Preliminary Evaluation of the Prescription Drug Monitoring Program

Recommendations:	**Waive from full evaluation** **Extend termination date by three years to July 1, 2019** **Require follow-up report by January 1, 2015** **Consider removing statutory requirement for technical advisory committee review of data requests from other states** **Expand annual reporting requirements**
Date Established:	2011 (enacted by Chapter 166 of 2011)
Prior Evaluations:	None
Organization:	Located in the Alcohol and Drug Abuse Administration, Department of Health and Mental Hygiene (DHMH); federal grants managed by the Governor's Office for Crime Control and Prevention (GOCCP) 17-member Advisory Board on Prescription Drug Monitoring (two vacancies) 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 5-member technical advisory committee reviews certain requests for information, assists the Secretary of Health and Mental Hygiene in responding to requests, and provides clinical guidance to assist authorized recipients in interpreting data (not yet appointed)
Staff:	3 full-time positions: program administrator, office secretary, information technology (IT) function analyst (vacant); contractual IT services overseen by GOCCP
Mission:	To 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 to promote a balanced use of prescription monitoring data
Purpose:	Monitor the prescribing and dispensing of all Schedule II – V controlled dangerous substances by all prescribers and dispensers in the State
Authorizing Statute:	Title 21, Subtitle 2A, Health-General Article
Evaluation Completed by:	Jennifer Ellick and Linda Stahr, Department of Legislative Services, 2013

Introduction

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 is expected to be fully operational by the end of calendar 2013. PDMP has a termination date of July 1, 2016, and is subject to review under the Maryland Program Evaluation Act; thus, the Department of Legislative Services (DLS) was required to complete a preliminary evaluation of the program during the 2013 interim. As PDMP is not yet fully operational, DLS reviewed implementation of the program to date, compared the structure of the program to those in other states, and assessed potential best practices. This report discusses prescription drug abuse and related deaths nationally and in Maryland; PDMPs in others states, including best practices and model legislation; and the structure and implementation of Maryland's PDMP to date. The report also identifies policy issues for further consideration as the State moves forward with implementation of the program.

Overview of Prescription Drug Abuse and Related Deaths Nationally and in Maryland

Currently, misuse of prescription drugs is second only to marijuana use as the nation's most prevalent illicit drug problem, with approximately 22 million people initiating nonmedical pain reliever use since 2002. Misuse of prescription drugs relates mostly to pain relievers such as oxycodone and hydrocodone, but also to benzodiazepines (tranquilizers). Oxycodone and hydrocodone belong to the group of drugs known as opioids, which also includes illegal drugs, notably heroin. As shown in **Exhibit 1**, in 2010-2011, about 1 in 22 Americans age 12 and older (4.57%) used pain relievers nonmedically. In Maryland, such use is estimated at about 1 in 26 individuals age 12 and older (3.89%). Prevalence of the nonmedical use of pain relievers is lower in Maryland than nationally, with Maryland ranking among the lowest quintile of states. Rates of usage vary by age group both nationally and in Maryland, with the highest prevalence among young adults ages 18 to 25.

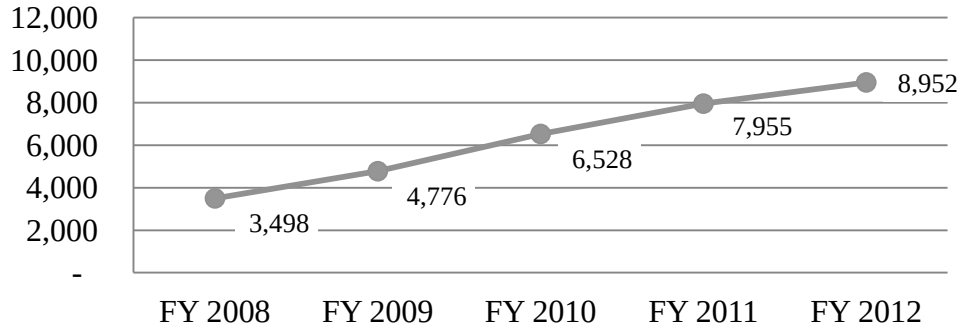
Exhibit 1
Rates of Nonmedical Use of Pain Relievers in 2010-2011

	Total Age 12+	Age 12-17	Age 18-25	Age 26+
All States	4.57%	6.09%	10.43%	3.37%
Maryland	3.89%	4.63%	9.13%	2.93%

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

Data regarding substance abuse problems among individuals admitted to State-supported alcohol and drug abuse treatment programs shows a rise in oxycodone and other opioid use. As shown in **Exhibit 2**, from fiscal 2008 through 2012, incidence of these substance use problems reported on admission increased by 156%.

Exhibit 2
Oxycodone/Other Opioid Use Reported Among Individuals Admitted to State-supported Substance Use Treatment Programs
Fiscal 2008-2012

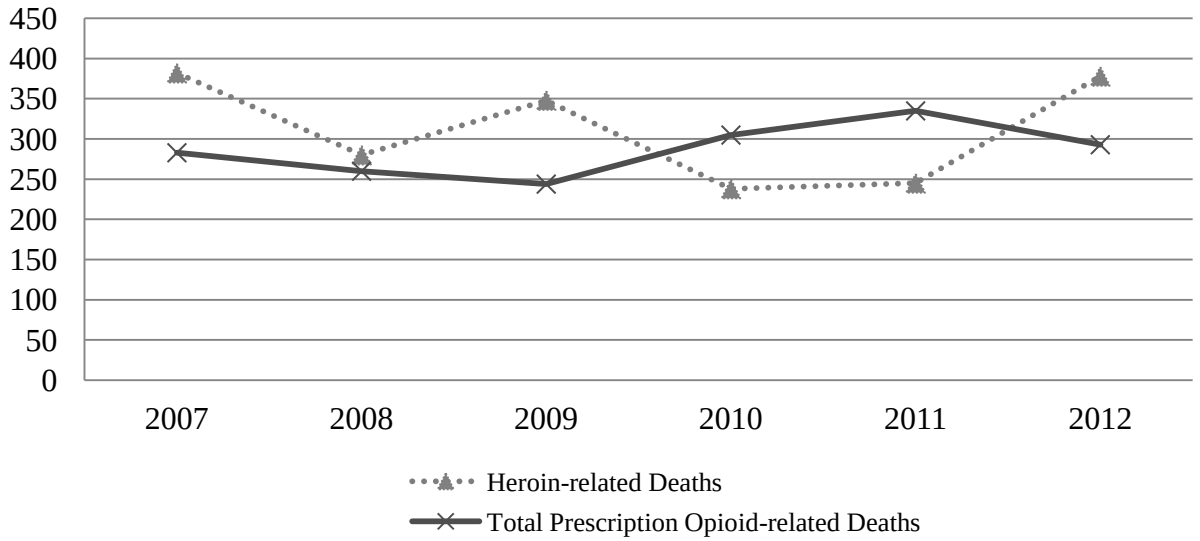


Source: Department of Health and Mental Hygiene

According to the federal Centers for Disease Control and Prevention (CDC), over the past two decades, drug overdoses have become the leading cause of injury death in the United States. Of the 38,329 drug overdose deaths in 2010, 60% (22,134) were related to prescription drugs, primarily prescription pain relievers.

Prescription drug-related deaths are less prevalent in Maryland than nationally. According to the Department of Health and Mental Hygiene (DHMH), 761 deaths in Maryland in 2012 were the result of recent ingestion or exposure to alcohol or another type of drug. Of these 761 deaths, 47% (358) were related to prescription drugs (including opioid- and benzodiazepine-related deaths). As shown in **Exhibit 3**, after increasing by 25% in 2009 and 10% in 2010, prescription opioid-related deaths *declined* by 12% from 2011 to 2012, primarily due to a 17% decrease in oxycodone-related deaths. Conversely, heroin-related deaths increased by 54% from 2011 to 2012. Reportedly, the 2012 reversal of the trend in substance use deaths results from the successful campaigns nationwide against diversion and abuse of prescription opioids, which have made prescription opioids more difficult and expensive to obtain than heroin.

Exhibit 3
Heroin and Prescription Opioid-related Deaths in Maryland
Calendar 2007-2012



Note: Total prescription opioid-related deaths include oxycodone-related deaths.
Source: Department of Health and Mental Hygiene

Prescription Drug Monitoring Programs Are a Tool to Address Abuse

To address the problem of prescription drug abuse, states have established prescription drug monitoring programs (PDMPs) – statewide electronic databases that gather information from pharmacies on dispensed prescriptions for controlled substances. While New York has had a PDMP since the early 1970s, Oklahoma was the first state to establish an electronic monitoring program in 1991. To date, 49 states (all but Missouri) have enacted PDMP legislation. As of October 2012, programs were *operational* in all but seven of these states (Maryland, Arkansas, Georgia, Montana, Nebraska, New Hampshire, and Wisconsin). PDMP legislation is pending in the District of Columbia.

In a PDMP, prescription data is made available on request from end users and sometimes distributed to end users via unsolicited reports. Data usually includes information relating to the patient, prescriber, pharmacy, medicine, dosage, and date dispensed. End users (recipients) of PDMP 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 payors, and other public health and safety agencies. State policies vary widely with regard to which categories of recipients are permitted to request and receive PDMP data and

under what conditions. Many PDMPs now provide secure online access for authorized recipients.

Research on the Effectiveness of PDMPs Nationally

Several studies have reviewed the effectiveness of PDMPs, concluding both positive and neutral observations through widely varying study designs. Some studies note that PDMPs are associated with a decrease in prescribing of Schedule II drugs, may be associated with decreased drug abuse and use of drug abuse treatment, are associated with a decrease in doctor shopping, and may reduce the per-capita supply of prescription drugs. Other studies have concluded that PDMPS are not associated with decreased overdose rates and have little impact in some states because prescribers are unaware of them or fail to use them. A 2012 report cited numerous studies and surveys regarding the effectiveness of PDMPs, noting the following success stories:

- A study of emergency room medical providers in Ohio found that 41% of those given PDMP data altered their prescribing for patients receiving multiple simultaneous narcotics prescriptions (61% of providers prescribed no or fewer narcotics than originally planned, while 39% prescribed more narcotics because the provider was able to confirm that there was no recent history of abuse).

- A study on Kentucky's PDMP indicated that almost 90% of providers or prescribers responding to a survey had at some point refused to prescribe or dispense a controlled substance based on information contained in a patient's report from the state's PDMP.

- A study comparing states with and without PDMPs found that those with programs had decreases in the amount of opioid shipments and admissions for prescription opioid substance use treatment.

- A 2002 report from the Government Accountability Office found that, following implementation of a PDMP, the average time to complete an investigation of doctor shopping dropped from 156 to 16 days in Kentucky and from 120 days to 20 in Nevada.

Potential Best Practices and Model Legislation

The PDMP Center of Excellence at Brandeis University (COE) compiled potential "best practices" that have been associated with maximizing PDMP effectiveness. COE identified 35 potential best practices but cautioned that "the empirical evidence is not extensive, and the research base on PDMP best practices is in an even earlier stage of development." Many of these practices also represent provisions found in the Prescription Monitoring Program Model Act (Model Act) prepared by the Alliance of States with Prescription Monitoring Programs. The similarly titled Model Prescription Monitoring Program Act, developed by the National Alliance for Model State Drug Laws, contains similar provisions. **Appendix 1** of this report compares potential best practices and Model Act features with the design of the Maryland PDMP.

An October 2013 report by Trust for America's Health (TFAH) titled *Prescription Drug Abuse: Strategies to Stop the Epidemic 2013* describes strategies to address the issue and rates states on 10 indicators of evidence-informed policies. Two of the 10 indicators relate directly to PDMPs: (1) does a state have an operational PDMP; and (2) does the state require mandatory use of PDMPs (any form of mandatory use requirement). Maryland scored one point for having an operational PDMP (even though the program will not be *fully* operational until the end of 2013) but scored a zero for not requiring mandatory PDMP use by providers. Maryland, like 10 other states, scored a 6 out of a possible 10 on the indicators. The report observes that PDMPs cannot be used to their full potential unless state policies connect individuals identified through PDMPs with treatment. **Appendix 2** compares Maryland's score on all 10 indicators with the combined scores of all states.

Comparing Maryland's PDMP with the Model Act, potential best practices, and indicators of evidence-informed policies, the State compares favorably in the range of drugs monitored, the information required to be submitted by a dispenser, confidentiality of monitored data, ease of access by authorized users, and integration with the State's health information exchange (HIE). The State does not meet potential best practices in the areas of unsolicited reporting, mandated enrollment or use, timely data sharing with other state PDMPs, and stable funding. The timeliness of Maryland PDMP data reporting (currently three days) falls within the acceptable interval of seven days, but it is not real time, as some other states are moving toward.

Funding of PDMPs in Other States

Federal grants have been essential to the establishment and improvement of PDMPs. Specifically, the Harold Rogers PDMP Grant Program provides funding to states for planning, implementing, and enhancing PDMPs. However, the program limits the amount and time period for which funding is available. Thus, state general funds are commonly used to fund PDMP operations. General funds provide consistent and reliable support for PDMPs, particularly if a program has strong stakeholder support. At least 10 states use general funds to support their PDMP.

Other sources of funding include controlled substance registration fees (13 states), professional licensing fees (3 states), health regulatory board funds (6 states), legal settlements (2 states), PDMP licensing fees (Oregon), health insurance licensing fees (New York), private donations (Florida), and Medicaid fraud settlements (Washington). Other potential funding methods may include assessed fines on licensees, asset forfeiture resulting from criminal activity, assessments on drug manufacturers, prescription fees, payments from third-party payors (in return for access to PDMP data), and fees assessed on PDMP authorized users. All of these sources and methods have advantages and disadvantages in terms of sustainability, ease of collection, burden on regulated professionals and entities, and diversion of funds from other purposes.

Maryland's Prescription Drug Monitoring Program Established in 2011

Chapter 166 of 2011 established Maryland's PDMP within DHMH. Chapter 166 required PDMP 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 controlled substance, 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. For each monitored prescription drug dispensed, a dispenser must electronically submit data to PDMP in accordance with regulations adopted by the Secretary of Health and Mental Hygiene. 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. Prescribers, including physicians and other health care practitioners authorized to prescribe drugs, are encouraged *but not required* to query PDMP regarding a patient's history of prescribed CDS before prescribing a monitored drug. Chapter 166 specified certain items to be included in regulations.

Chapter 166 also established the Advisory Board on Prescription Drug Monitoring. Within 180 days of the advisory board's first meeting, an interim report was required to be submitted to the General Assembly regarding PDMP's design, implementation, and funding. The advisory board submitted its preliminary report in July 2012.

Under Chapter 166, prescription monitoring data is confidential and 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 the law. However, the program is required to disclose prescription monitoring data, in accordance with regulations adopted by the Secretary, 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;
- an authorized administrator of another state PDMP;
- specific units of DHMH on approval of the Secretary of Health and Mental Hygiene for the purpose of furthering an existing *bona fide* individual investigation; or
- the technical advisory committee (TAC) of the program.

A person that receives prescription drug monitoring data from the program may not disclose the data, except as provided by regulations.

The program may also 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. Prior to disclosing any data for such purposes, the Secretary may require the submission of an abstract explaining the scope and purpose of the research. Furthermore, the Office of the Attorney General may seek appropriate injunctive or other relief to maintain the confidentiality of prescription monitoring data. In addition, the program may provide prescription drug monitoring data to – and request and receive prescription drug monitoring data from – another state's PDMP in a manner consistent with Chapter 166. Prescription monitoring data may not be used as the basis for imposing clinical practice standards.

The program's TAC, comprising specified members appointed by the Secretary, is required to review certain requests for information. Before PDMP discloses information to certain entities, TAC must review the request for information and provide clinical guidance and interpretation to assist the authorized recipient, as well as to assist in the Secretary's decision on how to respond to a request.

Chapter 166 also established civil penalties for knowingly failing to submit prescription monitoring data to the program and criminal penalties for knowingly disclosing, using, obtaining, or attempting to obtain by fraud or deceit, prescription monitoring data in violation of the law. A prescriber or dispenser who knowingly discloses or uses prescription monitoring data in violation of the law is subject to disciplinary action by the appropriate licensing entity. However, a prescriber or dispenser, acting in good faith, is not subject to liability arising solely from requesting or receiving (or failing to request or receive) data from the program or acting (or failing to act) on the basis of data provided by the program.

Implementation of Maryland's Prescription Drug Monitoring Program Nearly Complete

Implementation of Maryland's PDMP began following enactment of Chapter 166, and the program should be fully operational by the end of calendar 2013. Significant PDMP implementation activities are summarized in **Exhibit 4** and discussed in greater detail below.

Exhibit 4
Significant Implementation Activities

Date	Activity
July 2011	Program administrator is hired.
October 2011	Members of the Advisory Board on Prescription Drug Monitoring are appointed.
July 2012	Advisory Board on Prescription Drug Monitoring issues legislative report.
December 2012	Contract for information technology work is awarded to CRISP, which in turn contracts with HID for data collection and database hosting.
January 2013	PDMP regulations take effect.
July 2013	Dispenser registration with HID begins.
August 2013	Dispenser reporting to PDMP through HID begins.
September 2013	PDMP becomes partially operational.
December 2013	PDMP expected to become fully operational.

CRISP: Chesapeake Regional Information System for Our Patients
HID: Health Information Designs

Source: Department of Health and Mental Hygiene

Program Staffing

Although Chapter 166 did not take effect until October 2011, PDMP implementation began in July 2011, with the hiring of a program administrator. Currently, PDMP staff consists of three authorized full-time, regular positions in DHMH's Alcohol and Drug Abuse Administration (ADAA): a program administrator, who provides overall project management; an office secretary, who provides administrative support for the program and the advisory board; and an information technology (IT) functional analyst (vacant). The program has no plans to recruit for the IT functional analyst position because IT support is provided through contractual services, as discussed below.

Advisory Board on Prescription Drug Monitoring

The advisory board held its first meeting in October 2011 and since has met twice in 2011, three times in 2012, and twice in 2013. Two board member positions – one pharmacist and one patient – are vacant as of October, but recruitment is underway.

In July 2012, the advisory board submitted to the General Assembly a report containing a number of recommendations for program design, implementation, regulations, and legislation. Included among these was a recommendation for the integration of PDMP, to the greatest extent possible, within the new statewide HIE – the infrastructure designed to support the flow of health information between physician practices, hospitals, laboratories, radiology centers, and other health care institutions. The Maryland Health Care Commission previously designated the nonprofit corporation Chesapeake Regional Information System for Our Patients (CRISP) as the entity to construct Maryland's HIE.

Other advisory board recommendations related to implementation and funding included the development of a system that allows real-time data collection for dispensers of CDS; the ensured accuracy of dispenser reports and ability to identify unique patients in any database; a requirement for disclosure requests made by law enforcement, licensing boards, other units of DHMH, patients, and researchers to be individually processed; and efforts to remove legal barriers to interoperability with PDMPs operating in other states. The board's recommendations have, in large part, guided the program's subsequent implementation activities.

Program Expected to Become Fully Operational in December 2013

In December 2012, CRISP was awarded a contract to perform IT services for PDMP. Subsequently, CRISP awarded a contract to Health Information Designs (HID), a private company specializing in health care data analysis, for services including data collection and database hosting. Although PDMP is located in ADAA, the CRISP and HID contracts are overseen by the Governor's Office for Crime Control and Prevention (GOCCP).

Regulations implementing PDMP took effect in January 2013. Dispenser registration opened in July 2013, and dispenser reporting to the program began in August 2013. DHMH advises that PDMP became partially operational for provider and dispenser queries in September 2013 and is expected to become fully operational in December 2013.

While prescribers and dispensers are anticipated to be the main users of PDMP, data is also available to law enforcement, health occupations boards, certain units of DHMH, patients, researchers, and other states' PDMPs. However, these entities must submit requests through HID, with PDMP staff serving as the gatekeeper for access. Before PDMP discloses information to one of these entities, TAC must review the request. State regulations allow up to 10 days for review. However, as of October 2013, members of TAC have not yet been appointed.

Although program implementation will have taken more than two years to complete, this timeframe is comparable with that experienced by other states. In general, states that have

enacted PDMP legislation within the last 10 years have taken at least 2 years for full implementation. Any delays are attributable not only to PDMP's integration with HIE, but also to efforts to build upon lessons learned from other states' programs. Specifically, DHMH advises that Maryland's PDMP improves upon other states' programs with regard to provider workflow (*i.e.*, eliminating zero reporting), as well as the integrity of reported information.

Program Financing

In its July 2012 report to the General Assembly, the advisory board noted that the development of an electronic database within HIE through a contract with CRISP made it difficult to estimate the total cost of implementation. The advisory board further noted that the integration could result in higher upfront costs but also in long-term cost savings and programmatic benefits compared to the development of a stand-alone database. Total costs associated with procuring a data collection vendor and adapting the HIE structure were estimated at between $1 million and $2 million.

As of November 2013, PDMP received a total of $1.3 million in federal grants, including both Byrne Justice Assistance and Harold Rogers PDMP Implementation grants issued to GOCCP and ADAA. However, not all of these funds have been fully expended, as detailed below. In addition, ADAA advises that it was recently awarded a 2013 Harold Rodgers PDMP Data Driven Multidisciplinary Approaches to Reducing Rx Abuse grant of $400,000. The grant will be used to support implementation and development of an Overdose Fatality Review program, including pilot local overdose fatality review teams in Cecil and Wicomico counties, and will include coordination of access to overdose-related data sources such as PDMP.

Despite the availability of federal grant funds, $512,000 in general funds was appropriated in the fiscal 2014 ADAA budget for additional IT development. The amount of actual general fund expenditures, if any, will depend on the type and extent of IT development projects actually undertaken. To date, all program expenditures have consisted of federal rather than general funds. Program expenditures for fiscal 2012 through 2014 are shown in **Exhibit 5**.

PDMP advises that, due to the federal grant funds that have been available to the program in recent years, its current resources are sufficient to support the program's implementation and first full year of operation. However, as discussed below, a long-term funding source for the program has not yet been identified. Based on the program's projected fiscal 2014 expenditures and because the relevant federal grant programs are intended to support implementation, rather than continuous operation, of PDMPs – it is likely that, by fiscal 2015, the program will not be supportable by federal funds alone.

As indicated above, ADAA oversees PDMP while GOCCP administers federal grant funds for IT implementation and oversees contracts with CRISP and HID. Although such a division of program responsibilities between two agencies is potentially inefficient, there is currently no indication that it has created any impediments to program implementation in this case. Furthermore, DHMH advises not only that GOCCP has a specialized grants administration staff and existing grants management system, but also that GOCCP is the State agency that is

most familiar with the relevant federal program requirements and staff. Thus, PDMP's current arrangement for fiscal administration of grant funds is likely appropriate.

Exhibit 5
Prescription Drug Monitoring Program Expenditures
Fiscal 2012-2014

	FY 2012	FY 2013	Projected FY 2014	Total
Salaries and Wages	$50,406	$141,582	$202,204	$394,192
Grants to CRISP[1]	–	–	–	442,665
Information Technology[2]	0	0	512,000	512,000
Communications	2	791	650	1,443
Travel	710	343	931	1,984
Equipment	3,984	596	0	4,580
Dues and Memberships	0	200	0	200
Total	**$55,102**	**$143,512**	**$715,785**	**$1,357,064**

[1] Estimated total expenditures through November 30, 2013.

[2] Estimated fiscal 2014 expenditures represent the general fund appropriation for information technology enhancements, such as real-time reporting.

Source: Department of Health and Mental Hygiene; Governor's Office for Crime Control and Prevention

Policy Issues for Consideration as Implementation Moves Forward

Although PDMP is moving forward with implementation in accordance with statutory requirements, several aspects of the program that do not comply with potential best practices or the Model Act merit legislative attention.

Lack of Real-time Data Collection and Reporting Capability Impairs Usefulness

PDMP regulations include a requirement that prescription data be reported within three business days of dispensing, which satisfies the Model Act's recommendation that such data be reported within one week. COE advises, however, that a best practice would require such data to be collected in real time. Currently, at least two states (New York and Oklahoma) require real-time data collection, while several others require daily collection.

DHMH advises that PDMP's current data collection system does not, although recommended by the advisory board, allow for real-time reporting. HID, the vendor chosen by CRISP to host PDMP's database and collect prescription monitoring data from dispensers, uses batch file technology. **Because delays in reporting may impede interception of doctor shopping and prescription drug abuse, an upgrade of the system to allow for real-time**

reporting should be considered. If a decision is made to upgrade the system to allow for real-time reporting, then regulatory changes should be made to require real-time reporting by dispensers.

Statutory Requirement for Technical Advisory Committee Review Hinders Interoperability with Other States

Ideally, PDMPs facilitate prescription data sharing not only within, but also among, states. Of the 49 states with PDMPs, all but 6 (Florida, Georgia, Nebraska, Oklahoma, Pennsylvania, and Vermont) allow for interstate sharing.

As specified by Chapter 166, Maryland's PDMP is prohibited from disclosing data to another state's PDMP until TAC has reviewed the request and submitted written clinical guidance and interpretation. As noted by the advisory board, this review process "poses a significant barrier to interoperability implementation" by reducing the likelihood that Maryland will provide useful information to out-of-state practitioners (who are likely to have initiated a patient's prescription drug treatment prior to completion of TAC review). **Removal of this barrier to interstate operability should be considered.**

Reports Generated Only in Response to Specific Inquiries

While most PDMPs generate unsolicited as well as solicited reports, Maryland's program generates reports only in response to specific inquiries. This is inconsistent with the Model Act, which requires unsolicited reporting when a certain threshold is reached. The Model Act does not, however, identify a specific threshold to be used; rather, it instructs PDMPs to review prescription data that "appears to indicate if a person may be obtaining prescriptions in a manner that may represent misuse or abuse of controlled substances" and "identify information that appears to indicate if a violation of law or breach of professional standards may have occurred." For example, an unsolicited report might be sent to relevant parties when a patient has exceeded a specified number of filled CDS prescriptions of the same drug class, from a certain number of prescribers, or at a certain number of pharmacies within a specified period.

Studies have indicated that unsolicited reporting (or alert letters) raises program awareness and may lead practitioners to make increased data requests and/or take greater responsive action (including substance abuse screening and treatment referral). **Accordingly, unsolicited reporting in Maryland should be explored by the advisory board after the program has been fully implemented and operational for a year.**

Absence of Required Registration or Use May Limit Effectiveness

Like most other states, Maryland does not require prescribers or dispensers to register with or use PDMP before prescribing or dispensing controlled substances. Making PDMP voluntary before prescribing or dispensing has helped to soften opposition to PDMP legislation by health care practitioner groups. As noted previously, dispensers *are* required to report to PDMP once a prescription for a controlled substance has been filled (*i.e.*, dispensed to a patient).

Utilization rates before prescribing or dispensing have been very low in some states, prompting some observers to suggest that health care providers be required to access PDMP. No studies have been conducted to test the effectiveness of mandatory PDMP use; nonetheless, states including New York and Oklahoma have taken action in recent years to require health care providers to access prescription drug monitoring data before prescribing or dispensing certain drugs. According to TFAH, 16 states with PDMPs require at least some form of mandatory use of the program for providers. DHMH advises that making prescription drug monitoring data available timely and conveniently through HIE would encourage health care providers to access it. Periodic assessments of PDMP utilization may be warranted.

No Long-term Funding Source Identified

Federal funding sufficient to support PDMP is not expected to be available indefinitely, and a long-term funding source for the program has not yet been identified. Moreover, Chapter 166 specifically prohibits the imposition of user fees to support the program. PDMP advises that its current resources are sufficient to support the program's implementation and first full year of operation (at least through fiscal 2014). **DHMH should continue to investigate and recommend to the General Assembly potential sources of sustainable funding for PDMP.** DHMH estimates that the annual cost to support the program, including personnel and IT services, is approximately $580,000.

DHMH Plans to Conduct Independent Evaluation

PDMP staff advises that $100,000 of federal grant funds have been set aside for an independent evaluation of the program. DHMH has entered into a memorandum of understanding with the University of Maryland School of Pharmacy to conduct the evaluation. PDMP staff estimates that evaluation activities will begin as early as December 2013.

Recommendations

Based on this review, DLS recommends that the Legislative Policy Committee waive PDMP from full evaluation at this time and that legislation be enacted to extend the program's termination date by three years to July 1, 2019. DLS recommends a targeted full evaluation of the program in 2017, by which time the program should have three full years of data with which DLS may measure performance.

DLS further recommends that PDMP submit a follow-up report to the Governor, the General Assembly, and DLS by January 1, 2015, on (1) efforts to collect and make available, in real-time, PDMP data; (2) recommendations for a long-term funding source to support the program; and (3) the status of DHMH's independent evaluation of PDMP. The report should also discuss the status of any plans to pursue unsolicited reporting and/or mandatory utilization of PDMP data by providers.

In the meantime, the General Assembly should consider (1) removing the statutory requirement for TAC review of data requests from PDMPs in other states in order to promote interoperability and (2) expanding the required elements of PDMP's annual report to include the number of prescribers and dispensers registered with, and utilizing, PDMP.

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
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 seven days from dispensing date	✓ Maryland requires submission within at least three days from dispensing date
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 law *does not* permit unsolicited reporting

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	✓ Technical Advisory Committee (TAC) must review requests before sharing
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 a uniform reporting standard among state PDMPs	Generally complies with Model Act standard
Collect data on nonscheduled drugs implicated in abuse	State law does not authorize

Provision	**Maryland's Prescription Drug Monitoring Program**
Collect positive identification on person picking up prescriptions	Regulations require a patient identification number
Collect data on method of payment	✓
Reduce data collection interval; real-time data collection	Regulations require reporting within three days
Institute serialized prescription forms	Not required under State law
Integrate electronic prescribing with PDMP data collection	No integration
Improve data quality	Integration with health information exchange (HIE) should improve data quality
Data Linking and Analysis	
Link records to permit reliable identification of individuals	Integration with HIE promotes such linkage
Determine valid criteria for questionable activity Conduct periodic analyses of questionable activity	Maryland's PDMP does not allow unsolicited reporting, thus questionable activities are those that prompt a law enforcement or health agency to issue a subpoena or obtain permission of the Secretary, for the purpose of furthering an existing *bona fide* individual investigation
Conduct epidemiological analyses to assist in public health surveillance and prevention efforts	Could be used for this purpose

Provision	Maryland's Prescription Drug Monitoring Program
Develop automated expert systems to guide analyses	No automated expert systems to guide analyses to date
Record data on prescriber disciplinary status and patient lock-ins	Does not record such data
User Access and Report Dissemination	
Provide continuous online access to automated reports to authorized and authenticated users	✓
Optimize reporting to fit user needs	Integration with HIE should improve ease of access to reporting data
Integrate PDMP data with HIEs and electronic health record	PDMP is being integrated with State HIE
Send unsolicited reports and alerts to prescribers and dispensers when certain thresholds are reached	State law does not allow unsolicited reports
Publicize use and impact of PDMP	Too early to determine
PDMP Recruitment, Utilization, and Education	
Enable access to data by appropriate users	State law authorizes access to specific users for specific purposes

Provision	Maryland's Prescription Drug Monitoring Program
Proactively identify and conduct outreach to potential high-end users	
Conduct recruitment campaigns	PDMP has engaged in a variety of outreach and education activities in preparation for a fall 2013 implementation
Streamline certification and enrollment processing	
Mandate enrollment	State law does not mandate PDMP registration or use
Conduct promotional campaigns	✓
Improve data timeliness and access to enable more informed prescribing and improved detection of questionable activity	Partially complies by requiring data submission within three days of dispensing but not real-time submission
Conduct user education	✓
Mandate utilization	State law does not mandate PDMP registration or use
Institute financial incentives	No financial incentives
Delegate access	State law allows PDMP to disclose data to a licensed health care practitioner authorized by a prescriber or a dispenser, in connection with the medical care of a patient or the dispensing of a monitored prescription drug

Provision	Maryland's Prescription Drug Monitoring Program
Other	
Enact interstate data sharing among PDMPs	State law authorizes data sharing with other state PDMPs after review by TAC
Collaborate with other health agencies/organizations	State law does not allow
Evaluate PDMP through surveys of end users, audits of system utilization, and using PDMP and other data to evaluate program and policy changes	State law requires sunset review of PDMP; DHMH is planning an independent evaluation in the near future. PDMP staff advises that $100,000 in federal funds has been set aside for the evaluation. DHMH has contacted the University of Maryland School of Pharmacy and the Johns Hopkins University School of Public Health about potentially conducting the evaluation.
Secure adequate and consistent funding	No long-term funding source identified

Source: Alliance of States with Prescription Monitoring Programs, *Prescription Monitoring Program Model Act 2010 Revision* and The Prescription Drug Monitoring Program Center of Excellence, Heller School for Social Policy and Management, Brandeis University, *Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices*, Prepared for The Pew Charitable Trusts, September 20, 2012. Description of Maryland PDMP represents DLS assessment, based on review of statute, regulation, reports, and interviews with PDMP staff

Appendix 2. 10 Indicators of Evidence-informed Substance Abuse Policy

Indicator	Combined Score of All States	Maryland Score
Prescription Drug Monitoring Program: Does the state have an operational Prescription Drug Monitoring Program (PDMP)?	49	1
Mandatory Use of PDMP: Does the state require mandatory use of PDMPs by providers? (any form of mandatory use requirement)	16	0
Doctor Shopping Law: Does the state have a doctor shopping statute?	50	1
Support for Substance Abuse Services: Has the state expanded Medicaid under the Affordable Care Act, thereby expanding coverage of substance abuse treatment?	24	1
Prescriber Education Requirement: Does the state require or recommend education for prescribers of pain medications?	22	0
Good Samaritan Law: Does the state have a law to provide a degree of immunity from criminal charges/mitigation of sentencing for an individual seeking help for him or herself or others experiencing an overdose?	17	1
Support for Naloxone Use: Does the state have a law to expand access to, and use of, naloxone for overdosing individuals given by lay administrators?	17	1
Physical Exam Requirement: Does the state require a provider to *either* conduct a physical exam of the patient with a screening for signs of substance abuse *or* have a *bona fide* patient-physician relationship that includes a physician examination prior to prescribing prescription medications?	44	0
ID Requirement: Does the state have a law requiring or permitting a pharmacist to ask for identification prior to dispensing a controlled substance?	32	0
Pharmacy Lock-in Program: Does the state's Medicaid plan have a pharmacy lock-in program that requires individuals suspected of misusing controlled substances to use a single prescriber and pharmacy?	46	1

Note: A score of 1 means a state meets the indicator; a score of 0 means a state does not meet the indicator.

Source: Trust for America's Health, *Prescription Drug Abuse: Strategies to Stop the Epidemic 2013*, October 2013

Appendix 3. Written Comments of the Department of Health and Mental Hygiene

The department reviewed a draft of this preliminary evaluation and provided these written comments.

STATE OF MARYLAND
DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

December 3, 2013

Mr. Warren G. Deschenaux
Director
Office of Policy Analysis
Department of Legislative Services
90 State Circle
Annapolis, MD 21401

Dear Mr. Deschenaux:

Thank you for the opportunity to review an exposure draft of the preliminary sunset evaluation of the Prescription Drug Monitoring Program (PDMP), prepared by the Department of Legislative Services. We commend your staff for its examination of the implementation of the PDMP as well as the operations of programs in other states. We expect the PDMP to go live before the end of the year and are very excited for its potential to reduce the misuse, abuse and diversion of prescription drugs throughout the State.

The Department of Health and Mental Hygiene and the Prescription Drug Monitoring Advisory Board appreciate the recommendations that have been offered by the Department of Legislative Services. The Department and the Board support the recommendations contained in the evaluation. The expanded reporting requirements cover measures of PDMP implementation and impact that are critical for assessing the success of the PDMP. Elimination of the requirement that the Technical Advisory Committee review data requests from other states' PDMPs will remove ambiguity about the legal requirements for establishing interstate interoperability and allow Maryland's PDMP to connect to existing interstate data sharing hubs in a manner similar to other states' established practice.

We look forward to continuing to work with the General Assembly to ensure that the Prescription Drug Monitoring Program is implemented successfully.

Sincerely,

Laura Herrera, MD, MPH
Deputy Secretary for Public Health Services

Chair, Prescription Drug Monitoring Program
Advisory Board