Sunset Review: Evaluation of the Prescription Drug Monitoring Program



DEPARTMENT OF LEGISLATIVE SERVICES DECEMBER 2018

Sunset Review: Evaluation of the Prescription Drug Monitoring Program

Department of Legislative Services
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DEPARTMENT OF LEGISLATIVE SERVICES
OFFICE OF POLICY ANALYSIS
MARYLAND GENERAL ASSEMBLY

Victoria L. Gruber
Executive Director

Ryan Bishop
Director

December 31, 2018

The Honorable Thomas V. Mike Miller, Jr., President of the Senate
The Honorable Michael E. Busch, Speaker of the House of Delegates
Honorable Members of the General Assembly

Ladies and Gentlemen:

The Department of Legislative Services (DLS) has completed its evaluation of the Prescription Drug Monitoring Program (PDMP) as required by the Maryland Program Evaluation Act. This evaluation process is more commonly known as "sunset review" because the entities subject to evaluation are usually subject to termination; typically, legislative action must be taken to reauthorize them. This report was prepared to assist the committees designated to review PDMP – the Senate Finance Committee and the House Health and Government Operations Committee – in making their recommendations to the full General Assembly. The program is scheduled to terminate on July 1, 2019.

As part of this evaluation, DLS collected and analyzed information from a wide array of sources. This work included interviewing advisory board members, program staff, and professional association representatives; reviewing literature and studies on prescription drug monitoring best practices; and conducting a survey of individuals registered to use PDMP.

DLS finds that PDMP is fulfilling its statutory duties and mission since becoming operational in 2014, including successfully implementing mandatory use and registration, implementing many best practices, submitting timely and comprehensive reports to the General Assembly, and managing finances well. Feedback from members of the Advisory Board on Prescription Drug Monitoring, the Technical Advisory Committee, stakeholders, and national organizations regarding PDMP was consistently positive. A survey of registered users of PDMP also provided valuable feedback to enhance the program.

Based on these findings, DLS makes a total of 15 recommendations. DLS's primary recommendation is that statute be amended to remove PDMP from the list of governmental units subject to sunset evaluation and to repeal the program's termination date. In its annual report required under § 21-2A-05 of the Health-General Article for 2020, PDMP should report to the Governor and the General Assembly on the program's implementation of the nonstatutory recommendations contained in the report.

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We would like to acknowledge the cooperation and assistance provided by PDMP, the Advisory Board, and the Maryland Department of Health (MDH) throughout the review process. PDMP staff, advisory board members, and MDH were provided a draft copy of the report for factual review and comment prior to its publication; written comments from the board are enclosed as Appendix 3 to this report.

Sincerely,

Victoria L. Gruber
Executive Director

Ryan Bishop
Director

VLG:RB/JBC/km

Enclosure

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Executive Summary

Prescription drugs that contain controlled dangerous substances (CDS) are essential for the effective treatment of many medical conditions. However, misuse of prescription drugs (largely opioid pain relievers) can lead to a higher risk of substance use disorder, overdose, or death.

To address prescription drug abuse and drug diversion, states established prescription drug monitoring programs, statewide electronic databases that gather information from doctors prescribing and pharmacies dispensing CDS prescriptions. Programs are now operational in Guam, the District of Columbia, and every state but Missouri, and established, but not yet operational in St. Louis County, Missouri.

In a prescription drug monitoring program, data is made available on request from end users and sometimes distributed via unsolicited reports (data or reports sent proactively that may identify concerning behavior). Data includes information relating to the patient, prescriber, pharmacy, medicine, dosage, and date dispensed. End users are predominately prescribers and pharmacists but may include licensure boards, law enforcement and drug control agencies, medical examiners, drug courts and criminal diversion programs, addiction treatment programs, third-party payers, and other public health and safety agencies.

Research on the effectiveness of prescription drug monitoring programs is limited. Nonetheless, available research suggests that such programs have a positive impact on law enforcement and health care outcomes. Unintended consequences, both positive and negative, have also been identified.

Pursuant to the Maryland Program Evaluation Act, the Department of Legislative Services (DLS) has evaluated Maryland's Prescription Drug Monitoring Program (PDMP) that is scheduled to terminate on July 1, 2019. DLS finds that PDMP is successfully fulfilling its statutory duties and mission.

As part of this evaluation, DLS conducted numerous interviews; reviewed statutes, regulations, and legislative history; analyzed program data; attended an advisory board meeting; and reviewed advisory board meeting minutes. DLS also conducted a survey of individuals registered to use PDMP to provide insight into their experiences.

Since the establishment of PDMP in 2011, there have been a number of legislative changes altering the program, most significantly, mandatory registration and use requirements.

Two advisory entities, the Advisory Board on Prescription Drug Monitoring and the Technical Advisory Committee (TAC) provide assistance to PDMP.

The 22-member advisory board is fully appointed, has been operational since 2011, and has met its statutory mandates since the inception of PDMP. DLS finds that, although large, the size and composition of the board is generally appropriate, meetings are well run, and discussions are robust with actively engaged members.

DLS finds that advisory board members could benefit from additional training.

Recommendation 1: PDMP should institute a formal training program for new advisory board members on the responsibilities of members, including meeting protocols, and an overview of PDMP. This training should be applied consistently to new appointees on the advisory board.

In contrast to the advisory board, the role of TAC is still under development and, at the time of this evaluation, the committee has yet to fulfill requirements of Chapter 147 of 2016.

Chapter 147 increased the size of the committee from five to nine members, authorized TAC review of data requests, *authorized* review of unsolicited reports concerning indicators of misuse or abuse, and *required* review for unsolicited reports concerning possible violations of law or breaches of professional standards by prescribers and dispensers. At the time of this evaluation, the process for TAC's review of these unsolicited reports is still under development. However, PDMP indicates that TAC will begin review of PDMP data for outlier behavior and notify prescribers beginning in January 2019.

Although appointed, TAC is not yet fully operational and its role is evolving. In the short term, members of TAC should receive clarification regarding their duties. As TAC's role is further defined and the committee becomes operational, PDMP should report to the General Assembly on how it is functioning.

Recommendation 2: As the role of TAC is clarified and the committee becomes operational, PDMP should establish written protocols for TAC, including meeting requirements and the procedures for reviewing unsolicited reports and investigative data requests. PDMP should require at least one in-person meeting of TAC each year.

Recommendation 3: In the annual report required under § 21-2A-05 of the Health-General Article in 2019, PDMP should report to the Governor and the General Assembly on TAC. The report should include (1) the written protocols for TAC meetings and procedures for reviewing unsolicited reports and investigative data requests; (2) a summary of TAC meetings since the implementation of Chapter 147; and (3) recommendations on any changes necessary for TAC to meet the needs of PDMP.

Mandatory registration requires that anyone authorized to prescribe CDS sign up as a clinical user. This allows prescribers to access PDMP data but does not require any further action. Mandatory registration went into effect on July 1, 2017. By August 2018, 87% of prescribers and 91% of pharmacists were registered. As of February 2018, the Office of Controlled Substances Administration (OCSA) in the Maryland Department of Health (MDH) began withholding new or renewal CDS registrations to prescribers who were not registered with PDMP.

Mandatory use requires that prescribers actively query the PDMP system before beginning a new course of treatment for opioids or benzodiazepines and every 90 days thereafter while that course of

treatment continues, with limited exceptions. The requirement for mandatory use went into effect on July 1, 2018.

Comparing the number of opioid prescriptions dispensed in 2016, when neither mandatory registration nor mandatory use was in effect, to the number dispensed in 2018, when mandatory registration was in effect and mandatory use was in effect for three of the nine months covered, there is a reduction of 23.10%, or 677,490, fewer opioid prescriptions dispensed.

Recommendation 4: PDMP should continue outreach efforts to prescribers and pharmacists and monitor such efforts until functional full compliance with the mandatory registration mandate is achieved.

PDMP is required to provide data to specified entities for the purpose of furthering existing *bona fide*, individual investigations, including (1) federal, State, or local law enforcement agencies; (2) certain State licensing boards; (3) five entities within MDH on approval of the Secretary of Health (the Office of the Chief Medical Examiner, the Office of the Inspector General, the Office of Health Care Quality, the Medical Care Programs Administration, and OCSA); and (4) multiple fatality review entities (the State Child Fatality Review Team, the Material Mortality Review Program, a local child fatality review team, a local drug overdose fatality review team, or a health occupations medical review committee).

Before receiving an account, all investigative users are required to be trained by PDMP. As of August 2018, there were 240 registered investigative users.

While overall feedback on PDMP was positive, some health occupations boards expressed concerns about the process for requesting data from PDMP and the accuracy of PDMP data.

The Maryland Board of Physicians (MBP) and State Board of Nursing (BON) raised concerns about the requirement for an administrative subpoena voted on by a quorum of the board or an MBP disciplinary panel. BON meets monthly and has to wait for a board meeting in which a quorum is present each time the board wants to subpoena PDMP data. While waiting for the board to meet to vote on the subpoena, BON requests data directly from the pharmacy. Likewise, MBP stated that the requirement for a vote of approval by a disciplinary panel is an additional unnecessary step and that MBP subpoenas the pharmacy directly.

If the additional requirement for board approval of the subpoena is removed, the receipt of information can be accelerated and should include all of the prescriptions from the prescriber. This would provide for a more accurate, complete, and expeditious process than subpoenaing each pharmacy and subsequently compiling the data.

MBP also raised concerns about the reliability of PDMP data. For example, the board cited issues with patients being attributed to the incorrect doctor. Representatives from MBP have discussed these concerns with PDMP staff, who are working with MBP to figure out where data entry errors are occurring to ensure data quality moving forward.

Recommendation 5: Statute should be amended to remove the requirement for the vote of a quorum of the board or

disciplinary panel when a licensing entity requests prescription monitoring data.

Recommendation 6: MBP should continue to work with PDMP to address concerns regarding the accuracy of PDMP data.

PDMP is primarily supported through general funds appropriated through the State budget. The system is free for users to register and use. The PDMP budget is housed within the Behavioral Health Administration in MDH.

DLS finds that PDMP has managed finances well and succeeded in securing federal grants for planning, implementation, operations, and enhancements to the system. Additionally, PDMP has obtained significant funding through private donations. **As federal fund awards focus less on day-to-day operations, PDMP should consider soliciting additional private donations to fund operating expenses.**

PDMP has 10 total positions. PDMP is budgeted 5.0 full-time equivalent positions in fiscal 2019. As of December 2018, 1.0 regular position was vacant. PDMP has 5.0 contractual positions, 3.0 of which are vacant. PDMP relies heavily on contracts for personnel needs, with 50% of current program positions being contractual. **MDH should examine its contractual personnel to determine whether any other positions should be converted to regular positions.**

Forty-four states had operational prescription drug monitoring programs in place by 2012, making Maryland one of the last states to adopt such a program. However, in the five years since PDMP has been operational, the program has met nearly every suggested best practice. The best practices that Maryland has not yet implemented involve unsolicited reporting to prescribers and dispensers, user-led reports, and requiring identification from the individual picking up a prescription.

Unsolicited reports are typically sent to prescribers about questionable patient activity. Approximately 81% of prescription drug monitoring programs, including Maryland, send patient reports to prescribers. These reports help to identify patients who may be "doctor shopping," abusing or diverting CDS, or receiving unsafe amounts or combinations of prescription medications.

Unsolicited reporting of prescriber and dispenser behaviors is less common. Some states send reports on providers to licensing boards (61%), some directly to law enforcement (47%), and others have developed peer review committees that receive reports. States have also developed unsolicited reports of providers that get reported directly back to the provider in the form of a notification, letter, or report card.

Although Chapter 147 authorized unsolicited reporting, Maryland has not to date sent unsolicited reports on prescriber and dispenser behavior. Issues that have prevented implementation include limitations on the data that PDMP has access to collect and the need to establish appropriate thresholds for generating reports. For instance, PDMP data does not capture a prescriber's specialty, which is key to developing an unsolicited reporting mechanism.

Maryland's PDMP is currently developing unsolicited reports for prescribers regarding their own prescribing behavior. **In order to expand PDMP's functionality to include mandatory unsolicited reporting**

with TAC review, the committee should be fully operational and capable of fulfilling any expanded duties.

Recommendation 7: To allow more meaningful analysis, PDMP should collect additional data, specifically provider specialty information, before implementing unsolicited reporting on prescribers and dispensers.

A few states have developed user-led reports. This type of reporting allows a provider who has retrieved prescription drug monitoring data suggestive of a patient's questionable activity to send alerts to other providers who are treating the same patient. User-led reporting is an innovative unsolicited reporting mechanism that is currently only used by 14% of prescription drug monitoring programs nationally, but it is already considered a best practice.

While Maryland remains in the majority of programs that collect only the patient's identification at the time of dispensing, a recommended best practice implemented in 11 states is to collect identification for the individual picking up a prescription. Many times the individual at the pharmacy counter retrieving a prescribed medication is not the patient to whom the medication was prescribed.

Recommendation 8: PDMP should work with the State Board of Pharmacy to determine the feasibility of gathering information on the identification of the individual picking up a monitored prescription at the time it is dispensed.

Interstate sharing of prescription drug monitoring data helps to ensure that prescribers have a complete picture of their patients' prescription history. While Maryland law does not hinder PDMP from receiving information from other states' programs, it does limit *authorized users* of programs in other states from using data from Maryland's PDMP in certain electronic health record integrations.

Recommendation 9: Statute should be amended to allow authorized users of other states' prescription drug monitoring programs to access Maryland's prescription monitoring data.

Recommendation 10: Interstate data sharing agreements should be modified to ensure access of Maryland's PDMP users to other connected States' prescription drug monitoring program data.

As part of this evaluation, DLS conducted a survey of prescribers and dispensers registered with PDMP to provide insight into their experiences. A summary of the results of the full survey can be found in **Appendix 2**. DLS received responses from 3,568 individuals (a response rate of 6.44%).

Respondents were asked to rate their experience with PDMP in several areas, including training, technical assistance, and ease of logging into the system. Among regular users (those who access the system at least monthly), 47.13% indicated that training for users was good or very good, 12.45% indicated that it was poor or very poor, and 40.42% indicated their experience was neutral or not applicable.

With regard to technical support, 41.87% of regular users responded that such support was good or very good. However, 9.66% indicated that technical support was poor or very poor.

Regarding ease of logging into the system, 65.43% of regular users responded that their experience was good or very good, with 15.10% of respondents neutral. Nearly one-fifth (19.48%) of regular users responded that the ease of logging into the system was poor or very poor.

Three-quarters of regular users (75.44%) reported that the ability to access patient information was good or very good, while 80.89% indicated that the ability to assess patient prescription history was good or very good. More than two-thirds of regular users (70.54%) indicated that, in their experience, using PDMP has been helpful or very helpful in making prescribing or dispensing decisions.

The survey included an opportunity for respondents to comment on any improvements that might make the PDMP system more user friendly and/or effective. Common issues reflected in these comments involved concerns about the log-in process, a lack of clarity on how to use PDMP and the exceptions to mandated use, requests for interstate operability, and a lack of clarity among veterinarians on their requirements for using PDMP.

Recommendation 11: PDMP should work with Chesapeake Regional Information System for Our Patients (CRISP) to simplify the PDMP user experience, specifically the log-in process and password issues. PDMP and CRISP should investigate the feasibility of implementing single sign on and improving password issues related to resetting the password.

Recommendation 12: PDMP should continue to expand upon educational outreach efforts for registrants. This education should include a clear explanation of the individuals who are required to use PDMP, how to use PDMP, the exceptions to using PDMP, and information on the other states from which prescription drug monitoring data can be accessed and how to access the information.

Recommendation 13: PDMP should work with the State Board of Veterinary Medical Examiners to provide clear information to veterinarians who are required to register with PDMP as a condition of receiving their CDS license on whether and how veterinarians are to access PDMP.

Based on DLS observations, PDMP is fulfilling its statutory duties and mission since becoming operational in 2014. PDMP has (1) successfully implemented mandatory use and registration; (2) implemented many best practices; and (3) submitted timely and comprehensive required reports to the General Assembly. PDMP has historically managed finances well, successfully secured federal grants, and obtained significant funding through private donations.

Feedback from members of the advisory board, TAC, stakeholders, and national organizations was consistently positive. A survey of registered PDMP users provided valuable feedback to enhance the program.

Based on this review, DLS recommends the removal of PDMP from the list of governmental units subject to sunset evaluation under the Maryland Program Evaluation Act and repeal of the program's termination date.

No comparable Maryland program is subject to the Act. PDMP will continue to be subject to the operating budget review process and review by the Office of Legislative Audits if necessary. Further, a review of the legislative history of PDMP indicates that PDMP was subject to sunset evaluation over concerns that PDMP may have a negative impact on patient safety. DLS finds that, after four years of operation, such negative impacts have not been realized. Finally, a review of prescription drug monitoring programs in other states found that only 7 of 49 states are subject to termination or audit.

Recommendation 14: Statute should be amended to remove PDMP from the list of governmental units subject to sunset evaluation under the Maryland Program Evaluation Act and to repeal the program's termination date.

Recommendation 15: In the annual report required under § 21-2A-05 of the Health-General Article in 2020, PDMP should report to the Governor and the General Assembly on the program's implementation of the nonstatutory recommendations contained in this report.

Prescription Drug Monitoring Program

Primary Recommendations:	**Statute should be amended to remove the Prescription Drug Monitoring Program (PDMP) from the list of governmental units subject to sunset evaluation under the Maryland Program Evaluation Act and to repeal the program's termination date.**
Date Established:	2011
Most Recent Prior Evaluation:	Preliminary Evaluation, 2013 Primary Recommendation: Waive from full evaluation; extend termination date to July 1, 2019
Composition:	22-member Advisory Board (1 representative each from the Maryland Department of Health, the State Board of Pharmacy, the State Board of Physicians, the State Board of Nursing, the State Board of Dental Examiners, the State Board of Podiatric Medical Examiners, the Maryland Health Care Commission, the Maryland State Police, and the Maryland Association of County Health Officers; 4 physicians; 1 nurse practitioner; 1 pediatrician; 3 pharmacists; 1 local law enforcement official; 1 academic researcher; and 2 Maryland residents to represent the patient perspective) 9-member Technical Advisory Committee (1 pharmacist; 4 physicians with expertise in addiction medicine, pain management, and clinical use of controlled dangerous substances; 2 licensed, practicing medical professionals with expertise in providing care for patients with substance-related or mental health disorders; 1 licensed, practicing dentist; and 1 licensed medical professional practicing in the field of internal medicine or family practice)
Staff:	10 full-time (director, assistant director, office secretary, data quality specialist, program coordinator, special programs manager, 2 epidemiologists, database specialist, special programs coordinator)
Authorizing Statute:	Title 21, Subtitle 2A, Health-General Article

Chapter 1. Prescription Drug Monitoring in Context

Prescription drug monitoring programs were created in order to address the problem of prescription drug abuse. This chapter discusses the problem of prescription drug abuse, the goals of prescription drug monitoring programs, and the ability of prescription drug monitoring programs to address the problem of prescription drug abuse.

Overview of Prescription Drug Abuse Nationally and in Maryland

Prescription drugs that contain controlled dangerous substances (CDS) are essential for the effective treatment of a wide range of medical conditions. CDS prescription drugs include opioid pain relievers like oxycodone (OxyContin, Percocet, Percodan, Roxicet), hydrocodone (Vicodin and Lortab), and methadone prescribed for pain; benzodiazepines used to treat anxiety, panic attacks, seizures, and sleep disorders, such as alprazolam (Xanax) and diazepam (Valium); and stimulants like Adderall and Ritalin.

Misuse of prescription drugs (largely opioid pain relievers) can lead to a higher risk of serious adverse consequences such as substance use disorder, overdose, or death.

In 2017, an estimated 3.2 million people aged 12 and older misused prescription pain relievers. As shown in **Exhibit 1.1**, from calendar 2015 through 2016, about 1 in 22 Americans aged 12 and older (4.46%) and (4.43%) used pain relievers nonmedically across all states and across the South census region, respectively. In Maryland, such use was estimated at about 1 in 24 individuals aged 12 and older (4.15%). Prevalence of the non-medical use of pain relievers is generally lower in Maryland than in all the states or among states in the South census region (comprising 16 states, including Maryland, and the District of Columbia). One exception is among 18- to 25-year olds (the age group with the highest prevalence of non-medical use) for which the prevalence of non-medical use is the same both nationally and in Maryland, while slightly lower in the South census region.

Exhibit 1.1
Proportion of Individuals Who Used Non-medical Prescription Pain Relievers
Calendar 2015-2016

	Total Age 12+	Age 12-17	Age 18-25	Age 26+
All States	4.46%	3.72%	7.82%	4.00%
South Census Region	4.43%	3.94%	7.61%	3.96%
Maryland	4.15%	3.40%	7.82%	3.66%

Note: The South census region includes Alabama, Arkansas, the District of Columbia, Delaware, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia.

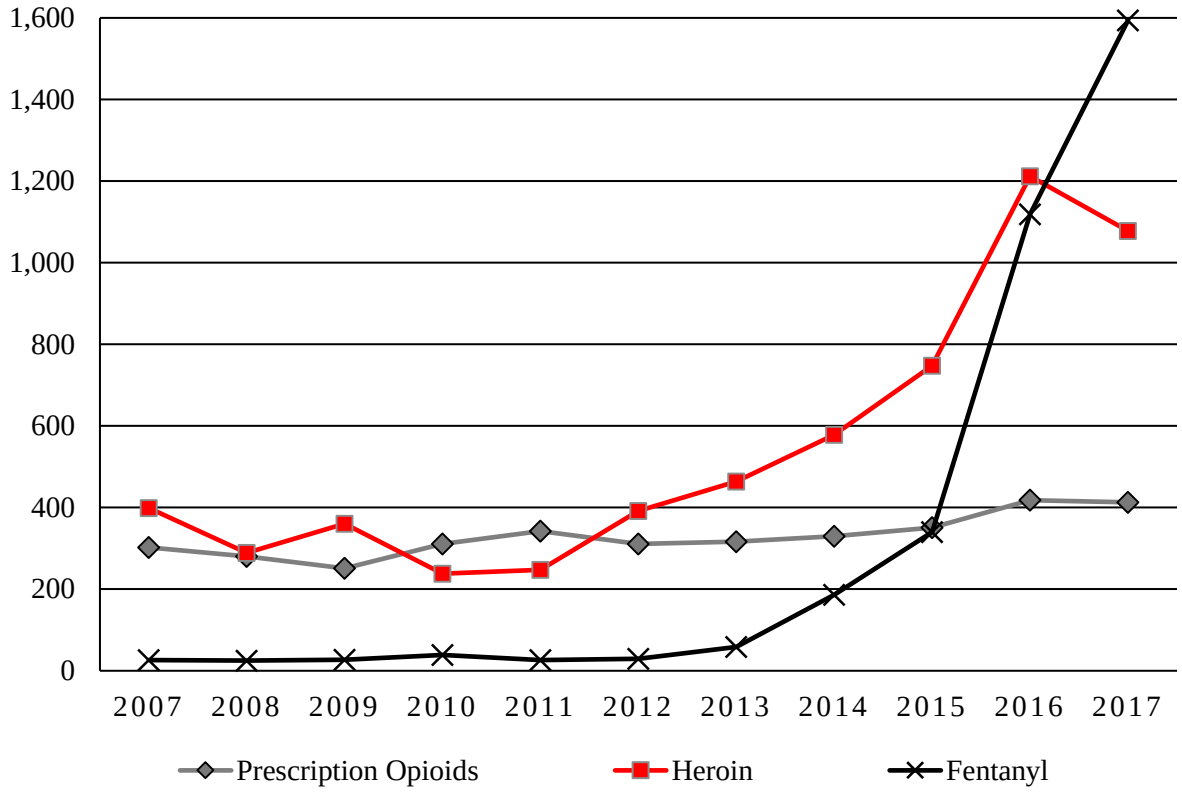
Source: U.S. Substance Abuse and Mental Health Services Administration

Estimates from the National Survey on Drug Use and Health suggest that, in 2016, 91.8 million adults (34.1%) used prescription opioids, while 11.5 million (4.3%) misused them. Among adults who misused prescription opioids, 62.2% reported using opioids without a prescription and 40.6% obtained prescription opioids for free from friends or relatives for their most recent episode of misuse.

The U.S. Substance Abuse and Mental Health Services Administration reports the misuse of prescription opioids and use of heroin is one of the most significant public health issues in the United States. Opioid abuse claims more lives than motor vehicle crashes. Additionally, the U.S. Centers for Disease Control and Prevention reports that opioid overdose deaths in the United States have been increasing since 1999, initially driven by prescription opioid misuse and more recently by heroin and other illicit opioid use. The National Institute on Drug Abuse reports that, in 2016, there were 42,249 opioid deaths nationally: 17,087 (40.4%) involved prescription opioids, 10,375 (24.6%) involved heroin, and 15,469 (36.6%) involved fentanyl. While finalized numbers for 2017 were not yet available as of October 2018, total opioid deaths nationally were estimated at 49,068 (a 16.1% increase over 2016).

As seen in **Exhibit 1.2**, opioid-related deaths in Maryland increased sharply beginning in 2012, particularly related to heroin and fentanyl. Between calendar 2016 and 2017, prescription opioid-related deaths and heroin-related deaths decreased slightly (for the first time since 2011 and 2010, respectively). However, fentanyl-related deaths increased by 42.4% (from 1,119 to 1,594).

Exhibit 1.2
Total Number of Drug-related Intoxication Deaths in Maryland
By Selected Substances
Calendar 2007-2017



Source: Maryland Department of Health

Prescription Drug Monitoring Programs Tools to Address Abuse

To address the problem of prescription drug abuse and drug diversion, states established prescription drug monitoring programs, statewide electronic databases that gather information from doctors prescribing and pharmacies dispensing CDS prescriptions. While New York has had a prescription drug monitoring program since the early 1970s, Oklahoma was the first state to establish an electronic monitoring program in 1991. Prescription drug monitoring programs are now operational in Guam, the District of Columbia, and every state but Missouri, and established, but not yet operational in St. Louis County, Missouri.

In a prescription drug monitoring program, prescription data is made available on request from end users and sometimes distributed to end users via unsolicited reports (data or reports sent proactively that may identify concerning behavior). Data usually includes information relating to the patient, prescriber, pharmacy, medicine, dosage, and the date dispensed. End users of prescription drug monitoring program data are predominately prescribers and pharmacists but may also include health occupations licensure boards, law enforcement and drug control agencies, medical examiners, drug courts and criminal diversion programs, addiction treatment programs, public and private third-party payers, and other public health and safety agencies. State policies vary widely with regard to which categories of recipients are permitted to request and receive data and under what conditions.

Goals of Prescription Drug Monitoring Programs Vary but Are Generally Based on Five Major Objectives

The goals of prescription drug monitoring programs are diverse, but all programs generally have the same major objectives: education and information; public health initiatives; early intervention and prevention; investigations and enforcement; and protection of confidentiality.

Providing education raises the general awareness of the problem of diversion and the illicit use of pharmaceuticals. Increased awareness alone can lead to reductions in drug diversion and abuse, but most programs go further providing prescribers with information on its own prescribing behaviors and trends and on the prescription trends of its patients.

Public health initiatives can be developed through the use and analysis of data obtained from prescription drug monitoring programs. Monitoring data has been used by states in the initiation of education and prevention programs, formulation of laws and regulations, development of CDS policies, and establishment of practice and treatment guidelines. This use of monitoring data allows for new initiatives to be better targeted at specific subsets of prescribers and dispensers when appropriate.

Early intervention and prevention includes deterrence of drug diversion based on a patient's, prescriber's, or dispenser's knowledge that there is a mechanism in place to track and identify illicit activities. Prescription drug monitoring programs may also provide information to law enforcement and/or regulatory agencies that allows them to identify diversion behaviors earlier than would be possible without the prescription monitoring data.

Many prescription drug monitoring programs use the data as a means to enforce the laws and regulations governing CDS. While regulatory agencies and law enforcement usually have access to the same type of information located in a prescription drug monitoring program, even where no program exists, data from such monitoring programs is much less time consuming to obtain and access because it is usually housed within a single database. This helps to significantly cut down on the time and resources that law enforcement agencies and regulatory bodies need in order to complete drug diversion investigations.

Use of prescription monitoring data must be balanced against the need to protect the privacy of patients, prescribers, and dispensers. Therefore, access to data is often limited, and data security is of paramount importance.

While Limited, Effectiveness Research on Prescription Drug Monitoring Programs Shows Positive Impact on Health Care and Law Enforcement

Research on the effectiveness of prescription drug monitoring programs is limited, and there are additional limitations within the research that is available including defining what effectiveness means, accounting for differences across programs, and considering confounding factors. For example, programs vary from state to state about what drugs are required to be reported, and most comparison studies do not distinguish between whether a state is using proactive or reactive models. Moreover, the data that is collected usually includes all opioid consumption, both medically appropriate and non-medical uses, which produces a flawed data set. However, if a study instead uses data related to substance use treatment admissions then that data will be flawed because it will miss data related to substance abuse that goes untreated.

Nonetheless, available research suggests that prescription drug monitoring programs have a positive impact on both law enforcement and health care outcomes.

- A 2002 study by the U.S. Government Accountability Office found that, following implementation of a prescription drug monitoring program, the average time to complete an investigation of doctor shopping dropped from 156 to 16 days, a 90% decrease. Similarly, the average time to complete investigations in Nevada and Utah decreased by 83% and 80%, respectively.

- A 2006 federally funded study found that prescription drug monitoring programs with a proactive model reduce the per capita supply of prescription pain relievers and stimulants, which in turn reduces the probability for drug abuse.

- A 2012 review article summarizing all other peer-reviewed research articles about prescription drug monitoring programs published between 2001 and 2011 concluded that prescription drug monitoring programs reduce doctor shopping, change prescribing behavior, and reduce prescription drug abuses.

- An additional study published in 2012 found that, while opioid abuse was increasing over time in all states, the rate of that increase was slower in states with prescription drug monitoring programs than in states without such programs.

- A 2013 survey of medical professionals in Indiana regarding the impact of prescription drug monitoring programs found that, of the respondents who had changed their prescribing practices, 90% reported prescribing fewer CDS, and over 50% of these respondents cited viewing prescription drug monitoring data as the main reason for the change.

- Following the March 2013 initiation of a prescription drug monitoring program in Arkansas, the number of individuals meeting a threshold for doctor shopping fell from 144 from March to May 2013, to 31 from December 2013 through February 2014.

- In April 2013, after Tennessee's new legislative mandate went into effect requiring prescribers to check the prescription drug monitoring program before prescribing certain CDS, the number of individuals meeting a threshold for doctor shopping declined by 36% in the three-month period following inception.

- A 2014 briefing document from the Prescription Drug Monitoring Program Training and Technical Assistance Center at Brandeis University concluded that prescription drug monitoring programs are effective in improving clinical decision making, reducing doctor shopping, reducing drug diversion, and assisting in other efforts to restrain the prescription drug abuse epidemic.

- A 2015 study in Kentucky examining the effectiveness of mandatory enrollment of prescribers and dispensers in prescription drug monitoring programs cited a 50% decrease in the number of individuals who are doctor shopping as well as the closures of nonphysician-owned pain management facilities as two positive outcomes.

- A 2017 study found that states with mandated registration in prescription drug monitoring programs were associated with a 9% to 10% reduction in population-adjusted numbers of Schedule II opioid prescriptions received by Medicaid enrollees.

- Another 2017 study found no correlation between prescription drug monitoring program implementation and non-medical use, and/or abuse of opioids but did report a correlation between prescription drug monitoring program implementation and a reduction in doctor shopping.

Unintended consequences, both positive and negative, of prescription drug monitoring program implementation have also been identified through research. Some positive effects include prescribers' or dispensers' ability to identify patients who are at risk of harmful drug interactions as a result of receiving legitimate prescriptions for multiple CDS, as well as prescribers' ability to monitor their own U.S. Drug Enforcement Administration number for potential fraudulent activity.

The following negative unintended consequences should also be considered:

- Prescribers may hesitate to prescribe a monitored medication even when it is the most appropriate option if they are concerned about potentially coming under scrutiny from law enforcement or licensing authorities. This may lead prescribers to replace monitored medications with inferior medications, those that are less effective or have more side effects that are not monitored.

- Patients may fear coming under scrutiny from law enforcement if they receive monitored prescriptions, even when used legitimately.

- Patients may have concerns about changes in prescribing behavior that may limit their ability to access needed medications solely because they are being reported to a prescription drug monitoring program.

- Patients may worry about the privacy and security of their personal prescription information when it is submitted to a prescription drug monitoring program.

- The existence of a prescription drug monitoring program in one state may push drug diversion activities over the border into another state with less restrictive reporting requirements.

- There could be a resulting uptick in the abuse of nonprescription opioids such as heroin and illicit fentanyl due to prescription drug monitoring program reporting in a state.

Chapter 2. Maryland's Prescription Drug Monitoring Program

The Sunset Review Process

This evaluation was undertaken under the auspices of the Maryland Program Evaluation Act (§ 8-401 *et seq.* of the State Government Article), which establishes a process better known as "sunset review" because most agencies subject to review are also subject to termination.

Maryland's Prescription Drug Monitoring Program (PDMP) was established by Chapter 166 of 2011 to address issues of prescription drug abuse and drug diversion. Implementation of the program began in July 2011, and the program became fully operational in 2014 (with clinical user access operational in December 2013, and investigative user access implemented in March 2014). The program had an initial termination date of July 1, 2016, and is subject to review under the Maryland Program Evaluation Act.

A preliminary evaluation of the program was conducted by the Department of Legislative Services (DLS) in 2013. Since PDMP was not fully operational at that time, DLS reviewed implementation of the program to date, compared the structure of the program to those in other states, and assessed potential best practices. The preliminary evaluation recommended (1) waiving the program from full evaluation; (2) extending the termination date of the program by three years to July 1, 2019; (3) requiring a follow-up report by January 1, 2015; (4) considering removing the statutory requirement for Technical Advisory Committee (TAC) review of data requests from other states; and (5) expanding annual reporting requirements.

Chapter 92 of 2014 extended the termination date of PDMP to July 1, 2019, authorized PDMP to disclose information to the authorized administrator of another state's PDMP for disclosure to prescribers, dispensers, and patients without the review, clinical guidance, and interpretation of TAC, and required PDMP's annual report to include the number of prescribers and dispensers registered with and using PDMP and the number of disclosures made to law enforcement.

This full evaluation was undertaken to provide the General Assembly with information to use in making the determination about whether to reauthorize PDMP and for what period of time.

Research Activities

To complete this evaluation, DLS staff collected and analyzed information from a wide array of sources. DLS research for this evaluation included:

- reviewing the statute and regulations governing PDMP in Maryland;

- reviewing the legislative and regulatory history of PDMP and proposed legislation relating to PDMP;
- interviewing current advisory board members, TAC members, and PDMP staff;
- interviewing representatives of professional associations, provider organizations, licensing boards of PDMP users, representatives from the State health information exchange (Chesapeake Regional Information System for Our Patients), and national prescription drug monitoring associations;
- attending an advisory board meeting and reviewing minutes of past advisory board meetings;
- assessing the financial data of PDMP;
- conducting a survey of individuals registered to use PDMP; and
- reviewing literature and studies on prescription drug monitoring programs, specifically best practices.

Throughout the evaluation process, PDMP staff, advisory board members, and TAC members were helpful and responsive to DLS' requests for information.

The survey conducted by DLS was intended to provide insight into the experiences of prescribers and dispensers registered to use PDMP. A link to the survey was sent by email to every individual registered with PDMP, a total of 55,347 individuals, including both active and inactive users. DLS received responses from 3,568 individuals (a response rate of 6.45%), including 1,725 physicians, 568 pharmacists, 457 nurse practitioners, 362 dentists, 230 physician assistants, 168 veterinarians, and 58 other individuals (including podiatrists, nurse midwives, and delegate users). Highlighted findings from the survey can be found in **Chapter 8**. A summary of the results of the full survey can be found in **Appendix 2**.

Report Objective and Structure

The objective of this report is to provide an overview of the functions and role of PDMP and to offer recommendations. This report consists of 9 chapters. **Chapter 1** provides context on the opioid problem nationally and in Maryland, as well as information on prescription drug monitoring programs generally. **Chapter 2** provides an overview of the sunset review process, a summary of Maryland's PDMP, and a review of major legislative and regulatory changes since the 2013 preliminary sunset evaluation. **Chapter 3** gives an overview of the advisory board and TAC. **Chapter 4** addresses mandatory registration and use policies. **Chapter 5** describes use of PDMP data by investigative users. **Chapter 6** discusses program finances, personnel resources,

and the PDMP website. **Chapter 7** explores best practices for prescription drug monitoring programs. **Chapter 8** summarizes and highlights findings from the user survey. **Chapter 9** presents DLS' conclusions and primary recommendations.

As supplements to the report, four appendices are included. **Appendix 1** describes national best practices regarding prescription drug monitoring**. Appendix 2** contains a summary of the results from the DLS survey of individuals registered with PDMP. **Appendix 3** includes draft legislation to implement the statutory recommendations contained in this report. The Maryland Department of Health (MDH) reviewed a draft of this report and provided the written comments included as **Appendix 4**. Appropriate factual corrections and clarifications have been made throughout the document; therefore, references in those comments may not reflect this published version of the report.

Maryland's Prescription Drug Monitoring Program

The mission of Maryland's PDMP is to (1) assist prescribers, dispensers, and public health professionals in the identification and prevention of prescription drug abuse and the identification and investigation of unlawful prescription drug diversion; and (2) to promote a balanced use of prescription monitoring data. Chapter 166 established PDMP with the requirement to monitor the prescribing and dispensing of all Schedule II through V controlled dangerous substances (CDS). Prescribing occurs when a health care practitioner writes a prescription for a CDS, while dispensing occurs when a pharmacist or other licensed dispenser fills the prescription and gives the prescription to a patient. Dispensing does not include a situation in which a prescription drug is administered directly to a patient by a health care provider.

As of July 1, 2017, all licensed pharmacists and all authorized prescribers of CDS, including physicians, physician assistants, dentists, podiatrists, nurse practitioners, advanced practice nurse midwives, and veterinarians are required to be registered with PDMP.

For each monitored prescription drug dispensed, a dispenser must electronically submit data to PDMP in accordance with regulations adopted by the Secretary of Health. Dispensers include not only pharmacies but also physicians, podiatrists, and dentists holding a permit from their respective licensing board allowing them to dispense prescription drugs.

As of July 1, 2018, all prescribers, excluding veterinarians who do not have a legally authorized use case to access PDMP data, are required to query PDMP regarding a patient's history of prescribed CDS before prescribing a monitored drug, unless the prescription is:

- for no more than a three-day supply;
- for cancer treatment or cancer-related pain;
- to a patient in an inpatient hospital;

- to a patient in hospice;
- to a patient residing in nursing or other assisted living facility;
- to treat or prevent acute pain for a period of not more than 14 days following:
    - a surgical procedure;
    - fracture;
    - significant trauma; or
    - childbirth;
- for a specific medicine included in a list compiled by the Secretary of Health of drugs with low potential for abuse; or
- in the event of electrical or technological issues.

The 22-member Advisory Board on Prescription Drug Monitoring makes recommendations on the design, implementation, and funding of the program; provides annual reports to the Governor and General Assembly; and provides general oversight of the program. Chapter 3 provides additional detail on the composition and duties of the advisory board.

PDMP collects a mass of data from all of its mandatory reporters. Data is confidential, privileged, and not subject to discovery, subpoena, or other means of legal compulsion in civil litigation. Prescription monitoring data is not a public record and may not be disclosed to any person except as specifically authorized under law. However, the program must disclose data, in accordance with regulations adopted by the Secretary of Health, to:

- a prescriber, or a licensed health care practitioner authorized by the prescriber, in connection with the medical care of a patient;
- a dispenser, or a licensed health care practitioner authorized by the dispenser, in connection with the dispensing of a monitored prescription drug;
- a federal, State, or local law enforcement agency, on issuance of a subpoena, for an existing *bona fide* individual investigation;
- a licensing entity, on issuance of an administrative subpoena voted on by a quorum of the board of the licensing entity, for purposes of a *bona fide* individual investigation;

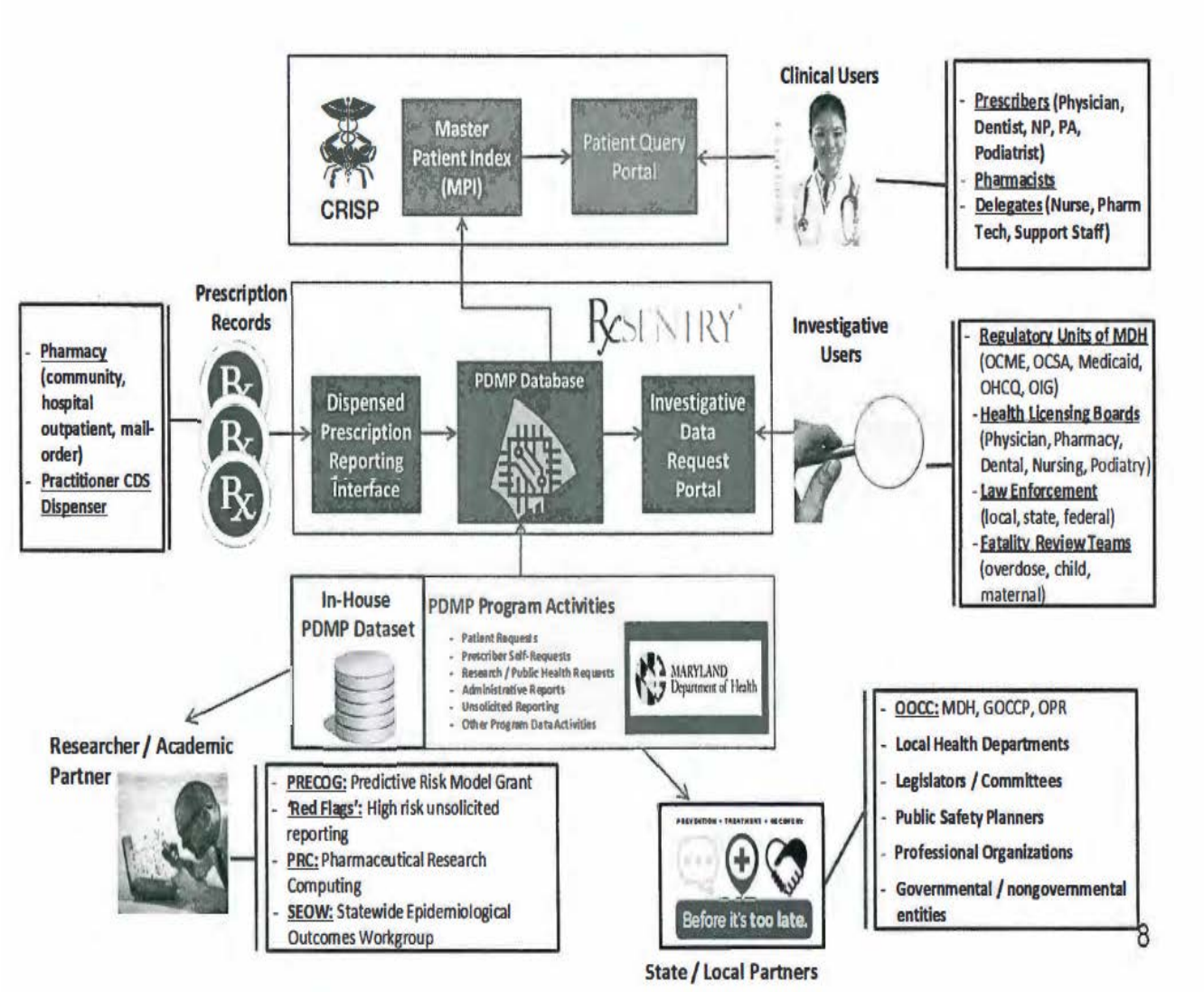
- a rehabilitation program under a health occupations board on issuance of an administrative subpoena;
- a patient with respect to prescription monitoring data about the patient;
- the authorized administrator of another state's prescription drug monitoring program;
- specific units of MDH on approval of the Secretary of Health for the purpose of furthering an existing *bona fide* individual investigation;
- TAC;
- the State Child Fatality Review Team or a local child fatality review team, on request from the chair of the State or local team;
- a local drug overdose fatality review team, on request from the chair of the local team;
- the Maternal Mortality Review Program, on request from the program; or
- a medical review committee, on request from the committee.

The program *may* disclose prescription drug monitoring data for research, analysis, public reporting, and education but only after redacting all information that could identify a patient, prescriber, dispenser, or other individual, and only in accordance with regulations. **Exhibit 2.1** provides a visual representation of PDMP stakeholders, both those inputting data and end users.

PDMP also has a nine-member TAC, consisting of specified members appointed by the Secretary of Health. The primary purpose of TAC is to review data indicating possible violations of law or breaches of professional standards and provide its clinical guidance and interpretation of the data to the program before unsolicited reports are sent to a prescriber or dispenser about their professional practice, and to approve new methods for identifying possible indicators of potential misuse or abuse by a patient. TAC reviews supplements quantitative data analysis tools and methods that PDMP employs to identify potentially illegal or inappropriate prescribing or dispensing. TAC may also review requests for PDMP data from outside sources. Chapter 3 provides more detailed information on the composition and role of TAC.

Exhibit 2.1

Prescription Drug Monitoring Program: Stakeholder Access and Use of Data



CDS: controlled dangerous substance
CRISP: Chesapeake Regional Information System for Our Patients
GOCCP: Governor's Office of Crime Control and Prevention
MDH: Maryland Department of Health
NP: nurse practitioner
OCME: Office of the Chief Medical Examiner
OCSA: Office of Controlled Substances Administration
OHCQ: Office of Health Care Quality
OIG: Office of the Inspector General
OHCQ: Office of Health Care Quality
OOCC: Opioid Operational Command Center
OPR: Office of Preparedness and Response
PA: physician assistant
PDMP: Prescription Drug Monitoring Program
Rx: prescription

Source: Maryland Department of Health

Legislative History of PDMP

Since the establishment of PDMP in 2011, the General Assembly has enacted several laws altering the program. **Exhibit 2.2** summarizes the legislative history of PDMP. Of the enactments, Chapter 147 of 2016 has had the most significant impact on PDMP as it required prescribers and dispensers to register with PDMP by July 1, 2017, and for prescribers to use PDMP before writing specified prescriptions by July 1, 2018. A discussion on the implementation of Chapter 147 is included in Chapter 4.

Exhibit 2.2
Legislative History of the Prescription Drug Monitoring Program

Year	Chapter	Change
2011	166	Establishes the Prescription Drug Monitoring Program (PDMP) in the Department of Health and Mental Hygiene (DHMH, now the Maryland Department of Health (MDH)) to monitor the prescribing and dispensing of Schedule II through V controlled dangerous substances CDS; establishes the Advisory Board of Prescription Drug Monitoring; establishes the Technical Advisory Committee (TAC).
2013	177	Adds the Division of Drug Control (now Office of Controlled Substances Administration) within DHMH to the list of entities to which PDMP must disclose prescription monitoring data for the purpose of furthering an existing *bona fide* individual investigation.
2014	651	Authorizes PDMP to review prescription drug monitoring data for indications of possible misuse or abuse of a monitored prescription drug and report the possible misuse or abuse to the prescriber or dispenser; requires PDMP to obtain clinical guidance regarding indications of possible misuse or abuse and interpretation of the data that indicated the possible misuse or abuse from TAC.
2014	92	Extends the termination date of PDMP to July 1, 2019; authorizes PDMP to disclose information to the authorized administrator of another state's PDMP for disclosure to prescribers, dispensers, and patients without the review, clinical guidance, and interpretation of TAC; requires PDMP's annual report to include the number of prescribers and dispensers registered with and using PDMP and the number of disclosures made to law enforcement.
2015	381	Expands the entities to which PDMP must disclose prescription drug monitoring data to include the State or a Local Child Fatality Review Team, a Local Drug Overdose Fatality Review Team, the Maternal Mortality Review Program, or a medical review committee appointed by or established in DHMH or a local health department; requires PDMP to disclose data to the State Board of Physicians on issuance of an administrative subpoena voted on by a quorum of a disciplinary panel of the board, for the purposes of furthering an existing *bona fide* investigation of an individual.

Year	Chapter	Change
2016	147	Requires certain prescribers and all pharmacists to register with PDMP by July 1, 2017; requires a prescriber, beginning July 1, 2018, to (1) request at least the prior four months of prescription monitoring data for a patient before initiating a course of treatment that includes prescribing or dispensing an opioid or a benzodiazepine; (2) request prescription monitoring data for the patient at least every 90 days until the course of treatment has ended; and (3) assess prescription monitoring data before deciding whether to prescribe or dispense – or continue prescribing or dispensing – an opioid or a benzodiazepine; provides that prescribers and pharmacists are subject to disciplinary action by the appropriate licensing entity for failure to comply with the mandatory registration and use requirements; expands the membership of TAC from five to nine members; alters the duties of TAC by authorizing, rather than requiring, TAC review of data requests; authorizes TAC review of unsolicited reports concerning indicators of misuse or abuse; requires TAC review of unsolicited reports concerning possible violations of law or possible breaches of professional standards by prescribers and dispensers.
2017	40	Expands the membership of the advisory board from 17 to 22 members to include the president of the State Board of Dental Examiners, the president of the State Board of Podiatric Medical Examiners, the Secretary of State Police, the president of the Maryland Association of County Health Officers, and an academic or research professional.
2018	772	Expands an exemption that a provider request data from PDMP when prescribing or dispensing an opioid or benzodiazepine to treat or prevent acute pain, for a period of up to 14 days, following a surgical procedure (rather than only surgical procedures in which general anesthesia was used).
2018	211	Authorizes MDH to access PDMP data for use in an annual MDH report on individuals in the State who suffered fatal overdoses involving opiates and other CDS.

Source: Laws of Maryland

Regulations Implementing PDMP

Section 21-2A-04 of the Health-General Article requires the Secretary of Health to adopt regulations that:

- specify the prescription monitoring data required to be submitted under the subtitle;
- specify the electronic or other means by which information is to be submitted (1) without unduly increasing the workload and expense on dispensers and (2) in a manner as compatible as possible with existing data submission practices of dispensers;

- specify that the information be submitted by dispensers once every 24 hours;

- specify that the PDMP (1) must provide the information technology software to dispensers necessary to upload prescription drug monitoring data to PDMP and (2) may not impose any fees or other assessments on prescribers or dispensers to support the operation of PDMP;

- identify the mechanism by which prescription monitoring data is disclosed to a person, in accordance with the subtitle;

- identify the circumstances under which a person may disclose prescription monitoring data received under PDMP;

- specify the process for PDMP's review of prescription monitoring data and reporting of either possible misuse or abuse of a monitored prescription drug under the subtitle or a possible violation of law or possible breach of professional standards under the subtitle;

- establish requirements for PDMP's retention of prescription monitoring data for three years; and

- require that (1) confidential or privileged patient information be kept confidential and (2) records or information protected by a privilege between a health care provider and a patient, or otherwise required by law to be held confidential, be filed in a manner that does not disclose the identity of the person protected.

Regulatory changes are summarized in **Exhibit 2.3** and have implemented legislation adopted by the General Assembly.

Exhibit 2.3
Regulatory Changes Related to the Prescription Drug Monitoring Program

Year	COMAR Citation	Major Change
2012	10.47.07.01–.08	Establish the Prescription Drug Monitoring Program (PDMP) in accordance with § 21-2A-04 of the Health – General Article.
2013	10.47.07.04 and .08	Add the Division of Drug Control to the list of entities that may request prescription monitoring data from PDMP; allow for the redisclosure of PDMP data to a State or Local Child Fatality Review Team or a medical review committee established by the Secretary of Health or a local health department.
2014	10.47.07.03–.09	Authorize PDMP to review prescription monitoring data for indications of possible misuse or abuse of a monitored prescription drug and report the misuse or abuse to the prescriber or dispenser of the drug. Before PDMP discloses the data, require TAC to review any prescription monitoring data upon which the program's report is based and, within 10 business days of submission of the data to the Technical Advisory Committee (TAC), submit to PDMP clinical guidance regarding indications of possible misuse or abuse and interpretation of the data that indicates possible misuse or abuse. If TAC has not provided clinical guidance and interpretation within 10 days, the department may report the potential misuse or abuse to the prescriber or dispenser. Allow PDMP to disclose prescription monitoring data to the authorized administrator of another state's prescription drug monitoring program, without review by TAC, only for disclosure to a prescriber, a dispenser, a licensed health care practitioner authorized by a prescriber or a dispenser, or a patient in a manner consistent with disclosures by PDMP. Allow prescription monitoring data to be redisclosed: for a law enforcement agency, a licensing entity, a rehabilitation program under a health occupations board, or a unit within the Department of Health and Mental Hygiene (now the Maryland Department of Health (MDH)) authorized by law to receive prescription monitoring data, to another agency cooperating with or providing support for the original data recipient's existing, *bona fide*, individual investigation; and to a local drug overdose fatality review team.

Year	COMAR Citation	Major Change
2015	10.47.07.05	Expand the entities to which PDMP must disclose prescription monitoring data to include, on approval of the Secretary of Health and for the purpose of furthering an existing *bona fide* individual case review: (1) the State Child Fatality Review Team or a Local Child Fatality Review Team; (2) a Local Drug Overdose Fatality Review Team; (3) the Maternal Mortality Review Program; or (4) a medical review committee appointed by or established in MDH or a local health department.
2018	10.47.07.02, .03, .05,.06, .08 and .09	Update and add definitions, alter reporting and registration requirements, provide for disclosures of prescription monitoring data to certain prescriber and pharmacist delegates under certain circumstances; alter provisions relating to the redisclosure of data and the retention of data; require a dispenser to report prescription monitoring data to the department at least every 24 hours, rather than within three business days after dispensing a monitored prescription drug, and in accordance with certain procedures.

COMAR: Code of Maryland Regulations

Source: Code of Maryland Regulations; *Maryland Register*

Chapter 3. Advisory Entities to the Prescription Drug Monitoring Program

Two advisory entities, the Advisory Board on Prescription Drug Monitoring and the Technical Advisory Committee (TAC) are statutory entities designed to provide assistance to the Prescription Drug Monitoring Program (PDMP). The advisory board is fully appointed, has been operational since 2011, and has met its statutory mandates since the inception of PDMP. However, the duties and membership of TAC were significantly altered by Chapter 147 of 2016, and it is not yet fully operational. PDMP does report that TAC review of PDMP data began at its December 10, 2018 meeting and that unsolicited reports regarding outlier behavior will begin being sent to prescribers in January 2019.

Advisory Board on Prescription Drug Monitoring

PDMP includes an Advisory Board on Prescription Drug Monitoring. The 22-member advisory board makes recommendations on the design, implementation, and funding of the program; provides annual reports to the Governor and General Assembly; and provides general oversight of the program.

Section 21-2A-05 of the Health – General Article requires the advisory board to meet at least three times each year. In addition, the advisory board is required to:

- make recommendations to the Secretary of Health relating to the design and implementation of PDMP, including recommendations relating to regulations, legislation, and sources of funding;

- provide annually to the Governor and the General Assembly a report that includes the number of prescribers and prescriber delegates registered with and using PDMP; the number of pharmacists and pharmacist delegates registered with and using PDMP; the number of disclosures made to federal, State, or local law enforcement agencies; an analysis of the impact of PDMP on patient access to pharmaceutical care and on curbing prescription drug diversion in the State; and any recommendation related to modification or continuation of PDMP;

- provide ongoing advice and consultation on the implementation and operation of PDMP, including recommendations related to changes in the program to reflect advances in technology and best practices in the field of electronic health records and prescription monitoring, changes to statutory requirements, and the design and implementation of an ongoing evaluation component of the program; and

- in conjunction with the Secretary of Health, consult with stakeholders and professionals knowledgeable about prescription drug monitoring programs as appropriate to obtain input and guidance regarding implementation of the program.

Advisory Board Appropriate Size and Includes Necessary Stakeholders

Per statute, the advisory board comprises the following:

- Secretary of Health, or designee;
- President of the State Board of Pharmacy, or designee;
- Chair of the State Board of Physicians, or designee;
- President of the State Board of Nursing, or designee;
- President of the State Board of Dental Examiners, or designee;
- President of the State Board of Podiatric Medical Examiners, or designee;
- Chairman of the Maryland Health Care Commission, or designee;
- four physicians with expertise in clinical treatment using controlled dangerous substances (CDS), including pain management, substance abuse, and behavioral disorders, appointed by the Secretary of Health after consultation with specified stakeholders;
- one nurse practitioner with expertise in clinical treatment using CDS, including pain management, substance abuse, and behavioral disorders, appointed by the Secretary of Health after consultation with the Maryland Nurses Association;
- one pediatrician, appointed by the Secretary of Health after consultation with the Maryland Chapter of the American Academy of Pediatrics;
- three pharmacists who represent the perspective of independent and chain pharmacies, appointed by the Secretary of Health after consultation with the Maryland Pharmacists Association, the Maryland Association of Chain Drug Stores, and any other appropriate organization;
- one local law enforcement official, appointed by the Secretary of Health after consultation with the Maryland Chiefs of Police Association and the Maryland Sheriff's Association;

- Secretary of the State Police, or designee;
- President of the Maryland Association of County Health Officers, or designee;
- one academic or research professional; and
- two Maryland residents who represent the perspective of patients, appointed by the Secretary of Health.

The advisory board is fully appointed, and members serve three-year terms. The Department of Legislative Services' (DLS) interviews of advisory board members and PDMP staff regarding the size and composition of the advisory board indicated that current advisory board members felt that the board, while large, was of appropriate size. Although there were varying suggestions for altering the composition, it was evident that members felt the advisory board provided sufficient stakeholder representation. The board includes 15 clinicians, and suggestions were made to add more nonclinician members for more balanced representation. While the Director of the Maryland Health Care Commission's Center for Health Information Technology and Innovative Care Delivery currently serves on the advisory board (as the designee of the Executive Director), there were suggestions to add an individual with technical expertise in health information technology to the advisory board's composition in the event that this designee no longer serves on the advisory board. Advisory board members consistently stated that they were provided meeting materials in sufficient time to prepare for meetings, meetings were well run, and discussions were robust with actively engaged members. Additionally, members felt their input was heard and considered.

Advisory Board Meets with Appropriate Frequency and Meets Statutory Mandates

Advisory board minutes posted to the PDMP website indicate that the board has met three times annually since 2011. Both the director of PDMP and members of the advisory board interviewed by DLS indicated that this meeting frequency is sufficient. In addition, advisory board members indicated that the board fulfilled the statutory mandates listed prior. DLS observed the solicitation of advisory board member input in the annual report at the August 30, 2018 meeting of the advisory board. In addition, DLS review of PDMP's annual reports found the reports to be comprehensive and in compliance with statutory mandates.

Advisory Board Members Received Inconsistent Training When Appointed to the Board

DLS interviews with advisory board members revealed that training upon appointment to the advisory board was inconsistent, with some members receiving no training, others provided documents to review, and a few having access to a webinar. While many advisory board members, particularly physicians or pharmacists already familiar with PDMP, thought no additional training

was necessary, those members with no prior familiarity with PDMP indicated they could have benefitted from a better overview of the functions of the advisory board, the purpose of PDMP in general, and the structure of Maryland's PDMP program specifically. For other members, this was the first advisory board they had been appointed to, and as such could have benefitted from a brief overview of the general responsibilities of being on an advisory board.

Recommendation 1: PDMP should institute a formal training program for new advisory board members on the responsibilities of members, including meeting protocols, and an overview of PDMP. This training should be applied consistently to new appointees on the advisory board.

TAC Is a Unique Entity

According to a 2016 report from the National Alliance of Model State Drug Laws, 30 states and the District of Columbia require an advisory commission, council, task force, or working group dedicated to the operation of their respective prescription drug monitoring program. As part of this evaluation, DLS reviewed the report to determine whether any other state utilized an entity similar to TAC. The review found three states with similar entities (Illinois, Massachusetts, and West Virginia), with Illinois being the most comparable to the Maryland model.

Illinois Peer Review Subcommittee

Illinois utilizes a peer review subcommittee consisting of three physicians and two pharmacists to establish a formal peer review of the professional performance of prescribers and dispensers and develop communications to transmit to prescribers and dispensers. The peer review subcommittee is required to periodically review the data contained within the prescription drug monitoring program to identify those prescribers or dispensers who may be prescribing or dispensing outside the currently accepted standards in the course of their professional practice. If identified, the peer review subcommittee may send the identified prescriber or dispenser a request for information regarding their prescribing or dispensing practices. The peer review subcommittee is required to refer a prescriber or a dispenser to the Illinois Department of Financial and Professional Regulation in certain situations, and the department may initiate an investigation and discipline.

Massachusetts Medical Review Group

Massachusetts utilizes a Medical Review Group (MRG) to advise the Massachusetts Department of Public Health on accepted medical practice standards related to the disclosure of information under its prescription drug monitoring program. MRG advises the department in the evaluation of prescription information and clinical aspects of the implementation of the program. Members of MRG are licensed health care practitioners and pharmacists and, to the extent feasible, at least one member must be licensed in the same discipline as the practitioner whose records are under review.

West Virginia Database Review Committee

West Virginia has a Controlled Substances Monitoring Program Database Review Committee consisting of two prosecuting attorneys, two physicians with specialties that require extensive use of controlled substances, and a pharmacist who is trained in the use and abuse of controlled substances. The review committee, working independently, may query the database based on parameters established by the program's advisory committee. The review committee may make determinations on a case-by-case basis on specific unusual prescribing or dispensing patterns indicated by outliers in the system or abnormal or unusual usage patterns of controlled substances by patients that the review committee has reasonable cause to believe necessitates further action by law enforcement or the appropriate licensing board. Only in those cases in which there is reasonable cause to believe a breach of professional or occupational standards or a criminal act may have occurred, the review committee must notify the appropriate professional licensing board and appropriate law enforcement agencies and provide pertinent information from the database.

Origin of Maryland's TAC

A review of the legislative history of Maryland's PDMP provides insight on why TAC is unique as compared to other states. TAC was not part of the enacting legislation (Chapter 166 of 2011) as introduced but was added as an amendment proposed by Medchi, The Maryland State Medical Society.

Medchi was opposed to the creation of a prescription drug monitoring program in the State over concerns that the program would have a chilling effect on physician prescribing practices. As such, Medchi was actively involved in proposing amendments to the bill as it moved through the General Assembly. Medchi's final report from April 11, 2011, states:

> "[p]erhaps the most important Medchi amendment was the creation of the physician dominated TAC which consists of five health care professionals (4 doctors and 1 pharmacist). The TAC will review any requests for information from law enforcement prior to the program being allowed to release the information in response to either a judicial subpoena, an administrative subpoena or any legal request. While MedChi supported the Program for its clinical value, it remains extremely skeptical of the law enforcement component. However, the amendment – with the restructuring of the Advisory Committee, the creation of a physician directed TAC and limitation of law enforcement access with recommendations from the TAC, make the legislation considerably more patient friendly than was the case of the beginning."

Role of TAC Still under Development

TAC was established under Chapter 166 and originally consisted of one pharmacist and four physicians with expertise in addiction medicine, pain management, and other areas related to the clinical use of CDS. Initially, PDMP was required to submit requests for prescription monitoring data from a law enforcement agency, licensing board, or an entity within the Maryland Department of Health to TAC for review. TAC was to provide clinical guidance and interpretation of the data to the Secretary of Health and to the entity making the request.

Chapter 651 of 2014 further expanded TAC's role by requiring PDMP to obtain TAC review and feedback before issuing unsolicited reports (reports that are not requested by PDMP users but instead sent by PDMP based on information suggestive of questionable activity) to prescribers and dispensers.

Chapter 147 expanded the membership of TAC and altered its duties. The size of the committee was increased from five to nine members, adding two medical professionals licensed and practicing in the State with expertise or experience in providing care for patients with substance-related or mental health disorders, a licensed dentist practicing in the State, and a medical professional licensed and practicing in the State in the field of internal medicine or family practice. Chapter 147 also altered the duties of TAC by *authorizing* rather than *requiring* TAC review of investigative data requests. In response, PDMP adopted a policy requiring TAC review of investigative requests only when an investigative user requested TAC review. Furthermore, Chapter 147 altered TAC's role regarding unsolicited reports by authorizing review of unsolicited reports concerning indicators of misuse or abuse and requiring review for unsolicited reports concerning possible violations of law or possible breaches of professional standards by prescribers and dispensers.

Chapter 147 requires TAC's review of unsolicited reports focusing on prescriber and dispenser behavior to include review of PDMP data and clinical guidance. The process for TAC's review of these unsolicited reports is under development. According to PDMP, TAC review will supplement quantitative data analysis tools and methods that PDMP will use to identify potentially illegal or inappropriate prescribing or dispensing. PDMP will consider TAC's guidance when determining whether and how to engage a provider about practice issues. The procedures for review of PDMP data to support unsolicited reporting to providers is under development. While PDMP does not submit each unsolicited report regarding possible patient drug misuse or abuse to TAC for review, TAC is consulted regarding the methodology and criteria that is used to identify indicators of misuse or abuse in order to generate the unsolicited reports.

The terms of the original five members of TAC expired in November 2016, and PDMP solicited nominations for nine members in 2016. As of January 2018, TAC was fully appointed. The newest appointed TAC members met once for an in-person training. Otherwise, as of November 2018, there have been two meetings by phone and electronic mail correspondence. There are no guidelines or quorum requirements for TAC meetings, although PDMP staff intends to consider meeting requirements and procedures as PDMP establishes the role of TAC in reviewing unsolicited reports and investigative data requests.

As part of this evaluation, DLS interviewed members of TAC. Members stated that TAC meetings had been productive and that the membership represents the required expertise. Although members understood their role, none of the members had reviewed an unsolicited report based on patient behavior (indicator of possible misuse or abuse) or investigative data request based on implemented policy. TAC members have not reviewed unsolicited reporting data based on prescriber or dispenser behavior as these procedures have been under development, though they have been presented with the priority "red flag" criteria under development for their input. Other members expressed a desire for in-person meetings and for an agenda to be sent in advance of the meetings.

TAC is not yet fully operational and its role is evolving. In the short term, members of TAC should receive clarification regarding their duties. As TAC's role is further defined and the committee becomes operational, PDMP should report to the General Assembly on how it is functioning.

Recommendation 2: As the role of TAC is clarified and the committee becomes operational, PDMP should establish written protocols for TAC, including meeting requirements and the procedures for reviewing unsolicited reports and investigative data requests. PDMP should require at least one in-person meeting of TAC each year.

Recommendation 3: In the annual report required under § 21-2A-05 of the Health-General Article for 2019, PDMP should report to the Governor and the General Assembly on TAC. The report should include (1) the written protocols for TAC meetings and procedures for reviewing unsolicited reports and investigative data requests; (2) a summary of TAC meetings since the implementation of Chapter 147; and (3) recommendations on any changes necessary for TAC to meet the needs of PDMP.

Chapter 4. Mandatory Registration and Use

Mandatory registration requires that anyone authorized to prescribe controlled dangerous substances (CDS) sign up as a clinical user. This allows prescribers to access Prescription Drug Monitoring Program (PDMP) data but does not require any further action. Mandatory registration went into effect on July 1, 2017. Mandatory use, however, requires that prescribers actively query the PDMP system before beginning a new course of treatment for opioids or benzodiazepines and every 90 days thereafter while that course of treatment continues, with limited exceptions. The requirement for mandatory use went into effect a year after mandatory registration on July 1, 2018. This chapter discusses implementation of the mandatory registration and use requirements in Maryland and the number of opioid prescriptions dispensed in Maryland in recent years.

Mandatory Registration Nearing Full Compliance

Chapter 147 of 2016 required all practitioners authorized to prescribe CDS (including physicians, physician assistants, nurse practitioners, nurse midwives, dentists, podiatrists, and veterinarians with CDS prescriptive authority) and all pharmacists to register with PDMP by July 1, 2017.

Exhibit 4.1 shows the percentage of prescribers and pharmacists that were registered with PDMP by October 2016 (one year prior to the mandate) and by August 2018 (10 months following the effective date of the requirement).

Exhibit 4.1
Prescription Drug Monitoring Program Registrations
October 2016 and August 2018

	Individuals Subject to Mandate	Registered Users	Percentage Registered
Prescribers			
Registered October 2016	33,807	20,331	60.13%
Registered August 2018	36,976	32,024	86.61%
Pharmacists			
Registered October 2016	11,296	3,573	31.63%
Registered August 2018	11,854	10,768	90.84%
Total Registered October 2016	**45,103**	**23,904**	**53.00%**
Total Registered August 2018	**48,830**	**42,792**	**87.60%**

Source: Maryland Department of Health

In October 2016, 60.13% of prescribers and 31.63% of pharmacists were registered to use PDMP. By August 2018, 86.61% of prescribers and 90.84% of pharmacists were registered. Chesapeake Regional Information System for Our Patients (CRISP) and PDMP staff continue to conduct outreach through health occupations licensing boards, professional organizations, and health care facilities to educate providers on how to comply with the registration mandate. In November 2017, PDMP staff sent individual letters to over 13,000 providers regarding their noncompliance with registration. Another round of letters was sent in advance of the mandated use effective date of July 1, 2018.

As of February 15, 2018, the Office of Controlled Substances Administration (OCSA) in the Maryland Department of Health began withholding new or renewal CDS registrations to prescribers who were not registered with PDMP. This policy should result in an increase in registered prescribers as CDS registrations expire and come up for renewal.

Stakeholder Collaboration Facilitated Implementation of Mandatory Use

As of July 1, 2018, prescribers are required to query PDMP prior to beginning a course of treatment that includes prescribing or dispensing an opioid or a benzodiazepine. Prescribers must continue to query PDMP every 90 days thereafter while the course of treatment continues, with limited exceptions.

In anticipation of the mandated use or query requirement, PDMP, in collaboration with CRISP, the Maryland Addiction Consultation Service (MACS), and the Maryland State Medical Society (commonly referred to as MedChi), took several steps to prepare providers. Mass emails with information about mandatory use were sent to all registered users of PDMP in May and June 2018. Additionally, a letter from the Secretary of Health and a use mandate fact sheet was sent to all prescribers registered with OCSA and to all pharmacists licensed in Maryland. A help line was also set up to answer questions related to mandatory use, with CRISP operation support handling technical questions, MedChi handling inquiries regarding implementation of mandatory use, and MACS handling clinical questions. Questions received during this period were also integrated into frequently asked questions on the PDMP website. Other outreach measures included emails to health occupations licensing boards, professional organizations, health officers, Beacon Health, and the Maryland Medicaid program. PDMP also created a video on how to comply with the mandate, which was added to the PDMP website.

Many of the complaints related to registering for and using PDMP before the mandatory use requirement related to the extra time required to log in to a separate system that was often slow and unreliable. However, when PDMP became integrated with CRISP, many of these concerns were alleviated. Feedback from a MedChi representative indicated that members found that the integration of PDMP into CRISP has provided much faster access.

Number of Opioid Prescriptions Has Declined Significantly Following Implementation of Mandatory Registration and Use

Exhibit 4.2 highlights the number of opioid prescriptions dispensed during the first nine months of each year from 2014 through 2018. After increasing by 10.34% from 2014 to 2015, the number of opioid prescriptions began decreasing in 2016. Although mandatory registration went into effect July 1, 2017, the number of opioid prescriptions dispensed fell by 12.42% in 2017.

Exhibit 4.2
Total Number of Opioid Prescriptions Dispensed
2014-2018

Year	Prescription Count	% Change Over Prior Year
2014	2,755,810	n/a
2015	3,040,897	10.34%
2016	2,932,764	-3.56%
2017	2,568,538	-12.42%
2018	2,255,274	-12.20%

Note: Data reflects prescriptions dispensed January 1 through September 30 of each year. Opioid prescriptions include all prescriptions containing a medication in the opioid class of drugs except medications containing buprenorphine in a formulation indicated for the treatment of opioid use disorder.

Source: Maryland Department of Health

With mandatory registration being in effect for all of 2018 and mandatory use going into effect on July 1, 2018, the number of opioid prescriptions dispensed decreased by 12.20%. Comparing the number of opioid prescriptions dispensed in 2016, when neither mandatory registration nor mandatory use was in effect, to the number dispensed in 2018, when mandatory registration was in effect and mandatory use was in effect for three of the nine months covered, there is a reduction of 23.10%, or 677,490 fewer opioid prescriptions dispensed.

Recommendation 4: PDMP should continue outreach efforts to prescribers and pharmacists and monitor such efforts until functional full compliance with the mandatory registration mandate is achieved.

Chapter 5. Investigative Users

One objective of prescription drug monitoring programs is to aid in the enforcement of laws and regulations governing controlled dangerous substances (CDS). Therefore, law enforcement, the Maryland Department of Health (MDH), and State licensing boards are given access to Maryland's Prescription Drug Monitoring Program (PDMP) data under certain circumstances to aid them in their investigations of illegal prescribing, dispensing, and procuring of CDS. This chapter addresses the number of investigative users registered with and using PDMP and discusses issues with the process for requesting investigative data for certain licensing boards.

Investigative Use of Prescription Monitoring Data Required by Law

Maryland's PDMP is required to provide data to the following entities for the purpose of furthering existing *bona fide*, individual investigations:

- federal, State, or local law enforcement agencies on issuance of a subpoena;
- specified State licensing boards on issuance of an administrative subpoena voted on by a quorum of the board;
- five entities within MDH on approval of the Secretary of Health (specifically, the Office of the Chief Medical Examiner, the Office of the Inspector General, the Office of Health Care Quality, the Medical Care Programs Administration, and the Office of Controlled Substances Administration); and
- multiple fatality review entities (specifically the State Child Fatality Review Team, the Maternal Mortality Review Program, a local child fatality review team, a local drug overdose fatality review team, or a health occupations medical review committee).

Before receiving a unique investigative user account, all investigative requesters are required to be trained by PDMP on the purposes and uses of the program and on how to make investigative requests. On March 21, 2014, PDMP initiated investigative data requesting functionality and, as of August 31, 2018, there were 240 registered investigative users.

Exhibit 5.1 shows the number of registered users by type of agency. Between calendar 2015 and 2018, the number of total registered investigative users grew by 75.18%. The largest growth in registrations was among law enforcement users (68.05%), with more gradual growth among licensing boards (29.72%) and MDH entities (10.71%).

Exhibit 5.1
Number of Registered Investigative Users
2015-2018

Type of Agency	2015	2016	2017	2018
Federal, State, and Local Law Enforcement	72	90	97	121
Licensing Board	37	40	43	48
Maryland Department of Health Entity	28	29	30	31
Fatality Review Entity	0	11	29	40
Total	**137**	**170**	**199**	**240**

Note: Data reflects the number of registered investigative users as of October 31, for 2015 through 2017, and as of August 31 for 2018.

Source: Maryland Department of Health

Investigative Use of Data Growing, Highest Among Law Enforcement Entities

As shown in **Exhibit 5.2,** as the number of registered investigative users has increased, so too has the number of authorized requests from investigative users. Between 2015 and 2018, the total number of authorized requests increased by 702.08%. The number of requests from all types of agencies has increased, most significantly among law enforcement (524.19%).

Exhibit 5.2
Number of Authorized Requests from Investigative Users
2015-2018

Type of Agency	2015	2016	2017	2018
Federal, State, and Local Law Enforcement	434	891	1,871	2,709
Licensing Board	12	43	175	289
Maryland Department of Health Entity	34	65	79	154
Fatality Review Entity	0	89	454	689
Total	**480**	**1,088**	**2,579**	**3,850**

Note: Data reflects the number of authorized requests as of October 31, for 2015 through 2017, and as of August 31 for 2018.

Source: Maryland Department of Health

In each individual year, law enforcement agencies account for between 48.74% and 52.94% of total registered users, while requests from law enforcement agencies comprise 85.94% to 90.42% of total investigative requests. On average, each law enforcement registered user made 22.38 requests per year, while licensing board, MDH users, and fatality review teams made 6.02, 4.96, and 17.45 requests per user, respectively. Some of this disparity in requests among user types can be accounted for by case volumes for law enforcement compared to entities within MDH. Lower requests from licensing boards likely reflect subpoena requirements, and licensing boards often subpoena pharmacies directly to get similar data.

Process for Requesting Data Too Restrictive for Licensing Boards

As part of this evaluation, the Department of Legislative Services (DLS) spoke with representatives from the health occupations licensing boards that access PDMP, including the boards of nursing, physicians, dental examiners, pharmacy, and podiatric medical examiners. While overall feedback on the program was positive, some boards expressed concerns about the process for requesting data from PDMP and the accuracy of PDMP data.

PDMP must disclose prescription monitoring data to a licensing entity other than the State Board of Physicians (MBP) on issuance of an administrative subpoena voted on by a quorum of the board of the licensing entity and only for purposes of furthering an existing *bona fide*, individual investigation. PDMP must disclose prescription monitoring data to MBP on issuance of an administrative subpoena voted on by a quorum of a disciplinary panel for the purpose of furthering an existing *bona fide* investigation of an individual. The subpoena process for MBP differs from the other boards because that board has two disciplinary panels.

The State Board of Nursing and MBP raised concerns about the requirement for an administrative subpoena voted on by a quorum of the board or disciplinary panel when requesting PDMP data. The State Board of Nursing meets monthly and has to wait for a board meeting in which a quorum is present each time the board wants to subpoena PDMP data. While waiting for the board to meet to vote on the subpoena, the State Board of Nursing requests PDMP data directly from the pharmacy. Likewise, MBP stated that the requirement for a vote of approval by a disciplinary panel is an additional unnecessary step and that MBP subpoenas the pharmacy directly.

The data requested by licensing boards must be in furtherance of an existing *bona fide*, individual investigation; MBP and the State Board of Nursing are subpoenaing the pharmacies directly when conducting investigations. If the additional requirement for board approval of the subpoena is removed, the receipt of information can be accelerated and should include all of the prescriptions from the prescriber. This would provide for a more accurate, complete, and expeditious process than subpoenaing each pharmacy that may have dispensed prescriptions of the prescriber and subsequently compiling the data.

Furthermore, MBP identified issues with having to issue multiple subpoenas to get the data it seeks. The State Board of Dental Examiners, the State Board of Pharmacy, and the State Board of Podiatric Examiners did not have issues with the administrative subpoena process. The State Board of Dental Examiners meets twice monthly, so voting on subpoenas can be done in a timely manner. The State Board of Podiatric Medical Examiners has only subpoenaed PDMP data on one occasion and had no issues.

In addition to issues regarding the subpoena process, MBP raised concerns about the reliability of PDMP data. For example, the board cited issues with patients being attributed to the incorrect doctor. Representatives from MBP have discussed these concerns with PDMP staff, who are working with MBP to figure out where data entry errors are occurring in order to ensure data quality moving forward. The other licensing boards interviewed by DLS did not express concerns with the accuracy of PDMP data.

Recommendation 5: Statute should be amended to remove the requirement for the vote of a quorum of the board or disciplinary panel when a licensing entity requests prescription monitoring data.

Recommendation 6: MBP should continue to work with PDMP to address concerns regarding the accuracy of PDMP data.

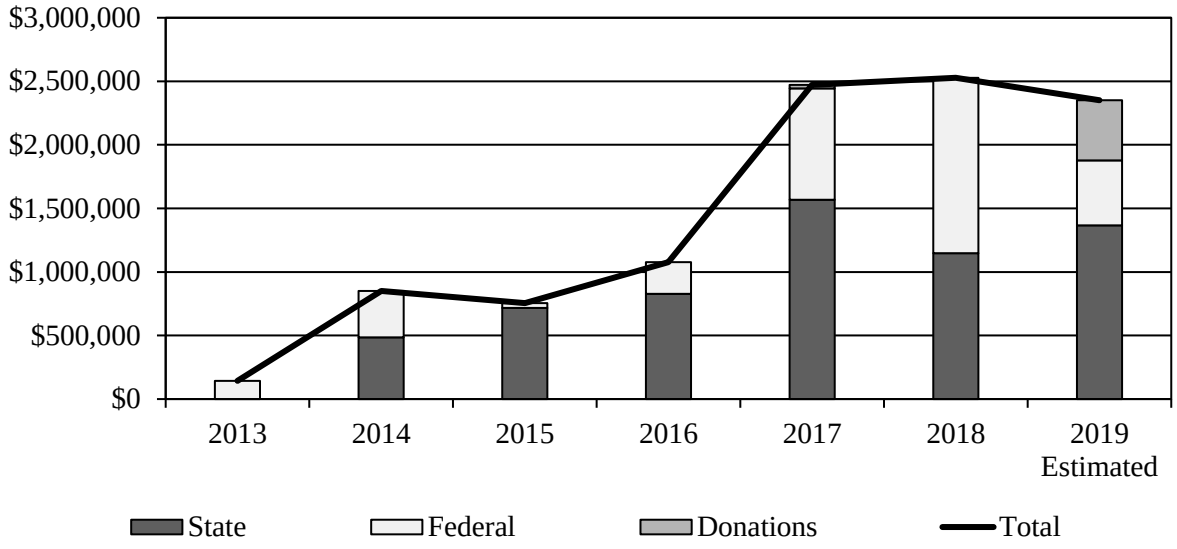
Chapter 6. Resources and Administration

Maryland's Prescription Drug Monitoring Program (PDMP) is primarily supported through general funds appropriated through the State budget. Unlike many of the State health occupations boards typically reviewed through the sunset evaluation process, which are self supported through user fees from individuals regulated by the board, PDMP is free for users to register and use. Indeed, Chapter 166 of 2011 prohibited the imposition of fees for prescribers and dispensers to support operation of PDMP. The PDMP budget is housed within the Behavioral Health Administration (BHA) in the Maryland Department of Health (MDH).

This chapter discusses the fiscal status and personnel resources of PDMP. The Department of Legislative Services (DLS) finds that PDMP has historically managed finances well and succeeded in securing federal grants for planning, implementation, operations, and enhancements to the system. Additionally, PDMP has obtained significant funding through private donations. Expansion of PDMP responsibilities has necessitated growth in expenditures in recent years.

As shown in **Exhibit 6.1**, PDMP expenditures have increased significantly since the program became operational, rising to more than $2.5 million in fiscal 2018.

Exhibit 6.1
Expenditure History of the Prescription Drug Monitoring Program
Fiscal 2013-2019 Estimated



Note: The Prescription Drug Monitoring Program became operational in fiscal 2012. Reimbursable funds in fiscal 2013 and 2014 from federal grants to the Governor's Office of Crime Control and Prevention are included in this chart as federal funds.

Source: Maryland Department of Health; Department of Legislative Services

Federal Grants Provided Significant Funding for Program

MDH has been awarded federal funds for PDMP through multiple funding streams. Federal grant awards between federal fiscal 2009 and 2013 were awarded from the Harold Rogers Prescription Drug Monitoring Program to support implementation and operations. All federal grant awards after those years have been for the purpose of expansion of the system.

Since fiscal 2011, MDH has received a total of $1.3 million in federal grants from the federal Harold Rogers Prescription Drug Monitoring Program for PDMP-related purposes. The first Harold Rogers grants funded planning and implementation of PDMP. In fiscal 2012, MDH received $400,000 in Harold Rogers funding for PDMP operations. Subsequent awards have funded PDMP-related data projects rather than direct operation costs or, as is the case for the most recent awards, funded non-PDMP-related opioid fatality reviews.

As shown in **Exhibit 6.2**, federal funds initially played a significant role in implementation and operations of PDMP. In fiscal 2017 and 2018, most federal funds were expended to support specific federal initiatives to enhance or expand the program, as discussed further in this chapter.

Exhibit 6.2
Federal Fund Expenditures by the Prescription Drug Monitoring Program
Fiscal 2013-2018

	2013	2014	2015	2016	2017	2018	Total
Implementation and Operations	$143,591	$363,422	$37,694	$228,764	$51,941	$0	$825,412
PRECOG	0	0	0	75	224,368	250,178	474,621
CDC-PfS	0	0	0	18,749	600,458	1,129,152	1,748,359
Total	**$143,591**	**$363,422**	**$37,694**	**$247,588**	**$876,767**	**$1,379,330**	**$3,048,392**

CDC-PfS: U.S. Centers for Disease Control and Prevention's Prescription Drug Overdose Prevention for States
PRECOG: Harold Rogers Prescription Drug Monitoring Program Predictive Risk Evaluation to Combat Overdose Grant

Note: Federal funds for implementation and operations are through Harold Rogers Prescription Drug Monitoring Program grants. An additional $268,945 of the PRECOG grant remains as of the close of fiscal 2018.

Source: Maryland Department of Health; Department of Legislative Services

In 2015, MDH was awarded a multi-year grant totaling $743,566 for the Harold Rogers Prescription Drug Monitoring Program Predictive Risk Evaluation to Combat Overdose Grant (PRECOG). Between fiscal 2016 and 2018, MDH expended $474,621 of the PRECOG award amount. It is anticipated that the remainder of the grant award will be spent in fiscal 2019 and 2020. This project is in collaboration with the Chesapeake Regional Information System for Our

Patients (CRISP) and researchers at The Johns Hopkins University and combines PDMP data with multiple other health and criminal justice data sets. Results of the project are intended to be implemented in PDMP program activities, will be disseminated to applicable stakeholders, and may inform future analyses.

MDH has been awarded approximately $3.7 million in federal funds from the U.S. Centers for Disease Control and Prevention's Prescription Drug Overdose Prevention for States (CDC-PfS) grant. Only a portion of the CDC-PfS award is spent on PDMP. The CDC-PfS grant funds multiple programs throughout MDH and is intended to provide state health departments with resources and support needed to advance interventions for preventing prescription drug overdoses. Within PDMP, $1.7 million from CDC-PfS was expended to support one-time information technology enhancements, activities to support the registration and use mandate, dashboards for State and local public health use, and expansion of in-house data analytics. Two positions are supported through CDC-PfS. Expenditures from this grant are budgeted in a separate program within BHA. This project is funded through August 2019.

Donations Have Supplanted Other Expenditures in Recent Years

Between fiscal 2016 and 2018, the Chesapeake Employers Insurance Company (CEIC) made a donation of $750,000 to PDMP in three installments of $250,000. This donation has been used to fund PDMP operations. In recent years, as federal funding for operations has declined, this donation has allowed operations to remain level funded.

In fiscal 2017, PDMP expended $27,312 in donations from CEIC, and the fiscal 2018 budget included $250,000 from CEIC. However, the funds were not expended at the close of the fiscal year. The fiscal 2019 PDMP budget includes $472,688 from CEIC. In future years, PDMP will likely have to budget additional general funds to maintain operating expenditures at current levels.

PDMP is unique in that it is a public-facing and well-known part of the response to the opioid crisis. In that respect, there may be additional opportunities for solicitation of private donations. **As federal fund awards focus less on day-to-day operations, PDMP should consider soliciting additional private donations to fund operating expenses.**

Soliciting donations for PDMP operations is not unprecedented. Florida established the Florida PDMP Foundation, a not-for-profit corporation, for the purpose of soliciting donations for Florida's PDMP. The foundation reported raising over $2.9 million in supplemental funds since its inception. To date, Florida is the only state to actively solicit donations for this purpose.

Contractual Spending Drives Expenditures

As shown in **Exhibit 6.3**, contractual spending comprises the largest portion (78.99%) of PDMP's fiscal 2019 budget. The largest share of this spending ($0.9 million) is for the electronic infrastructure through CRISP, while an additional $347,718 is budgeted to fund the registration mandate and querying of PDMP.

Exhibit 6.3
Prescription Drug Monitoring Program Expenditures by Category
Fiscal 2014-2019 Estimated

	2014	2015	2016	2017	2018	Estimated 2019
Personnel	$156,536	$381,836	$394,479	$337,732	$343,071	$388,301
Contractual	689,221	362,774	650,194	1,438,499	1,623,736	1,482,101
Other	3,544	11,416	12,961	4,382	7,124	5,799
Total	**$849,301**	**$756,026**	**$1,057,634**	**$1,780,613**	**$1,973,931**	**$1,876,201**

Note: Does not include expenditures from the U.S. Centers for Disease Control and Prevention's Prescription Drug Overdose Prevention for States.

Source: Maryland Department of Health; Department of Legislative Services

Growth in contractual spending is the largest driver of budgetary growth. Between fiscal 2014 and 2015, personnel expenses increased significantly from $156,536 to $381,836. Contractual expenses were nearly halved in that same time period, from $689,221 in fiscal 2014 to $362,774 in fiscal 2015. Personnel costs have remained relatively level since 2015. Contractual costs grew by 179.22% in fiscal 2016 to $650,184 and continued growing through fiscal 2017 and 2018 to $1.4 million and $1.6 million, respectively. Exhibit 6.3 does not account for expenditures through the CDC-PfS grant that is also primarily contractual spending.

Program Relies on Contracts for Personnel Needs

As shown in **Exhibit 6.4**, PDMP has 10 total positions. PDMP is budgeted 5.0 full-time equivalent positions in fiscal 2019. As of September 2018, 1.0 regular position is vacant. PDMP has 5.0 contractual positions, 3.0 of which are vacant. PDMP relies heavily on contracts for personnel needs. Two positions – a database specialist and special programs coordinator – are filled through a contract with the Maryland Institute for Policy Analysis and Research. In total, 50% of the positions at PDMP are contractual.

Exhibit 6.4
Prescription Drug Monitoring Program Positions
Fiscal 2019

Position Type	Description	Fund Source
Regular	Director, PDMP/OPADP (Program Manager III)	General Funds
Regular	PDMP Secretary (Office Secretary III)	General Funds
Regular	PDMP Coordinator (Health Policy Analyst III)	General Funds
Regular	Manager, Special Programs (Administrator IV)	General Funds
Regular	Epidemiologist I	General Funds
Contractual	Assistant Director, PDMP/OPADP (Program Manager II)	General Funds
Contractual	PDMP Data Quality Specialist (Admin. Officer III)	General Funds
Contractual	Epidemiologist I	Federal CDC-PfS
Contractual	Database Specialist	General Funds
Contractual	Administrator I	Federal CDC-PfS

CDC-PfS: Centers for Disease Control and Prevention and Prevention Prescription Drug Overdose Prevention for States grant
OPADP: Overdose Prevention Applied Data Program
PDMP: Prescription Drug Monitoring Program

Source: Maryland Department of Health; Department of Legislative Services

In some cases, such as when a position is funded through a federal grant, filling a contractual position may be necessary. PDMP has two positions that are fully funded through federal grants and should remain contractual positions. However, two positions that are likely regular – the assistant director and the data quality specialist – are currently contractual. MDH indicated that the assistant director is being converted to a regular position and recruitment is ongoing. **MDH should examine its contractual personnel to determine whether any other positions should be converted to regular positions.**

PDMP indicated that staff are currently operating at or above capacity, specifically citing difficulties recruiting and retaining staff as the main obstacle. Recruitment for new staff is time-consuming, and the small size of the office makes it difficult to execute program requirements while also recruiting and training new staff. Once the four vacant positions are filled, the workload will be more manageable. However, any expansion of PDMP duties will necessitate additional staff.

Three of the four current vacancies have been vacant for less than six months, while the fourth vacancy has never been filled. PDMP conducted a recruitment for the fourth vacancy, but

it was unable to be filled. The job description for that position as well as two of the three other vacancies are being revised before re-recruitment.

Program Website Comprehensive and Valuable Resource for Users

The PDMP website is a comprehensive compilation of information regarding the program. The website contains links to the law and regulations for PDMP, annual reports and required legislative reports, forms for requesting exemptions, and advisory board meeting schedules and minutes. Also included is a link with information on how to request PDMP data and how to receive the required training when requesting data. The website includes information for providers on the mandated registration and use requirement that features an explanatory video and frequently asked questions with links for providers explaining the registration and use requirements.

The website also includes clinical resources with information on educational and training resources designed to assist providers with improving treatment of patients with substance use and mental health disorders, chronic pain, or other health problems affected by the use or misuse of controlled dangerous substances prescriptions. PDMP keeps the website up to date, with the only lag in updating advisory board meeting minutes. DLS often used the information from the website in preparation of this evaluation and found that the information contained in the website to be useful and reliable.

The website can be found at https://bha.health.maryland.gov/pdmp/Pages/Home.aspx.

Chapter 7. Best Practices and Policy Issues

Prescription drug monitoring programs operate differently across the country. The Prescription Drug Monitoring Training and Technical Assistance Center at Brandeis University (TTAC) keeps data on prescription drug monitoring programs nationally to develop a Best Practice Checklist. This checklist allows states to compare their own prescription drug monitoring programs to advances across the nation and to gain insight into tools they may want to institute within their own state programs. This chapter reviews national best practices, including those that have and have not been implemented in Maryland. The chapter also describes current barriers to interstate sharing of prescription drug monitoring data.

Maryland Follows Almost All Best Practices for Prescription Drug Monitoring

Forty-four states had operational prescription drug monitoring programs in place by 2012, making Maryland one of the last states in the nation to adopt a prescription drug monitoring program. However, in the five years since Maryland's Prescription Drug Monitoring Program (PDMP) has been operational, the program has met nearly every suggested best practice.

TTAC's prescription drug monitoring program Best Practice Checklist for states was last updated in 2017. **Exhibit 7.1** highlights Maryland's implementation of the checklist to date. A more detailed comparison of Maryland's PDMP with the checklist is provided in **Appendix 1**. The best practices that Maryland has not yet implemented involve unsolicited reporting to prescribers and dispensers, user-led reports, and requiring identification from the individual picking up a prescription.

Exhibit 7.1

Maryland's Implementation of the Most Highly Recommended Practices From the Best Practice Checklist

Best Practice	Rationale	Maryland
Adopt the latest American Society for Automation in Pharmacy standards.	Uniform data collection standards facilitate improved data quality, data analysis, and interstate data sharing.	✓ The latest ASAP version is currently used in Maryland.
Integrate prescription drug monitoring program data with health information exchanges.	Simplifying the method of access for prescribers and dispensers makes it more likely the information will be used.	✓ PDMP data has been integrated with CRISP, Maryland's health information exchange.
Send unsolicited reports and alerts to appropriate users regarding patient activity.	Reports sent proactively to prescribers/dispensers notifying them that a patient may be engaged in questionable activity.	✓ PDMP proactively sends out notifications to prescribers regarding questionable patient activity.
Send unsolicited reports to appropriate users regarding prescriber/dispenser activity.	Reports sent proactively regarding inappropriate or illegal prescribing/dispensing behavior.	PDMP legislation *authorizes* unsolicited reports, but this functionality has not been implemented to date, but PDMP indicates that it will be operational in January 2019.
Allow for user-led reports on patient behavior to mutual prescribers and dispensers.	Enabling providers to send alerts as part of their medical practice increases the proactive dissemination of prescription drug monitoring data on potentially questionable activity by a patient.	User-led reports is an innovative unsolicited reporting mechanism that is currently in use by only 14% of prescription drug monitoring programs nationally. It has not been implemented in Maryland.
Collect data on method of payment for prescriptions, including cash transactions.	The method by which a person pays for their prescription can be an indicator of possible questionable activity, especially when cash is used.	✓ Maryland dispensers are required to enter a classification code for the type of payment rendered.
Collect positive identification for the person picking up prescriptions.	Collecting this information aids in an investigation following a suspected prescription diversion or fraud incident.	PDMP only collects identification information on the patient.

Best Practice	**Rationale**	**Maryland**
Reduce data collection interval.	More timely information is of greater use to authorized users; therefore, moving toward real time data collection increases the utility of prescription drug monitoring data for clinical practice.	✓ Maryland has moved from 7-day collection to 3-day collection to daily collection, though data is not yet available in real time.
Mandatory program enrollment for prescribers and dispensers.	Requiring prescribers and/or dispensers to enroll with the prescription drug monitoring program increases the likelihood that the data will be used in clinical care and dispensing.	✓ As of July 1, 2017, all licensed pharmacists and all physicians authorized to prescribe CDS must be registered.
Mandatory utilization for prescribers in clinical settings.	Mandating utilization seeks to increase the number of prescribers using prescription drug monitoring data for clinical care, particularly in specified circumstances.	✓ As of July 1, 2018, all prescribers are required to query PDMP when prescribing CDS and every 90 days thereafter.[1]
Allow for delegate users to access prescription drug monitoring data.	Allowing office staff to access prescription drug monitoring data on behalf of prescribers allows more time for the prescribers to treat patients.	✓ Allows for delegate users to access PDMP data on behalf of a specified prescriber.
Enact and implement interstate data sharing among prescription drug monitoring programs.	Data sharing among states helps give a prescriber a more accurate picture of a patient's prescription history, especially in bordering states.	✓ Currently connected with one interstate hub with 7 states.[2] Connecting with a second hub.

ASAP: American Society for Automation in Pharmacy
CDS: controlled dangerous substance
CRISP: Chesapeake Regional Information System for our Patients
PDMP: Prescription Drug Monitoring Program

[1] With limited exception as discussed in Chapter 1.
[2] Arkansas, Connecticut, District of Columbia, Minnesota, Pennsylvania, West Virginia, and Virginia

Source: Department of Legislative Services

Much of the discussion around best practices for prescription drug monitoring programs centers on unsolicited reporting, including the appropriate recipients of the reports, report content, and the manner of sending reports. State prescription drug monitoring programs have incorporated various methods for addressing unsolicited reporting.

Prescription drug monitoring programs typically share prescription history information in one of two ways: (1) on request of authorized users (solicited reports); or (2) by proactively sending reports of data suggestive of questionable activity involving controlled dangerous substances (CDS), such as doctor shopping or illicit prescribing and dispensing (unsolicited reports). Unsolicited reporting to prescribers, dispensers, licensing boards, and law enforcement agencies is recognized as a best practice for prescription drug monitoring programs nationally.

Unsolicited Reporting on Patient Activity Adopted in Maryland

Most commonly, unsolicited reports are sent to prescribers about questionable patient activity. Approximately 81% of prescription drug monitoring programs, including Maryland, send reports to prescribers. These reports help to identify patients who may be "doctor shopping," abusing or diverting CDS, or receiving unsafe amounts or combinations of prescription medications. These types of reports help practitioners make better decisions about prescribing and dispensing CDS, thus improving clinical care. Since January 2016, Maryland's PDMP has sent unsolicited reporting notifications to prescribers regarding patients with multiple provider episodes, which is a key indicator of misuse or abuse.

User-led Reporting Adopted in a Few States

A few states have developed user-led reports. This type of reporting allows a provider who has retrieved prescription drug monitoring data suggestive of a patient's questionable activity to send alerts to other providers who are treating the same patient. Allowing providers to do this as part of their medical practice increases the proactive dissemination of prescription drug monitoring data on potentially questionable activity by a patient with virtually no cost to the program. User-led reporting is an innovative unsolicited reporting mechanism that is currently only used by 14% of prescription drug monitoring programs nationally, but it is already part of the Best Practice Checklist.

Unsolicited Reporting on Prescriber and Dispenser Behaviors Vary Among States and Is Under Development in Maryland

While unsolicited reporting of prescriber and dispenser behaviors is also considered a best practice, it is less common than patient reporting. Some states send reports on providers to licensing boards (61%), some states send reports directly to law enforcement (47%), and others have developed peer review committees that receive reports. States have also developed unsolicited reports of providers that get reported directly back to the provider in the form of a notification, letter, or report card.

Some stakeholders express concerns about health care versus law enforcement uses of prescription drug monitoring data, particularly with regard to protection of personally identifiable health information. The amount of information contained in prescription drug monitoring programs raises concerns about privacy and data security. The American Medical Association (AMA) recommends that information from prescription drug monitoring programs be used first for education of the specific physicians involved prior to any civil action against these physicians. Additionally, the American Society of Addiction Medicine (ASAM) has expressed concern about the use of prescription drug monitoring data by those outside the health care system. Both AMA and ASAM stress the need to subject prescription drug monitoring data to the same standards applied to other patient medical records.

Although Chapter 147 of 2016 authorized unsolicited reporting, Maryland has not to date sent unsolicited reports on prescriber and dispenser behavior. Issues that have prevented implementation include limitations on the data that PDMP has access to and the need to establish the appropriate thresholds for generating reports. For instance, PDMP data does not capture a prescriber's specialty, which is information that is key to developing an unsolicited reporting mechanism.

Maryland's PDMP is currently developing unsolicited reports for prescribers regarding their own prescribing behavior. PDMP is developing an appropriate methodology and messaging so that PDMP continues to be a clinical support tool for users.

Recommendation 7: To allow more meaningful analysis, PDMP should collect additional data, specifically provider specialty information, before implementing unsolicited reporting on prescribers and dispensers.

Red Flags Project Could Assist in Future Unsolicited Reports

Maryland's PDMP is engaged in developing red flag alerts in conjunction with the Chesapeake Regional Information System for our Patients that will put data analysis of a patient's whole PDMP record directly in the electronic health record. This prevents a prescriber from having to do his or her own analysis of the raw data for each patient. Additionally, PDMP will be able to identify high-risk prescriber, dispenser, and patient behavior that could result in an unsolicited reporting notification with the offer of relevant educational resources. The goal is to alert providers to high-risk behavior and create pathways to behavior modification through educational outreach and assistance to decrease high-risk behaviors.

These red flags are designed to be clinically useful regarding a variety of notifications such as multiple open opioid prescriptions and cross-prescribed benzodiazepine and opioid prescriptions. Maryland's PDMP has successfully implemented a red-flag notification designed to notify prescribers when a patient has had a recent nonfatal overdose hospital event. The steps to developing more red-flag notifications are incremental, as feedback from clinical users must be integrated with information technology algorithms.

Collecting Identification Information on the Individual Picking Up a Prescription Could Aid Fraud and Diversion Investigations

While Maryland remains in the majority of programs that collect only the patient's identification at the time of dispensing, a recommended best practice implemented in 11 states is to collect identification for the individual picking up a prescription. Many times the individual at the pharmacy counter retrieving a prescribed medication is not the patient to whom the medication was prescribed. There have been accounts of a patient's family member or friend obtaining the medication from the pharmacy without the patient's consent or knowledge. Collecting identification of the individual picking up the prescription would aid in investigations following a suspected prescription diversion or fraud incident.

Recommendation 8: PDMP should work with the State Board of Pharmacy to determine the feasibility of gathering information on the identification of the individual picking up a monitored prescription at the time it is dispensed.

Maryland's Statute Impedes Interstate Data Sharing

Interstate sharing of prescription drug monitoring data helps to ensure that prescribers have a complete picture of their patients' prescription history. While Maryland law does not hinder PDMP from receiving information from other states' prescription drug monitoring programs, it does limit authorized users of prescription drug monitoring programs in other states from using data from Maryland's PDMP in certain electronic health record (EHR) integrations. For instance, Maryland currently shares data with West Virginia's prescription drug monitoring program through an interstate data sharing hub. Data flows between each state's PDMP through the hub, and Maryland PDMP data is authorized for view within the West Virginia PDMP interface for any authorized West Virginia clinical user. However, this does not mean that prescription drug monitoring program users in West Virginia have access to Maryland data in every EHR integration authorized by the West Virginia PDMP. This occurs because the statute authorizes PDMP data sharing with another state's prescription drug monitoring program but not with the authorized users of another state's prescription drug monitoring program, and thus data must flow through the other state's PDMP before being disclosed to an authorized end user.

Recommendation 9: Statute should be amended to allow authorized users of other states' prescription drug monitoring programs to access Maryland's prescription monitoring data.

Recommendation 10: Interstate data sharing agreements should be modified to ensure access of Maryland's PDMP users to other connected States' prescription drug monitoring program data.

Unsolicited Reporting of Prescriber and Dispenser Behavior to Law Enforcement or Licensing Boards

The most controversial policy issue related to PDMP involves the mandatory unsolicited reporting of prescriber and dispenser behavior to law enforcement or professional licensing boards. As discussed earlier, PDMP is currently authorized to make unsolicited reports of prescriber and dispenser behavior and is developing methodologies to implement unsolicited reporting.

Chapter 147, which authorized unsolicited reporting, also required the Maryland Department of Health (MDH) to recommend whether PDMP's authority should be expanded to allow unsolicited reporting to law enforcement agencies, health occupations licensing boards, or other units of MDH. The 2017 MDH report noted that PDMP was identifying patients with multiple provider episodes and continuing to work with partner academic researchers to develop code to "red flag" high-risk provider, dispenser, and patient behavior. MDH also indicated that, rather than expanding unsolicited reporting, the department's focus was on implementing mandatory registration and use deadlines and enhancing the operational coordination and effectiveness of the Office of Controlled Substances Administration (OCSA).

House Bill 88 and Senate Bill 1083 of 2018 would have required PDMP to review prescription monitoring data for indications of (1) possible misuse or abuse of a monitored prescription drug; or (2) a possible violation of law or breach of professional standards by a prescriber or dispenser. If either was indicated, PDMP would have been required to notify and provide education to the prescriber or dispenser.

The House of Delegates and Senate of Maryland passed different versions of these bills regarding the action to be taken by PDMP when finding a possible violation of law or breach of professional standards. As passed by the House of Delegates, PDMP would have been authorized to provide prescription monitoring data to OCSA for further investigation. However, if such data was provided to OCSA, PDMP would have been required to notify the prescriber or dispenser. As passed by the Senate, if a possible violation of law or breach of professional standards was indicated, PDMP would have been required to (1) notify the appropriate health occupations board if the Technical Advisory Committee (TAC) made a recommendation for a referral and found a probable violation of law or breach of professional standards; and (2) provide the board with the data necessary for an investigation.

On review of the bill files for House Bill 88 and Senate Bill 1083, testimony in opposition to the bills indicated that the referral of prescriber behavior to law enforcement or licensing boards was believed to be premature, undermine the objectives of PDMP, and negatively impact MDH's efforts to enhance the enforcement activities of OCSA. Additional testimony noted that PDMP was in the process of implementing mandatory registration and use deadlines and that provisions that increase the responsibility of PDMP would be best implemented after the system has demonstrated it can effectively handle the increase in utilization. Testimony submitted in support of the bills stated that MDH's required report under Chapter 147 indicated that PDMP was ready

and able to make unsolicited reports to a health occupations licensing board or to law enforcement, as appropriate.

The Maryland State Medical Society ultimately supported the Senate version of the bill, since a recommendation from TAC was required and referrals were made to health occupations licensing boards. Although both chambers passed different versions of the bills, the session ended before a compromise was reached. Now that mandatory registration and use has been implemented, legislation regarding mandatory unsolicited reporting is likely to be considered again.

Although TAC has been appointed and met, its role remains under development. In order to expand PDMP's functionality to include mandatory unsolicited reporting with TAC review, the committee should be fully operational and capable of fulfilling any expanded duties.

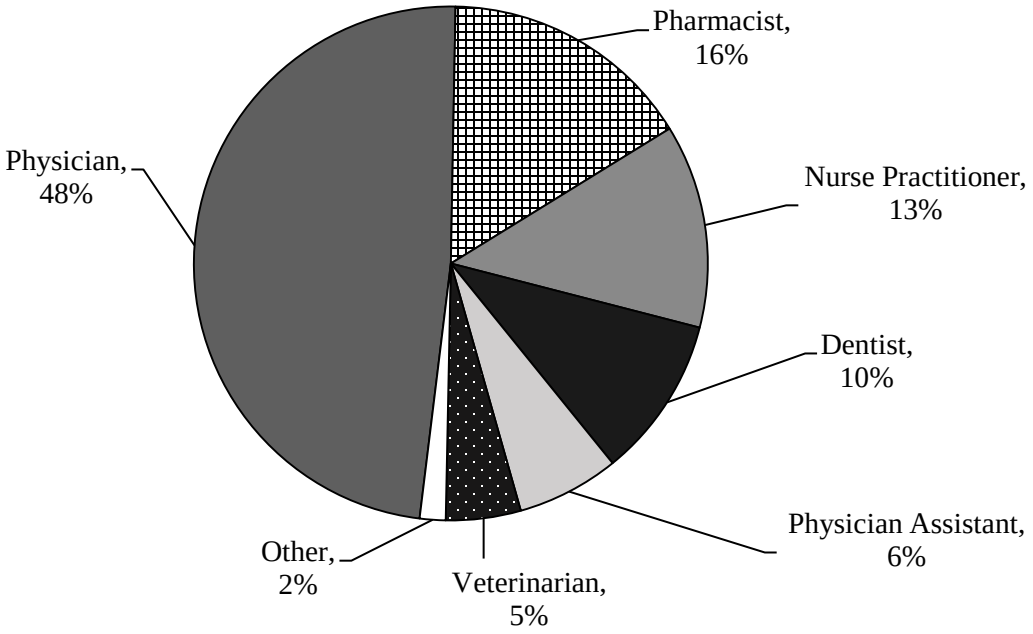
Chapter 8. Survey Results and User Feedback

As part of this evaluation, the Department of Legislative Services (DLS) conducted a survey of prescribers and dispensers registered with the Prescription Drug Monitoring Program (PDMP) to provide insight into their experiences with the program. The survey was conducted via SurveyMonkey, with a link sent by email to every individual registered with PDMP.

In total, the survey was sent to 55,347 individuals, including both active and inactive users. Of the 55,347 individuals sent the survey, 25,386 individuals (45.87%) opened the survey, 27,774 individuals (50.18%) did not open the survey, 1,361 individuals (2.46%) opted out of receiving information about the survey, and 826 individuals (1.49%) had emails that bounced back. A summary of the results of the full survey can be found in **Appendix 2**.

DLS received responses from a total of 3,568 individuals (a response rate of 6.44%). As shown in **Exhibit 8.1**, the largest proportion of respondents were physicians (48.35%) and pharmacists (15.92%).

Exhibit 8.1
Survey Respondents by Type of Registrant/User



Note: Other includes podiatrists, nurse midwives, and delegate users.

Source: Department of Legislative Services

One-third of Respondents Are Regular Users of System

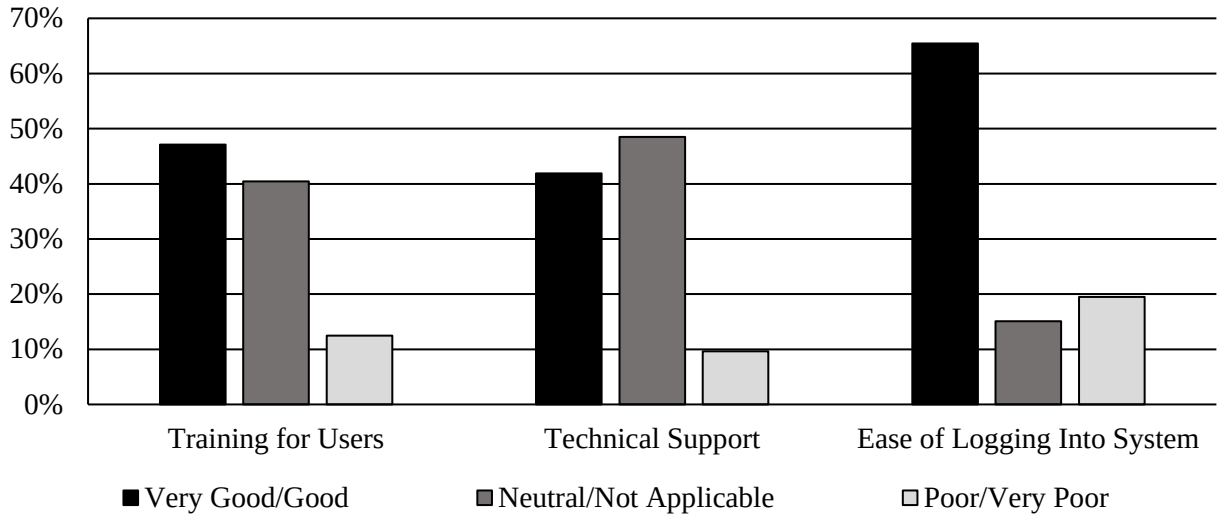
Of the total survey respondents, more than one-quarter (27.52%) use the system daily, 18.30% use the system weekly, 7.40% use the system monthly, 9.19% use the system a few times per year, and 11.49% rarely or never use the system as the prescriptions they write are exempt from mandated use. An additional 26.90% of respondents do not use the system at all. This likely reflects that both active and inactive registrants received the survey and that the mandatory registration requirement applies to a broader population than the mandatory use requirement.

Of those respondents who access the system regularly (at least monthly), a total of 1,899 respondents, 51.71%, use PDMP daily; 34.39% weekly; and 13.9% monthly. Among these regular users, 45.76% access PDMP from an office/practice, 30.65% from a hospital, 23.12% from a clinic, and 15.85% from a pharmacy.

Regular User Experiences Generally Positive or Neutral

Respondents were asked to rate their experience with PDMP in several areas, including training, technical assistance, and ease of logging into the system. As shown in **Exhibit 8.2**, 47.13% of regular users indicated that training for users was good or very good, 12.45% indicated that it was poor or very poor, and 40.42% indicated their experience was neutral or not applicable.

Exhibit 8.2
Rating of Regular User Experience with Prescription Drug Monitoring Program on Select Measures



Note: Regular users are defined as those who identified as accessing the system daily, weekly, or monthly.

Source: Department of Legislative Services

With regard to technical support, as shown in Exhibit 8.2, 41.87% of regular users responded that such support was good or very good. Nearly half (48.48%) indicated a neutral or not applicable response regarding technical support. However, 9.66% of regular users indicated that technical support was poor or very poor, and multiple comments were submitted expressing displeasure with the quality of technical support and the lack of availability of technical support outside of standard business hours.

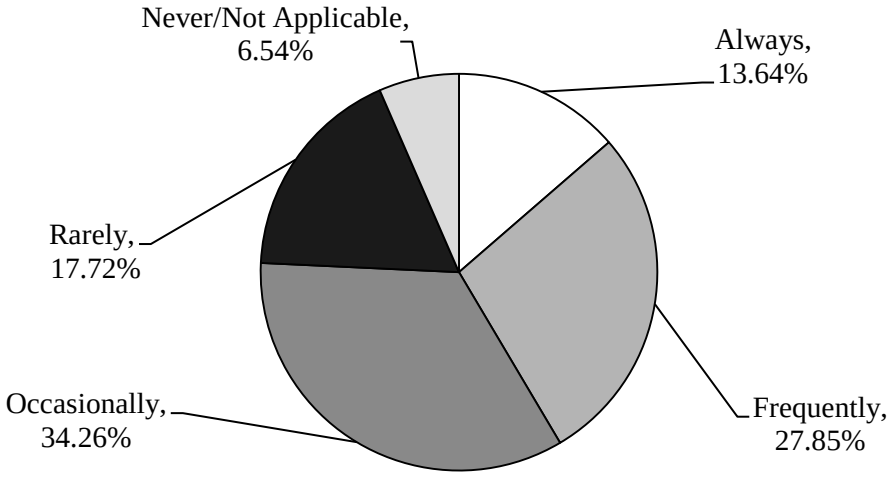
When asked about the ease of logging into the system, as shown in Exhibit 8.2, 65.43% of regular users responded that their experience was good or very good, with 15.10% of respondents neutral. Nearly one-fifth (19.48%) of regular users responded that the ease of logging into the system was poor or very poor.

Three-quarters of regular users (75.44%) reported that the ability to access patient information was good or very good, while 80.89% indicated that the ability to assess patient prescription history was good or very good. More than two-thirds of regular users (70.54%) indicated that, in their experience, using PDMP has been helpful or very helpful in making prescribing or dispensing decisions.

As shown in **Exhibit 8.3**, three-quarters of regular users indicated that PDMP always, frequently, or occasionally influences the clinical decisions they make with their patients.

Exhibit 8.3

Regular Users Responses Regarding How Often the Prescription Drug Monitoring Program Influences Clinical Decisions With Patients



Note: Regular users are defined as those who identified as accessing the system daily, weekly, or monthly.

Source: Department of Legislative Services

Feedback on Improvements to Prescription Drug Monitoring User Interface

In addition to questions about user experiences with and opinions of PDMP, the survey included an opportunity for respondents to comment on any improvements that might make the PDMP system more user friendly and/or effective. Common issues reflected in these comments involved concerns about the log-in process and other technical issues, a lack of clarity on how to use PDMP and the exceptions to mandated use, requests for interstate operability, and a lack of clarity among veterinarians on their requirements for using PDMP.

Log-in Process Could Be More User Friendly

Of the open-ended comments regarding system improvements, 199 individuals referenced issues with the efficiency and speed of logging into PDMP. Specific issues included frequent rejection of the username and password on the first attempt and difficulty locating where to log in. Suggestions for improvement included a single click process or a universal log in. Respondents also expressed frustration with the automatic time out from the system after 15 minutes (65 responses) and with the need to have to log-in with each patient search. According to PDMP, automatic time out, as adopted in the Chesapeake Regional Information System for Our Patients (CRISP) policy, reflects a health information technology industry standard.

Several issues were also raised related to passwords, specifically with the frequency with which passwords are required to be changed, the process required to update passwords, issues with getting locked out of the system due to an incorrect password, and having to reset the password at each log in if the system is used infrequently. Suggestions for improving password issues included better notification when a password is required to be changed, a simplified process for changing the password, and better password recovery options.

Fifty-six respondents cited technical issues with the system, including that the system overall was too slow and unavailable during high volume times.

Recommendation 11: PDMP should work with CRISP to simplify the PDMP user experience, specifically the log-in process and password issues. PDMP and CRISP should investigate the feasibility of implementing single sign on and improving password issues related to resetting the password.

Some Respondents Still Unclear on How to Use and Who Must Use System

Thirty-eight respondents requested more education and training on how to use PDMP, including clearer instructions for the log-in process and video tutorials on how to use PDMP. The survey also sought input on any changes, such as additional exceptions, that are needed to the mandated use requirement. The responses to this question suggest that there is confusion over the current exceptions from mandated use. For example, several respondents suggested exceptions that are already in place, such as for cancer patients, post-operative prescriptions, or individuals in

hospice. Although PDMP has done significant outreach involving mandatory use, the survey answers highlight the need for additional outreach and education.

Users Want More Interstate Data

Users who access Maryland PDMP data may also view data from Washington, DC; Virginia; West Virginia; Pennsylvania; Connecticut; Delaware; Minnesota; and Arkansas. PDMP is actively working with other states to establish the mutual exchange of prescription drug monitoring data. Despite this current capability to access information from other states (interstate data) and PDMP's efforts to expand interoperability, 62 respondents indicated a desire to access data from other states, including states such as Pennsylvania that are currently accessible or to continue to expand access to include all states.

Recommendation 12: PDMP should continue to expand upon educational outreach efforts for registrants. This education should include a clear explanation of the individuals who are required to use PDMP, how to use PDMP, the exceptions to using PDMP, and information on the other states from which prescription drug monitoring data can be accessed and how to access the information.

Registered Veterinarians Unclear of Expectations for Using System

As discussed in Chapter 4, as of February 2018, individuals with controlled dangerous substance (CDS) registrations must register with PDMP. An effect of this requirement is that veterinarians with CDS prescriptive authority must register with PDMP. Several veterinarians who responded to the survey expressed confusion as to what is required of them once they have registered. Some respondents indicated that, despite having registered, they did not receive guidance on how to access PDMP or even if they should access the system. Other veterinarians responded that they did not see the relevance of PDMP to veterinary practice and that their offices did not have the appropriate computer software to access PDMP.

Based on the survey responses, DLS contacted the State Board of Veterinary Medical Examiners to determine what information is provided to licensees regarding the requirement to register with PDMP. According to the board, the approval letter sent to new licensees includes information on the requirement to register with PDMP. However, the letter does not provide further information on the expectations of licensees for using PDMP. The board has sent email alerts to licensees that included information on the requirement for them to register with PDMP but that veterinarians are not required to use PDMP. Despite these outreach efforts, survey responses from veterinarians indicate that there is still confusion on the expectations for using PDMP.

Recommendation 13: PDMP should work with the State Board of Veterinary Medical Examiners to provide clear information to veterinarians who are required to register with PDMP as a condition of receiving their CDS license on whether and how veterinarians are to access PDMP.

Chapter 9. Conclusion and Recommendations

Pursuant to the Maryland Program Evaluation Act, the Department of Legislative Services (DLS) has evaluated the Prescription Drug Monitoring Program (PDMP), which is scheduled to terminate July 1, 2019. This full evaluation was undertaken to provide the General Assembly with information to use in making the determination about whether to reauthorize PDMP and for what period of time.

Based on DLS observations, PDMP is fulfilling its statutory duties and mission since becoming operational in 2014. For example, PDMP has (1) successfully implemented mandatory use and registration; (2) implemented many best practices and is looked to as a national leader in the integration of PDMP with electronic health records; and (3) submitted timely and comprehensive required reports to the General Assembly. PDMP has historically managed finances well, successfully secured federal grants, and obtained significant funding through private donations. Feedback from members of the Advisory Board on Prescription Drug Monitoring, the Technical Advisory Committee, stakeholders, and national organizations regarding PDMP was consistently positive. A survey of registered users of PDMP also provided valuable feedback to enhance the program. While this report makes recommendations for alterations or improvements, they are refinements or changes that the program is capable of implementing.

Based on this review, DLS recommends the removal of PDMP from the list of governmental units subject to sunset evaluation under the Maryland Program Evaluation Act and repeal of the program's termination date. No comparable Maryland program is subject to the Act, which generally includes State boards, councils, committees, and commissions that perform occupational licensing or oversight. As a program within the Behavioral Health Administration, PDMP will continue to be subject to the operating budget review process. The Office of Legislative Audits also has the authority to conduct audits of PDMP if necessary. Further, a review of the legislative history of PDMP indicates that PDMP was added to the list of entities subject to sunset evaluation over concerns that PDMP may have a negative impact on patient safety. Of particular concern at the time that the program was enacted was that prescription drug monitoring programs were costly proposals from law enforcement personnel that would do little to treat patients abusing prescription drugs and that may have a chilling effect, particularly on doctors who are involved in pain management. DLS finds that, after four years of operation, such negative impacts have not been realized. Finally, a review of prescription drug monitoring programs in other states found that only 7 of 49 states are subject to termination or audit.

Recommendation 14: Statute should be amended to remove PDMP from the list of governmental units subject to sunset evaluation under the Maryland Program Evaluation Act and to repeal the program's termination date.

Recommendation 15: In the annual report required under § 21-2A-05 of the Health-General Article for 2020, PDMP should report to the Governor and the General Assembly on the program's implementation of the nonstatutory recommendations contained in this report.

Appendix 1.

Comparison of Model Prescription Drug Monitoring Program Legislation and Best Practice with Maryland's Prescription Drug Monitoring Program

Provision	Maryland's Prescription Drug Monitoring Program (PDMP)
Alliance of States with Prescription Monitoring Programs Prescription Monitoring Program Model Act	
Monitor all Schedule II – V drugs	✓
Electronically submit at least 18 specified types of information for each prescription dispensed	✓ Maryland does not require the name of the person who receives the prescription if other than the patient
Submit required information within at least 24 hours from dispensing	✓
Submitted information must be confidential, with specified exceptions	✓
Designated state agency should review submitted information and notify (1) prescribers and dispensers of possible misuse or abuse and (2) law enforcement or professional licensing board of potential law violation of breach of professional standards	✓ Maryland sends unsolicited reports on patient behavior to prescribers but does not send reports to licensure boards or law enforcement

Provision	Maryland's Prescription Drug Monitoring Program
Designated state agency is authorized to provide prescription monitoring data only to specified persons	✓
Designated state agency may share information with other prescription monitoring programs	✓
Designated state agency is authorized to contract with another agency or private vendor to ensure effective operation of PDMP	✓
Designated state agency must adopt rules and regulations for implementing PDMP law	✓
Penalties imposed for knowingly failing to submit PDMP information as required, disclosing or using PDMP information contrary to law, or obtaining or attempting to obtain PDMP information by fraud or deceit	✓
Potential Best Practices	
Data Collection and Data Quality	
Collect data on all schedules of controlled substances	✓
Adopt latest American Society for Automation in Pharmacy reporting standard	✓

Provision	Maryland's Prescription Drug Monitoring Program
Collect data on nonscheduled drugs implicated in abuse	Not authorized
Collect positive identification on person picking up prescriptions	Not authorized
Collect data on method of payment	✓
Daily or real-time data collection	✓
Monitor pharmacy reporting compliance	✓
Institute effective data correction and missing data procedures	✓
Integrate electronic prescribing and PDMP data collection	Not fully integrated at this time
Data Linking and Analysis	
Use a proven method to match/link the same patient's record	✓
Conduct periodic analyses to identify at-risk patients, prescribers and dispensers	✓

Provision	Maryland's Prescription Drug Monitoring Program
Conduct epidemiological analyses for surveillance, early warning, evaluation, prevention	✓
Use automated expert software and systems to expedite analyses and reports	✓
Record data on prescriber disciplinary status and patient lock-ins	Not authorized
Link to prescriber specialty data	Not required to collect specialty data
User Access and Report Dissemination	
Provide continuous online access to automated reports to authorized and authenticated users	✓
Customized solicited reports for different types of end users	✓
User-friendly interfaces, *e.g.*, decision support tools, risk scores	✓
Enhance patient reports with summary data, *e.g.*, morphine milligram equivalents (MME), multiple provider episodes (MPE)	✓

Provision	Maryland's Prescription Drug Monitoring Program
Prescriber self lookup	✓
Batch (multipatient) report for prescribers and delegates	Not currently available, but may be possible
Integrate PDMP Reports with…	
Health information exchanges	✓
Electronic health records	✓
Pharmacy dispensing systems	✓

Provision	Maryland's Prescription Drug Monitoring Program
Provide PDMP Data to…	
Prescribers	✓
Dispensers	✓
Law enforcement	✓
Licensure boards	✓
Patients	✓
Medicare	✓
Medicaid	✓
Private third-party payers	Not authorized
Workers' compensation programs	Not authorized
Substance abuse treatment clinicians	✓
Medical examiners/coroners	✓
Drug courts	Not authorized
Researchers (encrypted/de-identified data)	✓

Provision	Maryland's Prescription Drug Monitoring Program
Send Unsolicited Reports and/or Alerts to…	
Prescribers	✓
Dispensers	✓
Law enforcement	Must subpoena
Licensure boards	Must subpoena
User-led alerts	Possible capability to set up
Letters to top prescribers	In the process for developing threshold for prescriber reports on their own behavior
Enrollment, Outreach, Education, Utilization	
Streamline/automate enrollment	✓
Presentations and training for end-user groups	✓
Online user guides and educational materials	✓
Proactive identification and outreach to enroll high impact users, *e.g.*, top prescribers	✓ All prescribers are required to be enrolled

Provision	**Maryland's Prescription Drug Monitoring Program**
Prescriber report cards	Cannot be instituted without access to specialty data to which PDMP is working toward gaining access
Delegate accounts	✓
Mandate PDMP enrollment for prescribers and dispensers	✓
Mandate PDMP training for prescribers and dispensers	✓
Mandate PDMP utilization for prescribers and dispensers	✓
PDMP Promotion	
Conduct presentations	✓
Distribute reports	✓

Provision	Maryland's Prescription Drug Monitoring Program
Website Content	
Annual PDMP reports	✓
Quarterly PDMP reports	Not required by statute
Data dashboards	✓
PDMP enhancement news	✓
Other reports	✓
Inter-organizational Coordination	
Interstate data sharing	✓
Collaborate with Other Health Agencies/Organizations in Applying and Linking PDMP Data:	
Veterans Affairs	Not fully implemented
Indian Health Service	Not fully implemented
Department of Defense	Not fully implemented

Provision	Maryland's Prescription Drug Monitoring Program
PDMP Usability, Progress, and Impact	
Conduct satisfaction and utilization surveys of end users	✓ The Department of Legislative Services (DLS) conducts surveys as part of the required sunset review process. PDMP gathers this type of information more informally from licensing boards and board members
Conduct audits of PDMP system utilization for appropriateness and extent of use	✓
Track/report progress in adoption practices	✓
Track/report PDMP enrollment and utilization data, prescribing, and risk measures (*e.g.*, MMEs, MPEs)	✓
Use PDMP data as outcome measures in evaluation program and policy changes	✓
Analyze other outcome data (*e.g.,* overdoses, deaths, hospitalizations, emergency room visits) to evaluate the PDMP's impact	✓

Provision	Maryland's Prescription Drug Monitoring Program
PDMP Funding and Sustainability	
Secure funding that is independent of economic downturns, conflicts of interest and changes in PDMP policies	✓ Primary funding through State general funds with supplemental funding from grants as they become available
Enact legislation to maintain sufficient funding over time	✓
Periodic review of PDMP performance to ensure efficient operations and identify opportunities for improvement	✓ PDMP is subject to periodic Sunset Review by DLS
Promote visibility of PDMP impact to motivate funding, *e.g.*, via annual reports and news releases	✓

Source: Alliance of States with Prescription Monitoring Programs, *Prescription Monitoring Program Model Act 2015 Revision* and The Prescription Drug Monitoring Program Training and Technical Assistance Center, Heller School for Social Policy and Management, Brandeis University, *Tracking PDMP Enhancement: The Best Practice Checklist*, Prepared for The Bureau of Justice Assistance, March 3, 2017. Description of Maryland PDMP represents DLS assessment, based on review of statute, regulation, reports, and interviews with PDMP staff.

Appendix 2
Summary of the Responses to the DLS Survey

The Department of Legislative Services (DLS), Office of Policy Analysis (OPA), of the General Assembly of Maryland is evaluating the Prescription Drug Monitoring Program (PDMP). As part of this evaluation, DLS is conducting a survey to gather feedback from system users on their experience with and opinion regarding PDMP.

The survey primarily consists of multiple choice questions and should take approximately 5 minutes to complete.

Your individual responses will not be shared with PDMP or any other State agency.

The survey will close at midnight on November 2, 2018, so please respond by then. If you have any questions, please contact Jared S. Sussman or Jennifer B. Chasse by telephone at (410) 946-5530 or by email at OPAsurveys@gmail.com.

Thank you in advance for your time and assistance.

1. What type of PDMP user/registrant are you?

Answered Question	3,568
Skipped Question	0

	Percent of Respondents	Number of Respondents
Physician	48.35%	1,725
Physician Assistant	6.45%	230
Nurse Practitioner	12.81%	457
Nurse Midwife	0.53%	19
Dentist	10.15%	362
Podiatrist	0.67%	24
Veterinarian	4.71%	168
Pharmacist	15.92%	568
Delegate user for prescriber	0.36%	13
Delegate user for pharmacist	0.06%	2
Total Respondents	**100.00%**	**3,568**

2. From which settings do you typically access PDMP? Please check all that apply.

Answered Question	3,568
Skipped Question	0

	Percent of Respondents	Number of Respondents
Though registered, I do not access the system.	25.31%	903
Hospital	22.03%	786
Pharmacy	10.26%	366
Clinic	15.22%	543
Office/practice	35.79%	1,277
Other (please specify)	4.09%	146
Total	**100.00%**	**3,568**

3. How often do you use the PDMP system?

Answered Question	3,568
Skipped Question	0

	Percent of Respondents	Number of Respondents
Daily	27.52%	982
Weekly	18.30%	653
Monthly	7.40%	264
A few times per year	9.19%	328
Rarely or never as the prescriptions I write are exempt from mandated use.	11.49%	410
Though registered, I do not use the system.	26.09%	931
Total	**100.00%**	**3,568**

4. Please rate your experience with PDMP in the following areas:

Answered Question	3,393
Skipped Question	175

	Very Poor	Poor	Neutral or Not Applicable	Good	Very Good	Number of Respondents
Training for users	4.49%	8.62%	52.57%	26.98%	7.35%	3,388
Technical support	3.16%	5.63%	62.12%	21.52%	7.57%	3,355
Ease of logging into system	5.69%	10.22%	37.87%	32.37%	13.86%	3,377
Ability to access patient information	3.32%	5.86%	39.62%	36.10%	15.10%	3,377
Ability to access patient prescription history	2.72%	4.64%	38.01%	35.34%	19.28%	3.381

5. What, if any, improvements might make the PDMP system more user friendly and/or effective?

Answered Question	1,799
Skipped Question	1,769

6. As of July 1, 2018, prescribers in Maryland must check PDMP prior to writing a prescription for an opioid or benzodiazepine, with some exceptions. Pharmacists must check PDMP if they have a reasonable belief that a controlled dangerous substance prescription is being filled for any purpose other than the treatment of an existing medical condition. Do you understand the exceptions to mandated use?

Answered Question	3,331
Skipped Question	237

	Percent of Respondents	Number of Respondents
Yes	82.68%	2,754
No	14.11%	470
Not applicable. I am not a prescriber or pharmacist nor am I a delegate to a prescriber or pharmacist.	3.21%	107
Total	**100.00%**	**3,331**

7. In your experience, are there any changes, such as additional exceptions, that are needed to the mandated use requirement for prescribers and pharmacists?

Answered Question	3,331
Skipped Question	237

	Percent of Respondents	Number of Respondents
No	85.65%	2,853
Yes (Please specify.)	14.35%	478

8. PDMP users can access date from other states' PDMPs (interstate data). Do you use interstate data when making prescribing or dispensing decisions?

Answered Question	3,271
Skipped Question	297

	Percent of Respondents	Number of Respondents
Yes	31.89%	1,043
Not yet, but I may in the future.	46.99%	1,537
No (and I do not plan to access interstate data).	21.13%	691
Total	**100.00%**	**3,271**

9. In your experience, how helpful has using PDMP been in making prescribing or dispensing decisions?

Answered Question	3,271
Skipped Question	297

Very Helpful	Helpful	Somewhat Helpful	Not Very Helpful	No Benefit	Not Applicable	Number of Respondents
25.50%	19.99%	14.95%	7.25%	7.31%	25.01%	3,271

10. How often does PDMP influence the clinical decisions you make with your patients?

Answered Question	3,271
Skipped Question	297

Always	Frequently	Occasionally	Rarely	Never	Not Applicable	Number of Respondents
8.99%	17.21%	23.91%	17.18%	9.32%	23.39%	3,271

11. Is there anything else you would like to share with DLS regarding your experiences with PDMP?

Additional Comments	1,397
Skipped Question	2,171

Appendix 3
Draft Legislation

J1 9lr0863

Bill No.: _____
Requested: _____
Committee: _____

Drafted by: Hopwood
Typed by: Rekea
Stored – 12/14/18
Proofread by _____
Checked by _____

By: **Leave Blank**

A BILL ENTITLED

AN ACT concerning

Prescription Drug Monitoring Program – Program Evaluation

FOR the purpose of requiring the Prescription Drug Monitoring Program to provide prescription monitoring data to authorized users, rather than the authorized administrator, of another state's prescription drug monitoring program; repealing the requirement that the issuance of a certain administrative subpoena be voted on by a quorum of the board of a licensing entity, or for the State Board of Physicians, a disciplinary panel, for the Program to be required to disclose prescription monitoring data to the licensing entity; repealing the termination date of the Program; repealing the requirement that the Department of Legislative Services conduct a certain evaluation of the Program under the Maryland Program Evaluation Act; requiring the Advisory Board on Prescription Drug Monitoring to include certain information in certain annual reports; and generally relating to the program evaluation of the Prescription Drug Monitoring Program.

BY repealing and reenacting, with amendments,
Article – Health – General
Section 21–2A–06(b)
Annotated Code of Maryland
(2015 Replacement Volume and 2018 Supplement)

BY repealing

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

Article – Health – General
Section 21–2A–10
Annotated Code of Maryland
(2015 Replacement Volume and 2018 Supplement)

BY repealing and reenacting, without amendments,
Article – State Government
Section 8–403(a)
Annotated Code of Maryland
(2014 Replacement Volume and 2018 Supplement)

BY repealing
Article – State Government
Section 8–403(b)(44)
Annotated Code of Maryland
(2014 Replacement Volume and 2018 Supplement)

BY repealing and reenacting, with amendments,
Article – State Government
Section 8–403(b)(45) through (56)
Annotated Code of Maryland
(2014 Replacement Volume and 2018 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

21–2A–06.

(b) The Program shall disclose prescription monitoring data, in accordance with regulations adopted by the Secretary, to:

(1) A prescriber, or a licensed health care practitioner authorized by the prescriber, in connection with the medical care of a patient;

(2) A dispenser, or a licensed health care practitioner authorized by the dispenser, in connection with the dispensing of a monitored prescription drug;

(3) A federal law enforcement agency or a State or local law enforcement agency, on issuance of a subpoena, for the purpose of furthering an existing bona fide individual investigation;

(4) **[**The State Board of Physicians, on issuance of an administrative subpoena voted on by a quorum of a disciplinary panel, as defined in § 14–101 of the Health Occupations Article, for the purposes of furthering an existing bona fide investigation of an individual;

(5)**]** A licensing entity **[**other than the State Board of Physicians**]**, on issuance of an administrative subpoena **[**voted on by a quorum of the board of the licensing entity**]**, for the purposes of furthering an existing bona fide individual investigation;

[(6)**] (5)** A rehabilitation program under a health occupations board, on issuance of an administrative subpoena;

[(7)**] (6)** A patient with respect to prescription monitoring data about the patient;

[(8)**] (7)** Subject to subsection (i) of this section, **[**the authorized administrator**]** **AUTHORIZED USERS** of another state's prescription drug monitoring program;

[(9)**] (8)** The following units of the Department, on approval of the Secretary, for the purpose of furthering an existing bona fide individual investigation:

(i) The Office of the Chief Medical Examiner;

(ii) The Maryland Medical Assistance Program;

(iii) The Office of the Inspector General;

(iv) The Office of Health Care Quality; and

(v) The Office of Controlled Substances Administration;

[(10)**] (9)** The technical advisory committee established under § 21–2A–07 of this subtitle for the purposes set forth in subsections (c), (d), and (e) of this section; or

[(11)**] (10)** The following entities, on approval of the Secretary and for the purpose of furthering an existing bona fide individual case review:

(i) The State Child Fatality Review Team or a local child fatality review team established under Title 5, Subtitle 7 of this article, on request from the chair of the State or local team;

(ii) A local drug overdose fatality review team established under § 5–902 of this article, on request from the chair of the local team;

(iii) The Maternal Mortality Review Program established under § 13–1203 of this article, on request from the Program; and

(iv) A medical review committee described in § 1–401(b)(3) of the Health Occupations Article, on request from the committee.

[21–2A–10.

Subject to the evaluation and reestablishment provisions of the Maryland Program Evaluation Act, this subtitle and all regulations adopted under this subtitle shall terminate and be of no effect after July 1, 2019.**]**

Article – State Government

8–403.

(a) On or before December 15 of the evaluation year specified, the Department shall:

(1) conduct a preliminary evaluation of each governmental activity or unit to be evaluated under this section; and

(2) prepare a report on each preliminary evaluation conducted.

(b) Each of the following governmental activities or units and the statutes and regulations that relate to the governmental activities or units are subject to preliminary evaluation in the evaluation year specified:

[(44) Prescription Drug Monitoring Program in the Maryland Department of Health (§ 21–2A–02 of the Health – General Article: 2013);**]**

[(45)**] (44)** Psychologists, State Board of Examiners of (§ 18–201 of the Health Occupations Article: 2020);

[(46)**] (45)** Public Accountancy, State Board of (§ 2–201 of the Business Occupations and Professions Article: 2022);

[(47)**] (46)** Racing Commission, State (§ 11–201 of the Business Regulation Article: 2021);

[(48)**] (47)** Real Estate Appraisers, Appraisal Management Companies, and Home Inspectors, State Commission of (§ 16–201 of the Business Occupations and Professions Article: 2020);

[(49)**] (48)** Real Estate Commission, State (§ 17–201 of the Business Occupations and Professions Article: 2019);

[(50)**] (49)** Residential Child Care Program Professionals, State Board for Certification of (§ 20–202 of the Health Occupations Article: 2021);

[(51)**] (50)** security systems technicians, licensing and regulation of (§ 18–201 of the Business Occupations and Professions Article: 2018);

[(52)**] (51)** Social Work Examiners, State Board of (§ 19–201 of the Health Occupations Article: 2021);

[(53)**] (52)** Standardbred Race Fund Advisory Committee, Maryland (§ 11–625 of the Business Regulation Article: 2021);

[(54)**] (53)** Veterinary Medical Examiners, State Board of (§ 2–302 of the Agriculture Article: 2018);

[(55)**] (54)** Waterworks and Waste Systems Operators, State Board of (§ 12–201 of the Environment Article: 2018); and

[(56)**] (55)** Well Drillers, State Board of (§ 13–201 of the Environment Article: 2018).

SECTION 2. AND BE IT FURTHER ENACTED, That, in the annual report required to be provided under § 21–2A–05(f)(3) of the Health – General Article for 2019, the Advisory Board on Prescription Drug Monitoring shall report on the technical advisory committee, including:

(1) the written protocols for technical advisory committee meetings and the procedures for reviewing unsolicited reports and investigative data requests;

(2) a summary of technical advisory committee meetings since the implementation of Chapter 147 of the Acts of the General Assembly of 2016; and

(3) recommendations on any changes necessary for the technical advisory committee to meet the needs of the Prescription Drug Monitoring Program.

SECTION 3. AND BE IT FURTHER ENACTED, That, in the annual report required to be provided under § 21–2A–05(f)(3) of the Health – General Article for 2020, the Advisory Board on Prescription Drug Monitoring shall report on the recommendations not enacted by Section 1 of this Act made by the Department of Legislative Services in the December 2018 publication "Sunset Review: Evaluation of the Prescription Drug Monitoring Program".

SECTION 4. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2019.

Appendix 4
Written Comments of the
Maryland Department of Health

MARYLAND
Department of Health

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

December 17, 2018

Victoria L. Gruber, Executive Director
Department of Legislative Services
90 State Circle
Annapolis. MD 21401-1991

Ryan Bishop, Director
Office of Policy Analysis
90 State Circle
Annapolis, MD 21401-1991

Dear Executive Director Gruber and Director Bishop:

The Maryland Department of Health (the "Department") appreciates the diligent work of the analysts in conducting the Prescription Drug Monitoring Program (PDMP) sunset evaluation. The Department thanks Jennifer Chasse, Erin Hopwood, Amber Gundlach, and Jared Sussman for their thorough analysis and collaborative efforts with PDMP and Department Staff. The Department recognizes the importance of this sunset review for PDMP and its role in supporting providers and their patients in the safe and effective use of prescription drugs. Your staff were responsive and have provided substantial feedback to the PDMP for its implementation of recent legislative changes and programmatic expansion, and continuing core operations.

Thank you for the opportunity to review and respond to the exposure draft of the report. The recommendations were helpful for identifying areas for continued enhancement of this important data tool used by many stakeholders in combating the opioid crisis. Enclosed please find a preliminary response from the Department regarding the recommendations in this report. The Department concurs with many of the recommendations in the report and awaits further instruction and actions on others.

The Department is committed to the success of the PDMP and its role in reducing inappropriate prescribing, dispensing, or use of prescription drugs in Maryland. The Department appreciates the recognition of the PDMP's ongoing efforts and looks forward to working with stakeholders for the continued success of the PDMP.

Sincerely,

Robert R. Neall
Secretary

Maryland Department of Health Response to Sunset Evaluation Report for the Prescription Drug Monitoring Program

Recommendation 1: PDMP should institute a formal training program for new advisory board members on the responsibilities of members, including meeting protocols, and an overview of PDMP. This training should be applied consistently to new appointees on the advisory board.

The Department of Health (the Department) concurs with this recommendation by the Department of Legislative Services (DLS).

Recommendation 2: As the role of TAC is clarified and the committee becomes operational, PDMP should establish written protocols for TAC, including meeting requirements and the procedures for reviewing unsolicited reports and investigative data requests. PDMP should require at least one in-person meeting of TAC each year.

The Department concurs with this recommendation by DLS.

Recommendation 3: In the annual report required under § 21-2A-05 of the Health–General Article in 2019, PDMP should report to the General Assembly on TAC. The report should include (1) the written protocols for TAC meetings and procedures for reviewing unsolicited reports and investigative data requests; (2) a summary of TAC meetings since the implementation of Chapter 147; and (3) recommendations on any changes necessary for TAC to meet the needs of PDMP.

The Department concurs with this recommendation by DLS.

Recommendation 4: PDMP should continue outreach efforts to prescribers and pharmacists and monitor such efforts until full compliance with the mandatory registration mandate is achieved.

The Department concurs with this recommendation by DLS but would like to note that 100% compliance will not be possible given a constant turnover of prescribers and pharmacists entering and leaving the state. As noted in this report, the Department expects that more individuals will register as their CDS licenses come up for renewal in the subsequent three years, creating a baseline for functionally full compliance. The PDMP Annual Report will provide updated figures and progress on this recommendation.

Recommendation 5: Statute should be amended to remove the requirement for the vote of a quorum of the board or disciplinary panel when a licensing entity requests prescription monitoring data.

The Department does not have a position on this recommendation by DLS and will defer to the General Assembly for their policy guidance.

Recommendation 6: The State Board of Physicians should continue to work with PDMP to address concerns regarding the accuracy of PDMP data.

The Department concurs with this recommendation by DLS.

Recommendation 7: To allow more meaningful analysis, PDMP should collect additional data, specifically provider specialty information, before implementing unsolicited reporting on prescribers and dispensers.

The Department concurs with this recommendation by DLS but would like to note that the limitations on the PDMP's ability to access and make use of data sources regarding provider specialty are technical in nature and are the subject of ongoing work.

Recommendation 8: PDMP should work with the State Board of Pharmacy to determine the feasibility of gathering information on the identification of the individual picking up a monitored prescription at the time it is dispensed.

The Department concurs with this recommendation by DLS.

Recommendation 9: Statute should be amended to allow authorized users of other states' prescription drug monitoring programs to access Maryland's prescription monitoring data.

The Department does not have position on this recommendation by DLS but would like to note that the Program's current focus is on providing accurate information and a good customer experience to Maryland providers and patients.

Recommendation 10: Interstate data sharing agreements should be modified to ensure access of Maryland's PDMP users to other connected States' prescription drug monitoring program data.

The Department does not have position on this recommendation by DLS but would like to note that the Program's current focus is on providing accurate information and a good customer experience to Maryland providers and patients.

Recommendation 11: PDMP should work with Chesapeake Regional Information System for Our Patients (CRISP) to simplify the PDMP user experience, specifically the log-in process and password issues. PDMP and CRISP should investigate the feasibility of implementing single sign on and improving password issues related to resetting the password.

The Department concurs with this recommendation by DLS.

Recommendation 12: PDMP should continue to expand upon educational outreach efforts for registrants. This education should include a clear explanation of the individuals who are required to use PDMP, how to use PDMP, the exceptions to using PDMP, and information

on the other states from which prescription drug monitoring data can be accessed and how to access the information.

The Department concurs with this recommendation by DLS.

Recommendation 13: PDMP should work with the State Board of Veterinary Medical Examiners to provide clear information to veterinarians who are required to register with PDMP as a condition of receiving their CDS license on whether and how veterinarians are to access PDMP.

The Department concurs with this recommendation by DLS

Recommendation 14: Statute should be amended to remove PDMP from the list of governmental units subject to sunset evaluation under the Maryland Program Evaluation Act and to repeal the program's termination date.

The Department concurs with this recommendation by DLS.

Recommendation 15: In the annual report required under § 21-2A-05 of the Health–General Article in 2020, PDMP should report to the Senate Finance Committee and the House Health and Government Operations Committee on the program's implementation of the nonstatutory recommendations contained in this report.

The Department concurs with this recommendation by DLS.