STATE OF NEW HAMPSHIRE
OFFICE OF LEGISLATIVE BUDGET ASSISTANT
AUDIT DIVISION

PROPOSED PERFORMANCE AUDIT SCOPE
CONTROLLED DRUG PRESCRIPTION HEALTH AND SAFETY PROGRAM

In 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." (Chapter 196:3, II, Laws of 2012 and Chapter 79:2, Laws of 2013) 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.

Expected Outcomes

As depicted in Enclosure 1, drug-related deaths in New Hampshire have increased since at least 1995. Reportedly, the illicit use of prescription drugs has increasingly contributed to this trend. The PDMP was one of at least 62 recommendations contained in the Governor's Commission on Alcohol and Drug Abuse Prevention, Intervention, and Treatment 2012 strategy to address drug-related deaths. Reflective of federal goals, the State strategy contemplated reducing deaths and non-medical use of prescription drugs by 15 percent over a five-year period through calendar year (CY) 2017. The strategy did not ascribe to the PDMP or other initiatives discreet, quantifiable outcome expectations. Neither was there an articulation of the time the strategy's initiatives would need before program effects were observable nor was a holistic outcome measurement system constructed. Consequently, each strategy element was likely implemented together with outcomes realized, or unrealized, at some undefined future date, and with no way to separate beneficial strategies from under-performing strategies. Innumerable confounding variables also likely existed, limiting objective determination about what outcomes were attributable to the PDMP in this environment. Analyses of similar programs nationally were limited and identified mixed outcomes, with more research into program effectiveness generally recommended. Like New Hampshire, programs nationally were likely implemented in the context of other efforts aimed at affecting drug abuse, and controlling the effect of these variables was not clearly accounted for in these analyses. Objectively establishing PDMP performance and quantifying its effects, including its effects on changes in the number and type of drug-related deaths, the number of instances of drug abuse, and the number of instances of overprescribing, in this complex and uncontrolled environment will likely be unachievable.

Nonetheless, such programs have been implemented in nearly every state and were reported to be useful in clinical, regulatory oversight, epidemiologic surveillance, and law enforcement functions. They may indirectly affect controlled substance misuse and prescribing rates. No direct impact on mortality has been demonstrated, however, and national-level research to inform the evidence base on PDMP outcomes was reportedly underway.

The State's PDMP was established to help address abuse, misuse, and diversion of controlled prescription drugs in federal Drug Enforcement Administration schedules II through IV, and

which led to deaths and unnecessary visits to health care practitioners and hospital emergency rooms. By providing secure access to controlled drug prescription histories, the PDMP was to help practitioners provide better care, identify fraudulent prescribing, limit prescription drug abuse, and reduce patient morbidity and mortality associated with controlled drugs. The PDMP was also "designed to create a greater sense of safety, security, and comfort in the health practitioner-patient relationship when controlled drugs are prescribed."

Program Administration

The Board was responsible for program implementation and operation and a 13-member Advisory Council was created to assist and advise the Board. To implement PDMP database management, the Board contracted with a third-party for a confidential web-based proprietary application to maintain prescribing and dispensing data, and facilitate analysis and reporting on the prescribing, dispensing, and use of selected controlled substances. The software underpinning the PDMP database allowed access to prescription records, enabled multi-state sharing of controlled substance histories, and supported the monitoring of prescribing and dispensing histories and trends. Dispensers started uploading prescribing data in September 2014 and in October 2014 prescribers could register with and use the PDMP.

The program encompassed not only the database application and prescribing data, but also the related rules, policy, procedures, and practices implemented to achieve desired program outcomes, as well as each registrant and the regulatory boards overseeing them. This included: 1) dispensers – persons authorized to deliver covered controlled substances; 2) prescribers – persons authorized to prescribe covered controlled substances; and 3) their delegates. Registering covered prescribers and dispensers reportedly was difficult and incomplete through CY 2016.

Statute required dispensers submit information on each schedule II through IV controlled substance dispensed. Prescriber use of the PDMP was initially only encouraged, but State law later required its use. Gaps between the total number of licensees within a particular profession and the number using the PDMP were reported, but PDMP data indicated queries increased from just under 60,000 in the second quarter of CY 2015 to over 90,000 in third quarter of CY 2016. Data limitations also affected the completeness and accuracy of PDMP data. Patient prescription records may have been missing from the database and may have included incorrect or incomplete data, and duplicates for the same prescription may have existed. In April 2017, compliance procedures for PDMP data were under development.

Enforcement authority over prescribers rested primarily with the regulatory boards responsible for overseeing individual professions. Reportedly, instances of over-prescribing were identified and prescribers disciplined. Whether changes in regulatory board enforcement were attributable to the PDMP was not established. Other enforcement authorities, such as law enforcement agencies, reportedly struggled to maximize the value of PDMP data.

Outcome Measurement

While the PDMP database contained a substantial amount of data, systematic analysis and report development was preliminarily initiated in late CY 2016. Program data indicated doses

dispensed for schedule II and schedule III pain relievers decreased from the fourth quarter of CY 2014 through the third quarter of CY 2016. Whether these changes were attributable to the PDMP was not established. National-level data indicated a similar trend, suggesting the phenomena observed in PDMP data may have also reflected other factors. More generally, there was no clear articulation of causation, correlation, or association between the State's PDMP and expected outcomes. This appeared attributable to the lack of a performance measurement system, and a lack of underlying demonstrations that such programs in general have specified outcomes. Consequently, we will likely be able to measure program effectiveness in terms of intermediate outcomes, such as required versus actual registrants, but likely be unable to measure effectiveness in terms of overall outcome, such as reduced drug-related deaths attributable to the PDMP's operation.

AUDIT SCOPE

Our audit will be designed to answer the following question:

How effective was the PDMP through State fiscal year 2017?

To address this question, we plan to:

- review relevant State and federal laws, rules, policies, procedures, plans, studies, audits, guidelines, and similar materials;
- review relevant studies, plans, audits, guidelines, and related materials from academia, interest groups, other states, and similar entities;
- interview individuals with relevant responsibilities and external stakeholders; and
- obtain, review, and analyze relevant State records and data.

Our work will focus on the Board's implementation of the program. We do not plan to:

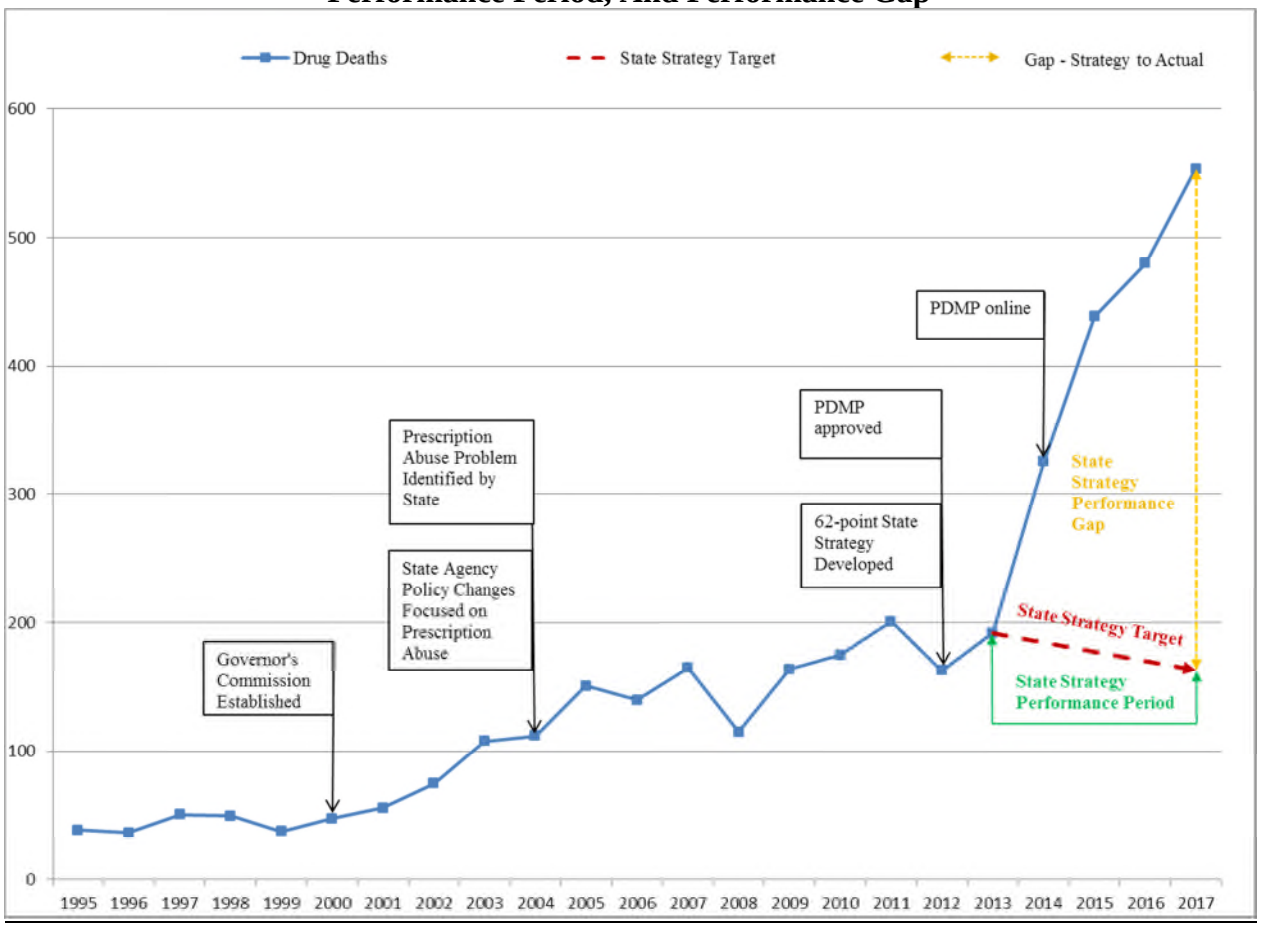
- evaluate the program holistically as we will not audit the effectiveness of other regulatory boards' implementation of related requirements or their use of PDMP data, nor will we audit the effectiveness of other potential users of PDMP data, such as law enforcement agencies;
- conduct independent general and application controls testing of the application underlying the PDMP, or of other agencies holding potentially relevant data;
- demonstrate actual historic or project potential future program outcomes;
- independently assess user and customer satisfaction;
- examine contracting processes or contract management; or
- audit program finances, including grant compliance and structural solvency.

We expect to present our final report to the Fiscal Committee by November 2017.

Enclosure

Enclosure 1

Drug Overdose Deaths[1], CY 1995 Through CY 2015[2] With CY 2016[3] And CY 2017[4] Projections, Major Milestones, And State Strategy Target[5], Performance Period, And Performance Gap



Notes:

1. Drug death data were obtained from the Office of the Chief Medical Examiner (OCME). Data as published did not differentiate between deaths due to use of prescription or illegal drugs.
2. Data before CY 2010 are interpolations derived from an undated OCME graphic published depicting drug versus traffic deaths, CY 1995 through CY 2010, and are consequently subject to error.
3. As of September 9, 2016. The total cases for CY 2016 were projected by OCME as several investigations were reportedly incomplete.
4. CY 2017 projection was LBA-estimated and based on average rate of change in drug deaths year-to-year for the period, CY 1995 through CY 2017.
5. State Strategy Target was LBA-estimated and based on the objective to reduce drug-related deaths 15 percent for the period covered by the strategy.

Source: LBA analysis.