MARYLAND
Department of Health

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

May 22, 2018

The Hon. Larry Hogan
Governor
100 State Circle
Annapolis, MD 21401–1991

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

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

Re: Health-General § 21–2A–05(f)(3)—Annual Prescription Drug Monitoring Program Report

Dear Governor Hogan, President Miller, and Speaker Busch:

Pursuant to Health-General § 21–2A–05(f)(3), Annual Prescription Drug Monitoring Program Report, the Maryland Department of Health respectfully submits the attached report detailing the status of the Prescription Drug Monitoring Program.

If you have any questions regarding this report, please contact Webster Ye, Deputy Chief of Staff, at (410) 767–6480 or webster.ye@maryland.gov.

Sincerely,

Robert R. Neall
Secretary

Enclosure

cc: Webster Ye, Director, MDH Deputy Chief of Staff
Dr. Barbara J. Bazron, MDH Deputy Secretary for BHA
Kate Jackson, Director of the Prescription Drug Monitoring Program
Sarah Albert, MSAR# 10789

2017 Annual Prescription Drug Monitoring Program Advisory Board Report
As Required by Health-General § 21–2A–05(f)(3)

Introduction

Section 21–2A–05 of the Health-General Article provides for the creation of the Advisory Board of the Prescription Drug Monitoring Program (Board). The Board is composed of representatives from health professional licensing boards whose licensees prescribe or dispense controlled dangerous substances (CDS); physicians; pharmacists; a nurse practitioner; local and state law enforcement representatives; representation from the Maryland Health Care Commission; representation from the local health departments; and patient representatives. The Board has met regularly since autumn 2011, and has provided feedback and recommendations on several topics, including regulations, information technology (IT), interstate data sharing and interoperability, program evaluation, funding, and educational initiatives.

Section 21–2A–05(f)(3) of the Health-General Article requires that the Board provide annually to the Governor and the General Assembly a report detailing the

(1) the number of prescribers and prescriber delegates registered with and using the Program;
(2) the number of pharmacists and pharmacist delegates registered with and using the Program;
(3) the number of disclosures made to federal law enforcement agencies or State or local law enforcement agencies;
(4) an analysis of the impact of the Program on patient access to pharmaceutical care and on curbing prescribing drug diversion in the State; and
(5) any recommendations related to modification or continuation of the Program.

PDMP Implementation and Operations Update

The Maryland Prescription Drug Monitoring Program (PDMP) collects controlled dangerous substance (CDS) prescription dispensing information and enables authorized users access to this data for the purpose of improving the health and safety of Maryland patients and the public. The PDMP is an electronic database that contains CDS Schedule II–V prescriptions dispensed in Maryland and can be disclosed as permitted by statute.

Since January 2017, and in conformance with the mission objectives of Health-General Article § 21–2A–02, the PDMP has focused on three primary initiatives:

(1) implement the July 1, 2017 PDMP mandatory registration requirement of CDS prescribers and pharmacists in collaboration with the Department's Office of Controlled Substances Administration, see Health-General Article § 21–2A–04.1(a);

(2) expand its outreach and education campaign to prescribers and pharmacists to facilitate PDMP registration, see Health-General Article § 21–2A–04.1(c); and

(3) increase PDMP operational capabilities to improve data collected quality and data analytics in preparation for the July 1, 2018, PDMP use and dispensing mandate, see Health-General Article § 21–2A–04.2(a).

Maryland clinicians are a key population of PDMP stakeholders, representing the largest group of end users. Chesapeake Regional Information System for our Patients (CRISP), the State-designated health information

exchange (HIE) and the Department's PDMP information technology provider, is the registration and access point for healthcare providers to view PDMP data. Significant enhancements to clinical user registration and access to PDMP data have been accomplished in 2017. Federal grant funding, state general funds, and legislative changes under House Bill (HB) 437 (Chapter 147 of 2016) together enabled these Program enhancements. The Program is pursuing a dual approach for clinical users of bringing PDMP data as close as possible into the clinician's workflow and also providing actionable ways to alert providers and display data.

The Program itself trains and registers investigative users, the other major PDMP end user group, to submit data requests pursuant to subpoena using a separate online system, RxSentry®, supported by CRISP's IT vendor, Appriss, Inc. In December 2016, Appriss purchased the RxSentry® product from long-time vendor, Health Information Designs (HID). Investigative users include local, State and federal law enforcement agents, investigators from licensing entities, regulatory Boards, units of the Department that are authorized to request data, and fatality review teams.

Prescribers/Pharmacists and Prescriber/Pharmacist Delegates Registered with and using the PDMP

Clinical User Landscape:

Significant increases in registration have occurred since the passage of HB 437 (Chapter 147, 2016) which implemented mandatory PDMP registration on July 1, 2017, and mandatory use of the PDMP for certain prescribing and dispensing scenarios starting July 1, 2018.

CRISP's independent outreach to integrate CRISP services into Maryland hospital electronic health records (EHRs) has benefited Maryland clinical user access to PDMP data. Clinical users at participating hospitals have options beyond logging into their individual CRISP Clinical Query Portal accounts. These options include Single Sign-On, which allows a clinician to pull up the PDMP and clinical data contained in CRISP for a patient they are viewing in their hospital's EHR with a single click and no separate log-in to CRISP's system. Another integration involves CRISP delivering PDMP data directly into the view of the clinician accessing their hospital electronic medical health records systems, called In-Context Notification. In-Context Notification is active within components of multiple major health care systems across Maryland.

Clinical User Registration and Access Data:

Under HB 437, all controlled dangerous substance (CDS) prescribers and pharmacists licensed to dispense CDS in Maryland must be registered with the PDMP by July 1, 2017, and effective February 15, 2018, a prescriber must be PDMP registered before being issued a new or renewal CDS Registration by the Office of Controlled Substances Administration (OCSA). Over 88% of the individuals (86.72% of prescribers and 92.59% of pharmacists) who fall under this mandate have registered as of May 4, 2018. CRISP and PDMP staff continue to conduct outreach through licensing boards, professional organizations, and major facilities in Maryland to educate providers about the registration mandate and how to be compliant. In November 2017, individual letters were sent to over 13,000 providers who were known or thought to be not registered. Another round of letters will be mailed to providers who continue to be unregistered in late spring 2018.

Table 1. Registered Clinical PDMP Users by User Type.

Type of User	# of Registered Users	# Individuals subject to Registraton Mandate	% of Individuals who are PDMP Registered
Prescriber*	31,094	35,857	86.72%
Pharmacist**	10,860	11,729	92.59%
Total Subject to Mandate	**41,954**	**47,586**	**88.16%**
Prescriber/Pharmacist Delegate	2,915	N/A	N/A

* Number of prescribers obtained from roster of licensees who have an active CDS registration with Office of Controlled Substances Administration (OCSA, formerly Division of Drug Control), the State CDS permit authority.

** Number of pharmacists obtained from a Board of Pharmacy roster containing total licensees in possession of an active Maryland pharmacy license.

Investigative User Registration and Disclosures

Between March 21, 2014, when the investigative data requesting functionality was initiated, and October 31, 2017, there have been a cumulative 2,579 valid requests for data reports from legally authorized investigators. Under the PDMP statute, the Program may disclose PDMP data to local, State, or federal law enforcement agencies, Maryland health professional Licensing Boards, and five agencies within the Department (Office of the Chief Medical Examiner, Office of the Inspector General, Office of Health Care Quality, Medicaid, and Office of Controlled Substances Administration), to further existing, bona fide, individual investigations. In addition, PDMP data can be disclosed to fatality review teams in order to further existing case review. There are 199 registered investigative users with accounts as of October 31, 2017.

Table 2. Total Number of Cumulative Investigative User Accounts and Cumulative Requests Submitted to Maryland PDMP, October 2015–October 2017.

Investigative Agency Type	# of Registered Users (cum.)			# of Requests (cum.)		
	Oct. 2015	Oct. 2016	Oct. 2017	Oct. 2015	Oct. 2016	Oct. 2017
Federal, State, Local Law Enforcement	72	90	97	434	891	1,871
Licensing Board	37	40	43	12	43	175
Department Agency	28	29	30	34	65	79
Fatality Review	0	11	29	0	89	454
Total	**137**	**170**	**199**	**480**	**1,088**	**2,579**

All investigative requesters have been trained by the Program on the purposes and uses of the PDMP and on how to make investigative requests from the PDMP; this training is required prior to receiving a unique

investigative user account.

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

In its 2014 Annual Report, the Board noted that access to PDMP data by key system users, such as healthcare providers, law enforcement investigators and other authorized requesters, had been in place for less than a year; therefore, analysis of outcomes on patient access to pharmaceutical care and curbing prescription drug diversion was just being initiated and the Board could not report on the Program's impact on patient access to pharmaceutical care and on curbing prescription drug diversion in Maryland at that time. The Program is now more able to compare number of controlled substance and opioid prescriptions dispensed and reported in the PDMP between 2014 and 2017. As the Program gains greater understanding of the data in the PDMP, it will continue to analyze the impact on patient access to controlled substances and on curbing prescription drug diversion.

Dispensed Prescription Data

The number of total Schedule II–V CDS prescriptions dispensed in or into Maryland and reported to the PDMP in corresponding time periods of years 2014–2017 (January 1–September 30 of each year) is shown in **Table 3** below. Prescriptions reported to the PDMP were dispensed in or into Maryland to a recipient with a Maryland address linked to the prescription but could have been prescribed by a provider who practices outside of Maryland. There are noted decreases between 2016 and 2017 for all controlled substances (-7.73% - **Table 3**), opioids (-12.42% - **Table 4**), benzodiazepines (-8.65% - **Table 6**), and stimulants (-2.96% - **Table 7**). Buprenorphine prescribed for the treatment of substance use disorder, or Medication Assisted Treatment (MAT), increased (+7.13%) between 2016 and 2017, a desired outcome of efforts to expand MAT across Maryland. Variations in specific medications, classes, and demographics of interest for January 1–September 30 in each year 2014, 2015, 2016, and 2017 are shown in **Tables 4-8**. New analytic methods were available for data reporting in 2017, and thus there may be differences as compared with data reporting in previous years. Consistent methods were applied to all years of data included in this report.

There are some important considerations when reviewing data output.

- Most data are reported in total number of prescriptions, which should not serve as a surrogate for number of patients. Additionally, changes from fewer prescriptions for large quantities of pills to more frequent small quantity prescriptions, as well as diagnosis or age-specific differences in prescribing trends, could skew reports based on total number of prescriptions. The PDMP will continue to work with State and national partners to apply best practices in reporting out prescription data.

- Total opioid prescription counts also include tramadol, an opioid that was moved by the federal Drug Enforcement Agency (DEA) from being unscheduled to a Schedule IV prescription, effective August 18, 2014.[†]

[†] Drug Enforcement Administration, U.S. Department of Justice. Final Rule on Schedules of Controlled Substances: Placement of Tramadol Into Schedule IV, online at http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0702.htm (effective August 18, 2014, retrieved May 17, 2018).

Therefore, for most of the period of 2014 included in this report, tramadol prescriptions were not reported to the Maryland PDMP, while all tramadol prescriptions from 2015 onward were required to be reported to the PDMP.

- PDMP has not validated the quality of data contained in most variables reported from dispensers, and thus errors may exist that disproportionately impact certain data elements. For example, while edit checks in our system require a valid date to be submitted as the date of birth, data entry typos could cause prescriptions to be attributed to the wrong age group.

- An analysis conducted comparing PDMP dispensing records against a national prescription comparator (IMS National Prescription Audit aggregate prescription data for Maryland), showed congruency of the IMS and PDMP data starting in August 2014, leading us to believe that there are gaps in reporting data prior to this date. The gaps are likely due to bringing all dispensers into compliance with the requirement to report dispensed prescriptions to the PDMP starting August 2013. Therefore, all calendar year 2014 data could be subject to underreporting.

Table 3. Total Controlled Substance Prescriptions Dispensed to Maryland Recipients, 2014–2017.

Year (Jan. 1–Sep. 30)	Prescription Count	% Change (Year to Year)
2014	6,421,601	N/A
2015	6,716,891	4.60%
2016	6,674,651	-0.63%
2017	6,158,746	-7.73%

Table 4. Total Opioid* Prescriptions Dispensed to Maryland Recipients, 2014–2017.

Year (Jan. 1–Sep. 30)	Prescription Count	% Change (Year to Year)
2014	2,755,810	N/A
2015	3,040,897	+10.34%
2016	2,932,764	-3.55%
2017	2,568,538	-12.42%

*Total opioids include all prescriptions containing a medication in the opioid class of drugs except medications containing burprenorphine in a formulation indicated for the treatment of opioid use disorder (OUD). Indication was determined based on U.S. Food and Drug Administration (FDA) indication for approved use for treatment of OUD. Strict adherence to approved indications may not occur. Prescriptions were not compared with diagnoses for patients to whom they were prescribed as PDMP does not have this information, and thus this measurable proxy was used.

Table 5. Total Buprenorphine-containing Prescriptions Dispensed by Treatment Indication,* 2014–2017.

Year (Jan. 1–Sep. 30)	SUD Treatment		Pain Treatment	
	Prescription Count	% Change (Year to Year)	Prescription Count	% Change (Year to Year)
2014	188,298	N/A	6,683	N/A
2015	192,885	+2.44%	6,743	+0.90%
2016	203,356	+5.43%	7,101	+5.31%
2017	217,846	+7.13%	7,384	+3.99%

*Buprenorphine is a medication within the opioid class of drugs, but which is prescribed in specific formulations for the treatment of pain as well as for the treatment of OUD. Indication was determined based on FDA indication for approved use for either the treatment of pain or treatment of OUDs. Strict adherence to approved indications may not occur. Prescriptions were not compared with diagnoses for patients to whom they were prescribed as PDMP does not have this information, and thus this measurable proxy was used.

Table 6. Total Benzodiazepine Prescriptions Dispensed, 2014–2017.

Year (Jan. 1–Sep. 30)	Prescription Count	% Change (Year to Year)
2014	1,367,058	N/A
2015	1,359,595	-0.55%
2016	1,355,785	-0.28%
2017	1,238,539	-8.65%

Table 7. Total Stimulant Prescriptions Dispensed, 2014–2017.

Year (Jan. 1–Sep. 30)	Prescription Count	% Change (Year to Year)
2014	850,374	N/A
2015	897,898	+5.59%
2016	959,393	+6.85%
2017	931,032	-2.96%

Table 8. Top Ten Controlled Substance Prescriptions Dispensed (Generic Name), 2014–2017.

Rank	2017 (Jan. 1–Sep. 30)		2016 (Jan. 1–Sep. 30)	
	Generic Name	**Rx Count**	**Generic Name**	**Rx Count**
1	OXYCODONE HCL	662,508	OXYCODONE HCL	713,571
2	ALPRAZOLAM	463,118	OXYCODONE HCL/ ACETAMINOPHEN	543,675
3	TRAMADOL HCL*	457,300	TRAMADOL HCL*	512,109
4	OXYCODONE HCL/ ACETAMINOPHEN	446,768	ALPRAZOLAM	504,054
5	DEXTROAMPHETAMINE/ AMPHETAMINE	432,692	HYDROCODONE/ ACETAMINOPHEN	475,131
6	HYDROCODONE/ ACETAMINOPHEN	394,643	DEXTROAMPHETAMINE/ AMPHETAMINE	418,294
7	CLONAZEPAM	304,476	CLONAZEPAM	328,606
8	LORAZEPAM	259,196	LORAZEPAM	284,186
9	METHYLPHENIDATE HCL	211,990	METHYLPHENIDATE HCL	243,335
10	LISDEXAMFETAMINE DIMESYLATE	194,933	ACETAMINOPHEN WITH CODEINE	197,472
	Total	**3,827,624**	**Total**	**4,220,433**

Rank	2015 (Jan. 1–Sep. 30)		2014 (Jan. 1–Sep. 30)	
	Generic Name	Rx Count	Generic Name	Rx Count
1	OXYCODONE HCL	696,899	HYDROCODONE/ ACETAMINOPHEN	673,416
2	OXYCODONE HCL/ ACETAMINOPHEN	596,485	OXYCODONE HCL	647,472
3	HYDROCODONE/ ACETAMINOPHEN	535,633	OXYCODONE HCL/ ACETAMINOPHEN	639,723
4	TRAMADOL HCL*	515,656	ALPRAZOLAM	506,372
5	ALPRAZOLAM	503,353	DEXTROAMPHETAMINE/ AMPHETAMINE	333,910
6	DEXTROAMPHETAMINE/ AMPHETAMINE	369,130	CLONAZEPAM	324,168
7	CLONAZEPAM	327,533	LORAZEPAM	284,245
8	LORAZEPAM	284,999	METHYLPHENIDATE HCL	233,278
9	METHYLPHENIDATE HCL	237,950	ACETAMINOPHEN WITH CODEINE	194,922
10	ACETAMINOPHEN WITH CODEINE	199,810	DIAZEPAM	184,830
	Total	**4,267,448**	**Total**	**4,022,336**

* Tramadol was not scheduled until partway through 2014.

Recommendations on Modification or Continuation of the Program

Legislation/Regulations

The Board is of the opinion that the Program should focus on implementing the currently legislative mandates and initiatives.

Since January 2017, and in conformance with the mission objectives of Health-General Article § 21–2A–02, the PDMP has focused on three primary initiatives:

(1) implement the July 1, 2017 PDMP mandatory registration requirement of CDS prescribers and pharmacists in collaboration with the Department's Office of Controlled Substances Administration, see Health-General Article § 21–2A–04.1(a)·

(2) expand its outreach and education campaign to prescribers and pharmacists to facilitate PDMP registration, see Health-General Article § 21–2A–04.1(c); and

(3) increase PDMP operational capabilities to improve data collected quality and data analytics in preparation for the July 1, 2018, PDMP use and dispensing mandate, see Health-General Article § 21–2A–04.2(a).

The Program is focusing on the following operational capability improvements in 2018:

- improving interstate data sharing;
- implementation of the original unsolicited reporting authority from 2014; and
- expanded data analysis and reporting – including building a predictive risk model for opioid prevention and refining the red flags program to analyze PDMP data.

Conclusion

The Board recommends that the Governor and General Assembly continue to support ongoing development of the PDMP and that the Program has made substantial strides in realizing currently set legislative goals in 2018. Over the next year, the Board will continue to support the Department by providing ongoing advice about emerging stakeholder PDMP needs, and issue guidance on key priority areas to improve health and safety outcomes related to CDS prescriptions in Maryland.

Attachment A

Advisory Board on Prescription Drug Monitoring—Membership

Chair (October 5, 2016–September 30, 2017)

Kim Leah Bright, MD
Secretary designee, Maryland Department of Health
Medical Director, Behavioral Health Administration

Chair (November 9, 2017 - Present)

Audrey Clark, MPA
Secretary's designee, Maryland Department of Health, Board Chair
Executive Director, Office of Controlled Substances Administration

Current Members (As of December 2017)

Daniel M. Ashby, MS, FASHP
President's designee, Board of Pharmacy
The Johns Hopkins Hospital Sr. Director of Pharmacy

Dale Baker, CPRS/RPS
Certified Peer Recovery Specialist

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

Amit Bhargava, MD, MS, RMSK, Medical Director
Advanced International Pain & Sports Medicine

Thomas C.C. Bond, III
Senior Director
Programs & Strategic Partnerships

Zachery Chattler, DPM
President's designee, Board of Podiatric Medical Examiners

Richard A. Debenedetto, PharmD, MS, AAHIVP
Assistant Professor, Department of Pharmacy Practice & Administration
University of Maryland Eastern Shore School of Pharmacy & Health Professions

Janet Getzey Hart
Pharmacist
Director, Government Affairs, Rite Aid

Arthur C. Jee, DMD
President's designee, Board of Dental Examiners
Oral Maxillofacial Surgery

Chris Jillson, MD

Emergency Medicine Physician, Alteon Health

Marcus Jones, Commander
Montgomery County Police 3rd District Station

Celeste M. Lombardi, MD
Chair's designee, Maryland Board of Physicians
Physician Advisor, Office of Quality, Safety & Improvement Director
Outpatient International Pain Service, Department of Neurology/Pain Management

Stephen A. Nichols, MD, FAAP, FAAPMR
Senior Attending Physician for Rehabilitation Services
Mt. Washington Pediatric Hospital Pediatric designee

Bonnie C. Oettinger, RN, MGA
President's designee, Maryland Board of Nursing
Executive Director, Lt. Joseph P. Kennedy Institute of Catholic Charities

Orlee Panitch, MD
Physician, Medical Emergency Professionals

Derek Peck, Captain
Secretary's designee, Maryland State Police
Criminal Enforcement Division

Larry Polsky, MD, MPH
President's designee, Maryland Association of County Health Officers
Health Officer, Calvert County

Joseph Scalese, III, RPh
Pharmacist, Weis Pharmacy

David Sharp, PhD
Chair's designee, Maryland Health Care Commission
Director, Center for Health Information Technology & Innovative Care Delivery

TBD
An academic or research professional