BOARD OF PODIATRIC MEDICAL EXAMINERS

OPEN SESSION MEETING

MINUTES

June 14, 2018

Room 110

The Public Session Meeting commenced at 1:04 PM, opened by Board Vice President, Dr. H. David Gottlieb.

Board members attending were Drs. Philip Cohen and Craig Friedman. Consumer members present were Frona Kroopnick and Sharon Bunch. Board President, Dr. Zachary Chattler and Board member Dr. Umezurike were absent.

Board staff present: Eva Schwartz, Executive Director, Rhonda Edwards, AAG, Board Counsel, Sheri Henderson, Deputy Executive Director, Elizabeth Kohlhepp, Licensing Coordinator, and Danielle Vallone, Board Investigator.

Representing MDH: Lillian Reese, Legislation.

Representing MPMA: Richard Bloch, Esq., Executive Director.

Guests Present: Dr. Jay LeBow.

COMAR 10.01.14.02.B:
Except in instances when a public body expressly invites public testimony, questions, comments, or other forms of public participation, or when public participation is otherwise authorized by law, a member of the public attending an open session may not participate in the session.

A. MINUTES:

1. Approval of minutes from the May 10, 2018 meeting

The minutes from the May 10, 2018 meeting were approved unanimously, as submitted.

B. OLD BUSINESS:

1. Proposed Regulations defining what is required to prove 5 years of Practice for a Full License COMAR 10.40.01.01

The Board previously voted to propose a new regulation requiring an affidavit during the licensing process to prove five years of active practice immediately preceding the application for licensure. This personal affidavit would be acceptable in lieu of the residency program affidavit, if the applicant chooses to apply via this route. The proposed regulation was printed on March 30, 2018 in the Maryland Register with a comment period that ended on April 30, 2018 with no comments. The regulation will become effective on July 2, 2018.

2. Proposed Regulation addressing Active podiatric practice- COMAR 10.40.08.02

The Board previously voted to propose a regulation to define active practice to be interpreted as requirement of an average 400 working hours of practicing podiatry per year, for five consecutive years. The comment period regarding this proposal ended April 30, 2018 and no comments were received. The regulation will become effective on July 2, 2018.

3. Proposed Amendment to COMAR 10.40.06.03- Advertising Regulation

The Board previously voted on a proposed amendment to COMAR 10.40.06- Advertising concerning the identification of a podiatrist as such, or as a foot and ankle specialist, or foot and ankle surgeon in advertisements or any media platforms. The comment period regarding this proposal ended on May 14, 2018 and no comments were received. The regulation will become effective on July 2, 2018.

4. SB 1223-Promulgating regulations regarding mandatory CME's required for prescribing and dispensing opioids

The Board reviewed a draft of proposed regulations based on SB 1223 - Controlled Dangerous Substances Registration- Authorized Providers- Continuing Education. The Bill requires that all CDS permit holders or those applying for a new/initial permit, will be mandated to complete 2 CME credits before initial issuance of permit and at permit renewal, specific to prescribing and or dispensing scheduled drugs. The bill also indicates that failure to do so can lead to ineligibility for renewal of the CDS permit/registration by the Office of Controlled Substance Administration. The Bill will go into effect on October 1, 2018. The Board tabled discussion on the proposed regulations until the July 12th meeting.

C. NEW BUSINESS:

1. HB- 88-Public Health- Prescription Drug Monitoring Program- Revisions: Maryland PDMP Use of Mandate Implementation

The Board received a copy of HB- 88-Public Health- Prescription Drug Monitoring Program- Revisions: Maryland PDMP Use of Mandate Implementation for informational purposes.

2. PDMP use mandate

The Board was made aware that the PDMP use mandate will go into effect on July 1, 2018. See additional information attached.

3. Review for eligibility for FULL License:

a. Amin Jahedi, DPM

b. Roberto Brandao, DPM

c. Paul Carroll, DPM

d. Michael Matthews, DPM

e. Haseeb Ahmad, DPM

The above identified licensure candidates were approved unanimously for the issuance of a full Maryland License.

D. OTHER:

1. The Board showed appreciation to Dr. Craig Friedman for his time served on the Board.

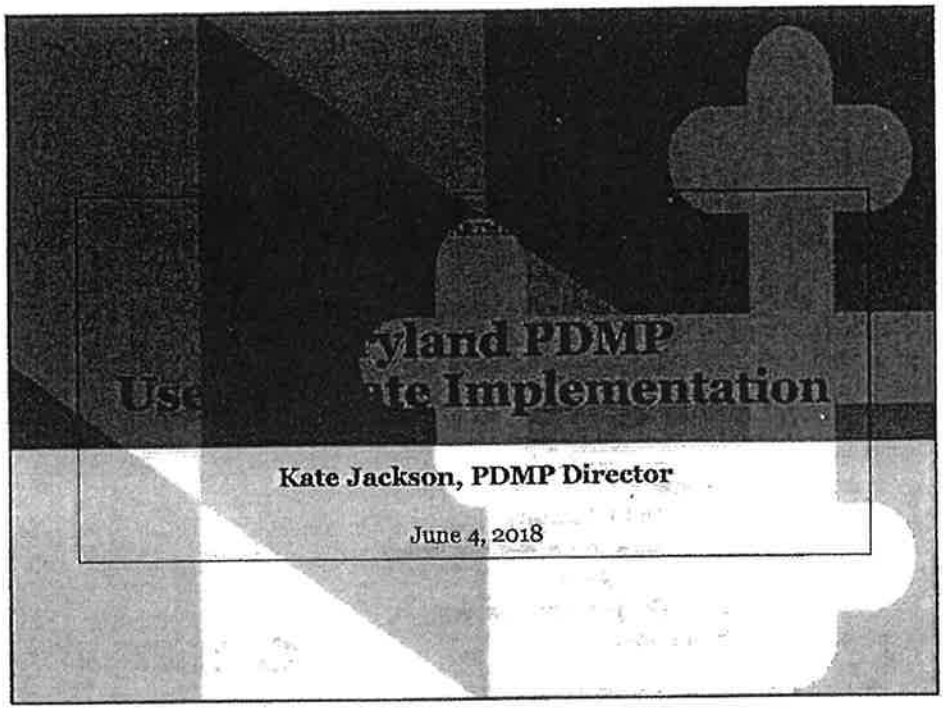
2. The Board discussed that it will no longer be accepting or answering scope of practice questions. If a podiatrist has a scope of practice related question, they should refer to the Board's scope of practice regulations or contact a health care attorney. Furthermore, the Board can not contact insurance providers regarding whether or not the use of certain codes are within a podiatrist's scope of practice.

3. The Board thanked the MPMA for a wonderful Day of Science this year.

With no further business, the Board meeting concluded at 1:41 PM.

Respectfully submitted,

Yvonne Umezurike, Secretary/Treasurer



Agenda

- Use Mandate for Prescribers & Pharmacists
- Outreach and Implementation Resources
- Solicitation of Questions / Feedback

MARYLAND Department of Health

Mailing / Email

Mass email using GovDelivery sent 5/30/2018 to:

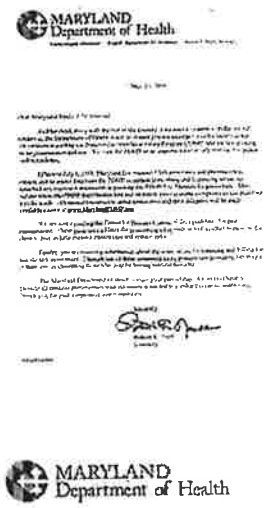
- PDMP-registered Prescribers and Pharmacists
- Using email address on file with PDMP registration

USPS Mailing sent week of 6/4/2018 to:

- All prescribers based on mailing address from OCSA
- All licensed pharmacists based on mailing address from Board of Pharmacy

Included documents:

- Cover letter from MDH Secretary
- Prescriber and Pharmacist specific Fact Sheet (Version 1.0, May 23, 2018)
- For prescribers, CDC guidelines and suicide assessment billing codes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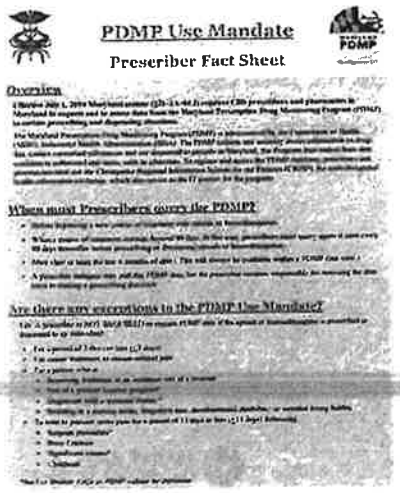
Fact Sheets

Available on the PDMP Website (www.MarylandPDMP.org)

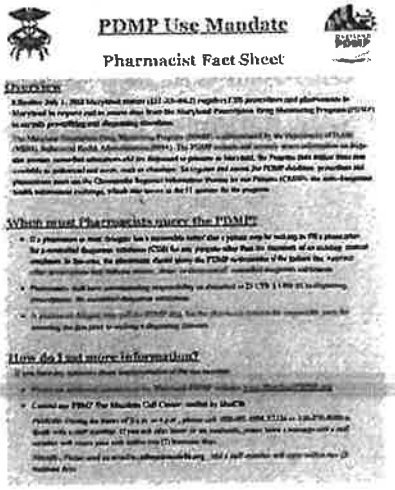

PDMP Use Mandate

Prescriber Fact Sheet

Overview

When must Prescribers query the PDMP?

Are there any exceptions to the PDMP Use Mandate?


PDMP Use Mandate

Pharmacist Fact Sheet

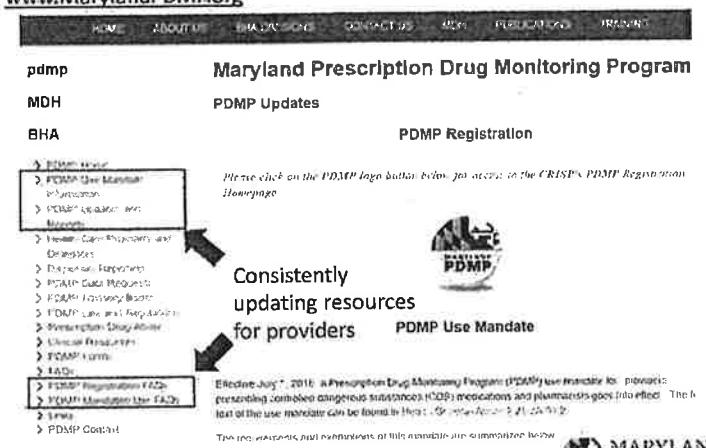
Overview

When must Pharmacists query the PDMP?

How do I get more information?

Website Updates

www.MarylandPDMP.org



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MARYLAND Department of Health

Call Center

How to advise **providers** about getting assistance:

IMPLEMENTATION / CLINICAL QUESTIONS:

- PDMP Use Mandate Call Center, staffed by MedChi
- **PHONE:** 800-492-1056 X3324 or 410-878-9688; Staffed 8 a.m. to 6 p.m. M-F with after-hours voicemail box (response within 2 business days)
- **EMAIL:** pdmp@medchi.org - staff reply within 2 business days.

TECHNICAL QUESTIONS:

- CRISP Operations Support staff
- **PHONE:** 877-952-7477
- **EMAIL:** support@crisphealth.org

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Questions / Feedback

Next Steps:

- PDMP video vignettes – Summer 2018
- Additional fact sheets: Delegates, Dos/Don'ts, Integration
- Updates to FAQs

For Boards to contact PDMP Office:

- **General Items:** mdh.pdmp@maryland.gov / 410-402-8686
- **Director, Kate Jackson:** kate.jackson@maryland.gov / 443-827-0792
- **Assistant Director, Sara Roberson:** sara.roberson1@maryland.gov / 410-402-8426

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MARYLAND Department of Health

PDMP Use Mandate

Prescriber Fact Sheet

Overview

Effective July 1, 2018 Maryland statute (§21–2A–04.2) requires CDS prescribers and pharmacists in Maryland to request and to assess data from the Maryland Prescription Drug Monitoring Program (PDMP) in certain prescribing and dispensing situations.

The Maryland Prescription Drug Monitoring Program (PDMP) is administered by the Department of Health (MDH), Behavioral Health Administration (BHA). The PDMP collects and securely stores information on drugs that contain controlled substances and are dispensed to patients in Maryland; the Program then makes these data available to authorized end users, such as clinicians. To register and access the PDMP database, prescribers and pharmacists must use the Chesapeake Regional Information System for our Patients (CRISP), the state-designated health information exchange, which also serves as the IT partner for the program.

When must Prescribers query the PDMP?

- Before beginning a new course of treatment with opioids or benzodiazepines
- When a course of treatment extends beyond 90 days. In this case, prescribers must query again at least every 90 days thereafter before prescribing or dispensing opioids or benzodiazepines
- Must view at least the last 4 months of data (This will always be available within a PDMP data view.)
- A prescriber delegate may pull the PDMP data, but the prescriber remains responsible for assessing the data prior to making a prescribing decision.

Are there any exceptions to the PDMP Use Mandate?

Yes. A prescriber is NOT REQUIRED to request PDMP data if the opioid or benzodiazepine is prescribed or dispensed to an individual:

- For a period of 3 days or less (≤3 days)
- For cancer treatment or cancer-related pain
- For a patient who is:
  - Receiving treatment in an inpatient unit of a hospital
  - Part of a general hospice program*
  - Diagnosed with a terminal illness *
  - Residing in a nursing home, long-term care, developmental disability, or assisted living facility
- To treat or prevent acute pain for a period of 14 days or less (≤14 days) following:
  - Surgical procedure*
  - Bone Fracture
  - Significant trauma*
  - Childbirth

**See Use Mandate FAQs on PDMP website for definitions*

The following scenarios** would also be considered exempt from the PDMP Use Mandate:

- When accessing PDMP data would result in a delay of treatment that would negatively impact the medical condition of the patient
- When electronic access is not operational, as determined by the Department of Health
- In the event of temporary electrical or technological failure

***If one of these exemptions applies, the provider must use reasonable medical judgment in determining whether to prescribe or dispense an opioid or benzodiazepine, and must document in the patient's health record the reason PDMP data was not accessed.*

What do I need to document in the medical record?

To comply with requirements of the use mandate, prescribers need to document in the patient's health record that the PDMP data was requested and assessed prior to prescribing the opioid or benzodiazepine.

How do I get more information?

If you have any questions about implementation of the use mandate:

- Please see additional resources on the **Maryland PDMP website: www.MarylandPDMP.org**
- Contact our **PDMP Use Mandate Call Center**, staffed by MedChi:

  PHONE: During the hours of 8 a.m. to 6 p.m., please call **800-492-1056 X3324** or **410-878-9688** to speak with a staff member. If you call after hours or on weekends, please leave a message and a staff member will return your call within two (2) business days.

  EMAIL: Please send an email to **pdmp@medchi.org** , and a staff member will reply within two (2) business days.

Version 1.0, May 23, 2018

PDMP Use Mandate

Pharmacist Fact Sheet

Overview

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When must Pharmacists query the PDMP?

- If a pharmacist or their delegate has a reasonable belief that a patient may be seeking to fill a prescription for a controlled dangerous substance (CDS) for any purpose other than the treatment of an existing medical condition. In this case, the pharmacist should query the PDMP to determine if the patient has received other prescriptions that indicate misuse, abuse, or diversion of controlled dangerous substances.
- Pharmacists shall have corresponding responsibility as described in 21 CFR § 1306.04 in dispensing prescriptions for controlled dangerous substances.
- A pharmacist delegate may pull the PDMP data, but the pharmacist remains the responsible party for assessing the data prior to making a dispensing decision.

How do I get more information?

If you have any questions about implementation of the use mandate:

- Please see additional resources on the **Maryland PDMP website: www.MarylandPDMP.org**
- Contact our **PDMP Use Mandate Call Center**, staffed by MedChi:

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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

MARYLAND
Department of Health

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

June 7, 2018

The Hon. Katherine Klausmeier Senate Chair
Joint Committee on Behavioral Health
and Opioid Use Disorders
103 James Senate Office Building
Annapolis, Maryland 21401

The Hon. Eric M. Bromwell, House Chair
Joint Committee on Behavioral Health
and Opioid Use Disorders
241 House Office Building
Annapolis, Maryland 21401

Re: Prescription Drug Monitoring Program House Bill 437, Chapter 147 (2016), Section 9 Contingency Determination

Dear Chairs Klausmeier and Bromwell:

The Maryland Department of Health (the "Department") has previously reported significant increases toward registering all controlled dangerous substance (CDS) prescribers and pharmacists with Maryland's Prescription Drug Monitoring Program (PDMP) in conjunction with the registration mandate as required by Health General 21-2A-04.1(a) and (b). At this time, the Department is seeking consultation related to activation of the PDMP use mandate intended to accompany the previously implemented registration mandate.

As required by Section 9 of House Bill 437 (2016), Section 3 (the "use mandate") is contingent on the Department's determination, made in consultation with the PDMP Advisory Board, the Joint Committee on Behavioral Health and Opioid Use Disorders (the "Joint Committee") and stakeholders, that required criteria are met to support activation of the use mandate.

By notice of this letter, the Department respectfully requests that the Joint Committee provide feedback on the Department's assessment that the parameters in Section 9 of HB 437 have been met. In order to meet the use mandate implementation date of July 1, 2018, we would appreciate any feedback and advice from the Joint Committee by **June 29, 2018**.

In addition to this letter, the Department is working with the following stakeholders for their input: (1) the Maryland State Medical Society; (2) the Maryland Nurses Association; (3) the Maryland Nurse Practitioner Association; (4) the Maryland Hospital Association; (5) the Maryland Podiatric Medical Association; (6) the Maryland State Dental Association; (7) the Maryland Pharmacist Association; (8) Maryland Institute for Emergency Medical Services Systems; and (9) Opioid Operational Command Center. In addition to those industry and community stakeholders, the Department continues to work with the Board of Physicians; Board of Pharmacy; Board of Nursing; State Board of Dental Examiners; Board of Podiatric Medical Examiners; for their input and comments.

The Department will review the input and determine if the contingencies under Subsection (a) of Section 9, HB 437, have been satisfied.

201 W. Preston Street · Baltimore, MD 21201 · health.maryland.gov · Toll Free: 1-877-463-3464 · TTY: 1-800-735-2258

Section 9 Summary

Section 3 of HB 437 requires that Maryland-licensed pharmacists and prescribers of controlled dangerous substances (CDS) must access and assess PDMP data prior to certain prescribing and dispensing situations, if the Secretary of the Maryland Department of Health determines the contingencies in HB 437 have been met. If the Secretary does not determine the contingencies have been met, the use mandate does not go into effect.

Section 9 of HB 437 provides:

(a) Section 3 of this Act is contingent on a determination by the Secretary of Health and Mental Hygiene, made in consultation with the Advisory Board on Prescription Drug Monitoring, the Joint Committee on Behavioral Health and Opioid Use Disorders, and stakeholders, that:

(1) the technical capabilities of the Prescription Drug Monitoring Program are sufficient to achieve a reasonable standard of access and usability by prescribers and pharmacists; and

(2) requiring a prescriber to request prescription monitoring data for a patient in accordance with § 21–2A–04.2 of the Health – General Article, as enacted by Section 3 of this Act, is important to protect public health and promote good patient care.

(b) The Secretary of Health and Mental Hygiene shall notify the Department of Legislative Services and, in accordance with § 2–1246 of the State Government Article, the Senate Finance Committee and the House Health and Government Operations Committee within 5 days after the Secretary determines that the contingencies under subsection (a) of this section have been satisfied.

(c) If the notice required under subsection (b) of this section is not received by the Department of Legislative Services on or before June 30, 2023, Section 3 of this Act shall be null and void without the necessity of further action by the General Assembly.

Attestation of consultation with the Advisory Board on Prescription Drug Monitoring

The Advisory Board on Prescription Drug Monitoring (PDMP Advisory Board) has been consulted throughout the development and deployment of new authorities and requirements of the PDMP. At its recent meeting, the PDMP Advisory Board was also presented with the requirements in Section 9, including the results of the Chesapeake Regional Information System for our Patients (CRISP) system performance testing. Board members were provided the opportunity to ask questions and were satisfied by the presentation.

Contingency Determination

To demonstrate that "the technical capabilities of the Prescription Drug Monitoring Program are sufficient to achieve a reasonable standard of access and usability by prescribers and Pharmacists", the Department directed PDMP information technology (IT) vendor and state-designated health information exchange (HIE) CRISP to complete a test of system performance. The test was designed to stress the CRISP infrastructure in a way that mimics anticipated increases in usage of CRISP after implementation of the use mandate, and to determine that this increased volume would neither slow down responsiveness of CRISP's system to its end users nor crash CRISP's system.

Baseline performance and upgrades

Baseline metrics of how quickly the CRISP system processes user queries (logging into system, searching for a patient, displaying data, and logging out of the system) were used as a benchmark for performance under the stress testing.

Within CRISP, providers can access PDMP data through several different views:

- **CRISP Portal** with PDMP Search (PDMP-specific screen), often called the unified landing page (ULP)
- **One-click access from an electronic health record (EHR)** that directs the user to the CRISP query portal with a PDMP tab
- **Zero-click access from an EHR** where the PDMP data displays without any extra clicks
- **E-Prescribing tools**, where PDMP data is inserted into the e-prescribing workflow

Figure 1 shows baseline performance of approximately 10 seconds start to finish, based on queries made in the ULP with a three-month look-back (January 1 – March 31, 2018).

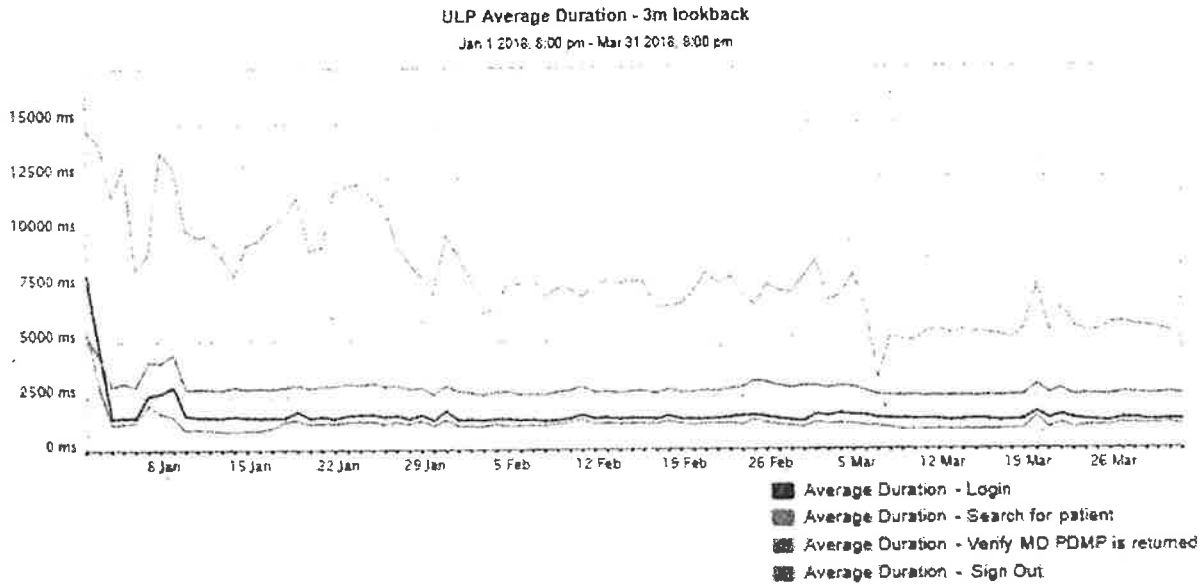

Figure 1. Baseline CRISP system performance of time to complete a query

To ensure optimal performance, CRISP has made and continues to invest in system upgrades. The PDMP data was moved to its own separate database. This allows Maryland PDMP queries to be completed without any performance impact based on other data being stored by CRISP. The PDMP database has an industry-standard (NCPDP) application programming interface (API) layer, which allows authorized external systems (like hospital EHRs or e-prescribing products) to incorporate PDMP data into other clinical user interfaces. Finally, CRISP has moved the PDMP database to the Microsoft Azure Cloud; cloud-based storage allows for automatic system scaling based on demand or use of the system. While the entire CRISP portal is scheduled to migrate to the cloud in 2018, the PDMP database was prioritized and migration has been completed.

System stress testing

In March 2018, the CRISP system was load tested to simulate conditions where the maximum expected number of concurrent clinical users would be querying for PDMP at the same time on the Unified Landing Page (ULP), the CRISP query portal hosting the PDMP Search functionality. The load of concurrent users was calculated as described below and displayed in Figure 2. Using 2017 PDMP data, it was determined that a total of 5,272,943 opioid and benzodiazepine prescriptions were dispensed. Where needed, assumptions were made to favor higher query volume over lower query volume. We assumed the exact same level of prescribing in 2018 and accounted for situations where a query would occur on both the prescribing and dispensing of each prescription. An extra 10% query volume buffer was added in. The CRISP system needs to handle non-PDMP queries alongside PDMP queries, and thus daily query volume from WV and DC users of CRISP were added. A total of 48,061 queries are expected within the ULP each day, with at least 80% of queries happening during the standard eight business hours. Therefore, approximately 50 concurrent users would represent the consistent volume of 40,000 queries being made over an eight-hour period. The system was tested to simulate the 50 concurrent users, and then doubled to simulate 100 concurrent users.

The results of the system testing are found in Figure 2 below. If 40,000 queries were performed by concurrent users within an 8-hour period, it would take a provider 15 seconds to log in, query for a patient, view the results, and log out. This is consistent with current query times, demonstrating no measurable degradation in performance.

The secondary goal of the testing was to validate that the system remains available even under intense load, which was simulated by doubling the number of queries hitting the system over the same time period. If 80,000 queries were performed within an 8-hour period, it would take a provider 20 seconds to log in, query for a patient, view the results, and log out. Although the workflow time increased on average by 5 seconds, at no point did we experience service interruption and the system was still usable. These results demonstrate CRISP's ability to provide access to PDMP data within reasonable standards of accessibility and usability.

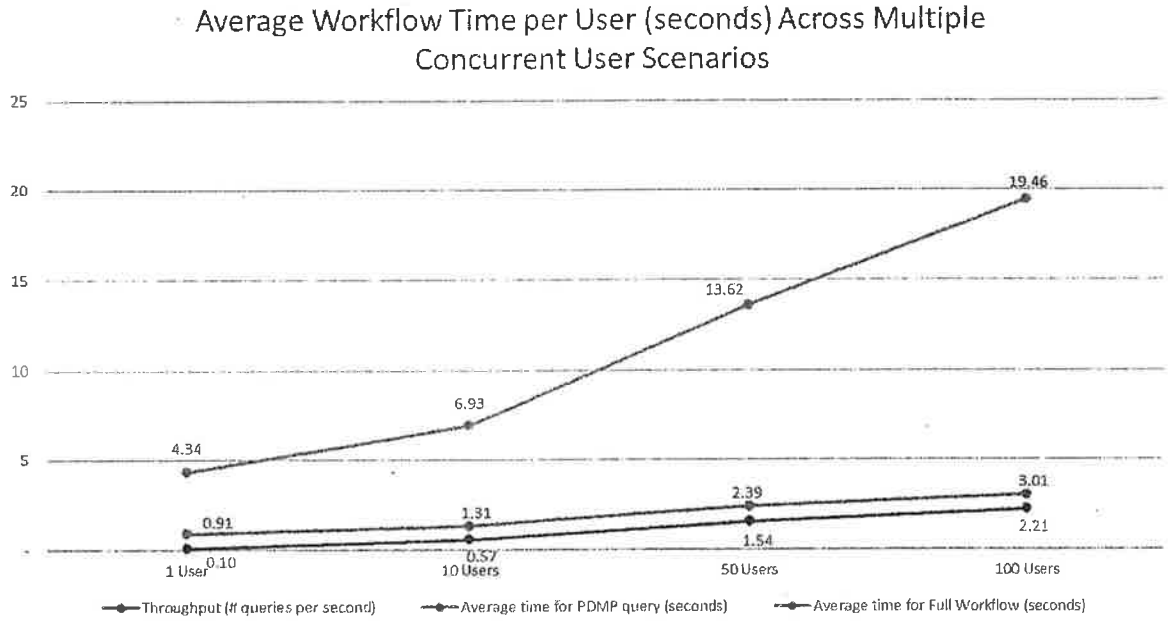

Figure 2. Average workflow time per CRISP user querying PDMP data across multiple scenarios of concurrent users.

Stress testing of the PDMP standalone database (or microservice) was completed to understand how integrations using direct connection to PDMP data would perform. These integrations include 'zero-click' access and e-prescribing tools utilizing Maryland PDMP data. The ULP described above is the most interactive workflow for clinical users and all providers have accounts to access PDMP data through the ULP. Many providers also access PDMP data through integration of PDMP data directly into EHRs or through e-prescribing tools. This enhanced data access was tested by running queries at specified rates for an hour to simulate differing levels of user traffic from Low to Heavy. The PDMP microservice currently receives approximately 120,000 queries per day; this traffic is expected to double under the Use Mandate and additional buffer was added. The final test assumed 330,000 queries per day over a peak business time of 10 hours, resulting in a maximum load testing at 30,000 per hour under Heavy traffic conditions. Figure 4 shows the

average response time for queries at each level of traffic. Even at the Heavy level of traffic, the average response time to display PDMP data was under one second. This result was deemed satisfactory.

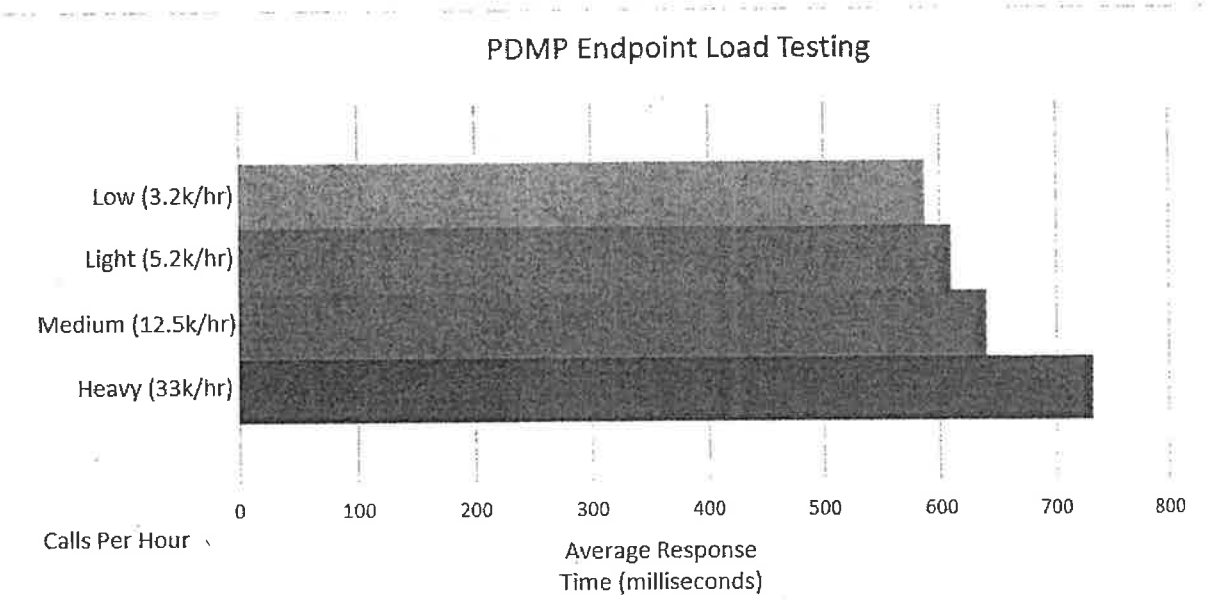

Figure 3. PDMP Standalone Database Load Testing showing response time at low to heavy rates of calls per hour.

While we feel confident in the testing that has been completed to date, CRISP and MDH continue to monitor performance and conduct auxiliary testing. Throughout 2018, additional servers are being added to ensure redundancy and scalability for the ULP workflow. CRISP will run the stress test for 50 concurrent users in production, with interstate sharing functionality enabled. The above testing included Maryland-only data. Maryland PDMP data displays using a call to the CRISP infrastructure and thus the response time is not dependent on pulling in data from other state PDMPs. Interstate data functionality is important to clinical users, and thus workflow testing including calls to the other state PDMPs will be conducted.

Use Mandate importance to public health and good patient care

PDMP data is an important tool in providing good patient care and requiring prescribers and pharmacists to access and assess PDMP data is important to protecting the public's health. This is substantiated through the 2015 CDC Guideline on Opioid Prescribing for Chronic Pain in Primary Care Setting. PDMP queries prior to prescribing opioids is one of the 12 recommendations. In addition, Maryland has taken steps to demonstrate its commitment to these guidelines and use of PDMP. HB1432 (Chapter 570, 2017) requires providers to prescribe CDS for the treatment of pain in line with CDC guidelines. In 2017, Maryland Medicaid Opioid Prescribing Policy included a requirement that "Providers should use the PDMP every time they write a prescription for CDS".

Next Steps

Following the Department's consideration of any input by the Joint Committee and the Stakeholders, the Department intends to report its determination to the Department of Legislative Services, the Senate Finance Committee and the House Health and Government Operations Committee that all contingencies in HB 437, Section 9 are satisfied.

Following that determination, communication will be made to applicable health licensing Boards and professional organizations about the effective date of the use mandate. Online materials will also be updated to reflect this change. Additional information is also included in the attached 2017 Annual Prescription Drug Monitoring Program Advisory Board Report.

Thank you for your consideration of this information. If you have any questions, please contact me or Webster Ye, Deputy Chief of Staff, at (410) 767–6480 or webster.ye@maryland.gov.

Sincerely,

Robert R. Neall
Secretary

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

cc:
Christine Farrelly, Executive Director, Board of Physicians
Deena Speights-Napata, Executive Director, Board of Pharmacy
Karen Evans, Executive Director, Board of Nursing
Tony Torain, Executive Director, State Board of Dental Examiners
Eva Schwartz, Executive Director, Board of Podiatric Medical Examiners
Vanessa Orlando, Executive Director, Board of Veterinary Medical Examiners
David Smulski, Senate Finance Committee
Lisa Simpson, House Health and Government Operations Committee