance with State laws were underpinned by administrative, clerical, and business processing functions, and supervision and coordination of, and assistance with, rulemaking, areas in which the OPLC had responsibilities. Turbulence in the assignment of the chief administrative employee for the Board through March 2017, and migration from attachment to DHHS to assignment to the OPLC may have contributed to a lack of clarity. So may have the lack of a PDMP Program Manager through May 2014 and other Board staff dedicated to the PDMP through SFY 2016, and inconsistent administrative support for the Council.

Recommendations:

We recommend the Board comply with State law and promulgate rules detailing:

- **its organizational structure, to include the Council and the role of staff;**
- **all formal and informal Board and Council procedures, and the role of staff;**
- **the course and methods of Board and Council operations, and the role of staff; and**
- **apportionment of roles and responsibilities between the Board and Council.**

We also recommend the Board:

- **develop, implement, and refine policy and procedure to ensure the Council fulfills its statutory and regulatory obligations;**

- **develop, implement, and refine policy and procedure to ensure ongoing surveillance of administrative rule validity, related requirements, and statutory changes to avoid future noncompliance;**
- **timely remediate audit findings; and**
- **clarify the terms and conditions of its relationship, and the relationship of the Council, to the OPLC via formal agreement.**

We recommend the OPLC facilitate Board rulemaking by fulfilling its supervision, coordination, and assistance responsibilities to help ensure Board rules comply with State law and provide the Board and Council necessary administrative, clerical, and business processing support.

Board Response:

We concur.

The Board has developed an organizational structure and will develop rules and policy and procedures concerning the Council and its interaction with the Board.

The Board and Council will develop a policy and procedure manual that will identify and manage all obligations of the Council to meet statutory requirements. This will be an ongoing project with a minimum 2-year timeline.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Rules concerning organization structure and the Council	*July 2018*
Board and Council responsibilities in administrative rule	*July 2018*

OPLC Response:

We concur.

OPLC will continue to work with the Board and Council to develop, implement, and maintain administrative rules relating to the PDMP and will provide necessary administrative, clerical, and business processing support.

Statutory Compliance

Several statutory requirements imposed compliance obligations on the Board. These requirements included substantive PDMP elements, as well as ministerial elements of administrative laws. The Board was functionally a stand-alone regulatory agency before its assignment to the OPLC, and thereafter retained responsibility for regulating the profession and administering the PDMP. Throughout, compliance with generally-applicable statutes was inconsistent, and there was substantive noncompliance in several areas.

The Right-to-Know Law

Access to Governmental Records and Meetings, commonly referred to as the Right-to-Know law, was intended to assure openness in the conduct of public business; provide the greatest possible public access to the actions, discussions, and records of public bodies; and provide accountability to the people. The law established numerous requirements related to public bodies' meetings and records.

Observation No. 20

Improve Compliance With The Right-to-Know Law

The Board's controls over Board and Council compliance with the Right-to-Know law were at an initial stage of maturity. The Right-to-Know law facilitated accountability, responsiveness, and public access to Board and Council operations and records. The law established procedures and requirements for Board and Council meetings, minutes, and public records. We found broad noncompliance with numerous requirements, jeopardizing the public's right to know.

Board and Council minutes inconsistently recorded the bodies:

- properly moved into nonpublic session from a public meeting,
- cited specific authority to enter into nonpublic session,
- took roll call votes to enter into nonpublic session,
- voted to seal nonpublic session minutes in public meetings, and
- took a roll call and obtained the votes of two-thirds of the members present to seal nonpublic session minutes.

We also noted these inconsistencies when attending Board and Council meetings during parts of CY 2017.

Additional Board Noncompliance

Additionally, the Board:

- inconsistently met quorum requirements, as we discuss in Observation No. 21;
- inadequately managed records, as we discuss in Observation No. 25;
- preceded a duly noticed public meeting with a nonpublic session that lacked notice, a public session from which to initiate the nonpublic session, and other elements indicative of compliance with the Right-to-Know law;
- discussed subjects in nonpublic session without apparent statutory basis; and
- held a non-emergency telephone conference call to discuss PDMP database management vendor selection with only one member physically present.

Additional Council Noncompliance

We found the Council inconsistently complied with both the spirit and letter of the Right-to-Know law. Council minutes demonstrated multiple instances of the body seeking to keep key elements of its statutorily-required criteria-setting work confidential without clear statutory authority underpinning such attempts, and even though State law required the criteria be adopted in rule. We also observed such efforts during parts of CY 2017.

Additionally, the Council inconsistently:

- met quorum requirements, as we discuss in Observation No. 22;
- posted notice of meetings in two public locations;
- created minutes clearly identifying its final decisions or motions, and associated votes; and
- created and maintained meeting minutes, which were permanent records under the Right-to-Know law, resulting in minutes for five meetings during SFY 2014 being missing, as we discuss in Observation No. 25.

Council minutes also demonstrated the body: 1) held an "Official Non-Meeting," an "informal meeting," and other meetings on scheduled meeting dates without a physical quorum but undertook public business nonetheless; 2) discussed subjects in nonpublic session without apparent statutory basis; and 3) knew it was subject to the Right-to-Know law when it began meeting in SFY 2013.

Public officials are subject to civil penalties if they are found to have violated the Right-to-Know law in bad faith, while meetings not complying with the law are subject to invalidation and other noncompliance can result in other sanctions.

Member Orientation And Training

The Board and the Council were required to provide new members with orientation materials, such as business procedures and any other pertinent information. The DOJ annually conducted an administrative law workshop for licensing boards, which provided training on administrative law to members of regulatory bodies, and published regular updates to the *Attorney General's Memorandum on New Hampshire's Right-to-Know Law, RSA 91-A* (*Memorandum*), providing instructions and examples designed to facilitate public agency compliance with the law. Neither body reportedly maintained orientation materials, and while most Board members reportedly attended DOJ training, Council members did not. We apprised Board staff of the apparent deficiencies, and efforts to remedy identified deficiencies were reportedly underway in early SFY 2018. The Board reportedly reinstituted the use of a Right-to-Know checklist during its meetings, and the checklist was also provided to the Council for its use. Board staff reported the DOJ's *Memorandum* may be included in future Board and Council orientation materials, and member and staff attendance at the DOJ administrative law workshop was anticipated. Also, the Board was reportedly developing policies and procedures in early SFY 2018.

Recommendations:

We recommend the Board:

- **develop policy and procedure to ensure consistent and ongoing Board and Council compliance with the Right-to-Know law;**
- **ensure all members receive relevant information on their duties and responsibilities as public servants;**
- **develop orientation materials for new members of both bodies, and include the *Memorandum*, *Financial Disclosure* statute, the Right-to-Know law, and other relevant administrative laws;**
- **ensure at least key officers of both bodies regularly attend the DOJ administrative law workshop;**
- **periodically review both bodies' compliance with law and policy; and**
- **secure administrative, clerical, and business processing assistance from the OPLC as needed.**

We recommend the OPLC provide the Board and Council necessary administrative, clerical, and business processing assistance to promote compliance with the Right-to-Know law.

Board Response:

We concur in part.

The Board agrees that there have been issues with following proper procedure during Pharmacy Board meetings. With respect to quorum issues in reference to financial disclosure forms, the Board does not have confidence that they were handled properly at the State level, as upon investigation, forms were found for two Board members that the audit stated were not filed in 2017. Steps have been taken with Board counsel approval to vote on specific issues that have been raised to provide consistency to the process.

The Board has developed policy and procedure for entering and exiting Board public and non-public meetings using forms developed by the DOJ. The Board has also developed "Board of Pharmacy Board Member Manual" for all current and prospective Board members and is in the process of developing the same for Council members.

The Board encourages all members to attend the administrative law workshop but notes that work constraints limit the availability of members of the Board and Council to attend said workshop.

Policy and law reviews will be at call of the President of the Board. The Board administrator will discuss policy and procedure development with Board.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Rules concerning observation in administrative rules	*July 2018*
All policy and procedures development	*See Observation No. 1*

LBA Rejoinder:

As we discuss in Observation No. 21, one of the two financial interest statements we located was defective and invalid, compromising quorum for at least one meeting in CY 2017. We contacted the Secretary of State's office to locate statements for certain members missing for CY 2012, CY 2014, and CY 2015. They were not located. Any lack of confidence the Board may have with the Secretary of State's office should be taken up therewith.

OPLC Response:

We concur.

The OPLC has had representatives from the DOJ to provide an overview of the Right-to-Know law. The Executive Director is creating a policy relative to all Right-to-Know requests; receipt of such requests; require all responses be carbon-copied; and developing a matrix to ensure compliance with the Right-to-Know law. We will continue to seek the guidance of the DOJ as necessary.

Observation No. 21

Ensure The Board Meets With A Quorum

The Board's controls over ensuring its meetings were held with a quorum were at a repeatable stage of maturity. The Board consisted of seven members, and four eligible members were required to achieve a quorum and conduct public business. The Board inconsistently conducted meetings with a quorum due in part to a failure to file financial disclosure statements, which made members ineligible to serve.

Board members filed 39 of 46 required financial disclosure statements between January 2012 and July 2017. We reviewed 65 Board meetings' minutes from January 2012 through July 2017 and found 13 meetings (20.0 percent) lacked a quorum. Of these 13 meetings, ten occurred in CY 2012, two in CY 2015, and one in February 2017. While most of the meetings held without a quorum contained Board actions related to Board licensing, discipline, and enforcement; four meetings contained votes to approve PDMP-related decisions such as supporting proposed legislation, expanding registrants of the PDMP, changing the software, and accepting reports. We identified at least 84 Board meetings but only located 65 meeting minutes (77.4 percent). We were unable to determine whether additional meetings had quorum issues affecting Board decisions.

When we apprised the Board of the deficiencies, members remedied financial disclosure statement non-filings for 2017. At its July 2017 meeting, the Board ratified its previous 2017 actions to remedy possible deficiencies because of a lack of a quorum due to member ineligibility. While it reportedly made the actions of the Board legally enforceable for the meeting lacking a quorum in 2017, it did not address the CY 2012 and CY 2015 meetings. Meetings without a quorum of eligible members present were susceptible to legal challenge.

Recommendations:

We recommend the Board:

- **comply with State law and only hold regular meetings with a quorum of eligible members physically present;**
- **develop, implement, and refine policy and procedure to ensure Board meetings comply with State law and Board members are eligible to serve; and**
- **review past Board meeting minutes for quorum issues and seek legal counsel to determine how to ratify prior Board actions taken in meetings without a quorum.**

Board Response:

We concur in part.

The Board agrees that a quorum is required for all Board business. The audit suggests that the fact that financial disclosure forms were not on file with the Secretary of State's office resulted in quorum-less meetings because Board members were not eligible to vote. The Board was never informed in any year that there was an issue with financial disclosure forms, and all members stated they had timely complied and mailed them to the Secretary of State's office. Upon investigation, two forms for Board members were found in CY 2017 to be in the possession of the office that were not listed on the website. The Board does not have the confidence that forms stated as missing in previous years are not in possession of the Secretary of State's office.

Nevertheless, the Board worked to ratify any decisions made without a quorum present, and did so September 20, 2017. Moving forward, OPLC administration will be verifying financial disclosure forms and relevant paperwork. The Board will, with the assistance of the OPLC, ensure all meetings comply with State law. Policy and procedure will be developed as part of an ongoing process.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Rules concerning observation in administrative rules	*July 2018*
All policy and procedures development	*See Observation No. 1*

LBA Rejoinder:

Quorum issues were not exclusively due to non-filing of statements of financial interest. Quorum issues also arose from telephone polls and other meetings lacking a physical quorum.

One of the two statements of financial interest we located was defective and invalid, compromising quorum for at least one meeting in CY 2017. We contacted the Secretary of State's office to locate statements for certain members missing for CY 2012, CY 2014, and CY 2015. They were not located. Any lack of confidence the Board may have with the Secretary of State's office should be taken up therewith.

Observation No. 22

Ensure The Council Meets With A Quorum

The Board's controls ensuring Council meetings were held with a quorum were at an initial stage of maturity. Between June 2012 and July 2013, Council membership consisted of 13 members representing various boards, agencies, and stakeholders. Membership was increased to 14 in July 2013. A majority of the Council was needed to achieve quorum and conduct public business: seven members between June 2012 and July 2013, and eight members thereafter. Since its inception, the Council held meetings without a quorum due to a failure to file statements of financial interest, as we discuss in Observation No. 23, and additionally due to a lack of a physical quorum at certain meetings. The Council created subcommittees and addressed PDMP-related items during their meetings, such as contracting, rules, surveys, memorandums of understanding, and reports from the PDMP Program Manager. Council minutes also demonstrated it held at least five meetings despite knowing it lacked a quorum. However, we could not assess the full scope of the Council's quorum problems due to incomplete recordkeeping through the audit period, which resulted in missing documentation. Council actions taken during meetings held without a quorum could be subject to legal challenge.

In total, 13 of 53 Council meetings (24.5 percent) for which minutes were available to us for review were held without a physical quorum of members present, in addition to lacking a quorum of eligible members due to non-filing of statements of financial interest. By not having Council members consistently appointed and physically present for meetings, full representation of the boards, agencies, and stakeholders could not be achieved. This exacerbated quorum issues, potentially compromising the effectiveness of the Council.

Members Attending Remotely

Council members could attend meetings remotely: 1) for an emergency meeting or 2) when it was not reasonably practical to attend in person. Except in an emergency, a quorum of a public body must be *physically present* at the location specified in the meeting notice. If a member attended remotely, the Council was obligated to:

- state in the minutes the reason for remote participation;
- ensure the member attending remotely was audible to the public;
- identify all persons present at the place from which the remote member was participating;
- take *all votes* by roll call; and
- ensure compliance with roll call requirements were documented in the minutes.

We reviewed the 53 available Council meeting minutes and found 37 (69.8 percent) documented meetings in which at least one member attended remotely. None of the 53 meeting minutes were labeled as, or appeared to be, emergency meetings. None of the minutes for the 37 meetings with remote attendance documented compliance with statutory requirements. Further, at least seven of the 37 meetings (18.9 percent) indicated a physical quorum was met, but only due to remote members in attendance, contrary to statute.

Non-participating Members

Several positions lacked a participating member for extended periods. For example:

- the Board of Veterinary Medicine appointee did not attend a meeting from August 2012 until March 2014;
- a Pharmacy Board appointee attended only one meeting from August 2014 until August 2015; and
- the New Hampshire Association of Chiefs of Police appointee did not physically attend a meeting after October 2012 but did attend remotely from November 2012 through September 2013 and from August 2015 through February 2016.

Vacancies

Several positions remained vacant for extended periods, and it was not always noted in Council minutes when members were new appointees of their respective board, agency, or stakeholder body:

- there was no appointed member representing the Board of Dental Examiners from July 2012 until January 2013;
- there was no appointed member representing the Board of Medicine from April 2013 until July 2014;
- at least two representatives of the Pharmacy Board and one representative of the Board of Medicine were listed as Council members for only one meeting each and without indication they were appointed by their respective boards; and
- a member representing a stakeholder body noted there would be a replacement appointee; however, minutes indicated the new appointee attended only one meeting, in which both representatives were listed as Council members, and the previous representative continued to do Council work and attend meetings as a non-member thereafter, until reappointed as an interim member a year later.

Recommendations:

We recommend the Board:

- **develop, implement, and refine policies and procedures to ensure the Council complies with State law, and Council members are both eligible to serve and the Council only holds meetings with a quorum of eligible members physically present; and**
- **review past Council meeting minutes for quorum issues and seek legal counsel to determine how to ratify prior Council actions taken in meetings without a quorum.**

The Board may also consider limiting the number of meetings members may miss before requesting removal and replacement of non-participating members by the appointing authority.

Board Response:

We concur.

The Council was never notified that they were required to submit a statement of financial interest annually; however, after counsel with the Board's attorney it was discovered that the financial interest paperwork was required, and the Council voted to approve and accept the past minutes. The Council has had ongoing issues with membership attendance and its ability to have a quorum present, as there has been turnover within the Council, and replacements have not yet been appointed by respective appointing authorities. The Board will seek statutory changes to replace the Council with an advisory committee composed of members of responsible medical regulatory boards. This committee will have responsibility for disseminating data to the individual boards and developing and analyzing data to identify issues relating to statutory requirements of the program. The Board does not believe the current makeup of the Council can adequately deal with the pharmaceutical issues currently being reviewed.

The Board administrator will work with the PDMP Program Manager to ensure that all minutes are done in compliance with the Right-to-Know law and are posted to the Board's website in a timely manner.

The Board administrator and PDMP Program Manager will develop policies and procedures concerning Council member eligibility and policies for Council meetings to address quorum issues. The Board has discussed moving to a quarterly meeting schedule for the Council. If the Board's statute reforms the Council into an advisory committee, the information will need to be subject to monthly review.

The Council worked to ratify any decisions made without a quorum present, and did so on September 19, 2017.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Rules concerning observation in administrative rules	*July 2018*
All policy and procedures development	*See Observation No. 1*

Financial Disclosures

The *Financial Disclosure* statute was intended to ensure the performance of official duties did not give rise to a conflict of interest and required the filing of statements of financial interests with the Secretary of State.

Observation No. 23

Improve Compliance With The *Financial Disclosure* Statute

Board and Council compliance with the *Financial Disclosure* statute was at an initial stage of maturity. At least since CY 2012, the Board inconsistently complied with the requirements of *Financial Disclosure*, and the Council was noncompliant from its inception through at least August 2017. Board and Council members were required to annually file a signed and dated statement of financial interests by the third Friday in January if currently serving, or within 14 days of assuming office. Although the Council was reportedly informed by the OPLC in CY 2017 they were not required to file statements, applicability to members of formal advisory committees, such as the Council, had been clarified and affirmed by the Executive Branch Ethics Committee since at least CY 2007:

> We… recognize a distinction between an informal advisory group where the members act in their own personal or business interests and an executive branch advisory committee that is created by statute, administrative rule, or pursuant to RSA 21-G:11…. A person who accepts an appointment by a private organization or authority to a statutorily established executive branch advisory commission is subject to the duty to file a statement of financial interest…. [I]ndividuals who appear as a designee on behalf of a public official have the same responsibility and obligation to ensure there is no conflict of interest and, therefore, must also file…. [F]ormal advisory committee members act on behalf of the agency while engaged in state business, are agreeing to act in the public interest, and therefore must file a statement of financial interests….

Failure to file a statement made members ineligible to serve and knowingly failing to comply was a misdemeanor. Not filing complete statements could also affect meeting quorum, subjecting decisions made during those meetings to question.

Board Noncompliance

Board members were required to file a total of 46 statements from January 2012 through June 2017. We found 39 (84.8 percent) were filed. Of the 39 submitted, two were not submitted timely, though no Board meetings occurred during those periods of ineligibility, and one was not

signed, stamped, or dated, making the member ineligible during their CY 2017 term. The seven unfiled statements affected the eligibility of six members to serve as follows:

- four Board members did not file their statements through May 2012, three remained unfiled through September 2012, and two members remained noncompliant throughout CY 2012;
- one Board member did not file a statement in CY 2014; and
- two Board members did not file statements in CY 2015.

Additionally, the Board President was required to provide the Secretary of State an organizational chart identifying Board and Council members required to file statements. Complete organizational charts were unfiled during CYs 2012 through November 2017.

Council Noncompliance

Council members were required to file a total of 100 statements since the inception of the Council in June 2012. We found three statements (3.0 percent) were filed pursuant to serving as a member of the Council, one in each CY 2013, CY 2014, and CY 2015. While other members submitted statements pursuant to their service with other boards or agencies, none were filed pursuant to their role as a member of the Council. During the August 2017 Council meeting, 11 of the 14 total members who were in attendance were notified of noncompliance and were observed completing financial disclosure statements to be filed with the Secretary of State.

Recommendations:

We recommend:

- **Board and Council members comply with the requirements of the *Financial Disclosure* statute and timely complete annual statements;**
- **the Board develop, implement, and refine policy and procedure to ensure ongoing Board and Council member compliance, and periodically review Board and Council members' compliance; and**
- **the Board's president annually submit to the Secretary of State an organizational chart of all Board and Council members required to file statements.**

We recommend OPLC management develop policy and procedures to help ensure supported regulatory bodies, including the Board and Council, receive necessary administrative and clerical support to comply with the *Financial Disclosure* statute.

Board Response:

We concur.

While we agree that the Board and Council must comply with the Financial Disclosure Statute on a yearly basis, we disagree that the Board has not been in compliance. Board members have

stated they provided the forms as requested and note that two that were stated as being missing in 2017 were found at the Secretary of State's office. The Council did not believe they were required to submit this form, and this was purportedly confirmed by the OPLC. The Board notes that this misunderstanding has been corrected and actions have been taken to remediate any lingering issues. The administrative staff of the OPLC is now charged with maintaining the proper documentation for all Board and Council members and will coordinate to ensure that members shall not participate in meetings unless in full compliance with the law.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Rules concerning observation in administrative rules	*July 2018*
All policy and procedures development	*See Observation No. 1*

OPLC Response:

We concur.

OPLC's Executive Director is drafting a policy covering the process for documenting financial disclosure statements completed by all board, commission, and council members supported by the OPLC. This process will involve spreadsheet tracking of all current board, commission, and council members and updating this tracking system annually by the mid-January deadline and other times as necessary, when new members are appointed.

Rulemaking

The *Administrative Procedure Act* provided rules were each regulation, standard, form, or other statement of general applicability adopted by the Board to: 1) implement, interpret, or make specific statutes it enforces or administers or 2) prescribe or interpret Board policy, procedure, or practice requirements binding persons other than Board staff. Forms were Board documents establishing requirements for persons other than Board staff to provide the Board information, and the format in which such information must be submitted. Without proper adoption in rule, Board requirements were invalid and unenforceable.

Observation No. 24

Improve Rulemaking

Board rulemaking for the PDMP was at an initial stage of maturity. Since CY 2008, we have commented on Board rulemaking. We noted in our 2008 audit the Board reported its rules needed to be updated to adequately address the changing nature of the Board's operations. We recommended the Board review its rules to ensure continued adequacy. In CY 2015, we followed up and found the Board had substantially, but not fully, resolved prior rule issues and identified additional rule-related issues. We recommended the Board improve certain inspection-related forms and promulgate necessary rules.

Since July 2015, the OPLC has been responsible for supervision, coordination, and assistance to the Board in rulemaking, and while the Board reported ongoing efforts to review its rules, inconsistencies remained and gaps had yet to be fully identified. Actions to address our 2015 audit recommendations were incomplete through SFY 2017, and additional rulemaking requirements accompanying the addition of the PDMP to the Board's responsibilities were inconsistently addressed. We found ongoing rule-related inadequacies noted in prior audit work, and additional mechanical inadequacies, such as forms without version or edition control; substantive inadequacies, such as ad hoc rulemaking and subsequent enforcement; and form inconsistencies with rule. For example:

- The *Request For Waiver Of Reporting Requirements For New Hampshire Prescription Drug Monitoring Program* form, which allowed pharmacies to formalize their eligibility for a series of legislative-established exemptions or waive reporting requirements, was not codified in rule. The form was required without an enabling rule; contained provisions imposing requirements on pharmacies, including annual renewal, without enabling rule or law; and required "suitable" substantiating documentation without directly defining "suitable" on the form itself or defining "suitable" elsewhere in rule.

- The *Waiver Form* for dispensers to request exemption from electronic data submission requirements was not codified in rule, nor was there any version or edition control on the form. The form provided only the lack of a computer or Internet access as a suitable reason for a waiver, while the underlying rule provided the waiver request was to demonstrate financial hardship. Statute provided waivers could be issued to a dispenser "unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information by paper form or other means, provided all information required… is submitted in this alternative format and within the established time limit," without making reference to demonstrating a financial hardship.

- The *Extension Form* for dispensers unable to timely submit required data to the PDMP database lacked a version date and was not adopted in rule, with rules instead stating an extension could be granted by phone and confirmed with an email.

- Pharmacies and other dispensers not dispensing controlled drugs in any given day were required to submit a *Zero Report* daily without an enabling rule or underlying statutory requirement. The statute and enabling rules were framed to require reporting of specified, required data, not to require reporting on the absence of data.

- Department of Information Technology (DoIT) standards for user names and passwords were imposed upon all PDMP registrants without adoption in rule and without an underlying statutory requirement.

- Board rules did not reflect the planned data quality compliance requirements pending implementation at the end of SFY 2017, as we discuss in Observation No. 17.

- The Board's organizational rules were not updated to reflect the addition of the Council and lacked several other significant features, as described in Observation No. 19.

- The form letter provided to pharmacies not timely reporting dispensing of schedule II through IV controlled drugs provided 15 days to commence daily reporting, while rule provided seven days.

- The rule-based definition of a regulatory board subject to the PDMP excluded the Naturopathic Board of Examiners, licensees of which had been subject to the PDMP since its inception, and which was explicitly added to the language of the statute effective in January 2017.

- The *Patient Request Form – Prescription Drug Monitoring Information* lacked version or edition control.

In total, 13 other observations in this report make additional recommendations related to Board rules.

Recommendations:

We recommend the Board:

- **ensure rules reflect underpinning statutes and encompass all professions subject to PDMP requirements;**
- **define relevant terms in rule;**
- **ensure all forms are properly adopted and cited in rule, accurately reflect rule-based requirements, and contain version or edition controls;**
- **ensure any requirements intended to be binding upon anyone other than the Board are adopted in rule;**
- **dispense with *Zero Report* requirements;**
- **ensure form and rule deficiencies identified in prior audits are timely remedied; and**
- **obtain necessary assistance from the OPLC to attain and maintain compliance with State law.**

We recommend the OPLC fulfill its responsibilities to supervise, coordinate, and assist the Board with rulemaking to help ensure the Board attains and maintains ongoing compliance with State law.

Board Response:

We concur.

The Board notes that over the last 5 years, the Board has reviewed and updated current rules and created new rules. It currently has one set of expired rules in the legislative process and 7

other rules being added (collaborative practice, advanced practice technicians, quality assurance, inspections) or updated (standards of practice, technician training) to meet the requirements of the profession. While the Board has also recently updated PDMP rules, it recognizes that more work must be done. The Board, along with the Council, will review and update relevant rules and forms, define terms in rule, and write rules for maintaining the PDMP.

The Board notes that concerns relative to zero reporting requirements have been addressed in its most recent rulemaking proposal. It is now written in rule that if there is no schedule II through IV controlled drug dispensed, the dispenser must provide a zero report. These reports are important to certify daily uploading of data.

New rules from prior audits concerning inspections, forms, and violation notices are under Board review and discussed elsewhere in audit report. All other internal forms are or will be documented in the policy and procedure manual.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Rule writing- PDMP maintenance of program/add forms	*July 2018*
All policy and procedures development	*See Observation No. 1*

OPLC Response:

We concur.

As stated in other responses, the OPLC will continue to strive to fulfill its statutory mandate to supervise and coordinate rulemaking for all boards, commissions, and councils that fall within its administration.

Fiscal Management

Any costs incurred by the Board for the implementation and operation of the PDMP could be supported through grants, gifts, or user contributions. In the event funding was inadequate, the Board was authorized to curtail, temporarily suspend, or cancel the PDMP. PDMP revenues and expenditures changed little between SFY 2014 and SFY 2017. Most PDMP revenues were derived from federal grants through SFY 2016, due to a statutory restriction that required implementation and operation costs could be supported only through grants, gifts, or user contributions. The PDMP received $15,517 in private grants in SFY 2014 and $868,871 in federal grants through SFY 2016. The PDMP was a sub-grantee of the DOJ. The DOJ conducted an onsite review of PDMP grant compliance in early SFY 2018, reporting no significant concerns with its programmatic and financial operations relating to a CY 2015 federal grant award.

In SFY 2016, the Legislature authorized the PDMP to receive $130,000 in general fund appropriations for the biennium ending June 30, 2017. These funds were not fully expended. The appropriation was extended through SFY 2019 and was augmented by a contingent appropriation

of up to an additional $100,000, with the Fiscal Committee's approval. General funds were provided to cover PDMP costs left unfunded due to reduced grant receipts. PDMP expenditures are depicted in Table 3.

Table 3

PDMP Expenditure Breakdown, SFY 2014 Through SFY 2017

Expenditure Category	SFY				Subtotal	Percent
	2014	2015	2016	2017		
Benefits	$ 1,947	$ 36,989	$ 38,988	$ 55,862	$ 133,786	20.7
Personal Services, Temporary Appointment	7,579	406	0	0	7,985	1.2
Personal Services, Temporary Fulltime	2,365	65,557	67,930	110,112	245,964	38.0
Supplies	39	152	1,764	2,687	4,642	0.7
Telecommunications	629	1,238	452	693	3,012	0.5
Contract For Program Services	0	67,008	59,096	118,645	244,749	37.8
In-State Travel Reimbursement	0	811	402	270	1,483	0.2
Membership Fees	0	0	200	0	200	0.0
Office Equipment	0	0	2,520	539	3,059	0.5
Transfer To General Services	0	0	0	2,339	2,339	0.4
Transfer To The DoIT	0	0	0	478	478	0.1
Total	**$ 12,559**	**$ 172,161**	**$ 171,352**	**$ 291,625**	**$ 647,697**	**100.0**

Source: LBA analysis of unaudited PDMP expenditures.

The funding provisions purportedly limited oversight of the PDMP by general funded entities, including the Board, which likely affected the control environment. Further, the PDMP was not consistently included in budgets by the OPLC.

With the expanded provision of general funds in CY 2017, the PDMP was required to develop "a plan for sustainable funding, which shall not include moneys from the general fund, by November 1, 2017." The draft two-year budget proposal supporting the PDMP funding plan for the next biennium averaged over $608,000 per year, while the Board's annual non-PDMP expenditure for SFY 2016 was nearly $747,000, and the PDMP's SFY 2017 expenditures were nearly $292,000. The projected annualized yearly PDMP costs equaled 81.4 percent of the Board's SFY 2016 expenditures and 208.2 percent of the PDMP's SFY 2017 expenditures.

Records Management

The Board and the Council were created to serve the public and were generally expected to keep the public informed regarding how their duties were being carried out. Adequate control of public records was integral to complying with the Right-to-Know and other laws. Maintaining sufficient documentation was a necessary part of an effective management control system.

Observation No. 25

Improve Records Management

The Board's controls over PDMP-related public records under its purview were at an initial stage of maturity. Inadequate records management undermined PDMP effectiveness and underpinned statutory noncompliance in several areas.

To help protect the rights of the State and the individuals it directly affected, the Board was required to:

- establish and maintain an economical and efficient records management program;
- make and maintain records containing adequate and proper documentation of its organization, functions, policies, decisions, procedures, and essential transactions;
- develop detailed record retention schedules, and lists of permanent State records;
- preserve permanent records and dispose of records without permanent or historical value according to law;
- preserve the physical integrity of records; and
- ensure public records were available to the public.

The Board lacked a functional program controlling Board and Council records. The Board lacked current, relevant policies and procedures. Records were in various forms and in multiple locations without adequate indexing or an inventory to readily locate even permanent records. Older hardcopy Board records held in storage were subject to deterioration.

Certain Board and Council meeting minutes, which were permanent records under State law, were unavailable. Of the 77 Board meetings we identified as occurring during the audit period, meeting minutes for 65 (84.4 percent) were available. Of the 60 Council meetings we identified as occurring during the audit period, meeting minutes for 55 (91.7 percent) were available. Of the five missing minutes, two were memorialized by member's notes, one by only an agenda, and the remaining two had no documented record. As we discuss in Observation No. 10, required biennial, annual, and other reports were either never created or could not be located by Board staff. Records, such as organizational charts of individuals obligated to file statements of financial interest and the statements themselves, were either never created or not retained, as we discuss in Observation No. 23. Further, the Board could not provide complete basic PDMP data and information related to fundamental programmatic functions. Other records were reportedly lost with the migration between original and new PDMP database management vendors.

The Board lacked rule, policy, and procedure on classifying, labeling, and segregating data. With the large volumes of confidential PDMP data and potentially confidential information derived therefrom, appropriately marking data and information as either confidential or not could have aided in identifying and properly segregating confidential information, and helped ensure confidential information was properly protected, and public information was readily available. This likely also applied to other Board functions, such as inspections, investigations, and licensing, and to records related to legal counsel. Mechanisms regarding privacy that did exist were primarily contractual and related to technical aspects of securing the database by the original database management vendor and accessing PDMP software by restricting user access, preventing unauthorized users through access controls, and ensuring appropriate levels of access to authorized users. Furthermore, the Board did not adopt rules to align with the statutory requirement that data be purged from the PDMP database after three years. However, this was reflected in the contract with the original PDMP database management vendor. No rules or policies existed to regulate whether the State would create, how it would create, and how it would retain metadata generated from PDMP data, or regulate de-identification. Further, it was unclear whether the State could keep certain data after three years, even if it had been purged of identifiable information.

Since July 2015, the OPLC was responsible for the administrative, clerical, and business processing responsibilities of the Board and Council; maintaining official records, but only for applicants and licensees; supervising, coordinating, and assisting the Board with rulemaking; and maintaining the confidentiality of information, documents, and files. Board staff reported policy and procedure development was underway in early SFY 2018, and the OPLC issued five policy documents in early SFY 2018, with one regulating the availability of draft and final meeting minutes.

Recommendations:

We recommend the Board:

- **comply with State law by developing a records management system which includes Board and Council records, controls public and nonpublic records, and encompasses the complete record lifecycle;**
- **develop and implement policy and procedure to ensure Board and Council records containing adequate and proper documentation of Board and Council policies, decisions, procedures, and transactions are created and maintained;**
- **promulgate rules to implement elements of the program affecting individuals outside the Board;**
- **ensure Board and Council records are available timely at the Board's office;**
- **seek to collect historical Council records;**
- **seek and obtain from the OPLC necessary assistance in developing and operating the records management system; and**
- **include a component addressing records management in its strategy and plan.**

We recommend OPLC management assist the Board and Council by performing administrative, clerical, and business processing responsibilities for the Board and Council;

maintaining the confidentiality of information, documents, and files; and instituting policy and procedure to facilitate Board and Council compliance with recordkeeping and management requirements.

Board Response:

We concur.

The Board will develop a system of record keeping that will maintain the integrity of all Board and Council records and will work with OPLC rulemaking personnel to ensure all required rules are up-to-date.

The Board's office will have both hard copy and computer file records of both Board and Council meeting records available. The Board will be unable to access all records that have been stored off site in a non-temperature/humidity controlled environment, as they are not in condition suitable for storage in a computer system.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
Will be included in strategic plan draft	*See Observation No. 5*
All policy and procedures development	*See Observation No. 1*

OPLC Response:

We concur.

The OPLC will seek assistance from the Secretary of State's Archives and Records Management Division to develop, or amend, existing retention schedules. With a retention schedule in place, management will begin drafting an internal policy relative to records management. We will allot time annually to destroy records that are beyond the retention date or no longer of use, review all existing records, and archive where appropriate.

Prior Audits

Our 2008 and 2015 audits contained findings affecting this audit. The PDMP, the Council, and the OPLC were not within the scope of our prior audit work. In our 2008 audit, we issued 19 observations identifying deficiencies in management oversight, policies and procedures, and frequency of inspections. In our 2015 audit, we followed up on six of the 19 observations from the 2008 audit that were relevant to inspections and found none were completely resolved. The 2015 audit contained ten observations focused on Board inspection management.

Observation No. 26

Prioritize And Timely Resolve Prior Audit Findings

The Board failed to resolve prior audit findings and lacked relevant management controls. Taking corrective actions to timely resolve audit findings was essential for the Board to operate efficiently and effectively, and achieve its objectives. We followed up on ten of 19 observations and recommendations from our 2008 audit and each of the ten observations and recommendations from our 2015 audit. Topics included managing risk, establishing policies and procedures, incorporating inspection procedures in rule, and re-evaluating Board fees, which contributed to ineffective PDMP implementation. In addition, we discuss other unresolved audit findings, including lack of:

- a performance management system in Observations No. 1 through No. 4, No. 6, No. 8, and No. 9,
- filing required external reports in Observation No. 10,
- establishing an inspection management system to track data and remedy database deficiencies in Observation No. 12,
- collaborating with other boards to identify licensees subject to inspection in Observation No. 12,
- formalizing an organizational structure in Observation No. 19, and
- updating Board rules in Observation No. 24.

We determined that 19 of 20 prior observations related to this audit remained completely unresolved, while the twentieth was not fully resolved.

Appendix G contains a summary of the status for each prior audit observation we examined during the course of this audit.

Managing Risk

The Board lacked a formal, holistic approach to managing organizational risk, such as establishing routine risk assessments, a fraud prevention program, or a risk-based inspection schedule. Managing risk is a fundamental principle of effective management control and should be integrated throughout the Board's activities. Identifying, analyzing, and responding to risks were essential to achieving Board objectives and developing a strategy and related plans.

During 2008 audit, we identified examples of risks facing the Board, including controls over financial operations, licensing fraud, and inspection scheduling. We recommended the Board implement a fraud prevention and detection program with reporting policies and training; establish a risk assessment process and continually review processes to identify and mitigate risks; and evaluate inspection results to determine whether inspection scheduling changes were necessary to direct limited resources efficiently and effectively while responding to risk. The Board concurred. During 2015 audit, we found the Board had not evaluated inspection results to direct resources efficiently and effectively. We recommended the Board establish policies and

procedures for scheduling and performing inspections to respond to areas of higher risk. The Board concurred.

In May 2017, the Board reported it provided inspectors training and updated rules based on industry risk but lacked formal policies and procedures and did not evaluate or incorporate risk-based inspection scheduling until October 2017, when preliminary draft rules indicated risk-based scheduling would be included in certain inspections. Additionally, the Board had not established a fraud detection and prevention program or formal risk assessment process, reporting that Board staff would address policies and procedures to prevent fraud related to federal privacy laws. However, overall responsibility for a fraud prevention program resided with OPLC management following the consolidation of many regulatory boards in SFY 2016. Through October 2017, OPLC management had not provided a response regarding establishing fraud prevention programs or risk assessment processes.

Regardless, the Board did not address audit recommendations prior to consolidation, and it was still responsible for day-to-day activities subject to potential fraud and other risks related to inspection services and licensing that necessitated mitigation through related policies, procedures, and continuous evaluation. Further, although the Board indicated the OPLC was responsible for financial management, fiscal risks associated with the sustainability of the PDMP remained a Board responsibility. The Board's lack of a formal, holistic approach to managing risk likely contributed to the many instances of statutory noncompliance, inadequate or nonexistent control structures over operations, insufficient reporting, deficient data quality, inadequate security controls, and a lack of performance standards and measures to evaluate outcomes. Further, lack of a risk-informed strategy would likely undermine a strategic approach to managing Board resources and optimizing PDMP effectiveness and efficiency.

Policies And Procedures

The Board lacked current policies and procedures in several areas. Formal, comprehensive policies and procedures were necessary to establish expectations, directives, and accountability to achieve objectives while mitigating risk. Periodically reviewing policies, procedures, and related control activities were essential to achieving the Board's objectives. Significant changes in the Board's processes, such as integrating the PDMP throughout its operations, further emphasized the need for the Board to timely review policies, procedures, and control activities to help ensure successful implementation and effectiveness.

The Board's inspection manual was outdated, last updated in CY 1999 and did not reflect current inspection practices or include aspects of PDMP compliance. In CY 2015, Board staff reported that they were beginning to update the policy manual following recommendations from our 2008 audit but had not completed the process. We recommended updating the inspection manual to reflect current rules and inspection practices as well as include policies and procedures for issuing violations for noncompliance and handling potential conflicts of interest. The Board concurred. In May 2017, the Board reported it had not updated the policy manual and lacked current policy and procedures for each of its three main functional subdivisions: inspections and investigations, the PDMP, and licensing. By September 2017, several recommended policy

updates were reportedly in draft form and the manual was in the process of receiving additional revisions.

Inspection Procedures In Rule

The Board lacked statutorily-required rules detailing inspection procedures. Effective and sufficient rules explicitly implement and interpret the relevant statutes enforced and administered by the Board in order to allow the public and regulated agencies to understand agency policies, procedures, and practices, thereby reducing risk of misinterpretation. Since CY 2008, the Board reported rules did not adequately address the changing nature of its operations. In CY 2015, we found rules remained inadequate, generally lacking inspection procedures. We recommended the Board adopt procedural inspection rules for each type of licensee, to which the Board concurred. While the Board reported in September 2017 that it continuously reviewed rules since the prior audits and updated them as necessary, rules still lacked inspection procedures, and no PDMP-related inspection procedures were incorporated, perpetuating rule inadequacies.

Current PDMP-related rules were implementation-focused and did not address the systems necessary to operate and optimize the PDMP or related inspection procedures, reportedly due to restrictions in statute regarding sharing of confidential PDMP information and related processes. However, as we discuss in Observation No. 11, the Board had primary enforcement authority over registration, failure to submit required information, knowingly submitting incorrect information, and failure to report the dispensing of a schedule II through IV controlled drug that concealed a pattern of diversion. In early SFY 2018, the Board reported it was in the process of: 1) creating policies and procedures and draft inspection forms incorporating aspects of the PDMP and 2) drafting policies, procedures, and rules for inspections of all in-State licensees.

Re-evaluate Board License Fees

The Board continued to collect excess revenue from licensees and considered additional increases to cover future PDMP operating costs. The Board established fees for applications for a license, registration, or renewal, and other administrative costs. Board fees were required to cover its full costs, including the cost of support and administrative services provided by other agencies, or 125 percent of the direct cost of the Board, whichever was greater. Since CY 2008, we have commented on Board fee-setting practices. In CY 2015, we found the Board collected over $1.2 million in excess revenue from SFY 2010 through SFY 2014, and Board licensees were paying for inspections of other professionals. We recommended the Board reassess fees to ensure licensees were being charged a fair amount to administer the Board. The Board concurred. However, the Board subsequently reported still collecting revenue in excess of 125 percent of its direct costs, by nearly $1.2 million in SFY 2016 alone.

From June 2014 through June 2016, the PDMP was funded mostly through federal grants with some private grant funds. As the availability of grant funds declined, the PDMP was authorized to receive limited general fund appropriations in SFY 2016 and SFY 2017, and was required to develop a sustainable funding plan, which could not include general funds, by November 1, 2017. As part of the two-year draft sustainable funding proposal, the Board proposed to increase fees for non-resident pharmacies as well as certain manufacturing, wholesale, and distributing

facilities to contribute an estimated $656,350 to a dedicated fund for the PDMP, legislation for which it expected to propose in SFY 2018. The Board also proposed dedicating ten percent of revenue in excess of the 125 percent requirement from all medical regulatory boards that were both subject to the PDMP and collecting 125 percent of costs, toward the dedicated PDMP fund. The draft proposal estimated the revenue from this source to include:

- $116,857 from the Pharmacy Board,
- $38,847 from the Board of Nursing,
- $15,743 from the Board of Dentistry, and
- $2,367 from the Board of Medicine.

The draft two-year budget proposal supporting the funding plan for the PDMP averaged over $608,000 per year, while the Board's annual expenditure for SFY 2016 was nearly $747,000. The proposed annualized yearly PDMP costs were equal to 81.4 percent of the Board's SFY 2016 expenditures.

During the audit period, the Board reported attempting to analyze budgetary resources and fees, but had difficulty obtaining timely information from the OPLC. Additionally, the Board did not include potential grant funding in the proposed sustainable funding plan out of concerns federal funding would no longer be available; however, continuing to pursue and receive grants could offset proposed needed dedicated funds and incorporate alternative viable revenue resources.

Recommendations:

We recommend the Board:

- **develop, validate, and implement policy and procedures to ensure audit recommendations are timely resolved and incorporate processes into its strategy and plans to ensure continuous monitoring and evaluation of the adequacy of its management controls;**
- **review both new and prior observations in order to prioritize their importance, estimate the level of work required for the Board and the OPLC to adequately address them, and develop realistic plans and a schedule to make needed changes while considering the amount of routine work the Board and its staff faces; and**
- **formally and holistically integrate risk management into its strategy, plans, operations, policies, procedures, and other activities to help ensure risk is mitigated and objectives are met.**

Board Response:

We concur in part.

The Board does not agree that failure to resolve previous audits had any impact on the success of the PDMP. The Board believes that the current stability and department structure moving forward will benefit both the Board's office, as well as the PDMP.

The Board concurs that a basic change in inspection practices based on risk to the public can be beneficial; as such, it has developed both a three-tier risk inspection program and guidelines to inspect other boards' licensees subject to the Pharmacy Board's oversight. The Board aims to inspect practitioners once every 5 years, while those who have controlled drugs on the premises will be subject to biennial inspections. All of these inspections will be in addition to the other inspections for which the Board is responsible.

The Board has limited oversight of non-resident pharmacies and other entities that ship prescription drugs into our State. The Board has sought, and will continue seek, legislative authority to strengthen Board oversight of non-resident pharmacies and other entities that ship prescription drugs into our State. The Board estimates that at least 50 percent of all prescriptions filled by New Hampshire residents are filled outside of State lines by mail order establishments, but the Board cannot hold out-of-State pharmacists to the same standards our statutes and rules require in-State pharmacists to follow.

New inspection rules are being reviewed by the Board, which include inspection information for the PDMP. The Board's ability to evaluate inspection results in the aggregate is nonexistent, but recently updated licensing software does give the Board some ability to evaluate results. However, all inspection information will need to be entered by hand with specific data points of interest that compliance considers a priority singled out. The Board notes that this will be extremely time consuming at the outset but presents an opportunity for operational improvement in the future.

The compliance policy and procedure manual has, and will continue to be, updated. New software will allow us to file both inspection reports and subsequent violations to individual pharmacy permit holders and pharmacists, an issue noted in previous audits. All new inspection reports will have an added component of a PDMP "report card" on compliance with required information and contain information on prescribing and compliance issues associated with PDMP.

The Board does concur that we need to review license fees to include all aspects, including the PDMP, to cover basic functions. The Board plan for funding the PDMP is ongoing.

Policy and procedures will be developed as part of a new Board of Pharmacy manual to address recommendations for management controls. Ongoing improvement in staff communication and utilization of inspection data with a focus on metric analysis will be included. The Board administrator will review and address previous audit recommendations. An outline of staffing needs based on the current workload will be developed and include PDMP compliance issues and will be included on the strategic plan's timeline. Finally, the Board administrator will analyze relevant data and, in conjunction with the OPLC, develop risk-based strategies for issues affecting Board operations. Staff will review violation notices, reports of investigation, and inspection reports to continue to look at risk and adjust inspection processes as needed.

TIMELINES FOR THE REMEDIATION OF AUDIT OBSERVATIONS	
No additional milestones, addressed throughout Board responses	
All policy and procedures development	*See Observation No. 1 and as discussed throughout Board responses*

TIMELINES FOR THE REMEDIATION OF 2008 AND 2015 AUDIT OBSERVATIONS	
Established a system to capture and report inspectional activity	*October 2017*
Established a process to track individual violations	*October 2017*
Established policies and procedures for non-domestic pharmacy investigations	*November 2017*
Reviewed Board administrative rules	*November 2017*
Update compliance investigator policy manual	*December 2017*
Review scope of inspectional efforts	*January 2018*
Ensure inspection forms reflect statutory and administrative rule requirements	*January 2018*
Violation form in administrative rule	*January 2018*
Establish performance goals and measurements	*January 2018*
Improve reliability of inspection data	*January 2018*
Consider risk-based inspection schedule	*January 2018*
Adopt rules for inspecting licensees	*April 2018*
File biennial report	*June 2018*
Clarify organizational structure	*July 2018*
Establish policies and procedures promoting out-of-State entity licensing	*July 2018*
Ensure out-of-State licensees are inspected similarly to in-State licensees	*July 2018*
Ensure Board fees are reasonable	*July 2019*

OPLC Response:

We concur in part.

The OPLC Executive Director has been actively drafting policies with the support of the Division Directors, the DOJ, and the Department of Administrative Services to mitigate agency risk. We will create a policy where the leadership team will meet at least annually to discuss open action items in response to audits.

Prior audit findings related to financial operations and managing financial risk were resolved with the consolidation of the OPLC in 2015. All checks and cash are endorsed upon receipt and given to the Division of Administration for deposit on a daily basis. The Division of Administration manages financial risk with segregation of duties and ensuring best practices by following Department of Administrative Services Manual of Procedures *and Treasury*

Department policy. It will be suggested the Board of Pharmacy reduce their license fees to ensure compliance with 125 percent of direct costs requirements. An analysis will be done to determine how much, and if all license types should be decreased.

As stated above; formal, written policies are in the process of being created. The leadership team will create and implement a 5- to 10-year plan and review at least annually to ensure we are on target and within budget guidelines.

APPENDIX A
SCOPE, OBJECTIVES, AND METHODOLOGY

In calendar year (CY) 2012, the Legislature established the Controlled Drug Prescription Health and Safety Program, commonly called the Prescription Drug Monitoring Program (PDMP), within the Pharmacy Board (Board). State law required we "conduct a performance audit of the program on or before December 31, 2017 for the use of the speaker of the house of representatives, the president of the senate, and the governor, in evaluating the effectiveness of the program…including but not limited to changes in the number and type of drug-related deaths, the number of instances of drug abuse, and the number of instances of overprescribing." We held an entrance conference with the Board, the Board's administrator, the PDMP Program Manager, and administrative staff from Office of Professional Licensure and Certification at the Board's April 2017 meeting.

Scope

The audit was designed to answer the following question:

How effective was the PDMP through State fiscal year (SFY) 2017?

Objectives And Methodology

Operating And Control Environment

To gain an understanding of the PDMP's operating and control environment, we:

- interviewed Board members and staff;
- reviewed relevant State laws, rules, Executive Orders, opinions, policies, procedures, plans, studies, audits, evaluations, guidelines, reports, and similar materials;
- reviewed model laws, differences in structure and requirements across multiple states' prescription monitoring programs, relevant federal guidelines, other states' audits of similar programs, and court cases;
- reviewed Board organizational charts and staff supplemental job descriptions;
- attended six Board and five Controlled Drug Prescription Health and Safety Program Advisory Council (Council) meetings, including public and nonpublic sessions;
- reviewed and analyzed prior audits and evaluated the status of relevant past audit recommendations; and
- reviewed service contracts used by the Board to obtain PDMP-related services and related materials.

Effectiveness

To determine the effectiveness of the PDMP, we:

- conducted 16 interviews with Board members, Council members, and Board and Office of Professional Licensure and Certification management and staff;
- surveyed all Board and Council members, the results are in Appendix D;
- surveyed all non-pharmacy regulatory boards whose licensees were subject to the PDMP, the results are in Appendix E;
- surveyed a non-randomly selected sample of law enforcement officers in the State, the results are in Appendix F;
- reviewed public and nonpublic minutes of the Board and the Council, and public and nonpublic PDMP reports and attached materials provided to the Board;
- conducted 12 interviews with 25 key stakeholders, including representatives from the Governor's Commission on Alcohol and Drug Abuse Prevention, Intervention, and Treatment (Commission), the Office of the Chief Medical Examiner (OCME), the Division of Public Health Services, the Bureau of Emergency Medical Services, the Bureau of Drug and Alcohol Services, the Overdose Fatality Review Committee, the State Police Narcotics and Investigations Unit, the Administrative Prosecutions Unit, the State Police Forensic Lab, the Board of Veterinary Medicine, and external stakeholders;
- reviewed available results of surveys of PDMP-registered prescribers and dispensers conducted by the Council;
- reviewed and analyzed available PDMP data and information, PDMP reports, and reports created to meet federal grant-reporting requirements;
- reviewed and analyzed PDMP forms for compliance with the *Administrative Procedures Act* and the *Controlled Drug Act*;
- reviewed financial interest statements filed by Board and Council members;
- reviewed service contracts used by the Board to obtain PDMP-related services and related materials;
- reviewed and analyzed financial information;
- reviewed and analyzed relevant studies, plans, audits, evaluations, guidelines, and related materials from academia, interest groups, other states, and similar entities; and
- obtained, reviewed, and analyzed relevant public and nonpublic State records and data.

LBA Surveys

We conducted three surveys supporting the audit's objectives.

Board And Council Survey

To obtain feedback from Board and Council members on PDMP outcomes, effectiveness measures, implementation, and operations, we surveyed all members of the Board and the Council. We sent out 21 surveys and received 18 complete responses for an 85.7 percent response rate.

The results of this survey are in Appendix D.

Other Regulatory Boards Survey

To obtain feedback regarding the efficiency and effectiveness of the PDMP, registration and utilization, compliance, enforcement, discipline, program monitoring, oversight, planning, data confidentiality and security, and overall utility, we surveyed all members of various regulatory boards whose licensees were subject to the PDMP. We sent surveys to the 50 members of the boards. We received 32 responses for a 64.0 percent response rate.

The results of this survey are in Appendix E.

Law Enforcement Survey

To obtain feedback from the law enforcement community on members' knowledge and use of the PDMP, we sent surveys to members of the State Association of Chiefs of Police, county attorneys and sheriffs, members of the State's Drug Task Force, and Department of Justice investigators and attorneys. We relied upon single points of contact at the Association of Chiefs of Police and the Drug Task Force to relay the survey link to members. A total of 224 individuals were sent surveys, and we received 51 responses for a 22.8 percent response rate.

The results of this survey are in Appendix F.

Maturity

To assess the maturity of the Board's relevant control systems and subsystems related to the audit's objectives, we developed a maturity model suitable for application to the PDMP. Maturity models establish a systematic basis of measurement for describing the "as is" state of an organization or process. The use of a maturity model can also enable continuous improvement of performance. While outcome metrics can provide the ultimate criteria for measuring the success of a program, understanding how effectively the processes leading to those outcomes are designed and functioning can facilitate systematic process improvements. Relevant components for the model were: planning, processes, process formality, stakeholder expectations, communication, data and technology, results, and accountability and responsibility. Generally, the first, or lowest, level was an absence of controls and process discipline, while the highest, or fifth, level was reserved for those processes exhibiting optimization or best practice execution. The model is depicted in Table 4.

Table 4

Maturity Model For The PDMP

Maturity Scale	Level 1 Initial	Level 2 Repeatable	Level 3 Integrated	Level 4 Managed	Level 5 Optimized
Strategic Planning	No strategic planning or defined goals	•Small team responsible for planning •Strategy dictated to the rest of the organization	•Structured and open planning involving people throughout the organization •Process occurs every few years	Plans are developed and revised regularly	•Strategy drives critical decisions •Organization maintains a continuous improvement planning process
Processes	Development of initiatives, objectives, and associated processes	Development of performance measures, targets, and associated processes	Development of analysis and reporting processes	Development of performance improvement processes	•Fully integrated processes •Flexible in case of change
Planning and Process Formality	•Informal, ad hoc •Minimal documentation •Inconsistent •Only occasionally done	•Semiformal •Some documentation •Mostly inconsistent •Sometimes done on an as-needed basis	•Formal •Modestly documented •Somewhat inconsistent •Often done	•Formal •Well-documented •Minimally inconsistent •Usually done, except in exceptional circumstances	•Mastery of formal processes •Well-documented •Standardized •Always done, standard operating procedure
Stakeholder Expectations	Stakeholder expectations are identified or tracked informally	Process decision-making is based on stakeholder expectations and feedback	•Key stakeholders are identified •Expectations critical to quality satisfaction are documented •Success in meeting expectations is monitored	•Stakeholder feedback is collected •Improvement projects underway	•Stakeholder feedback validates that the process meets or exceeds stakeholder expectations •Proactive initiatives are in place to minimize rework
Communication	Sporadic communication	Management communicates overall issues	Management is more formal and structured in its communication	Mature communication techniques are applied, standard communication tools are in use	Proactive communication of issues based on trends exists
Data and Technology	•Manual system •Plans for automated system	Automated system exists, meets basic user needs	Good system in place, widely available, meets all key user need	Strong system in place, fully integrated, meets nearly all user needs	State-of-the-art system in place, continually improving to meet user needs
Results	Results focused on evaluating inputs	Results focused on evaluating processes	Results focused on evaluating outputs	Results focused on evaluating outcomes	Results focused on evaluating impact
Accountability and Responsibility	•No definition of accountability and responsibility •Ownership of issues taken on a reactive basis	•Individual assumes responsibility and is usually held accountable •Confusion about responsibility when problems occur	•Responsibility and accountability are defined, owners have been identified •Owner is unlikely to have full authority to exercise responsibilities	Responsibility and accountability are accepted and working in a way that enables an owner to fully discharge his/her responsibilities	•Owners are empowered to make decisions and take action •Acceptance of responsibility has cascaded down throughout the organization

Source: LBA created.

Board Data

PDMP Data

PDMP data used in Figures 2, 3, 13, and 14 were limited in several respects. The Board disavowed the accuracy, completeness, and adequacy of PDMP data; disclaimed liability for errors and omissions; and acknowledged data screening efforts did not identify and correct all errors. Limitations of which we were aware included:

- No processes were in place to quantify the completeness of the database. An unknown number of patient prescription records may have been missing from the PDMP database. Prescriptions records missing certain fields cannot be uploaded to the database, while some records with certain invalid fields also could not be uploaded.
- An unknown number of patient prescription records may have included incorrect data. The PDMP database allowed entry of irrational data and permitted blank field entries. The Board never set accuracy and completeness standards against which the database vendor could validate data submissions.
- An unknown number of patient prescription records may have been duplicates.
- PDMP data were structurally incomplete, as not all dispensers were required by statute to upload information.
- Between October 2014 and November 2015, the PDMP database retained information for six months if there were no indications of drug abuse or diversion, and, following statutory changes, thereafter retained information for three years. Board staff considered data submitted after either April or May 2015 to be complete.
- The techniques used to extract PDMP data and create the information depicted, and the controls applied to ensure quality, were not specified.

Additional limitations to the data in Figure 13 included:

- Query was undefined, but included any modification to an account, such as a password change.
- The reason for zero queries reported in quarters 1 and 2, CY 2015 was not provided.

The data in Figure 14 were further limited. While we removed identifiable duplicate users and test accounts, other unidentifiable test accounts or duplicates may have remained.

Council Surveys

The survey data depicted in Figure 4 were derived from the Council's prescriber and dispenser surveys and were limited in several respects. Limitations of which we were aware included:

- Survey results from the Council's CY 2016 survey of prescribers included practitioners registered with the PDMP. The survey had an estimated response rate of approximately 23 percent. The mandate to query the PDMP had not yet been implemented for prescribers.

- Survey results from the Council's CY 2017 survey of dispensers included practitioners registered with the PDMP. The survey had an estimated response rate of approximately 16 percent. The survey was distributed based on the registrants in the PDMP database maintained by the original database vendor immediately prior to the migration to the new PDMP database and new database management vendor. Only aggregated draft summary results were provided.
- Controls related to the surveys' administration and related to analysis were unstated.

Board Diversion Data

Board diversion data derived from pharmacy reports of controlled drug losses used in Figure 10 were limited in several respects. Limitations of which we were aware included:

- Formal policies and procedures on handling and reviewing pharmacy reports from which the data were derived were absent. As of August 2017, CY 2015 and CY 2016 reports were centrally logged in a database, while other years' reports were only in hardcopy, limiting systematic analysis and potential detection of ongoing diversion.
- Initial pharmacy reports were not often followed by a final report, making it difficult to know whether an initial report was resolved or the cause of loss was later determined**.**
- It was difficult to ascertain which controlled drugs, and their dosage units, were involved in each incident when not reported initially.
- An unknown number of losses or thefts potentially were not reported to the Board as required.

Additionally, we limited inclusion of data as follows:

- based on Board rules, we included data on reports of losses of 15 or more total dosage units and reports of any dosage units if a significant loss, theft, pilferage, or armed robbery was reported;
- data included only confirmed reports of diversion or likely reports of diversion; and
- drugs that were not scheduled, of an unknown schedule, or schedule V were excluded.

Other State Agency Data

To understand what data other State agencies might possess that could help us understand PDMP outcomes, we contacted several agencies. We did not undertake any general or application control reviews of other State agency data, nor were such reviews conducted by the owning agencies. No State agency dataset we present was created with the intention of demonstrating a PDMP outcome, and their use for such a purpose was limited in many respects. The quality of each dataset was never empirically established. Some data from other State agencies were focused on specific drugs or drug classes, some in schedules regulated by the PDMP but others were not. These datasets may also contain data on other drugs in schedules regulated by the PDMP. We present excerpts from the various datasets as the best available data to provide context only, and not to demonstrate a PDMP outcome. The agencies owning the various

datasets reported their data to be of sufficient quality for their own use. Any data-related questions should be referred to the responsible agency.

OCME, Department Of Justice

OCME overdose death data used in Figures 1, 8, and 9 were limited in several respects. Limitations of which we were aware included:

- Changes in data collection methods results in inconsistent data over time.
- Not all deaths required OCME involvement, so some deaths may not have been included in OCME data. Final causes of death may differ from preliminary conclusions, and changes in aggregate counts for years may result.
- Data as published did not differentiate between deaths due to use of prescription drugs or illegal substances. Systematic differentiation between prescription and illicit substances contributing to death did not occur; reportedly, it was difficult to determine if the contributing substances were licit or illicit.
- There were many instances where a decedent possessed more than one contributing substance in their system at the time of death. A single death may be included more than once in certain totals.
- OCME ended reporting the substance of primary cause of death in CY 2015; data reflect all substances contributing to a death as identified by OCME. Other substances may have been present, but were not listed.
- Overdose deaths may be underestimated, particularly those related to opioids.
- Fentanyl-related deaths include all licit and illicit forms of fentanyl.
- Overdose death data for CY 2017 was projected by OCME staff based on cases determined or pending through September 20, 2017. The methodology was unstated.
- Neither systematic differentiation between prescription drugs and illicit substances contributing to death, nor systematic differentiation between legal and illegal forms of the same substances occurred. Determining whether a drug was a prescription drug could have been subjective.
- Certain data fields were unreliable, partially due to incomplete data.
- Substances contributing most to each death were listed in descending order through CY 2015. In CY 2016, substances were no longer entered in order of their contribution to a death, limiting analysis thereafter.
- Total number of drugs identified as a result of OCME analysis may be incomplete.

Additionally, we:

- interpolated some data before CY 2010 from an undated OCME graphic published depicting overdose versus traffic deaths, CY 1995 through CY 2010, potentially subjecting those data depicted in Figure 1 to error; and
- estimated the State strategy target depicted in Figure 1 based on the objective to reduce drug-related deaths 15 percent for the period covered by the Commission's strategy.

Also, nationwide overdose death data included in Figure 9 were unavailable for CY 2016 and CY 2017.

Bureau Of Emergency Medical Services, Department Of Safety

Bureau of Emergency Medical Services data from the National Emergency Medical Services Information System used in Figure 7 were limited in several respects. Limitations of which we were aware included:

- Due to the distributed nature of data entry, data collection was inconsistent and incomplete. Some training was provided for data entry; however, many individuals responsible for data entry "just figured it out." Some data entry forms were not properly completed, excluding an unknown number of cases of naloxone administration.
- Efforts to normalize the data usually pertained to facility or town names, not clinical data. There was no established process to normalize data.
- Data included an unknown number of naloxone administrations in response to non-opioid overdose events. Reportedly, as many as half of the administration cases may not have needed naloxone because it had no effect on the patient as their condition was not the result of an opioid overdose. Naloxone was often used as a diagnostic tool. The slowdown in administrations beginning in CY 2015 through CY 2016 was reportedly likely due to the more judicious use of the drug.
- Some records may not have documented whether or not naloxone was administered because some providers were wary of legal ramifications.
- Naloxone administrations were flat between CY 2010 and CY 2012.
- Data did not reflect the types of substances causing overdoses requiring naloxone administrations until the system was updated on June 1, 2016.
- Data did not reflect the dosage of naloxone administered. Two or more administrations of naloxone could occur during a single case if more than one provider issued the drug.An unknown number of naloxone administrations by non-medical personnel may be excluded. Expanded public access to naloxone was provided through pharmacies and distribution events during this period, and over 10,000 naloxone kits were reportedly distributed between September 2015 and July 2017.
- Naloxone administrations for CY 2017 were estimated by Bureau of Emergency Medical Services staff based on 1,067 confirmed administrations, January through July 2017.

Division Of Public Health Services, Department Of Health And Human Services

The Division of Public Health Services collected the Automated Hospital Emergency Department Data used in Figure 6, which were limited in several respects. Limitations of which we were aware included:

- Data collected did not represent a diagnosis, but represented symptoms of patients seeking care at an emergency department.

- Chief complaint data were not entered based on a standard list of complaints, were not subject to editing or data quality checks, and therefore included varied and nonspecific complaints and misspellings.
- Data collected using early generations of standardized codes were less useful than later generations when identifying opioid-related emergency department encounters. New codes may have provided an opportunity for a more detailed analysis of sub-groups, but only represented data from CY 2015. Encounters may have had more than one standard code assigned to them.
- Heroin-related encounters were encounters specifically designated with a standard code or specified in the chief complaint text. Some heroin-related visits may be excluded.
- There was no fentanyl-specific code, and encounters could only be identified using chief complaint text. Between CY 2011 and CY 2015, only 29 fentanyl-related emergency department encounters were identified using chief complaint text, and none were identified using standard codes. Opioid-related encounters included an unknown number of fentanyl-related encounters.
- While 26 State-licensed acute care hospitals provided data to the State, two hospitals did not submit data with standard codes.
- One hospital did not report data from January 1, 2011 through December 31, 2015.
- Coding may have been inaccurate; overall accuracy was estimated to be 83 percent.
- Data were not reviewed or checked for accuracy by submitting facilities before submitting facilities transmitted the data to the State.
- Some opioid-related encounters may not have been represented due to misspellings, use of generic drop-down values, or other typographical errors.
- Not all encounters related to opioid use may have involved an opioid overdose.
- There was no way to measure shifts of individuals seeking care at an urgent care facility versus a hospital emergency department.

Bureau Of Drug And Alcohol Services, Department Of Health And Human Services

Bureau of Drug and Alcohol Services treatment admissions data used in Figure 5 were limited in several respects. Limitations of which we were aware included:

- Data were limited to admissions at State-funded treatment facilities, where treatment providers received contracts to provide treatment access to individuals who lacked insurance coverage and had limited ability to pay for treatment services. Data excluded those admissions paid by other means, such as Medicaid or private insurance.
- Entering specific drug names was optional and recorded during intake. Reporting primary substance of use was optional; an unknown number of admissions may be excluded.
- Primary substance of use was identified based on an assessment given at the point of admission.
- Data often may not provide enough detail to identify illicit prescription drugs versus those who abused prescription drugs with a prescription.

- Fentanyl was not a separate selection choice when identifying primary substance of use.
- The heroin category likely included heroin in combination with synthetic opioids, such as fentanyl.
- The techniques used to extract data and create the information depicted, and the controls applied to ensure quality, were not specified.

Additionally, we selected admissions for the top four most common substances of use, excluding alcohol. Alcohol was the second most commonly reported substance of use.

Forensic Laboratory (Lab), Department Of Safety

Lab data on drug analyses used in Figure 11 were limited in several respects. Limitations of which we were aware included:

- Lab drug analysis management data provided a limited insight into the Lab's cases. Data primarily reflected analysis of drugs associated with possession and illicit prescription drug cases. Cases other than for possession were reportedly rare.
- Data included only submissions to the Lab that were tested and confirmed for the purpose of presenting evidence in a court proceeding. Many submissions were not tested because the associated case was adjudicated in a manner other than a trial.
- Lab data were limited in terms of the period covered and the number of analysts providing data. An unknown number of cases were excluded as a result.
- Data were not collected to distinguish between illicit or licit substances.

Narcotics And Investigations Unit (NIU), Department Of Safety

NIU substance seizures data used in Figure 12 were limited in several respects. The limitations of which we were aware included:

- The data included licit and illicit substances seized as a result of investigations and operations in which NIU was involved. No statewide repository of data on substances seized in connection with law enforcement activity statewide existed.
- Substance seizures for CY 2011 were not reported.
- Illicit substances excluded marijuana plants and included cocaine, crack cocaine, marijuana, heroin, methamphetamine, ecstasy, mushrooms, bath salts, and spice.
- Longitudinal data on cases was collected for annual and fiscal year reporting purposes, and information recorded in paper files differed by year. Data collection methods after CY 2014 differed and merging the two datasets was impractical.
- Substance seizures data provided a limited insight into the NIU's cases. The number of cases under investigation and the amount of drugs seized as a result of investigations in any given year was reportedly affected by the amount of time spent per investigation, the importance of the investigation, the timing of the investigation, and whether other desirable outcomes were realized, making comparisons of the amount of drugs seized difficult across years.

- Reportedly, many prescription drug diversion cases involved a single person attempting to fill prescriptions to support their own drug addiction, and such cases were not always pursued.

Exclusions

To constrain the scope and duration of the audit, we excluded certain components of potential audit work related to the PDMP. We did not:

- evaluate the PDMP holistically, as we did not audit the effectiveness of other, non-Pharmacy Board, regulatory boards' implementation of related requirements or their use of PDMP data and information;
- audit the effectiveness of other potential users of PDMP data and information, such as law enforcement agencies;
- demonstrate actual historic, or project potential future, PDMP outcomes;
- independently assess user and customer satisfaction;
- examine contracting processes or contract management; or
- audit PDMP finances, including grant compliance, structural solvency, and viability of future funding plans.

The PDMP relied on information technology to carry out its mission effectively. However, Board technology controls and data quality and reliability were not central to the audit, and we did not undertake holistic quality or reliability assessments, or independently review general and application controls.

Audit Work Outside The Audit Period

The audit period included SFY 2012 through SFY 2017. However, audit work was not limited to the audit period where management control weaknesses outside the audit period affected the Board's effectiveness.

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APPENDIX B
BOARD RESPONSE TO AUDIT

OFFICE OF PROFESSIONAL LICENSURE AND CERTIFICATION
STATE OF NEW HAMPSHIRE
DIVISION OF HEALTH PROFESSIONS
Board of Pharmacy
Prescription Drug Monitoring Program
121 South Fruit Street
Concord, N.H. 03301-2412
Telephone 603-271-2350 · Fax 603-271-2856

PETER DANLES
Executive Director

JOSEPH SHOEMAKER
Health Profession Director

MICHAEL BULLEK
Administrator/Chief of Compliance

MICHELLE RICCO JONAS
Program Manager

December 4, 2107

Stephen C. Smith, MS, CPA
Director of Audits
State of New Hampshire
Office of Legislative Budget Assistant, Audit Division
State House, Room 102
Concord, NH 03301

RE: Audit of New Hampshire Board of Pharmacy - Controlled Drug Prescription Health & Safety Program

Dear Director Smith,

On behalf of the Commissioners of the New Hampshire Board of Pharmacy "Board" I thank you and your team for conducting a comprehensive and thorough performance audit.

In June 2012 the state of New Hampshire released its' strategy to reverse the growing opioid epidemic in our state. One of the 62 discreet elements in this strategy was the creation of the Controlled Drug Prescription Health and Safety Program commonly referred to as the Prescription Drug Monitoring Program "PDMP" via statute. The intent of the PDMP is to assist practitioners (prescribers and dispensers), as stakeholders, with information to identify when patients may be using prescribed controlled drugs (schedules II-IV) for non-medical use as diverting, abusing, or misusing.

From the beginning, the PDMP has faced financial constraints as the initial statute that launched this program specified there shall be no state general funds appropriated for the implementation or operation of the program. This limitation has required the PDMP to function solely on grants, gifts, and public contributions including time provided by members of the Advisory Council and the Board.

The PDMP data can suggest the potential for non-medical use of prescribed controlled drugs; however actual non-medical use requires extensive research by Board staff and staff of other boards to appropriately document non-medical use. Funding constraints have hindered the engagement of Board staff to thoroughly and extensively investigate non-medical use and conduct enforcement activities related to substantive findings.

Over the past 36 months, the Board has experienced significant staff turnover, staff vacancies, organizational turbulence, frequent changes in the underpinning laws, in addition to the funding constraints.

In the past few months the Board has hired a new Administrator, changed Board leadership, while working with the Office of Professional Licensure and Certification "OPLC" administrative team to accomplish the following:

- Creation of an orientation manual for new Board members and a draft for members of the Advisory Council
- Updated the Board's compliance policy and procedure manual pending Board approval
- Compliance to the Right to Know Law, quorums for meetings, and Financial Interest Statements
- Drafted new inspection forms and rules to support risk based inspections pending board approval

I concur with the overarching theme identified in the audit that the Board, the OPLC and the Advisory Council need to improve overall operational efficiencies and performance of the PDMP. As the President of the Board, I am committed to collaborating and working with relevant stakeholders to implement audit recommendations.

Support from our legislative body is needed to establish long term funding to continue and sustain the PDMP; and to make revisions to statutes as outlined in the audit to provide the framework necessary for the Board and Advisory Council to build on the PDMP achievements while reaching clearly defined objectives.

Sincerely,

GARY MERCHANT, R.PH., MBA

President, NH Board of Pharmacy

APPENDIX C
OFFICE OF PROFESSIONAL LICENSURE AND CERTIFICATION RESPONSE TO AUDIT

OFFICE OF PROFESSIONAL LICENSURE AND CERTIFICATION
STATE OF NEW HAMPSHIRE
DIVISION OF HEALTH PROFESSIONS
121 South Fruit Street
Concord, N.H. 03301-2412
Telephone 603-271-2219 · Fax 603-271-6990

PETER DANLES
Executive Director

JOSEPH SHOEMAKER
Division Director

November 27, 2017

Stephen C. Smith, MS, CPA
Director of Audits
State of New Hampshire
Office of Legislative Budget Assistant, Audit Division
State House, Room 102
Concord, New Hampshire 03301

RE: Audit of New Hampshire Pharmacy Board – Controlled Drug Prescription Health & Safety Program

Dear Director Smith:

Thank you for conducting the comprehensive performance audit for the New Hampshire Pharmacy Board Controlled Drug Prescription Health & Safety Program (Board) within the Division of Health Professions of the Office of Professional Licensure & Certification (OPLC). As you know, the OPLC is tasked with improving the administrative efficiency of all boards, councils, and commissions within its administration; this performance audit has, therefore, been as useful for the OPLC as it has been for the Board.

In reviewing the audit report and recommendations, I notice a major theme centering on the relationship of OPLC with the Board and the extent to which the OPLC can and should be involved in Board operations. I see this theme extending beyond the scope of this particular audit and into the OPLC's relationship with all the boards, commissions, and councils within its administration. I am hopeful that in the future the OPLC is empowered with the administrative autonomy to implement policies to accomplish these recommendations on an office-wide scale.

Any initial trepidation of helping the Board through this process was ameliorated by the diligence and professionalism of your team. I look forward to the opportunity to work with your office again in furtherance of the OPLC's statutory mandate to improve the efficiency of all boards, commissions, and councils within its administration.

Sincerely,

Peter Danles
Executive Director

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APPENDIX D
SURVEY OF NEW HAMPSHIRE PHARMACY BOARD MEMBERS AND CONTROLLED DRUG PRESCRIPTION HEALTH AND SAFETY PROGRAM ADVISORY COUNCIL MEMBERS

To obtain key officials' views of the Controlled Drug Prescription Health and Safety Program, commonly called the Prescription Drug Monitoring Program or PDMP, we sent questionnaires to the seven members of the New Hampshire Pharmacy Board and the 14 members of the Controlled Drug Prescription Health and Safety Program Advisory Council. We received 18 complete responses for an 85.7 percent response rate. We combined and simplified similar answers to open-ended questions and presented them in topical categories; multipart responses were counted in multiple categories where applicable. Some totals in the following tables may not add up to 100 percent due to rounding or where respondents could respond multiple times to the same question. Other open-ended responses were edited for readability or clarity.

Question 1. Please identify whether you are a member of the Pharmacy Board or the Advisory Council.

Answer Options	**Count**	**Percent**
Member of the Pharmacy Board	7	36.8
Member of the Advisory Council	12	63.2
respondent answered question	**19**	
respondent skipped question	**0**	

Question 2. What do you believe to be expected PDMP outcomes?

Outcomes: Program results designed to achieve a program goal or objective.

Comments	**Count**	**Percent**
Identify/prevent/reduce controlled substance misuse and abuse.	14	73.7
Identify/reduce inappropriate prescribing.	8	42.1
Identify/reduce doctor shopping.	7	36.8
Identify/reduce drug diversion.	7	36.8
Reduce prescriptions written and controlled substance use.	5	26.3
Improve patient care.	5	26.3
Reduce morbidity/mortality.	2	10.5
Reduce inappropriate dispensing.	1	5.3
Savings in healthcare funds when needless exams and testing are not done for doctor shoppers.	1	5.3
Collect data on schedule II-IV drugs.	1	5.3
Meet legislative requirements that direct providers to utilize the PDMP with their prescriptive authority; require providers to show evidence of continuing education regarding opioid prescribing, pain management, and substance abuse disorder.	1	5.3
Improved patient and provider safety and security; add another piece to the anti-drug efforts of our state.	1	5.3
There are not any stated outcomes in the statute.	1	5.3
provided comment	**19**	
did not provide comment	**0**	

Question 3. To the best of your knowledge, does State law specify expected PDMP outcomes?

Outcomes: Program results designed to achieve a program goal or objective.

Answer Options	Count	Percent
Yes	9	47.4
No	10	52.6
Do not know	0	0.0

respondent answered question **19**
respondent skipped question **0**

Question 4. How thoroughly have expected PDMP outcomes in State law been integrated into:

Outcomes: Program results designed to achieve a program goal or objective.

Answer Options	Thoroughly integrated	Somewhat integrated	Minimally integrated	Not at all integrated	Do not know	Response Count
Pharmacy Board Rules	2 (22.2%)	2 (22.2%)	1 (11.1%)	0 (0.0%)	4 (44.4%)	9
Pharmacy Board Policy	3 (33.3%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	4 (44.4%)	9
Program Practice	4 (44.4%)	4 (44.4%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	9
Regulatory Board Oversight	4 (44.4%)	4 (44.4%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	9

respondent answered question **9**
respondent skipped question **0**
not asked question **10**

Question 5. Has anyone ever reviewed State law for expected PDMP outcomes?

Outcomes: Program results designed to achieve a program goal or objective.

Answer Options	Count	Percent
Yes	6	31.6
No	3	15.8
Do not know	10	52.6

respondent answered question **19**
respondent skipped question **0**

Question 6. Which of the following entities has reviewed State law for expected PDMP outcomes? *(Select all that apply.)*

Outcomes: Program results designed to achieve a program goal or objective.

Answer Options	Count	Percent
Pharmacy Board	5	83.3
Advisory Council	6	100.0
Program staff	4	66.7
Other (please specify)	1	16.7
respondent answered question	**6**	
respondent skipped question	**0**	
not asked question	**13**	

Question 6. Text Responses, Other:	Count
Practitioners	1
provided comment	**1**

Question 7. Please indicate whether providing better care to patients truly in need of controlled drug prescriptions is a reasonable outcome of the PDMP. *(Select all that apply.)*

Answer Options	Count	Percent
Reasonable DIRECT outcome	11	57.9
Reasonable INDIRECT outcome	5	26.3
Reasonable SHORT-TERM outcome	6	31.6
Reasonable LONG-TERM outcome	7	36.8
NOT a reasonable outcome	3	15.8
respondent answered question	**19**	
respondent skipped question	**0**	

Question 8. Please indicate whether identifying practitioners who are fraudulently prescribing controlled drugs is a reasonable outcome of the PDMP. *(Select all that apply.)*

Answer Options	Count	Percent
Reasonable DIRECT outcome	15	78.9
Reasonable INDIRECT outcome	4	21.1
Reasonable SHORT-TERM outcome	5	26.3
Reasonable LONG-TERM outcome	8	42.1
NOT a reasonable outcome	1	5.3
respondent answered question	**19**	
respondent skipped question	**0**	

Question 9. Please indicate whether complying with all State and federal Health Insurance Portability and Accountability Act (HIPAA) privacy and security laws and regulations is a reasonable outcome of the PDMP. *(Select all that apply.)*

Answer Options	Count	Percent
Reasonable DIRECT outcome	9	47.4
Reasonable INDIRECT outcome	5	26.3
Reasonable SHORT-TERM outcome	2	10.5
Reasonable LONG-TERM outcome	4	21.1
NOT a reasonable outcome	5	26.3
respondent answered question	**19**	
respondent skipped question	**0**	

Question 10. Please indicate whether reducing the rate of patient morbidity associated with controlled drugs is a reasonable outcome of the PDMP. *(Select all that apply.)*

Morbidity: Rate of disease.

Answer Options	Count	Percent
Reasonable DIRECT outcome	6	31.6
Reasonable INDIRECT outcome	5	26.3
Reasonable SHORT-TERM outcome	3	15.8
Reasonable LONG-TERM outcome	14	73.7
NOT a reasonable outcome	3	15.8
respondent answered question	**19**	
respondent skipped question	**0**	

Question 11. Please indicate whether reducing the rate of patient mortality associated with controlled drugs is a reasonable outcome of the PDMP. *(Select all that apply.)*

Mortality: Rate of deaths.

Answer Options	Count	Percent
Reasonable DIRECT outcome	8	42.1
Reasonable INDIRECT outcome	4	21.1
Reasonable SHORT-TERM outcome	4	21.1
Reasonable LONG-TERM outcome	13	68.4
NOT a reasonable outcome	3	15.8
respondent answered question	**19**	
respondent skipped question	**0**	

Question 12. Please indicate whether creating a greater sense of safety, security, and comfort in the practitioner-patient relationship is a reasonable outcome of the PDMP. *(Select all that apply.)*

Answer Options	Count	Percent
Reasonable DIRECT outcome	5	26.3
Reasonable INDIRECT outcome	6	31.6
Reasonable SHORT-TERM outcome	3	15.8
Reasonable LONG-TERM outcome	10	52.6
NOT a reasonable outcome	4	21.1
respondent answered question	**19**	
respondent skipped question	**0**	

Question 13. Are there other reasonable outcomes to expect of the PDMP?

Answer Options	Count	Percent
No	5	26.3
Yes (please specify outcomes and indicate whether they are direct, indirect, short-term, or long-term)	14	73.7
respondent answered question	**19**	
respondent skipped question	**0**	

Question 13. Text Responses, Other reasonable outcomes:	**Count**
Track prescribing trends and practices in an effort to evaluate whether there is a reduction in prescribing through utilization of the PDMP.	1
Reduction in inappropriate healthcare expenditures due to a reduction in doctor shopping.	1
There are so many direct and indirect outcomes that could be expected from the successful implementation of a PDMP program including many socioeconomic ones.	1
Improved communication and care coordination between providers and dispensers. Additional note: I indicated "not reasonable outcome" for the Health Insurance Portability and Accountability Act item, because I do not understand this to be an outcome. I do think it is an essential operational/procedural requirement, but do not equate that with a program "outcome."	1
Long-term statistics on opiate prescriptions, dispensed quantity, etc. per geographic area as related to other healthcare statistics.	1
To better inform substance use disorder prevention and treatment practices.	1
Long term: Provide information on the increase/decrease of prescription shoppers, providers overprescribing, whether the dispensing of controlled drugs is increasing/decreasing, and if there is a correlation to the increase/decrease of addiction and deaths from controlled drugs.	1
Reduced numbers of opioid dependent individuals seeking street drugs.	1
Question 5: Providing better care to patients who are truly in need of controlled drug prescriptions is a reasonable outcome of the PDMP. If this is indeed an outcome that Legislators desired, the PDMP is not a mechanism in which to do that. The PDMP cannot "provide better care to patients." Doctors, nurses, pharmacists do that, not the PDMP. Question 6: Identifying practitioners who are fraudulently prescribing controlled drugs is a reasonable outcome of the PDMP. The problem here is that Pharmacy Board staff are classified as law enforcement officers. Therefore, if they had information that would help, they are prohibited from disseminating it. Question 7: Please indicate whether complying with all State and federal Health Insurance Portability and Accountability Act privacy and security laws and regulations is a reasonable outcome of the PDMP. There are plenty of ways and mechanisms ALREADY available to ensure compliance with Health Insurance Portability and Accountability Act et. al. The PDMP is not designed to improve that. Question 8: Reducing the rate of patient morbidity associated with controlled drugs is a reasonable outcome of the PDMP. I have to assume that was the intent, however it is not defined in the statute. Furthermore, it would only apply to controlled prescription drugs, as that is the only type of drugs PDMP monitors and records. Question 9: See above.	1
See my earlier comments. (Identification of doctor shoppers/diverters)	1
Fewer dosage forms available on the streets.	1
Modifying how practitioners prescribe schedule II-IV drugs.	1
Changing the dispensing practices as well by supplying information to the pharmacist to better assess the validity of the prescription prior to dispensing again, avoiding overfilling of known problem medications.	1
Measurement of patient utilization of treatment programs for opioid addiction and success rate of said treatment programs. Long term and indirect.	1
provided comment	**14**

Question 14. Please indicate whether changes in the number of drug-related deaths is a reasonable measure of effectiveness for the PDMP. ***(Select all that apply.)***		
Answer Options	**Count**	**Percent**
Reasonable DIRECT measure	5	26.3
Reasonable INDIRECT measure	7	36.8
Reasonable SHORT-TERM measure	1	5.3
Reasonable LONG-TERM measure	10	52.6
NOT a reasonable measure	4	21.1
respondent answered question	**19**	
respondent skipped question	**0**	

Question 15. Please indicate whether changes in the type of drug-related deaths is a reasonable measure of effectiveness for the PDMP. ***(Select all that apply.)***		
Answer Options	**Count**	**Percent**
Reasonable DIRECT measure	4	21.1
Reasonable INDIRECT measure	6	31.6
Reasonable SHORT-TERM measure	2	10.5
Reasonable LONG-TERM measure	13	68.4
NOT a reasonable measure	4	21.1
respondent answered question	**19**	
respondent skipped question	**0**	

Question 16. Please indicate whether changes in the number of instances of drug abuse is a reasonable measure of effectiveness for the PDMP. ***(Select all that apply.)***		
Answer Options	**Count**	**Percent**
Reasonable DIRECT measure	4	21.1
Reasonable INDIRECT measure	6	31.6
Reasonable SHORT-TERM measure	1	5.3
Reasonable LONG-TERM measure	8	42.1
NOT a reasonable measure	7	36.8
respondent answered question	**19**	
respondent skipped question	**0**	

Question 17. Please indicate whether changes in the number of instances of overprescribing is a reasonable measure of effectiveness for the PDMP. ***(Select all that apply.)***		
Answer Options	**Count**	**Percent**
Reasonable DIRECT measure	15	78.9
Reasonable INDIRECT measure	4	21.1
Reasonable SHORT-TERM measure	6	31.6
Reasonable LONG-TERM measure	7	36.8
NOT a reasonable measure	1	5.3
respondent answered question	**19**	
respondent skipped question	**0**	

Question 18. Are there other reasonable measures of effectiveness for the PDMP?		
Answer Options	**Count**	**Percent**
No	12	63.2
Yes (please specify the measures of effectiveness and indicate whether they are direct, indirect, short-term, or long-term)	7	36.8
respondent answered question	**19**	
respondent skipped question	**0**	

Question 18. Text Responses, Other reasonable measures of effectiveness:	**Count**
Many of the previous questions need to be qualified and be proven to be the result of a properly implemented PDMP. With properly written and executed legislation, a PDMP program can be a valuable tool.	1
Provider/dispenser self-report of program utility/effectiveness.	1
Prescribers are routinely using the PDMP as part of their practice.	1
The only measure of effectiveness of the PDMP should be with morbidity, mortality, and abuse related to prescription drugs. Question #12 should read: "Prescription-drug related deaths," not just "drug related deaths." I am going to answer direct outcome, but keep in mind my answer is to "prescription drug related deaths." Question #13: Type of deaths are unrelated to NH PDMP, as the source of drugs involved in deaths is often unknown. Drugs involved in deaths could have come from MA, ME, VT, or even Canada. Question #14: PDMP does not measure any indicators of drug abuse, therefore it is unreasonable to correlate PDMP information with instances of drug abuse. Question #15: Define "overprescribing." That has not been defined and is quite subjective among practitioners. As a pharmacist, it is outside my scope of practice to determine if a provider is "overprescribing" and the PDMP certainly cannot determine that information.	1
Patient expectation that a paradigm shift in prescribing is occurring away from narcotics.	1
Measures over overdispensing by dispensers.	1
Separation of morbidity and mortality from opioids into legal drugs vs. illegal drugs (street drugs). Short and long term, and indirect.	1
provided comment	**7**

Question 19. Please indicate the extent to which educational outreach efforts have been successful in providing information on registration, utilization, program data access, confidentiality, and security to PDMP stakeholders.					
Answer Options	**Successful – all are aware of requirement and have received relevant information**	**Somewhat successful – most are aware of requirements; some need to receive relevant information**	**Not at all successful – few are aware of requirements; most have not received relevant information**	**Do not know**	**Response Count**
PDMP-eligible Prescribers	5 (26.3%)	12 (63.2%)	0 (0.0%)	2 (10.5%)	19
Dispensers	9 (47.4%)	7 (36.8%)	0 (0.0%)	3 (15.8%)	19
Regulatory Boards	9 (47.4%)	8 (42.1%)	1 (5.3%)	1 (5.3%)	19
Law Enforcement	1 (5.3%)	9 (47.4%)	2 (10.5%)	7 (36.8%)	19
Patients	0 (0.0%)	4 (21.1%)	6 (31.6%)	9 (47.4%)	19
			respondent answered question		**19**
			respondent skipped question		**0**

Question 20. Are there other stakeholders who have been targeted by program educational outreach efforts?		
Answer Options	**Count**	**Percent**
No	15	78.9
Yes (please specify stakeholders and the extent to which education outreach efforts have been successful)	4	21.1
respondent answered question	**19**	
respondent skipped question	**0**	

Question 20. Text Responses, Other stakeholders:	**Count**
Hospital administrators	1
Health care system, employers of prescribers/dispensers, public health stakeholders	1
Department of Health and Human Services, Legislators	1
I do not know	1
provided comment	**4**

Question 21. Did you have, or do you have, any concerns about the ability of the program to identify prescribers and dispensers who are eligible for PDMP registration?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	2	11.1
Yes, and my concerns have been somewhat mitigated	2	11.1
Yes, and my concerns have not been at all mitigated	2	11.1
No, I have not had this concern	11	61.1
Do not know	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 22. Did you have, or do you have, any concerns about the ability of the program to register prescribers and dispensers identified as eligible for PDMP registration?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	2	11.1
Yes, and my concerns have been somewhat mitigated	3	16.7
Yes, and my concerns have not been at all mitigated	1	5.6
No, I have not had this concern	11	61.1
Do not know	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 23. Did you have, or do you have, any concerns about the ability of the program to remove prescribers, dispensers, and delegates who are no longer eligible for PDMP access?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	0	0.0
Yes, and my concerns have been somewhat mitigated	3	16.7
Yes, and my concerns have not been at all mitigated	3	16.7
No, I have not had this concern	9	50.0
Do not know	3	16.7
respondent answered question	**18**	
respondent skipped question	**1**	

Question 24. Did you have, or do you have, any concerns about the inclusion of veterinarians in the PDMP?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	0	0.0
Yes, and my concerns have been somewhat mitigated	6	33.3
Yes, and my concerns have not been at all mitigated	8	44.4
No, I have not had this concern	4	22.2
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 25. Did you have, or do you have, any additional concerns about program registration?		
Answer Options	**Count**	**Percent**
No	16	88.9
Yes (please specify concerns and the extent to which they have been mitigated)	2	11.1
respondent answered question	**18**	
respondent skipped question	**1**	

Question 25. Text Responses, Additional concerns:	**Count**
With poorly written legislation and several attempts to define terms, in a way that will fit a desired outcome instead of correcting the legislation, has led to confusion with regards to those who need to register and those who believe they do not need to register. Many of those who are potentially at the very heart of the problem have had legislative changes made to exempt themselves. Those who dispense or prescribe should register, period. The prescription drug abuse problem has and always will act like water, and flow to the path of least resistance.	1
Veterinarians should be included on the PDMP, but I believe they successfully passed an exemption in the Legislature. Veterinarians often prescribe Tramadol, a very common drug of abuse.	1
provided comment	**2**

Question 26. Did you have, or do you have, any concerns about the frequency with which the PDMP is used by non-veterinarian prescribers?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	2	11.1
Yes, and my concerns have been somewhat mitigated	7	38.9
Yes, and my concerns have not been at all mitigated	1	5.6
No, I have not had this concern	7	38.9
Do not know	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 27. Did you have, or do you have, any concerns about the frequency with which the PDMP is used by veterinarian prescribers?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	2	11.1
Yes, and my concerns have been somewhat mitigated	3	16.7
Yes, and my concerns have not been at all mitigated	9	50.0
No, I have not had this concern	4	22.2
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 28. Did you have, or do you have, any concerns about the frequency with which the PDMP is used by non-veterinarian dispensers?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	2	11.1
Yes, and my concerns have been somewhat mitigated	8	44.4
Yes, and my concerns have not been at all mitigated	1	5.6
No, I have not had this concern	6	33.3
Do not know	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 29. Did you have, or do you have, any concerns about the frequency with which the PDMP is used by veterinarian dispensers?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	0	0.0
Yes, and my concerns have been somewhat mitigated	5	27.8
Yes, and my concerns have not been at all mitigated	8	44.4
No, I have not had this concern	4	22.2
Do not know	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 30. Did you have, or do you have, any concerns about the use of the PDMP by delegates?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	1	5.6
Yes, and my concerns have been somewhat mitigated	2	11.1
Yes, and my concerns have not been at all mitigated	0	0.0
No, I have not had this concern	12	66.7
Do not know	3	16.7
respondent answered question	**18**	
respondent skipped question	**1**	

Question 31. Did you have, or do you have, any concerns about inaccurate, incomplete, or untimely reporting of prescription information by PDMP users?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	1	5.6
Yes, and my concerns have been somewhat mitigated	9	50.0
Yes, and my concerns have not been at all mitigated	2	11.1
No, I have not had this concern	6	33.3
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 32. Did you have, or do you have, any additional concerns about program utilization?		
Answer Options	**Count**	**Percent**
No	12	66.7
Yes (please specify concerns and the extent to which they have been mitigated)	6	33.3
respondent answered question	**18**	
respondent skipped question	**1**	

Question 32. Text Responses, Additional concerns:	**Count**
I disagreed with the Legislature excusing veterinarians from querying the database before prescribing.	1
Utilization in all practice settings need to be incorporated into the existing computer systems that are used. This would eliminate the need to enter into another system in order to perform the required functions. This would greatly reduce the time and effort needed and therefore increase utilization.	1
It seems to me that there are many prescribers registered in the system who are not active prescribers of controlled drugs in NH (hold a NH license, but are retired, out of state, practice in a specialty, or rarely/never entails controlled drug prescriptions, etc.). I think this will probably always be the case and require constant updating of the user database, but it presents a challenge for interpreting aggregate stats on utilization, provider perceptions, etc.	1
There are a number of practice specialties that must report and currently, the program is overseen by the Pharmacy Board. However, the Board has no authority over doctors, nurse practitioners, dentists, etc.	1
Hopefully, the new platform in July will address the concerns of reports, correct data, etc.	1
Vendor software used by the program lacks robustness to create reports to meet program requirements. This may be related to the inadequate funds for the program to purchase additional features and programming support. In addition, software is not user-friendly, challenging users to utilize the program.	1
provided comment	**6**

Question 33. Did you have, or do you have, any concerns about inappropriate or unlawful use of PDMP data?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	3	16.7
Yes, and my concerns have been somewhat mitigated	2	11.1
Yes, and my concerns have not been at all mitigated	0	0.0
No, I have not had this concern	13	72.2
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 34. Did you have, or do you have, any concerns about program controls over data confidentiality or security?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	2	11.1
Yes, and my concerns have been somewhat mitigated	4	22.2
Yes, and my concerns have not been at all mitigated	0	0.0
No, I have not had this concern	12	66.7
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 35. Did you have, or do you have, any concerns about vendor controls over data confidentiality or security?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	3	16.7
Yes, and my concerns have been somewhat mitigated	0	0.0
Yes, and my concerns have not been at all mitigated	0	0.0
No, I have not had this concern	11	61.1
Do not know	4	22.2
respondent answered question	**18**	
respondent skipped question	**1**	

Question 36. Did you have, or do you have, any additional concerns about data confidentiality or security?		
Answer Options	**Count**	**Percent**
No	18	100.0
Yes (please specify concerns and the extent to which they have been mitigated)	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 37. Did you have, or do you have, any concerns about the ability of the review of prescribing and dispensing information by program staff and the vendor?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	1	5.6
Yes, and my concerns have been somewhat mitigated	4	22.2
Yes, and my concerns have not been at all mitigated	1	5.6
No, I have not had this concern	12	66.7
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 38. Did you have, or do you have, any concerns about reports made by program staff to the applicable regulatory boards for investigation of instances of possible fraudulent conduct or violation of law?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	0	0.0
Yes, and my concerns have been somewhat mitigated	1	5.6
Yes, and my concerns have not been at all mitigated	4	22.2
No, I have not had this concern	13	72.2
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 39. Did you have, or do you have, any concerns about notifications from program staff to practitioners regarding individuals obtaining controlled substances from multiple practitioners or dispensers?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	0	0.0
Yes, and my concerns have been somewhat mitigated	1	5.6
Yes, and my concerns have not been at all mitigated	4	22.2
No, I have not had this concern	13	72.2
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 40. Did you have, or do you have, any additional concerns about program reporting or use of data?		
Answer Options	**Count**	**Percent**
No	14	77.8
Yes (please specify concerns and the extent to which they have been mitigated)	4	22.2
respondent answered question	**18**	
respondent skipped question	**1**	

Question 40. Text Responses, Additional concerns:	**Count**
I have many concerns about the program providing timely reports to the Board. We have received minimal and untimely reports of raw numbers that provide no actionable data. Reports are to be turned into the Board on the Friday prior to the Board meeting and thus far, not one report has been provided on time. Only a few times has any report even been handed out at the meeting.	1
Where I expressed concerns/somewhat mitigated, the concerns are related to adequate program staff capacity to keep up with the demands of user registration and support, vendor communications/upgrades, etc. while also having sufficient time for data analysis, review, notification/investigation functions. Need more staff capacity/resources.	1

Question 40. Text Responses, Additional concerns: *(Continued)*	**Count**
The data is submitted to the Pharmacy Board. However, due to the constraints of the statute, it is very difficult for board staff to act on this information. Due to the fact that compliance officers are considered "law enforcement," this information cannot be disseminated without proper legal steps. The Legislature has mandated a program, yet the information is tied up in a way where it is difficult to use.	1
Lack of reports in general and specifically for dispensers. That would allow us to properly enforce the rules.	1
provided comment	**4**

Question 41. To what extent have processes been implemented to collect information on the outcomes and impact of the PDMP including: satisfaction of users of the program, impact on prescribing patterns, impact on referrals to regulatory boards, and other relevant measures?

Implemented: Formally put into place.

Answer Options	**Count**	**Percent**
Fully implemented	1	5.6
Somewhat implemented	13	72.2
Not at all implemented	3	16.7
Do not know	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 42. Did you have, or do you have, any additional concerns about the ability of the program to collect and prepare relevant information and analyses on the program's outcomes and impact?

Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	0	0.0
Yes, and my concerns have been somewhat mitigated	9	50.0
Yes, and my concerns have not been at all mitigated	4	22.2
No, I have not had this concern	4	22.2
Do not know	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 43. Please indicate which of the following entities is responsible for monitoring compliance with program requirements, administrative rules, and law. *(Select all that apply.)*

Answer Options	Program Requirements	Administrative Rules	Law	Not Applicable	Response Count
Vendor	12 (66.7%)	6 (33.3%)	10 (55.6%)	3 (16.7%)	18
Program staff	16 (88.9%)	13 (72.2%)	11 (61.1%)	1 (5.6%)	18
Pharmacy Board	15 (83.3%)	15 (83.3%)	17 (94.4%)	1 (5.6%)	18
Advisory Council	12 (66.7%)	10 (55.6%)	11 (61.1%)	4 (22.2%)	18
Other regulatory boards	12 (66.7%)	11 (61.1%)	10 (55.6%)	1 (5.6%)	18

respondent answered question **18**
respondent skipped question **1**

Question 44. Are there other entities with responsibility for monitoring compliance with program requirements, administrative rules, or law?

Answer Options	Count	Percent
No	11	61.1
Yes (please specify entities and whether monitoring responsibilities are for program requirements, administrative rules, or law)	7	38.9

respondent answered question **18**
respondent skipped question **1**

Question 44. Text Responses, Other entities with responsibility:	Count
When the law is broken, the legal system.	2
I believe the Department of Justice.	2
The Department of Justice, the Attorney General, and the Legislature.	2
The Legislature and the Attorney General.	1
The law, in establishing the Advisory Council, allows for potential confusion. The Council is charged with developing criteria for a number of issues. However, the law limits the amount of criteria that can be developed and how it can be disseminated. Further, the law charges the Board with the greatest responsibility, but I feel the Council, due to the size and nature of its purposes, undermines the role of the Board, creating confusion and a lack of consistency.	1
The LBA.	1
There has been much interference by the Department of Justice, the Governor, and the drug czar without involving the Pharmacy Board who houses the program. This has led to ineffective and poorly written laws and rules, and a general lack of understanding on everyone's roles and responsibilities.	1

provided comment **7**

Question 45. Did you have, or do you have, any concerns about monitoring compliance with registration requirements?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	3	16.7
Yes, and my concerns have been somewhat mitigated	6	33.3
Yes, and my concerns have not been at all mitigated	0	0.0
No, I have not had this concern	8	44.4
Do not know	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 46. Did you have, or do you have, any concerns about monitoring compliance with utilization requirements?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	0	0.0
Yes, and my concerns have been somewhat mitigated	8	44.4
Yes, and my concerns have not been at all mitigated	2	11.1
No, I have not had this concern	7	38.9
Do not know	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 47. Did you have, or do you have, any concerns about monitoring compliance with data confidentiality and security requirements?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	5	27.8
Yes, and my concerns have been somewhat mitigated	2	11.1
Yes, and my concerns have not been at all mitigated	1	5.6
No, I have not had this concern	10	55.6
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 48. Did you have, or do you have, any concerns about monitoring the effectiveness of the program?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	0	0.0
Yes, and my concerns have been somewhat mitigated	10	55.6
Yes, and my concerns have not been at all mitigated	3	16.7
No, I have not had this concern	5	27.8
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 49. Did you have, or do you have, any additional concerns about monitoring compliance with program requirements, administrative rules, or law?		
Answer Options	**Count**	**Percent**
No	14	77.8
Yes (please specify entities and whether monitoring responsibilities are for program requirements, administrative rules, or law)	4	22.2
respondent answered question	**18**	
respondent skipped question	**1**	

Question 49. Text Responses, Other concerns:	**Count**
The need for this program is not in question, as the fragmented and poorly written legislation has led to many factions having some control and the Pharmacy Board, who has the ultimate responsibility, not being able to move forward in a meaningful way. The Advisory Council and Program Director seem to be constantly overstepping authority, not providing the Board with timely reports of their activity and ignoring the Board's request for information.	1
The RSA develops a means for collecting data, but does not define the purpose of the collection. Further, it creates an administrative entity and ties its hands of any real power. The data, due to the law, is so tightly held that it fails to establish purpose or productivity. Further, it feels there are too many administrative heads (i.e., the Pharmacy Board, the Council, etc.). The Board is tasked with a great amount of responsibility, yet given no resources to do so. Additionally, although the Board is responsible for the program, it must also take input from the Council, resulting in an inefficient quagmire of bureaucracy. As a taxpayer, I think it is interesting the State is paying to audit a program it does not pay for.	1
Not even sure who is responsible for compliance; everyone thinks it is the Pharmacy Board, but our compliance investigators are law enforcement and therefore, are limited to investigate without a subpoena.	1
The RSA does not clearly establish goals for the program.	1
provided comment	**4**

Question 50. Please indicate which of the following entities is responsible for enforcing program registration requirements. ***(Select all that apply.)***		
Answer Options	**Count**	**Percent**
Vendor	0	0.0
Program staff	13	72.2
Pharmacy Board	14	77.8
Advisory Council	2	11.1
Other regulatory boards	13	72.2
Other	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 51. Please indicate which of the following entities is responsible for enforcing program utilization requirements. ***(Select all that apply.)***		
Answer Options	**Count**	**Percent**
Vendor	1	5.6
Program staff	11	61.1
Pharmacy Board	13	72.2
Advisory Council	2	11.1
Other regulatory boards	13	72.2
Other	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 51. Text Responses, Other:	**Count**
See RSA 318-B:36; I-VII.	1
provided comment	**1**

Question 52. Please indicate which of the following entities is responsible for enforcement related to possible prescriber misconduct. ***(Select all that apply.)*** *Prescriber misconduct: Conduct such as illegal prescribing or overprescribing.*		
Answer Options	**Count**	**Percent**
Vendor	0	0.0
Program staff	3	16.7
Pharmacy Board	10	55.6
Advisory Council	1	5.6
Other regulatory boards	15	83.3
Law enforcement	4	22.2
Department of Justice's Administrative Prosecutions Unit	8	44.4
Other	3	16.7
respondent answered question	**18**	
respondent skipped question	**1**	

Question 52. Text Responses, Other:	**Count**
Law enforcement/the Department of Justice brought in as necessary.	1
The RSA is not clear on this. I assume it is the Administrative Prosecutions Unit, but the RSA does not give authority to the Board of Medicine, and the Pharmacy Board does not have authority over physicians.	1
The appropriate board, so medicine, dentistry, nursing, etc.	1
provided comment	**3**

Question 53. Please indicate which of the following entities is responsible for enforcement related to possible patient misconduct. *(Select all that apply.)*

Patient misconduct: Conduct such as doctor shopping or prescription fraud.

Answer Options	Count	Percent
Vendor	0	0.0
Program staff	5	27.8
Pharmacy Board	7	38.9
Advisory Council	1	5.6
Other regulatory boards	7	38.9
Law enforcement	12	66.7
Other	2	11.1
respondent answered question	**18**	
respondent skipped question	**1**	

Question 53. Text Responses, Other:	Count
Nobody has enforcement over this, or at least easily. The Pharmacy Board's inspectors are considered law enforcement. Law enforcement does not have access to the PDMP without a court order (RSA 318-B:34; RSA 91-A; Ph 1505.03).	1
Not aware of any vehicle to enforce patient behavior.	1
provided comment	**2**

Question 54. Did you have, or do you have, any concerns about the extent to which enforcement responsibilities and authorities are clearly defined in State law or administrative rule?

Answer Options	Count	Percent
Yes, and my concerns have been fully mitigated	0	0.0
Yes, and my concerns have been somewhat mitigated	7	38.9
Yes, and my concerns have not been at all mitigated	3	16.7
No, I have not had this concern	6	33.3
Do not know	2	11.1
respondent answered question	**18**	
respondent skipped question	**1**	

Question 55. Did you have, or do you have, any concerns about enforcing registration requirements?

Answer Options	Count	Percent
Yes, and my concerns have been fully mitigated	1	5.6
Yes, and my concerns have been somewhat mitigated	6	33.3
Yes, and my concerns have not been at all mitigated	0	0.0
No, I have not had this concern	11	61.1
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 56. Did you have, or do you have, any concerns about enforcing utilization requirements?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	0	0.0
Yes, and my concerns have been somewhat mitigated	9	50.0
Yes, and my concerns have not been at all mitigated	1	5.6
No, I have not had this concern	7	38.9
Do not know	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 57. Did you have, or do you have, any concerns about enforcing data confidentiality and security requirements?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	2	11.1
Yes, and my concerns have been somewhat mitigated	3	16.7
Yes, and my concerns have not been at all mitigated	0	0.0
No, I have not had this concern	13	72.2
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 58. Did you have, or do you have, any concerns about enforcement related to possible prescriber or dispenser misconduct or violation of law?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	1	5.6
Yes, and my concerns have been somewhat mitigated	7	38.9
Yes, and my concerns have not been at all mitigated	3	16.7
No, I have not had this concern	7	38.9
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 59. Did you have, or do you have, any concerns about enforcement related to possible patient misconduct or violation of law, such as inappropriately obtaining controlled substances from multiple practitioners or dispensers?		
Answer Options	**Count**	**Percent**
Yes, and my concerns have been fully mitigated	0	0.0
Yes, and my concerns have been somewhat mitigated	7	38.9
Yes, and my concerns have not been at all mitigated	5	27.8
No, I have not had this concern	4	22.2
Do not know	2	11.1
respondent answered question	**18**	
respondent skipped question	**1**	

Question 60. Did you have, or do you have, any additional concerns about enforcing compliance with program requirements, administrative rules, or law?		
Answer Options	**Count**	**Percent**
No	15	83.3
Yes (please specify concerns and the extent to which they have been mitigated)	3	16.7
respondent answered question	**18**	
respondent skipped question	**1**	

Question 60. Text Responses, Other concerns:	**Count**
Yes, there are a few "holes." With so many Boards, enforcement will be varied. It would be nice to have common enforcement requirements agreed upon by the various boards.	1
Enforcement responsibilities and authorities are not clearly defined in State law and therefore, result in the same confusion in the rules. The program provides data, but lacks the tools necessary to stop, deter, or punish misconduct by prescribers or patients.	1
There is no clear entity charged with enforcement in the rules. Not sure who would perform this task. It is another weakness in the law and rules, which will lead to a failure to reach desired outcomes.	1
provided comment	**3**

Question 61. Please indicate which of the following entities is responsible for strategic planning and developing program processes. ***(Select all that apply.)***		
Answer Options	**Count**	**Percent**
Vendor	4	22.2
Program staff	14	77.8
Pharmacy Board	13	72.2
Advisory Council	16	88.9
Other regulatory boards	5	27.8
Other	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 62. Does the Pharmacy Board have sufficient input into or oversight of strategic planning and the development of program processes?		
Answer Options	**Count**	**Percent**
Yes	10	55.6
No, insufficient input or oversight	6	33.3
No, too much input or oversight	0	0.0
Do not know	2	11.1
respondent answered question	**18**	
respondent skipped question	**1**	

Question 63. Who is responsible for developing relevant criteria to evaluate program results? *(Select all that apply.)*		
Answer Options	**Count**	**Percent**
Vendor	4	22.2
Program staff	13	72.2
Pharmacy Board	13	72.2
Advisory Council	16	88.9
Other regulatory boards	6	33.3
Other	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 63. Text Responses, Other:	**Count**
The Board is responsible per RSA, but is not given enough authority (due to other constrictions in the RSA) or resources to do so.	1
provided comment	**1**

Question 64. Does the Pharmacy Board have sufficient input into or oversight of the development of program results?		
Answer Options	**Count**	**Percent**
Yes	7	38.9
No, insufficient input or oversight	6	33.3
No, too much input or oversight	0	0.0
Do not know	5	27.8
respondent answered question	**18**	
respondent skipped question	**1**	

Question 65. How clear is the Pharmacy Board's role in overseeing the PDMP, including developing administrative rules and guidance related to program outcomes?		
Answer Options	**Count**	**Percent**
Clear	5	27.8
Somewhat clear	8	44.4
Not at all clear	4	22.2
Do not know	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 66. How clear is the Advisory Council's role in overseeing the PDMP, including developing administrative rules and guidance related to program outcomes?		
Answer Options	**Count**	**Percent**
Clear	7	38.9
Somewhat clear	7	38.9
Not at all clear	4	22.2
Do not know	0	0.0
respondent answered question	**18**	
respondent skipped question	**1**	

Question 67. Has the Pharmacy Board had an appropriate level of involvement in making changes to the PDMP statute?		
Answer Options	**Count**	**Percent**
Yes	8	44.4
No, insufficient involvement	7	38.9
No, too much involvement	0	0.0
Do not know	3	16.7
respondent answered question	**18**	
respondent skipped question	**1**	

Question 68. Has the Pharmacy Board had an appropriate level of involvement in making changes to PDMP administrative rules?		
Answer Options	**Count**	**Percent**
Yes	11	61.1
No, insufficient involvement	5	27.8
No, too much involvement	0	0.0
Do not know	2	11.1
respondent answered question	**18**	
respondent skipped question	**1**	

Question 69. Has the Advisory Council had an appropriate level of involvement in making changes to the PDMP statute?		
Answer Options	**Count**	**Percent**
Yes	12	66.7
No, insufficient involvement	1	5.6
No, too much involvement	3	16.7
Do not know	2	11.1
respondent answered question	**18**	
respondent skipped question	**1**	

Question 70. Has the Advisory Council had an appropriate level of involvement in making changes to PDMP administrative rules?		
Answer Options	**Count**	**Percent**
Yes	11	61.1
No, insufficient involvement	2	11.1
No, too much involvement	4	22.2
Do not know	1	5.6
respondent answered question	**18**	
respondent skipped question	**1**	

Question 71. Is the current location of the PDMP under the Pharmacy Board the most appropriate location for the program?		
Answer Options	**Count**	**Percent**
Yes	15	83.3
No, it should be located (please specify)	3	16.7
respondent answered question	**18**	
respondent skipped question	**1**	

Question 71. Text Responses, PDMP location:	**Count**
No, this should be "housed" in the State Police or Medical Board.	1
The Department of Justice.	1
The Department of Health and Human Services.	1
provided comment	**3**

Question 72. Do you have anything else you would like to add?	
Comments	**Count**
No.	2
The Advisory Council should be eliminated. It is a poorly run group that has ignored their responsibility to the Board. In my opinion, they are to advise, not act. A better use of time would be a committee of members of the various boards that would meet to disseminate information and ideas on program effectiveness and enhancements.	1
Because the program addresses a broad public interest in addressing a public health problem, it should be broadly supported with general funds.	1
The RSA is cumbersome and allows for the growth of bureaucratic processes due to the fact that a number of entities have a role in the process. This results in rules that lack full authority, and members across a number of professions trying to answer to a board that doesn't have the authority to provide oversight to them.	1
I am concerned that the PDMP remains small. I am not in favor of it ballooning into a large, bureaucratic, costly department that continues to grow and become irrelevant. In fact, as a practitioner, I would like to see an endpoint to certain prescribing habits, eliminating specific opioids, and restricting prescribing access, resulting in sundowning the program.	1
The RSA should be further developed to establish clear program objectives and priorities for PDMP, and provide appropriate funding to meet the objectives.	1
provided comment	**7**
did not provide comment	**12**

Question 73. I would like to provide additional comments. Please contact me via:		
Answer Options	**Count**	**Percent**
Email:	1	100.0
Phone:	0	0.0
respondent answered question	**1**	
respondent skipped question	**18**	

Question 74. If you would like to receive a link to our report when it becomes public, please provide the email address where you would like to receive the link. (This email address will not be reported or retained after the report is made public.)		
Answer Options	**Count**	**Percent**
No, thank you	6	40.0
Yes (please provide email address)	9	60.0
respondent answered question	**15**	
respondent skipped question	**4**	

APPENDIX E
SURVEY OF MEMBERS OF BOARDS REGULATED BY THE CONTROLLED DRUG PRESCRIPTION HEALTH AND SAFETY PROGRAM

We sent surveys to the 50 members of boards regulated by the Controlled Drug Prescription Health and Safety Program, commonly called the Prescription Drug Monitoring Program or PDMP, to obtain their views. We received 32 responses for a 64 percent response rate. We combined and simplified similar answers to open-ended questions and presented them in topical categories; multipart responses were counted in multiple categories where applicable. Some totals in the following tables may not add up to 100 percent due to rounding or where respondents could respond multiple times to the same question. Other open-ended responses were edited for readability or clarity.

Question 1. Please identify the State board of which you are currently a member.		
Answer Options	**Count**	**Percent**
Board of Dental Examiners	8	25.0
Naturopathic Board of Examiners	3	9.4
Board of Nursing	6	18.8
Board of Optometry	3	9.4
Board of Medicine	5	15.6
Board of Podiatry	4	12.5
Board of Veterinary Medicine	3	9.4
Other	0	0.0
respondent answered question	**32**	
respondent skipped question	**0**	

Question 2. Who is responsible for enforcing PDMP registration requirements? ***(Please select all that apply.)***		
Answer Options	**Count**	**Percent**
PDMP Vendor	4	12.5
PDMP staff	8	25.0
Pharmacy Board	11	34.4
PDMP Advisory Council	9	28.1
Regulatory board of licensee	21	65.6
Other	2	6.3
respondent answered question	**32**	
respondent skipped question	**0**	

Question 2. Text Responses, Other:	**Count**
Unknown/unclear.	1
I was told there was no enforcement compliance in place.	1
provided comment	**2**

Question 3. Are all your board's licensees, who are required to register with the PDMP, now registered?		
Answer Options	**Count**	**Percent**
Yes	7	21.9
Do not know	23	71.9
No (please explain why not)	2	6.3
respondent answered question	**32**	
respondent skipped question	**0**	

Question 3. Text Responses, Why not:	**Count**
Not all practitioners are aware of the new policy.	1
I do not have access to that information.	1
provided comment	**2**

Question 4. Did you have, or do you continue to have, concerns about PDMP registration in the following areas?					
Answer Options	**Yes, and my concerns have been fully mitigated**	**Yes, and my concerns have been somewhat mitigated**	**Yes, and my concerns have not been at all mitigated**	**No, I have not had any concerns**	**Response Count**
Identifying prescribers and dispensers who are eligible for PDMP registration	2 (6.3%)	10 (31.3%)	8 (25.0%)	12 (37.5%)	32
Registering prescribers and dispensers identified as eligible for PDMP registration	2 (6.3%)	13 (40.6%)	6 (18.8%)	11 (34.4%)	32
Removing prescribers, dispensers, delegates no longer eligible for PDMP access	1 (3.1%)	7 (21.9%)	9 (28.1%)	15 (46.9%)	32
Granting waivers or exemptions	1 (3.1%)	7 (21.9%)	8 (25.0%)	16 (50.0%)	32
Inclusion of veterinarians in the PDMP	4 (12.5%)	6 (18.8%)	6 (18.8%)	16 (50.0%)	32
respondent answered question					**32**
respondent skipped question					**0**

Question 4. Text Responses, Other:	**Count**
The software still lists medications under the pet owner, and not the pet. The date of birth for two owners may not match and therefore, will be ineffective, leading to federal Health Insurance Portability and Accountability Act concerns. Other states have since exempted veterinarians.	1
provided comment	**1**

Question 5. Who is responsible for enforcing PDMP utilization requirements? *(Please select all that apply.)*		
Answer Options	**Count**	**Percent**
PDMP Vendor	6	18.8
PDMP staff	9	28.1
Pharmacy Board	15	46.9
PDMP Advisory Council	8	25.0
Regulatory board of licensee	17	53.1
Other	3	9.4
respondent answered question	**32**	
respondent skipped question	**0**	

Question 5. Text Responses, Other:	**Count**
Unsure/do not know.	3
provided comment	**3**

Question 6. Are all your board's licensees, who are required to use the PDMP, now using it as required?		
Answer Options	**Count**	**Percent**
Yes	5	15.6
Do not know	25	78.1
No (please explain why not)	2	6.3
respondent answered question	**32**	
respondent skipped question	**0**	

Question 6. Text Responses, Why not:	**Count**
Use is not always consistent.	1
Based on cases investigated for other reasons, the PDMP is not always utilized properly.	1
provided comment	**2**

Question 7. Did you have, or do you continue to have, concerns about PDMP utilization in the following areas?					
Answer Options	**Yes, and my concerns have been fully mitigated**	**Yes, and my concerns have been somewhat mitigated**	**Yes, and my concerns have not been at all mitigated**	**No, I have not had any concerns**	**Response Count**
Dispensers submitting information for each dispensing of a schedule II-IV controlled substance	3 (9.4%)	8 (25.0%)	6 (18.8%)	15 (46.9%)	32
Prescribers querying the program for an initial II-IV opioid prescription	4 (12.5%)	9 (28.1%)	7 (21.9%)	12 (37.5%)	32
Prescribers periodically querying the program, at least twice per year	4 (12.5%)	8 (25.0%)	6 (18.8%)	14 (43.8%)	32
Legislative exemptions for veterinarians	5 (15.6%)	3 (9.4%)	4 (12.5%)	20 (62.5%)	32
			respondent answered question		**32**
			respondent skipped question		**0**

Question 8. Has your board received notification through June 30, 2017 from PDMP staff regarding any of the following licensee compliance issues? ***(Please select all that apply.)***		
Answer Options	**Count**	**Percent**
Failure to submit information required under RSA 318-B:33 or knowingly submitting incorrect information related to registering as a prescriber/dispenser and reporting information for dispensing schedule II-IV controlled substances.	1	3.1
Failure to report the dispensing of schedule II-IV controlled substances that conceal a pattern of diversion of controlled substances.	1	3.1
Prescribing or dispensing controlled substances in schedule II-IV without having registered with the program.	1	3.1
Knowingly disclosing program information to unauthorized persons.	0	0.0
Using program information in an unauthorized manner.	1	3.1
Knowingly accessing, altering, destroying, or disclosing program information except as authorized or attempting to obtain such information by fraud, deceit, misrepresentation, or subterfuge.	0	0.0
None that I am aware of.	29	90.6
Other	2	6.3
respondent answered question	**32**	
respondent skipped question	**0**	

Question 8. Text Responses, Other:	**Count**
Do not know.	2
provided comment	**2**

Question 9. Did your board open an investigation as a result of receiving notice of PDMP noncompliance?		
Answer Options	**Count**	**Percent**
Yes, investigations are always opened after notification of noncompliance.	1	33.3
Yes, investigations are sometimes opened after notification of noncompliance.	0	0.0
Do not know.	1	33.3
No, no action was taken following notification of noncompliance.	0	0.0
Not applicable; no notifications of noncompliance were received.	1	33.3
No, but other action was taken. (please explain)	0	0.0
respondent answered question	**3**	
respondent skipped question	**29**	

Question 10. Which of the following thresholds does your board follow as an indication doctor shopping may be occurring? *Doctor shopping is, generally, when a person consults multiple practitioners for treatment and/or multiple dispensing locations solely to obtain additional controlled drugs or prescriptions for controlled drugs.*		
Answer Options	**Count**	**Percent**
A person consults **two** or more practitioners	7	21.9
A person consults **three** prescribers and visits **three** dispensing locations	4	12.5
A person consults **five** prescribers and visits **five** dispensing locations	0	0.0
A person consults **ten** prescribers and visits **ten** dispensing locations	0	0.0
There is **no current** doctor shopping threshold	7	21.9
Do not know	11	34.4
Other (please specify)	3	9.4
respondent answered question	**32**	
respondent skipped question	**0**	

Question 10. Text Responses, Other:	**Count**
We would have nothing to base this on, as "human" animals are the only species that we are not allowed to treat. Therefore, we would have no basis for a threshold. Seems like this is something that has a "right" answer and should be decided by psychologists and addiction specialists.	1
We do not investigate doctor shopping, as we have no jurisdiction over patients' actions.	1
We are still looking at this issue. We will likely land at three prescriber consults.	1
provided comment	**3**

Question 11. How successful has the PDMP been in helping your board's licensees to control doctor shopping by patients seeking to access or abuse controlled substances?		
Answer Options	**Count**	**Percent**
Very successful	3	9.4
Somewhat successful	5	15.6
Somewhat unsuccessful	0	0.0
Not successful	0	0.0
Do not know	24	75.0
respondent answered question	**32**	
respondent skipped question	**0**	

Question 12. Do you expect PDMP staff will notify your board when:			
Answer Options	**Yes**	**No**	**Count**
The threshold for "doctor shopping" has been met	23 (71.9%)	9 (28.1%)	32
A high morphine equivalent dose level is prescribed	23 (71.9%)	9 (28.1%)	32
A dangerous combination of drugs is prescribed	24 (75.0%)	8 (25.0%)	32
Other potential violations of law may exist	29 (90.6%)	3 (9.4%)	32
Potential violations of professional standards may exist	29 (90.6%)	3 (9.4%)	32
respondent answered question			**32**
respondent skipped question			**0**

Question 12. Text Responses, Other:	**Count**
Naturopathic Doctors cannot prescribe opioids, so I do not expect this to be an issue for our profession.	1
I have no idea what they will do in these circumstances given limited funding of the program, etc.	1
We do not have the resources to investigate all PDMP threshold excursions, but believe these excursions should be reported to prescribing providers.	1
provided comment	**3**

Question 13. How many information requests concerning a licensee's compliance has your board made to PDMP staff through June 30, 2017?		
Answer Options	**Count**	**Percent**
None	10	31.3
1 to 5	2	6.3
6 to 10	0	0.0
More than 10	0	0.0
Do not know	20	62.5
respondent answered question	**32**	
respondent skipped question	**0**	

Question 14. Approximately how many total notifications of potential licensee noncompliance has your board received from PDMP staff through June 30, 2017?		
Answer Options	**Count**	**Percent**
None	11	34.4
1 to 5	4	12.5
6 to 10	0	0.0
More than 10	0	0.0
Do not know	17	53.1
respondent answered question	**32**	
respondent skipped question	**0**	

Question 15. How sufficient are notifications on licensee noncompliance your board receives from the PDMP program staff?		
Answer Options	**Count**	**Percent**
Sufficient – Notifications and reporting are regularly sent to the board regarding a licensee without always requiring requests.	1	3.1
Somewhat sufficient – Notifications and reporting are sometimes sent to the board regarding a licensee.	2	6.3
Insufficient – Notifications regarding a licensee are rarely or never sent to the board and are only received if the board requests information.	1	3.1
Do not know	28	87.5
respondent answered question	**32**	
respondent skipped question	**0**	

Question 16. How many times has your board opened an investigation related to a licensee's PDMP compliance or resulting from PDMP prescribing or dispensing information through June 30, 2017?		
Answer Options	**Count**	**Percent**
None	16	50.0
1 to 3	2	6.3
4 to 6	0	0.0
7 to 10	0	0.0
More than 10	0	0.0
Do not know	14	43.8
respondent answered question	**32**	
respondent skipped question	**0**	

Question 17. How many times has your board exercised disciplinary action against a licensee related to PDMP compliance or resulting from PDMP prescribing or dispensing information through June 30, 2017?		
Answer Options	**Count**	**Percent**
None	17	53.1
1 to 3	3	9.4
4 to 6	0	0.0
7 to 10	0	0.0
More than 10	0	0.0
Do not know	12	37.5
respondent answered question	**32**	
respondent skipped question	**0**	

Question 18. Was the Pharmacy Board or PDMP program staff made aware of these disciplinary actions?		
Answer Options	**Count**	**Percent**
Yes	1	6.7
No	0	0.0
Sometimes	0	0.0
Do not know	14	93.3
Not applicable – there have been no cases	0	0.0
respondent answered question	**15**	
respondent skipped question	**0**	
not asked question	**17**	

Question 19. Did you have, or do you continue to have, concerns about enforcing compliance with PDMP program requirements, administrative rules, or law in the following areas?					
Answer Options	**Yes, and my concerns have been fully mitigated**	**Yes, and my concerns have been somewhat mitigated**	**Yes, and my concerns have not been at all mitigated**	**No, I have not had any concerns**	**Response Count**
Extent to which enforcement responsibilities and authorities are clearly defined in State law or administrative rule	2 (6.3%)	9 (28.1%)	9 (28.1%)	12 (37.5%)	32
Enforcing registration requirements	2 (6.3%)	9 (28.1%)	8 (25.0%)	13 (40.6%)	32
Enforcing utilization requirements	2 (6.3%)	11 (34.4%)	6 (18.8%)	13 (40.6%)	32
Enforcing data confidentiality and security requirements	4 (12.5%)	8 (25.0%)	5 (15.6%)	15 (46.9%)	32
Enforcement related to possible prescriber or dispenser misconduct or violation of law	2 (6.3%)	9 (28.1%)	8 (25.0%)	13 (40.6%)	32
Enforcement related to possible patient misconduct, such as inappropriately obtaining controlled substances from multiple practitioners or dispensers	2 (6.3%)	6 (18.8%)	11 (34.4%)	13 (40.6%)	32
			respondent answered question		**32**
			respondent skipped question		**0**

Question 19. Text Responses, Other:	**Count**
My experience over 30 years is boards and law enforcement have not investigated doctor shoppers. Insurance companies sometimes do.	1
provided comment	**1**

Question 20. Which of the following are reasonable <u>outcomes</u> to expect of the PDMP?
(Please select all that apply.)

Outcomes are program results designed to achieve a program goal or objective.

*Direct outcome: Program results designed to achieve a program goal or object and are **directly observable**.*

*Indirect outcome: Program results that are influenced by direct outcomes and are **not directly observable**.*

*Short-term outcome: Expected program results that achieve a program goal or objective after the program has been in place for **a short time**.*

*Long-term outcome: Expected program results that achieve a program goal or objective after the program has been in place for **some time**.*

Answer Options	Reasonable <u>DIRECT</u> outcome	Reasonable <u>INDIRECT</u> outcome	Reasonable <u>short-term</u> outcome	Reasonable <u>long-term</u> outcome	NOT a reasonable outcome	Response Count
Provide **<u>better care</u>** to patients truly in need of controlled drug prescriptions	15 (46.9%)	5 (15.6%)	2 (6.3%)	11 (34.4%)	6 (18.8%)	32
Identify practitioners **<u>fraudulently prescribing</u>** controlled drugs	21 (65.6%)	4 (12.5%)	2 (6.3%)	7 (21.9%)	4 (12.5%)	32
Comply with all State and federal Health Insurance Portability and Accountability Act (HIPAA) privacy and security laws and regulations	11 (34.4%)	11 (34.4%)	2 (6.3%)	7 (21.9%)	7 (21.9%)	32
Reduce the rate of patient **<u>morbidity</u>** *(rate of disease)* associated with controlled drugs	11 (34.4%)	3 (9.4%)	2 (6.3%)	13 (40.6%)	7 (21.9%)	32
Reduce the rate of patient **<u>mortality</u>** *(rate of deaths)* associated with controlled drugs	12 (37.5%)	3 (9.4%)	1 (3.1%)	13 (40.6%)	7 (21.9%)	32
Create a **<u>greater sense of safety</u>**, **<u>security</u>**, and **<u>comfort</u>** in the practitioner-patient relationship	9 (28.1%)	5 (15.6%)	1 (3.1%)	9 (28.1%)	8 (25.0%)	32
				respondent answered question		**32**
				respondent skipped question		**0**

Question 20. Text Responses, Other:	**Count**
Questions 2 and 4-6, I do not have any way to determine, but the survey would not allow me to leave them blank. Are there published parameters and goals? Are those goals measureable?	1
provided comment	**1**

Question 21. Please indicate which of the following are reasonable <u>measures of effectiveness</u> for the PDMP. *(Please select all that apply.)*

Measures of effectiveness clearly represent the nature of expected program results.

*Direct measures of effectiveness: Measures that are **directly observable** and clearly represent the nature of expected program results.*

*Indirect measures of effectiveness: Measures that are subjective, **not directly observable**, and do not clearly represent the nature of expected program results.*

*Short-term measures of effectiveness: Measures that clearly represent the nature of expected program results after the program has been in place for a **short time**.*

*Long-term measures of effectiveness: Measures that clearly represent the nature of expected program results after the program has been in place for **some time**.*

Answer Options	**Reasonable <u>DIRECT</u> measure**	**Reasonable <u>INDIRECT</u> measure**	**Reasonable <u>short-term</u> measure**	**Reasonable <u>long-term</u> measure**	**NOT a reasonable measure**	**Response Count**
Changes in the number of drug deaths	16 (50.0%)	5 (15.6%)	2 (6.3%)	12 (37.5%)	6 (18.8%)	32
Changes in the type of drug deaths	14 (43.8%)	6 (18.8%)	2 (6.3%)	12 (37.5%)	6 (18.8%)	32
Changes in the number of instances of drug abuse	11 (34.4%)	3 (9.4%)	1 (3.1%)	14 (43.8%)	8 (25.0%)	32
Changes in the number of instances of overprescribing	17 (53.1%)	5 (15.6%)	3 (9.4%)	14 (43.8%)	2 (6.3%)	32
respondent answered question						**32**
respondent skipped question						**0**

Question 21. Text Responses, Other:	**Count**
Since the deaths are not reported as due to prescription vs. “street” drugs, this is not measurable. And since there is no accurate way to determine how many prescription opioids lead to “street” drugs, it is unclear if this is effective.	1
provided comment	**1**

Question 22. Did you have, or do you continue to have, concerns about the monitoring of PDMP requirements, administrative rules, or law in the following areas?					
Answer Options	**Yes, and my concerns have been fully mitigated**	**Yes, and my concerns have been somewhat mitigated**	**Yes, and my concerns have not been at all mitigated**	**No, I have not had any concerns**	**Response Count**
Monitoring compliance with registration requirements	1 (3.1%)	11 (34.4%)	9 (28.1%)	11 (34.4%)	32
Monitoring compliance with utilization requirements	2 (6.3%)	11 (34.4%)	9 (28.1%)	10 (31.3%)	32
Monitoring compliance with confidentiality requirements	2 (6.3%)	8 (25.0%)	4 (12.5%)	18 (56.3%)	32
Monitoring compliance with security requirements	2 (6.3%)	8 (25.0%)	6 (18.8%)	16 (50.0%)	32
Monitoring program effectiveness	2 (6.3%)	10 (31.3%)	8 (25.0%)	12 (37.5%)	32
			respondent answered question		**32**
			respondent skipped question		**0**

Question 23. Please indicate the extent to which educational outreach efforts have been successful in providing information on PDMP registration, utilization, program data access, confidentiality, and security.					
Answer Options	**Successful – all are aware of requirements and have received relevant information**	**Somewhat successful – most are aware of requirements but some still need to receive relevant information**	**Not at all successful – few are aware of requirements and most have not yet received relevant information**	**Do not know**	**Response Count**
Prescribers	5 (15.6%)	10 (31.3%)	6 (18.8%)	11 (34.4%)	32
Dispensers	2 (6.3%)	9 (28.1%)	2 (6.3%)	19 (59.4%)	32
Regulatory board of which you are a member	11 (34.4%)	11 (34.4%)	3 (9.4%)	7 (21.9%)	32
Other regulatory boards	2 (6.3%)	7 (21.9%)	0 (0.0%)	23 (71.9%)	32
Law Enforcement	4 (12.5%)	4 (12.5%)	0 (0.0%)	24 (75.0%)	32
Office of the Chief Medical Examiner	4 (12.5%)	3 (9.4%)	0 (0.0%)	25 (78.1%)	32
Patients	1 (3.1%)	3 (9.4%)	9 (28.1%)	19 (59.4%)	32
				respondent answered question	**32**
				respondent skipped question	**0**

Question 24. In general, please describe how sufficient communications to the regulatory boards from the Pharmacy Board and PDMP program staff have been regarding program updates and changes.		
Answer Options	**Count**	**Percent**
Sufficient – updates, responses, questions, and changes are timely and clearly stated with open dialogue between the boards.	4	12.5
Somewhat sufficient – updates, responses, questions, and changes are not always timely and at times not clear.	11	34.4
Insufficient – updates, responses, questions, and changes are rarely or never communicated.	8	25.0
Do not know	9	28.1
respondent answered question	**32**	
respondent skipped question	**0**	

Question 25. Who is responsible for PDMP strategic planning? *(Please select all that apply.)*		
Answer Options	**Count**	**Percent**
Vendor	3	9.4
PDMP staff	17	53.1
Pharmacy Board	17	53.1
PDMP Advisory Council	19	59.4
Regulatory boards	8	25.0
Other (please specify)	4	12.5
respondent answered question	**32**	
respondent skipped question	**0**	

Question 25. Text Responses, Other:	**Count**
Unsure/do not know.	4
provided comment	**4**

Question 26. Does your board have sufficient input into PDMP strategic planning?		
Answer Options	**Count**	**Percent**
Yes, sufficient input	5	15.6
No, insufficient input	10	31.3
Do not know	17	53.1
respondent answered question	**32**	
respondent skipped question	**0**	

Question 27. Does your board have sufficient input into PDMP processes?		
Answer Options	**Count**	**Percent**
Yes, sufficient input	4	12.5
No, insufficient input	11	34.4
Do not know	17	53.1
respondent answered question	**32**	
respondent skipped question	**0**	

Question 28. Does your board have sufficient input into the development of program objectives and outcome measures?		
Answer Options	**Count**	**Percent**
Yes, sufficient input	5	15.6
No, insufficient input	10	31.3
Do not know	17	53.1
respondent answered question	**32**	
respondent skipped question	**0**	

Question 29. How clear is the Pharmacy Board's role in overseeing the PDMP, including developing administrative rules and guidance related to program outcomes?		
Answer Options	**Count**	**Percent**
Clear	3	9.4
Somewhat clear	4	12.5
Not at all clear	12	37.5
Do not know	13	40.6
respondent answered question	**32**	
respondent skipped question	**0**	

Question 30. Is the current location of the PDMP under the Pharmacy Board the most appropriate location for the program?		
Answer Options	**Count**	**Percent**
Yes	15	46.9
Do not know	16	50.0
No, it should be located within:	1	3.1
respondent answered question	**32**	
respondent skipped question	**0**	

Question 30. Text Responses, Should be located within:	**Count**
It is OK, except the Pharmacy Board does not understand differences in veterinary medicine regulations.	1
provided comment	**1**

Question 31. How familiar are you with the PDMP Advisory Council?		
Answer Options	**Count**	**Percent**
Very familiar	1	3.1
Somewhat familiar	4	12.5
I only know of the PDMP Advisory Council's existence	17	53.1
I have not heard of the PDMP Advisory Council	10	31.3
respondent answered question	**32**	
respondent skipped question	**0**	

Question 32. How clear is the PDMP Advisory Council's role in overseeing the PDMP, including developing administrative rules and guidance related to program outcomes?		
Answer Options	**Count**	**Percent**
Clear	1	20.0
Somewhat clear	2	40.0
Not at all clear	2	40.0
Do not know	0	0.0
respondent answered question	**5**	
respondent skipped question	**0**	
not asked question	**27**	

Question 33. Did you have, or do you continue to have, concerns about program data or reporting in the following areas?					
Answer Options	**Yes, and my concerns have been fully mitigated**	**Yes, and my concerns have been somewhat mitigated**	**Yes, and my concerns have not been at all mitigated**	**No, I have not had any concerns**	**Response Count**
Data accuracy and reliability	1 (3.1%)	7 (21.9%)	9 (28.1%)	15 (46.9%)	32
Reviewing prescribing and dispensing information	2 (6.3%)	7 (21.9%)	7 (21.9%)	16 (50.0%)	32
Reporting to applicable regulatory boards instances of possible fraudulent conduct, violation of law, or breach of professional standards for investigation	1 (3.1%)	9 (28.1%)	10 (31.3%)	12 (37.5%)	32
Notifying practitioners of individuals engaged in obtaining controlled substances from multiple practitioners or dispensers	1 (3.1%)	10 (31.3%)	9 (28.1%)	12 (37.5%)	32
			respondent answered question		**32**
			respondent skipped question		**0**

Question 33. Text Responses, Other:	**Count**
Regarding data accuracy/reliability, the PDMP has regularly cited a low participation number for veterinary licensees in the PDMP. This has been on the number of veterinarians licensed in the State (~1000), but PDMP registration is based on the Drug Enforcement Administration (DEA) registration, rather than State licensure. I am not aware that the PDMP has ever contacted the DEA to get the number of veterinary DEA registrants, so that they can be sure their reports are accurate and reliable. I spoke with the registration coordinator for DEA New England to get this number. As of late January, there were 543 NH veterinary registrations with the DEA. As such, the PDMP assumptions about who must be registered are/were off by ~46%. During discussions about HB291, the PDMP/Pharmacy Board stated it could not provide reports about veterinary statistics because that functionality was not available.	1
provided comment	**1**

Question 34. Did you have, or do you continue to have, concerns about data confidentiality or security in the following areas?

Answer Options	**Yes, and my concerns have been fully mitigated**	**Yes, and my concerns have been somewhat mitigated**	**Yes, and my concerns have not been at all mitigated**	**No, I have not had any concerns**	**Response Count**
Unauthorized access to PDMP information	2 (6.3%)	7 (21.9%)	2 (6.3%)	21 (65.6%)	32
Inappropriate or unlawful use of PDMP data	3 (9.4%)	4 (12.5%)	3 (9.4%)	22 (68.8%)	32
Program controls over data confidentiality or security	2 (6.3%)	5 (15.6%)	2 (6.3%)	23 (71.9%)	32
Vendor controls over data confidentiality or security	3 (9.4%)	3 (9.4%)	4 (12.5%)	22 (68.8%)	32
respondent answered question					**32**
respondent skipped question					**0**

Question 34. Text Responses, Other:	**Count**
My lack of concern with these questions as well as previous ones is based on my limited knowledge of the program and data.	1
provided comment	**1**

Question 35. In general, how useful is the PDMP to the profession your board regulates?	
Comments	**Count**
Not sure/do not know.	9
Very useful.	5
Useful.	3
Somewhat useful.	3
Minimally useful.	3
Not useful.	2
I am not sure how useful this is to the Board of Dentistry, but it is useful in general to discourage drug abuse.	1
The PDMP should be important when determining whether a patient is doctor shopping.	1
Our licensees do not use these scheduled drugs very often.	1
Not helpful at all. Scripts written to pharmacies can be monitored there. Animal size differences make the 48-hour and two-week rules useless. The Advisory Council does not work with current board member schedules.	1
It is a good tool towards awareness of prescription abuse and the control of prescription writing behavior.	1
It has the potential to be very useful. Outliers are immediately visible.	1
It is minimally used, as veterinarians prescribe tramadol and no other schedule substances for pain control. It will help to decrease the amount of tramadol prescribed.	1
Not all of our licensees carry a Drug Enforcement Administration number, but for those who do, this will be useful.	1
It was not designed with veterinary prescribing in mind, thus it requires constant tweaking to address the substantial differences in veterinary and human medicine.	1
provided comment	**32**
did not provide comment	**0**

Question 36. Since the program was implemented in the fall of 2014, have there been noticeable changes in prescribing habits by your board's licensees?		
Answer Options	**Count**	**Percent**
Increase in controlled drug prescriptions	0	0.0
No change in controlled drug prescriptions	5	15.6
Decrease in controlled drug prescriptions	9	28.1
Do not know	17	53.1
Other (please specify)	1	3.1
respondent answered question	**32**	
respondent skipped question	**0**	

Question 36. Text Responses, Other:	**Count**
Seems like there has been a decrease in dosages and prescribing, but this cannot be attributed entirely to the PDMP.	1
provided comment	**1**

Question 37. To what is this change attributable? *(Please select all that apply.)*		
Answer Options	**Count**	**Percent**
The PDMP	4	40.0
Prescribing rules	6	60.0
Greater awareness of overprescribing concerns	7	70.0
Increased board investigations related to prescribing controlled substances	2	20.0
Increased board discipline related to prescribing controlled substances	3	30.0
Other (please specify)	2	20.0
respondent answered question	**10**	
respondent skipped question	**0**	
not asked question	**22**	

Question 37. Text Responses, Other:	**Count**
Fear by practitioners that their prescribing will be questioned.	1
Too scared to write prescriptions, resulting in under prescribing.	1
provided comment	**2**

Question 38. What program features or software functions, if any, could be improved to increase effectiveness and utilization of the program?	
Comments	**Count**
Unsure/do not know.	14
None.	3
Needs to be more user-friendly.	4
Sign-in/accessing the program.	2
N/A	2
Education to Board members.	1
More awareness of the program's purpose and ongoing activities may enhance effectiveness.	1
The current program cannot be retrofitted to work with veterinary. Animals need a unique identifier, not a made up birthday that matches one or the other owner, etc.	1
All of them – especially access to the website and registration of delegates.	1
It keeps changing and cannot really give feedback.	1
Use of a microchip number to identify the veterinary patient.	1
I would like to see outcome information distributed appropriately to providers and the Board of Medicine. Also, I am not sure how effective the process is to ensure that all providers are registered and to identify those who are prescribing inappropriately.	1
provided comment	**32**
did not provide comment	**0**

Question 39. Do you have anything else you would like to add?	
Comments	**Count**
No.	24
The roll-out has been very inefficient from our board's perspective. The veterinary community is still very confused. I still talk to veterinarians who have not heard about it. I have heard from vets who check the box on their renewal that says they are registered when they are not (usually due to a lack of understanding and not malice). I am still not sure how this is supposed to prevent street drug overdoses. The poor integration of veterinary into the software will not prevent doctor shopping because there is no real way to identify a specific animal short of a microchip. A woman may bring her dog here and gives us her date of birth. Her husband may take the same dog to an emergency veterinarian and gives them his date of birth. Same dog, yet different in the system. It is a mess.	1
provided comment	**25**
did not provide comment	**7**

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APPENDIX F
SURVEY OF LAW ENFORCEMENT

To obtain law enforcement officials' views of the Controlled Drug Prescription Health and Safety Program, commonly called the Prescription Drug Monitoring Program or PDMP, we sent surveys to 224 local, county, and State law enforcement officials, including local chiefs of police, county sheriffs, county attorneys, members of the State's Drug Task Force, and DOJ investigators and attorneys. We received 51 responses for a 22.8 percent response rate. We combined and simplified similar answers to open-ended questions and presented them in topical categories; multipart responses were counted in multiple categories where applicable. Some totals in the following tables may not add up to 100 percent due to rounding or where respondents could respond multiple times to the same question. Other open-ended responses were edited for readability or clarity.

Question 1. Please identify your affiliation.		
Answer Options	**Count**	**Percent**
County attorney	4	7.8
County sheriff	5	9.8
Local police chief	29	56.9
Division of State Police	0	0.0
State Department of Justice	10	19.6
Other (please specify)	3	5.9
respondent answered question	**51**	
respondent skipped question	**0**	

Question 1. Text Responses, Other:	**Count**
NH Attorney General Drug Task Force Member	1
State Liquor Enforcement and Licensing	1
University System of NH	1
provided comment	**3**

Question 2. How familiar are you with New Hampshire's PDMP?		
Answer Options	**Count**	**Percent**
Very familiar	11	22.9
Somewhat familiar	18	37.5
I only know of the PDMP's existence	16	33.3
I had not previously heard of the PDMP	3	6.3
respondent answered question	**48**	
respondent skipped question	**3**	

Question 3. Please indicate which of the following types of prescription drug-related investigations or cases your agency has conducted, assisted with, or prosecuted over the past year. ***(Please select all that apply.)***		
Answer Options	**Count**	**Percent**
Drug overdose deaths	33	70.2
Doctor shopping by patients	7	14.9
Forged or altered prescriptions	14	29.8
Fraudulent prescribing	6	12.8
Misuse of prescription drugs	30	63.8
Theft of prescription drugs	28	59.6
Theft of prescription pads	2	4.3
None of the above	0	0.0
Other (please specify)	4	8.5
respondent answered question	**47**	
respondent skipped question	**4**	

Question 3. Text Responses, Other:	**Count**
None.	2
Driving While Under the Influence of Drugs (prescription).	1
Drug Diversion.	1
provided comment	**4**

Question 4. Have law enforcement officials in your agency ever accessed PDMP information for use in investigations?		
Answer Options	**Count**	**Percent**
Yes	12	26.1
No	21	45.7
Do not know	13	28.3
respondent answered question	**46**	
respondent skipped question	**5**	

Question 5. Why has your agency not attempted to obtain access to PDMP information for use in investigations? ***(Please select all that apply.)***		
Answer Options	**Count**	**Percent**
Unaware of the PDMP	3	14.3
Unaware law enforcement could access the PDMP	14	66.7
Insufficient time to incorporate into investigations	0	0.0
Insufficient resources to request and review information	0	0.0
No relevant investigations	4	19.0
Other (please explain)	1	4.8
respondent answered question	**21**	
respondent skipped question	**0**	
not asked question	**30**	

Question 5. Text Responses, Other:	**Count**
The requirement for a court order is too burdensome for the type of investigations we do.	1
provided comment	**1**

Question 6. To the best of your knowledge, when accessing PDMP information, did your agency identify any problems with the accuracy of the information?		
Answer Options	**Count**	**Percent**
Yes	0	0.0
No	6	50.0
Do not know	6	50.0
respondent answered question	**12**	
respondent skipped question	**0**	
not asked question	**39**	

Question 7. To the best of your knowledge, when accessing PDMP information, how useful was the information for your agency's investigation or case?		
Answer Options	**Count**	**Percent**
Useful	5	41.7
Somewhat useful	4	33.3
Not at all useful	0	0.0
Do not know	3	25.0
respondent answered question	**12**	
respondent skipped question	**0**	
not asked question	**39**	

Question 8. Please indicate the extent to which the PDMP's educational outreach efforts have been successful in providing members of your agency relevant information on registration, utilization, program data access, confidentiality, and security.		
Answer Options	**Count**	**Percent**
Successful – all are aware of requirements and have received relevant information	2	4.4
Somewhat successful – most are aware of requirements; some need to receive relevant information	6	13.3
Not at all successful – few are aware of requirements; most have not received relevant information	20	44.4
Do not know	17	37.8
respondent answered question	**45**	
respondent skipped question	**6**	

Question 9. Are you familiar with this process and its associated requirements whereby law enforcement can obtain access to PDMP information?		
Answer Options	**Count**	**Percent**
Yes	18	42.9
No	24	57.1
respondent answered question	**42**	
respondent skipped question	**9**	

Question 10. In your opinion, is the process for law enforcement to obtain access to PDMP information easy to understand and interpret?		
Answer Options	**Count**	**Percent**
Easy to understand and interpret	9	50.0
Somewhat easy to understand and interpret	8	44.4
Not easy to understand and interpret	1	5.6
Do not know	0	0.0
respondent answered question	**18**	
skipped question	**0**	
not asked question	**33**	

Question 11. To what extent does the lack of direct law enforcement access to PDMP information negatively affect your agency's investigations?		
Answer Options	**Count**	**Percent**
Not at all	2	4.8
Minimally	11	26.2
Moderately	8	19.0
Significantly	9	21.4
Do not know	12	28.6
respondent answered question	**42**	
respondent skipped question	**9**	

Question 12. To the best of your knowledge, please indicate which of the following entities is responsible for enforcement related to possible <u>prescriber misconduct</u> identified through the NH PDMP. <u>Prescriber misconduct</u> is conduct such as illegal prescribing or overprescribing. *(Please select all that apply.)*		
Answer Options	**Count**	**Percent**
PDMP vendor	0	0.0
PDMP program staff	2	4.8
Pharmacy Board	19	45.2
PDMP Advisory Council	1	2.4
Other regulatory boards	11	26.2
Law enforcement agencies	22	52.4
NH Department of Justice's Administrative Prosecutions Unit	18	42.9
Do not know	10	23.8
Other (please specify)	3	7.1
respondent answered question	**42**	
respondent skipped question	**9**	

Question 12. Text Responses, Other:	**Count**
The Narcotics and Investigations Unit	1
The Attorney General	1
U.S. Drug Enforcement Administration	1
provided comment	**3**

Question 13. To the best of your knowledge, please indicate which of the following entities is responsible for enforcement related to possible <u>patient misconduct</u> identified through the NH PDMP. <u>Patient misconduct</u> is conduct such as doctor shopping or prescription fraud. *(Please select all that apply.)*

Answer Options	**Count**	**Percent**
PDMP vendor	3	7.3
PDMP program staff	1	2.4
Pharmacy Board	7	17.1
PDMP Advisory Council	2	4.9
Other regulatory boards	5	12.2
Law enforcement agencies	32	78.1
Do not know	9	22.0
Other (please specify)	0	0.0
respondent answered question	**41**	
respondent skipped question	**10**	

Question 14. Please provide any recommendations for improving New Hampshire's PDMP in the comment box below.

Comments	**Count**
Provide more education and training for law enforcement.	9
Eliminate the search warrant requirement for law enforcement.	2
Make data available for other grants and studies on the effects of opioid use/abuse, especially when it can be done by redacting personal identifiers.	1
Mandate that doctors use this service. More access by law enforcement.	1
1. Enable physicians' assistants and qualified/permitted nurses to access the PDMP for physicians. 2. Every time a patient is being considered for any Schedule II, a query of the PDMP must be required. 3. Eliminate the warrant requirement; it completely dissolves any opportunity for proactive law enforcement. 4. Give the Federal Bureau of Investigation and the Food and Drug Administration the same access to the PDMP as the State, and give them the ability to share information.	1
N/A	1
respondent answered comment	**14**
respondent skipped question	**37**

Question 15. Do you have anything else you would like to add?	
Comments	**Count**
No.	7
N/A	1
This tool is vital!	1
Institute electronic prescriptions; if the Department of Motor Vehicles can do it for vehicle inspections, we can do it for the PDMP.	1
respondent answered comment	**10**
respondent skipped question	**41**

Question 16. If you would like to receive a link to our report when it becomes public, please provide the email address where you would like to receive the link. (This email address will not be reported or retained after the report is made public.)		
Answer Options	**Count**	**Percent**
No	24	60.0
Yes (please provide email address)	16	40.0
respondent answered question	**40**	
respondent skipped question	**11**	

APPENDIX G
STATUS OF PRIOR AUDIT FINDINGS

Two prior LBA audits contained findings affecting this audit: our *Board Of Pharmacy Financial Audit Report for the six months ended December 31, 2008*, issued June 2009 (2008 audit) and our *Board Of Pharmacy Inspections* performance audit report issued May 2015 (2015 audit). A copy of both prior reports can be accessed online at our website http://www.gencourt.state.nh.us/LBA/default.aspx.

The following is the status of ten of the 19 observations applicable to this audit found in our 2008 audit.

No.	Title	Status
1.	Organizational Structure Should Be Clarified	○ ○ ○
5.	Formal Fraud Prevention And Detection Program Should Be Established	○ ○ ○
6.	Formal Risk Assessment Process Should Be Implemented	○ ○ ○
7.	Scope Of Inspectional Efforts Should Be Reviewed	○ ○ ○
8.	System To Capture And Report Inspectional Activity Should Be Established	○ ○ ○
9.	Policies And Procedures Should Be Established For Non-Domestic Pharmacy Investigations	○ ○ ○
10.	Policies And Procedures Should Be Established For Processing Administrative Fines	○ ○ ○
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	○ ○ ○

Status Key

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

The following is the status of all ten observations applicable to this audit found in our 2015 audit, as of September 2017.

No.	Title	Status
1.	Adopt Rules For Inspecting Licensees	○ ○ ○
2.	Update Compliance Investigator Policy Manual	○ ○ ○
3.	Ensure Inspection Forms Reflect All Statutory And Administrative Rule Requirements	○ ○ ○
4.	Violation Form Should Be In Administrative Rule	● ○ ○
5.	Ensure Board Fees Are Reasonable	○ ○ ○
6.	Establish Performance Goals And Measurements	○ ○ ○
7.	Improve Reliability Of Agency Inspection Data	○ ○ ○
8.	Establish A Process To Track Violations Related To Individual Pharmacists	○ ○ ○
9.	Ensure Out-Of-State Licensees Are Inspected Similarly To In-State Licensees	○ ○ ○
10.	Consider A Risk-Based Inspection Schedule	○ ○ ○

Status Key

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