



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 30, 2014

The Honorable Martin O'Malley
Governor
State of Maryland
Annapolis, MD 21401-1991

The Honorable Thomas V. Mike Miller, Jr.
President of the Senate
H-107 State House
Annapolis, MD 21401-1991

The Honorable Michael E. Busch
Speaker of the House
H-101 State House
Annapolis, MD 21401-1991

Re: Health - General Article § 21-2A-05 – 2014 Report of the Analysis of the Advisory Board on Prescription Drug Monitoring on the Impact of the Prescription Drug Monitoring Program

Dear Governor O'Malley, President Miller and Speaker Busch:

Pursuant to Health – General Article, Section 21-2A-05(f)(3)(ii), the Advisory Board on Prescription Drug Monitoring (Board) submits this report on the analysis of the Board of the impact of the Prescription Drug Monitoring Program (PDMP) in the Department of Health and Mental Hygiene (DHMH) on patient access to pharmaceutical care and on curbing prescription drug diversion in the State, as well as the Board's recommendations related to continuation of or modifications to the PDMP. Senate Bill 883, Chapter 166 of the Acts of 2011, established the PDMP to assist prescribers, dispensers, and public health professionals in identifying and preventing prescription drug abuse, as well as identifying and investigating unlawful prescription drug diversion.

Thank you for your consideration of this report. If you have any questions, please contact Kathleen Rebbert-Franklin, Deputy Director for Population-Based Behavioral Health, Behavioral Health Administration, at (410) 402-8612.

Sincerely,

Mona K. Gahunia, D.O.

Chair, Advisory Board on Prescription Drug Monitoring

Enclosures

cc: The Honorable Thomas M. Middleton
The Honorable Peter A. Hammen
Gayle Jordan-Randolph, M.D.
Brian Hepburn, M.D.
Allison Taylor, J.D., M.P.P.
Kate Jackson, M.P.H.

Joshua M. Sharfstein, M.D.
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**Department of Health and Mental Hygiene
Prescription Drug Monitoring Program Annual Report**

Health - General Article § 21-2A-05(f)(3)(ii)
2014 Report of the Analysis of the Advisory Board on Prescription Drug Monitoring
on the Impact of the Prescription Drug Monitoring Program

Introduction

Title 21, Subtitle 2A of the Health-General Article (enacted by Senate Bill 883, Chapter 166 of the Acts of 2011) requires that the Department of Health and Mental Hygiene (Department) create a Prescription Drug Monitoring Program (PDMP) to reduce the misuse, abuse and diversion of prescription drugs throughout the State. As outlined in the Health-General Article, the duties of the PDMP (also referred to as the Program), include:

- monitoring the prescribing and dispensing of prescriptions that contain controlled dangerous substances;
- creation of an electronic database of controlled dangerous substances prescription information; and
- making this data available to a statutorily-defined group of individuals and entities responsible for ensuring the health and welfare of patients and the lawful use of controlled dangerous substances.

The Secretary of the Department has assigned responsibility for programmatic development of the PDMP to the Behavioral Health Administration (BHA) in the Department.

Section 21-2A-05 of the Health-General Article provides for the creation of the Advisory Board on Prescription Drug Monitoring (Board). The Board is composed of a diverse array of stakeholders (see Attachment), including representatives from health professional licensing boards, physicians, pharmacists, a nurse practitioner, a local law enforcement representative, and patient representatives. The Board has met 10 times since the membership was first appointed in the fall of 2011, and has provided feedback and recommendations on a number of topics, including regulations, information technology, interstate data sharing and interoperability, program evaluation, funding, and education initiatives.

Section 21-2A-05(f)(3)(ii) of the Health-General Article also requires that the Board provide annually to the Governor and, in accordance with § 2-1246 of the State Government Article, the General Assembly, an analysis of the impact of the Program on patient access to pharmaceutical care and on curbing prescription drug diversion in the State, including any recommendation related to modification or continuation of the Program. This 2014 Annual Report is submitted pursuant to this requirement.

PDMP Implementation and Operations Update

Since the submission of the Board’s 2013 Annual Report, Maryland’s PDMP has moved from planning and implementation to operations. On December 20, 2013, Chesapeake Regional Information System for our Patients (CRISP), the state-designated health information exchange and the Department’s PDMP information technology provider, opened general registration to healthcare providers to access PDMP data through the online health information exchange query portal. Prescriber and dispenser access was initially granted to a pilot group of users in September 2013. In February 2014, the Program began training and registering a pilot group of local law enforcement users to submit data requests using a separate online system. Processing of law enforcement data requests (pursuant to subpoena) began in March 2014. The Program has also trained and registered investigators from licensing entities and units of the Department that are authorized to request data.

In accordance with requirements of Health-General Article, §21-2A-05(3), PDMP registration and utilization summary statistics are provided in the chart below. As of October 28, 2014, there were 7,320 prescribers and dispensers registered to use the PDMP. Of these users, 6,124 were active users, having accessed the system within the last 90 days.

Type of Active User	# of Active Users
Prescriber (including physicians, physician assistants, nurse practitioners, dentists, podiatrists)	3,686
Prescriber Delegate (including nurses without prescriptive authority, social workers, psychologists, professional therapists and counselors, etc.)	801
Dispenser (pharmacists)	1,586
Dispenser Delegate (pharmacy technicians and interns)	51
Total	6,124

As shown in the chart below, between March 21, 2014 – when data requesting functionality was initiated – and October 22, 2014, there were 58 requests for data reports from federal, State or local law enforcement agencies.

Law Enforcement Agency Type	# of Requests
Federal	3
State	0
Local	55
Total	58

Analysis of PDMP Impact on Patient Access to Pharmaceutical Care and on Curbing Prescription Drug Diversion

In its 2013 Annual Report, the Board noted that only certain portions of the Program were operational, and therefore the Board could not report on the Program's impact on patient access to pharmaceutical care and on curbing prescription drug diversion in Maryland. Access to PDMP data by key system users, such as healthcare providers, law enforcement investigators and other authorized requesters, has been in place for less than a year; therefore, analysis of outcomes on patient access to pharmaceutical care and curbing prescription drug diversion is just being initiated. This includes a Department-funded Program evaluation to be undertaken by the University of Maryland, School of Pharmacy and the Johns Hopkins Bloomberg School of Public Health. This independent evaluation is discussed later in this document.

In addition, the Program is poised to begin expanded activities through a newly legislated unsolicited reporting authority (Chapter 651 of the Acts of 2014), enabling the Program to proactively send prescribers and dispensers information about potentially inappropriate patient prescription use and prescribing trends around controlled dangerous substances. Analysis of these activities should provide a rich understanding of the impact of the Program on key operational goals, such as correlating PDMP use with changes in prescribing patterns of users. The Program is planning to collect feedback from stakeholders on whether dispenser reporting, prescriber and dispenser access to PDMP data, and law enforcement and other requestor utilization of data reports have affected patients' ability to legitimately access pharmaceutical care or altered existing drug diversion trends. However, the Board cannot report at this time that PDMP operations have had an impact.

Recommendations on Modification or Continuation of the Program

The Board has recommendations on the following areas: (1) unsolicited reporting; (2) interstate data sharing; (3) regulations; (4) program evaluation; and (5) education initiatives.

Unsolicited Reporting

Unsolicited reporting is the proactive dissemination of PDMP data or notification to PDMP users about questionable or deviant prescription patterns. Among other things, these patterns may indicate inappropriate prescribing or dispensing or the presence of patient abuse or misuse of controlled dangerous substances. Unsolicited reporting is considered a best practice by the Department of Justice, Bureau of Justice Assistance's Prescription Drug Monitoring Program Center of Excellence at Brandeis University, and has been or is currently being adopted by a majority of states. Proactive reporting to prescribers and dispensers will allow the Program to better support clinical decision-making around prescribing controlled dangerous substances, improve legitimate patient access to pharmaceutical care, and assist prescribers and dispensers in identifying prescription drug diversion.

Chapter 651 of 2014 (HB 1296; Prescription Drug Monitoring Program – Review and Reporting of Possible Misuse or Abuse of Monitored Prescription Drugs) amended the original PDMP statute to adopt unsolicited reporting requirements established in other states. The statute establishes the authority for the Program to review the PDMP for indications of possible misuse or abuse of a monitored prescription drug. If a review indicates possible misuse or abuse, the Program may provide a proactive report to the prescriber or dispenser of the prescription drug. The PDMP's existing Technical Advisory Committee must review the prescription drug monitoring data prior to it being released to the prescriber or dispenser of a controlled dangerous substance.

Unsolicited Reporting regulations were developed by the Program, as directed by Chapter 651. The Board has reviewed and supports the proposed regulations, which are currently being submitted for public comment. The Program is operationalizing this new authority in consultation with the Board.

Interstate Data Sharing

Among other things, Chapter 92 of 2014 (HB0255, Prescription Drug Monitoring Program – Sunset Extension and Program Evaluation) authorizes disclosure of PDMP data by the Program to other state PDMPs and permits the Maryland PDMP to access other states' PDMP data, allowing for interstate data sharing. PDMP interoperability between states is currently being undertaken across the country and aligns with the State's goals for the Maryland PDMP.

Interstate data sharing allows legally authorized PDMP users in one state to access another state's PDMP data according to the legal requirements of both states. The Program is currently in discussions with the National Association of Boards of Pharmacy to establish an MOU for use of their interstate data sharing platform, PMP InterConnect. The Program is also reviewing the feasibility and

desirability of an additional product called NARxCHCEK, which queries a state's PDMP to create a NARxCHECK Score and detailed report about a patient's history with controlled dangerous substance prescriptions. Many healthcare providers in other states have reported that this tool is helpful in point-of-care prescription decision-making. Establishing interstate data sharing, and possibly NARxCHECK, will provide an improved PDMP user interface and the Board supports such interoperability efforts. The Board will continue to provide feedback on these and any other enhancements to the CRISP user interface.

Regulations

Regulations required by Chapter 651 (HB 1296) and Chapter 92 (HB 255) of 2014 have been drafted and it is anticipated that these regulations will be promulgated in early 2015. The proposed regulatory changes establish the authority for the review of prescription drug monitoring data for indications of possible misuse or abuse of a monitored prescription drug and allow reporting of possible misuse or abuse to prescribers and dispensers registered with the program. These regulations also require the PDMP Technical Advisory Committee to review prescription drug monitoring data prior to being released to a prescriber or dispenser of a monitored prescription drug. The regulations specify when data can be shared for the purpose of individual investigations. Finally, they expand the number of fatality review teams that can receive re-disclosed PDMP data, and remove language not required by statute.

Additionally, the Department has drafted regulations through the Division of Drug Control (DDC) that will impact the Program, if adopted. The Department proposes to amend the current controlled dangerous substance regulations (COMAR 10.19.03.03) to impose two new requirements as conditions of obtaining an initial or renewed controlled dangerous substance permit. The regulations would require that prescriber applicants register with the PDMP and complete a Department-approved substance use disorder treatment education module. These new requirements will not be implemented until the Secretary determines that CRISP has the capability to accommodate the increased registration volume and that DDC has implemented an effective web-based controlled dangerous substance permit registration system. To balance the additional requirements, DDC has proposed extending the controlled dangerous substance permit period to three years. The goals of this amendment are to increase awareness of the PDMP, provide education about controlled dangerous substance prescribing and use of the PDMP, as well as educate prescribers about substance use disorder treatment options; all of which would assist in providing legitimate access to pharmaceutical care while addressing prescription drug diversion, misuse and abuse. Additionally, mandatory registration with the PDMP supports the unsolicited reporting activities of the Program by creating an accurate database of prescriber and dispenser contact information, and ensuring that all prescribers who will be contacted by the Program already have access to PDMP data.

The Board supports expanding PDMP system registration and educating prescribers on the benefits of the PDMP. The Board does have concerns about the impact on the controlled dangerous substance permit process and the implementation of these new requirements. The Board will continue to monitor the progress of these proposed regulations and will work with the Department as needed.

Program Evaluation

The Department has entered into an agreement with the University of Maryland, School of Pharmacy, which, along with the Johns Hopkins School of Public Health, will design an ongoing evaluation of PDMP impact and outcomes. The Memorandum of Understanding (MOU) for this evaluation project was fully executed on October 20, 2014. An initial kick-off meeting between researchers and the Department occurred on October 30, 2014. The evaluation's scope of work will address the following needs:

- Need 1: Conduct a prescriber-level study of the adoption, implementation and maintenance of the Maryland PDMP. Document and evaluate the uptake of the PDMP by prescribers in key clinical settings, including hospitals, emergency departments, urgent care clinics, pain management clinics, behavioral health treatment providers, etc. Assess barriers to and facilitators to PDMP use; retention and/or adaptation of key features and uses of the PDMP, and capacity-building for successful program implementation in key settings.
- Need 2: Identify baseline and post-PDMP implementation prescribing and dispensing patterns for pharmaceutical controlled substances with a focus on opioids and benzodiazepines.
- Need 3: Measure the effectiveness of the Maryland PDMP, from a population health perspective, by analyzing longitudinal data to assess the effect of the program on: rates of hospital inpatient stays for poisoning related to pharmaceutical controlled substances; emergency department visits for poisoning related to pharmaceutical controlled substances; poisoning deaths related to pharmaceutical controlled substances; and access to and/or use of treatment and recovery services for individuals with prescription drug-related substance use disorders.
- Need 4: Evaluate whether the Maryland PDMP has had unintended consequences, including reducing legitimate access to pharmaceutical care and uptake in use of illicit substances.

Evaluation activities are designed to meet the statutory requirement for ongoing evaluation of the Program under §21-2A-05(4)(iii) and will inform on the impact of the Program on patient access to pharmaceutical care and on curbing prescription drug diversion in the State.

Education Initiatives

The Department has worked with the Board and diverse stakeholder organizations to increase knowledge of the Program throughout the State. BHA has engaged with the Boards of Pharmacy and Physicians, DDC, and other agencies that oversee controlled dangerous substance dispensers to ensure that dispensers have up-to-date information on the reporting requirement. In the months before and after implementation of the reporting requirement, BHA and the PDMP information technology vendors have fielded numerous inquiries from pharmacists and dispensing practitioners and have provided direct education and technical assistance on all manner of issues. Investigative report requestors receive small-group or one-on-one training in the PDMP and in submitting investigative report requests prior to receiving access to the system. Additionally, prescribers and dispensers must undergo a web-based training prior to completing registration with CRISP and receiving PDMP

access. The PDMP Manager, CRISP personnel and Board members have continued to give in-person presentations on the PDMP to a number of audiences and organizations. Program staff attended conferences, including the US Department of Justice Bureau of Justice Assistance Harold Rogers PDMP Conference, held in September 2014 in Washington DC.

Pursuant to Executive Order 01.01.2014.12 from the Governor's office during the summer of 2014, the Behavioral Health Administration began developing an online education module dedicated to understanding substance abuse treatment resources in Maryland, which included questions around PDMP access and use. Also during the summer of 2014, the Department initiated an overdose response media campaign and is working with local authorities to provide educational materials that can be distributed to community healthcare providers and the general public. Lastly, a number of local health departments have made PDMP education a component of their local overdose prevention plans. The Board is supportive of the educational initiatives undertaken by the Program and continues to play an active role in increasing visibility and education around the PDMP across a wide variety of stakeholder groups throughout the State.

Conclusion

During the past year, the Department made substantial progress with fully implementing the PDMP, increasing visibility and uptake of the Program, enhancing Program capabilities through legislative and regulatory pathways, and continuing to work with the Board to increase the Program's ability to support the prevention of prescription drug abuse and diversion. Therefore, the Board recommends that the Governor and General Assembly continue to support ongoing development of the PDMP. Over the next year, the Board will continue to support the Department by providing ongoing guidance on Program development and conducting trainings and other educational initiatives for the members' respective stakeholder groups.

Attachment

Advisory Board on Prescription Drug Monitoring – Membership

Chair

Mona K. Gahunia, DO
Chief Medical Officer, Department of Health and Mental Hygiene

Members

Hoover Adger, Jr., MD, MPH, MBA
Director, Adolescent Medicine, Johns Hopkins Hospital

Captain Daniel D. Alioto
Commander, Vice Narcotics Division, St. Mary's County Sheriff's Office

Janet M. Beebe, CRNP
Nurse Practitioner, Bowie Internal Medicine Associates

Shirley Devaris, RN, JD
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J. Ramsay Farah, MD, MPH
Regional Medical Director, Clinical Services, UnitedHealthcare Medical Director, Phoenix of Health, LLC

Vinu Ganti, MD
Primary Care Physician, Private Practice

Janet Getzey Hart, RPh
Director, Government Affairs, Rite Aid

Lenna Israbian-Jamgochian President, Maryland Board of Pharmacy
Regional Pharmacy Manager, Safeway Pharmacy

Gail Amalia B. Katz, MPH
Health Care Administrator, Retired

Orlee Panitch, MD
Physician, Medical Emergency Professionals

Ligia Peralta, MD
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Faryal Qureshi, PharmD, BCPS, DAAPM
Pharmacist, Clinical Pharmacy Specialist - Critical Care, VA Maryland Health Care System

Thelma B. Wright, MD
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