STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
Behavioral Health Administration • Spring Grove Hospital Center • Dix Building
55 Wade Avenue • Catonsville, Maryland 21228
Larry Hogan, Governor – Boyd K. Rutherford, Lt. Governor - Dennis R. Schrader, Secretary
Barbara J. Bazron, Ph.D., Executive Director

January 24, 2017

The Honorable Larry Hogan
Governor
State House
100 State Circle
Annapolis, MD 21401-1925

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(f)(3)(ii) - 2016 Report of the Analysis of the Advisory Board on Prescription Drug Monitoring on the Impact of the Prescription Drug Monitoring Program

Dear Governor Hogan, 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 relating to 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 modification or continuation of the PDMP. Senate Bill 883, Chapter 166 of the Acts of 2011 established a 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 regarding the report, please contact Kathleen Rebbert-Franklin, Deputy Director for Population-Based Behavioral Health, Behavioral Health Administration, at (410) 402-8612.

Sincerely,

Kim Leah Bright

Kim Leah Bright, MD
Chair, Advisory Board on Prescription Drug Monitoring
Medical Director, Behavioral Health Administration

Enclosures

Cc: The Honorable Thomas M. Middleton
The Honorable Shane Pendergrass
Barbara J. Bazron, PhD
Shauna Donohue
Kate Jackson, MPH
Webster Ye
Kathleen Rebbert-Franklin, LCSW-C
Dennis R. Schrader
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David Smulski
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Michael Baier

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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. The duties of the PDMP (also referred to as the Program within this report), as outlined in the PDMP law, include:

- monitoring the prescribing and dispensing of prescriptions that contain controlled dangerous substances (CDS);
- creation of an electronic database of CDS 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 CDS.

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, including representatives from health professional licensing boards, physicians, pharmacists, a nurse practitioner, a local law enforcement representative, and patient representatives. The Board has met regularly since the membership was first appointed in autumn 2011, and has provided feedback and recommendations on a number of topics, including regulations, information technology (IT), interstate data sharing and interoperability, program evaluation, funding, and educational initiatives. Current Board membership is listed in Attachment A.

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 on 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 2016 Annual Report is submitted pursuant to this requirement.

PDMP Implementation and Operations Update

In the three years since submission of the Board's first Annual Report, the Maryland PDMP has completed planning and implementation, and now focuses efforts on operations and expansion of the Program.

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. Enhancements to clinical user registration and access to PDMP data have been accomplished in 2016 and groundwork has been laid for further development in the coming year. Federal grant funding, state general fund support from the Lt. Governor's Emergency Heroin and Opioid Task Force, and legislative changes under HB437 (Chapter 147, 2016), together enable 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 to submit data requests pursuant to subpoena using a separate online system, RxSentry®, supported by IT 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 new in 2016, fatality review teams.

Legislation passed in 2015 (SB757, Chapter 381) authorized disclosure of PDMP data to State and local fatality review teams, confidential medical review committees who bring together a wide range of stakeholders and data to understand a fatality and learn lessons to propose policy changes. Fatality review teams able to request PDMP data include local Overdose Fatality Review teams, the State Child Fatality Review team, and the Maternal Mortality Review Program, all created under state statute.

CLINICAL USERS

In accordance with requirements under Health-General Article, §21-2A-05(3), PDMP registration and utilization summary statistics are provided below.

Clinical User Landscape:

As previously stated, all clinical users register for and access PDMP data through CRISP. During the first years of PDMP operations, a modest, but steady, increase in registration and use was observed. Significant increases in registration have occurred since the passage of HB437 (Chapter 147, 2016), the state statute that implemented mandatory PDMP registration by July 1, 2017 and mandatory query for certain prescribing and dispensing scenarios starting July 1, 2018. A contemporaneous, though less significant, increase in clinical user access has also been observed.

CRISP's independent outreach to integrate CRISP services into Maryland hospital electronic medical records (EMRs) 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 CRISP patient profile for a patient they are viewing in their hospital's EMR with a single click and no separate log-in to CRISP. Another integration involves CRISP delivering PDMP data directly into the view of the clinician accessing their hospital EMR, called In-Context Notification. These new methods of accessing PDMP data have driven significant increases in clinical user access.

Clinical User Registration and Access Data:

As of October 23, 2016 there are 26,524 Prescribers, Pharmacists, and Delegates (both Prescriber and Pharmacist Delegates) registered to use the PDMP. Of these, 18,261 (68.85%) are active users, having accessed the system within the last 90 days. If a registered clinical user does not log into CRISP within a 90-day period, that user's account is locked, consistent with industry practice. In order to unlock one's account, the user must contact CRISP for a password reset. Registration status is not impacted by whether a user's account is active or inactive; users remain fully registered even when an account is locked. CRISP currently provides PDMP staff with regular reports on PDMP registrants, including their active/inactive status; these reports also include information on overall query volume of PDMP data. In anticipation of the upcoming PDMP use mandate to go into effect July 1, 2018 under HB437, CRISP and PDMP staff are developing the capacity to audit and report out with far greater granularity on the volume of use by individual providers and practitioner categories. This methodology will also serve as the infrastructure for monitoring compliance with this use mandate and with evaluating other PDMP interventions aimed at increasing use of PDMP data by providers. It is intended that more robust analyses on PDMP registrant queries of PDMP data in CRISP will be included in subsequent PDMP Annual Reports.

Under HB437, all controlled dangerous substance (CDS) prescribers and pharmacists licensed to dispense CDS in Maryland must be registered with the PDMP by July 1, 2017. Over 50% of the individuals (60.14% of prescribers and 31.63% of pharmacists) who fall under this mandate have already met (or conditionally meet) the registration mandate, as of October 23, 2016. 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. Table 1 shows the total number of registered and active accounts, by user type.

Table 1. Registered and Active Clinical PDMP Data.

Type of User	# of Registered Users	# of Active Users (% of Registered)	# Licensees subject to Registration Mandate	% of Licensees who are PDMP Registered
Prescriber	20,331	14,366 (70.66%)	33,807*	60.14%
Pharmacist	3,573	2,439 (68.26%)	11,296**	31.63%
Prescriber and Pharmacist Delegates	2,620	1,456 (55.57%)	N/A	N/A
Total	**26,524**	**18,261** (68.85%)	**45,103**	**53.00%**

* 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 communication with Board of Pharmacy staff October 26, 2016 about total licensees in possession of an

active Maryland pharmacy license.

Likely due to the impending registration mandate and CRISP's efforts to provide access to clinicians through hospital EMRs, we observe an increasing number of new registrants each month through 2016. Increases in number of PDMP registrants within each local jurisdiction between 2015 and 2016 vary. Table 2 shows the number of monthly new registrants and Table 3 shows cumulative registrants by local jurisdiction.

Table 2. Number of New Registrants by month, January – October 2016

Month	Number of New Registrants
January 2016	655
February 2016	587
March 2016	694
April 2016	1,689
May 2016	662
June 2016	930
July 2016	1,553
August 2016	1,259
September 2016	3,068
October 2016	2,518
TOTAL	**13,615**

Table 3. Number of Cumulative PDMP Registrants by Jurisdiction, October 2015 – October 2016.

Jurisdiction	# of Registrants		% Change
	October 2015	October 2016	
Allegany	88	205	+132.95
Anne Arundel	741	1,120	+51.15
Baltimore City	3,524	10,272	+191.49
Baltimore County	1,744	2,377	+36.30
Calvert	97	138	+42.27
Caroline	21	23	+9.52
Carroll	185	286	+54.59
Cecil	184	257	+39.67
Charles	137	190	+38.69
Dorchester	46	59	+28.26
Frederick	394	620	+57.36
Garrett	56	73	+30.36
Harford	495	641	+29.49
Howard	294	439	+49.32
Kent	30	33	+10.00
Montgomery	2,244	4,088	+82.17
Prince George's	1,250	1,818	+45.44
Queen Anne's	62	79	+27.42
Somerset	19	20	+5.26

St. Mary's	237	236	-0.42
Talbot	83	113	+36.14
Washington	158	309	+95.57
Wicomico	222	415	+86.94
Worcester	101	220	+117.82
Unknown / Outside Maryland	1,719	2,417	+40.61
Total	**14,131**	**2,6448**	**+87.16**

Figure 1 shows the increase in registered clinical users since clinical user access was opened through October 23, 2016. Increases have occurred across all clinical user types: Prescriber, Pharmacist, and Delegate (Prescriber Delegate and Pharmacist Delegate), with the most significant increases temporal to changes in the PDMP statute. A sharp rise in Prescriber accounts began after passage of HB437 on April 26, 2016. When HB437 became effective on October 1, 2016, the definition of a Delegate expanded to include both licensed and unlicensed prescriber and pharmacy staff, likely accounting for the large jump in Delegate accounts. Dips in the number of registered user accounts occur when CRISP conducts periodic audits with hospitals and other facilities whose staff have Single Sign-On (SSO) accounts; at the time of audits, if an individual user with an SSO account has left the organization, that account is terminated. Because SSO accounts are necessarily linked to employment at a participating facility, all clinical users subject to the PDMP registration mandate will be given individual Query Portal Accounts independent of any SSO account. Individual Query Portal Accounts are not terminated, only locked for non-use. There are currently 5,973 SSO users with PDMP data access (as of November 22, 2016).

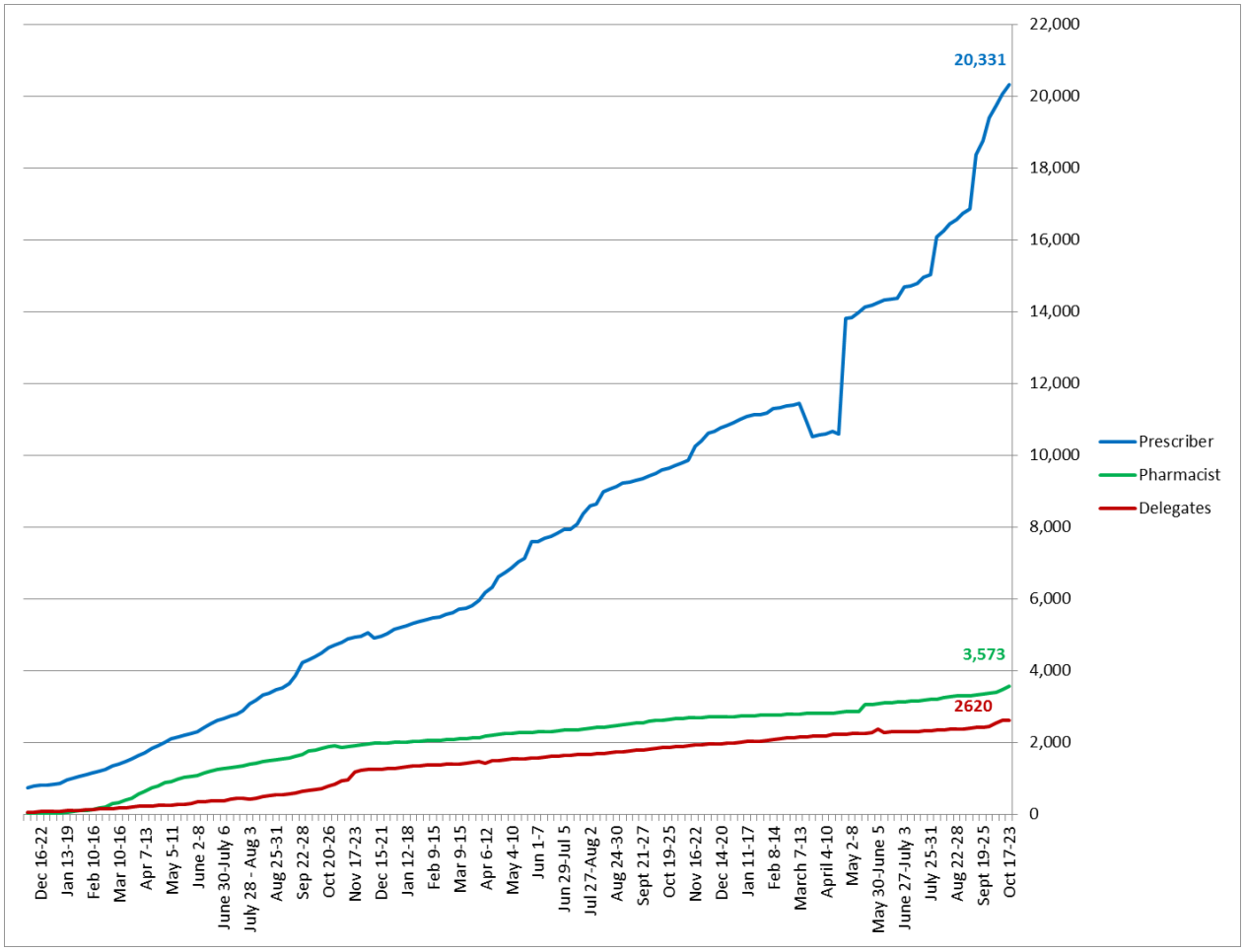


Figure 1. Clinical User Registration, by User Type, December 2013 – October 2016.

Figure 2 shows the increase in active users and total clinical PDMP queries since clinical user access was opened, December 20, 2013, through October 23, 2016. Access is broken down by queries of the system through the CRISP Query Portal or Single Sign-On (orange bars) and EMR-based viewing of PDMP data through In-Context Notifications (blue bars). Clinical users are averaging approximately 45,000 weekly queries (with an all-time high of 48,032 queries), up from an average of 20,000 weekly queries in October 2015. Figures 2 and 3 show changes in query volume and active PDMP users.

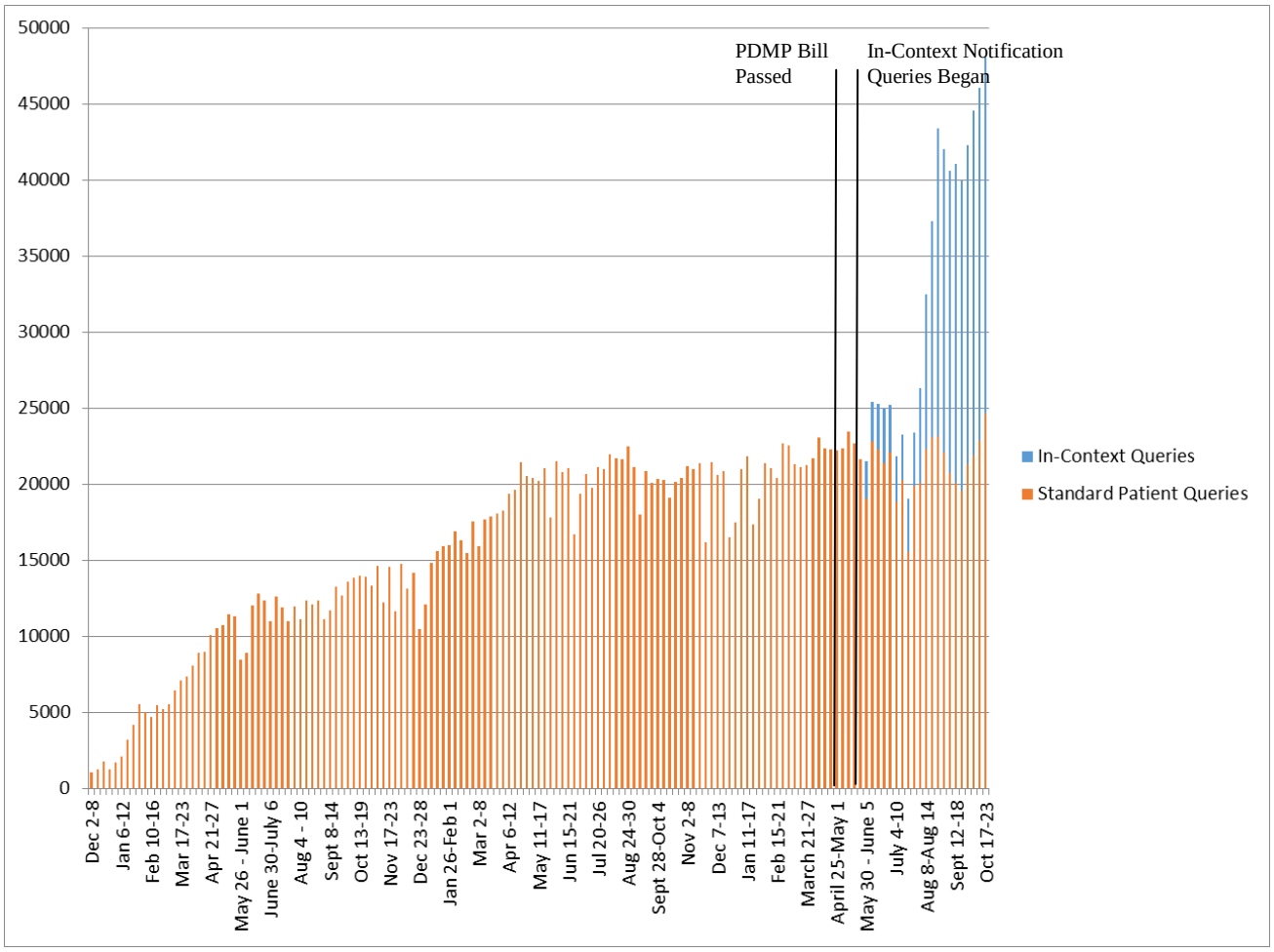


Figure 2. Total Weekly Clinical PDMP Queries, December 2013 – October 2016.

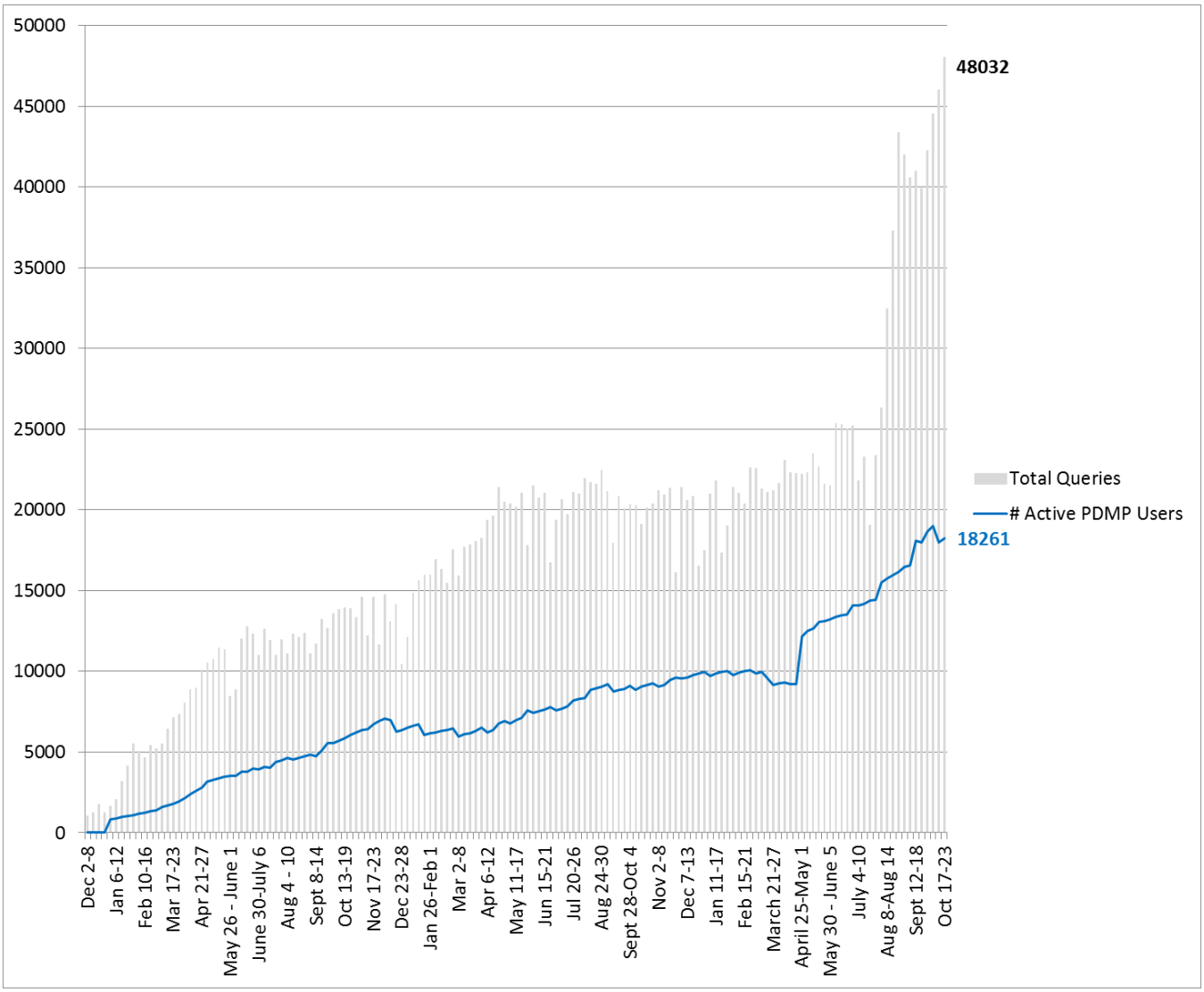


Figure 3. Active Clinical User Accounts and Total Clinical PDMP Queries, December 2013 – October 2016.

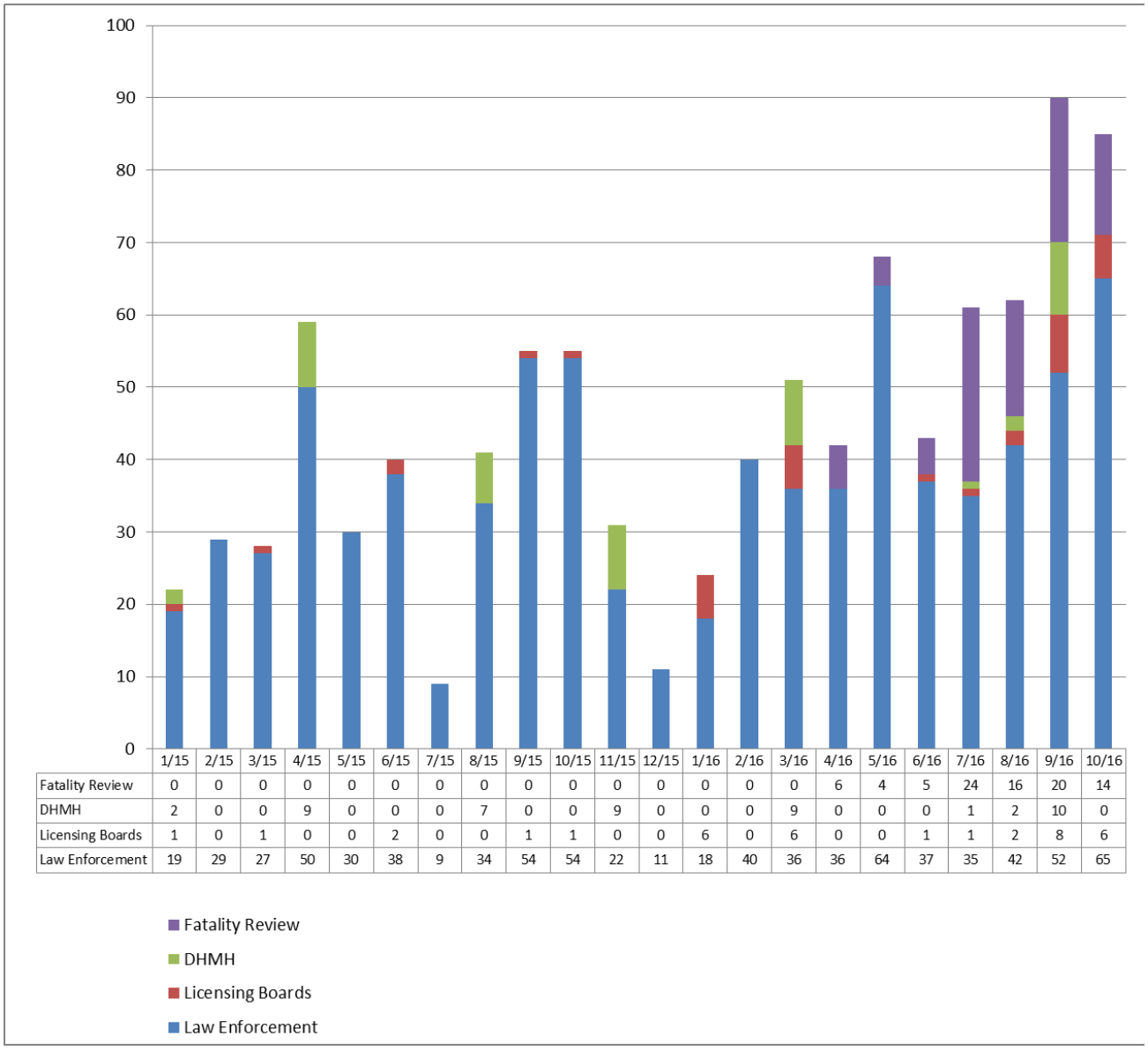
INVESTIGATIVE USER REGISTRATION AND USE DATA

Between March 21, 2014, when the investigative data requesting functionality was initiated, and October 31, 2016, there have been a cumulative 1,088 valid requests for data reports from legally authorized investigators. Under the PDMP law, the Program may disclose PDMP data to local, state, or federal law enforcement agencies, Maryland health professional Licensing Boards, and five (5) agencies within DHMH (Office of the Chief Medical Examiner, Office of the Inspector General, Office of Health Care Quality, Medicaid, and Office of Controlled Substances Administration), in order to further existing, bona fide, individual investigations. In addition, under SB757 (Chapter 381, 2015), PDMP data can be disclosed to fatality review teams in order to further existing case review. Accounting for these investigative requests is a total of 170 registered investigative users with accounts as of October 31, 2016. Table 4 shows the breakdown of investigative user accounts and total number of valid investigative data requests by user type: local, state, or federal law enforcement, licensing board, fatality review team, or DHMH agency.

Table 4. Total Number of Cumulative Investigative User Accounts and Cumulative Requests Submitted to Maryland PDMP, October 2015 – October 2016.

Investigative Agency Type	# of Registered Users (cum)			# of Requests (cum)		
	Oct 2015	Oct 2016	% Change	Oct 2015	Oct 2016	% Change
Federal, State, Local Law Enforcement	72	90	+25.00	434	891	+105.30
Licensing Board	37	40	+8.11	12	43	+258.33
DHMH Agency	28	29	+3.57	34	65	+91.18
Fatality Review	0	11	N/A	0	89	N/A
Total	**137**	**170**	**+24.09**	**419**	**1,088**	**+159.67**

All investigative requestors 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. Figure 4 shows monthly requests, by requestor type submitted to the Maryland PDMP from January 1, 2015 through October 31, 2016.



	1/15	2/15	3/15	4/15	5/15	6/15	7/15	8/15	9/15	10/15	11/15	12/15	1/16	2/16	3/16	4/16	5/16	6/16	7/16	8/16	9/16	10/16
Fatality Review	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	6	4	5	24	16	20	14
DHMH	2	0	0	9	0	0	0	7	0	0	9	0	0	0	9	0	0	0	1	2	10	0
Licensing Boards	1	0	1	0	0	2	0	0	1	1	0	0	6	0	6	0	0	1	1	2	8	6
Law Enforcement	19	29	27	50	30	38	9	34	54	54	22	11	18	40	36	36	64	37	35	42	52	65

Figure 4. Monthly Investigative Data Requests by Requestor Type, January 2015 – October 2016.

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, has 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. We are now able to compare number of controlled substance and opioid prescriptions dispensed and reported in the PDMP between 2014 and 2016. We now have the capacity to also report out on PDMP activities, such prescriber and dispenser access to PDMP data, law enforcement and other requestor utilization of data reports, and unsolicited reporting activities. As the Program is gaining greater understanding of the data in the PDMP, it will work, in consultation with the Advisory Board, to build additional reporting that is programmatically and clinically relevant, and provides context to the analysis of the PDMP's impact on patient access to controlled substances and on curbing prescription drug diversion.

DISPENSED PRESCRIPTION DATA

The number of total Schedule II-V controlled dangerous substance (CDS) prescriptions dispensed in or into Maryland and reported to the PDMP in corresponding time periods of 2014, 2015, and 2016 (January 1 – October 31 of each year) is shown in Table 5 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. While there was an increase in total CDS prescriptions observed between 2014 and 2015 (+3.79%), we see a slight decrease between 2015 and 2016 (-1.49%). Variations in specific medications, classes, and demographics of interest for January 1 – October 31 in each year 2014, 2015, and 2016, are shown in Tables 6 – 15.

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.
- The counts for total opioid prescriptions include buprenorphine-containing opioids, which may be prescribed for either pain management or substance use disorder (SUD) treatment. BHA has supported an increase in buprenorphine-containing medicated assisted treatment for SUDs; any positive effect from this effort will skew total opioid prescription counts upward.
- Total opioid prescription counts also include tramadol, an opioid that was moved by DEA from

being unscheduled to a Schedule IV prescription, effective August 18, 2014.[1] Therefore, for the majority of the period of 2014 included in this report, tramadol prescriptions were not reported to the Maryland PDMP, while all tramadol prescription in 2015 were required to be reported to the PDMP.

- As PDMP staff have only recently developed facility with analyzing PDMP data, we have not validated the quality of data contained in most variables reported from dispensers. 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. Data quality evaluation and improvement will be a focus in the coming year.

Table 5. Total Controlled Substance Prescriptions Dispensed, 2014 – 2016.

Year (Jan 1 – Oct 31)	Prescription Count	% Change (Year to Year)
2014	7,213,572	N/A
2015	7,486,710	+3.79
2016	7,374,883	-1.49

Table 6. Top Ten Controlled Substance Prescription Dispensed (Generic Name), 2014 – 2016.

Rank	2016 (Jan 1 – Oct 31)		2015 (Jan 1 – Oct 31)		2014 (Jan 1 – Oct 31)	
	Generic Name	Rx Count	Generic Name	Rx Count	Generic Name	Rx Count
1	OXYCODONE HCL	789,323	OXYCODONE HCL	778,730	HYDROCODONE/ ACETAMINOPHEN	741,557
2	OXYCODONE HCL / ACETAMINOPHEN	598,420	OXYCODONE HCL / ACETAMINOPHEN	662,779	OXYCODONE HCL	726,438
3	TRAMADOL HCL*	565,101	HYDROCODONE / ACETAMINOPHEN	593,635	OXYCODONE HCL / ACETAMINOPHEN	711,067
4	ALPRAZOLAM	556,212	TRAMADOL HCL*	574,364	ALPRAZOLAM	565,784
5	HYDROCODONE/ ACETAMINOPHEN	523,092	ALPRAZOLAM	560,414	ZOLPIDEM TARTRATE	483,039
6	DEXTROAMPHET-AMINE / AMPHETAMINE	465,458	ZOLPIDEM TARTRATE	456,971	DEXTROAMPHET-AMINE/ AMPHETAMINE	374,994
7	ZOLPIDEM TARTRATE	441,256	DEXTROAMPHET-AMINE / AMPHETAMINE	414,946	CLONAZEPAM	361,937
8	CLONAZEPAM	362,682	CLONAZEPAM	365,412	LORAZEPAM	317,759
9	LORAZEPAM	313,415	LORAZEPAM	317,479	METHYLPHENIDATE HCL	262,047
10	METHYLPHENIDATE HCL	275,624	METHYLPHENIDATE HCL	267,179	ACETAMINOPHEN WITH CODEINE	218,605
Total		**4,890,583**	**Total**	**4,991,909**	**Total**	**4,763,227**

* Tramadol was not scheduled until partway through 2014

[1] Drug Enforcement Administration, Department of Justice. Final Rule on Schedules of Controlled Substances: Placement of Tramadol Into Schedule IV. http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0702.htm Accessed November 4, 2015.

Table 7. Top Ten Controlled Substance (Generic Name) Therapeutic Class, 2014 - 2016

Generic Name (alphabetically)	Therapeutic Class
ACETAMINOPHEN WITH CODEINE	Opioid
ALPRAZOLAM	Benzodiazepine
CLONAZEPAM	Benzodiazepine
DEXTROAMPHETAMINE / AMPHETAMINE	Stimulant
HYDROCODONE/ ACETAMINOPHEN	Opioid
LORAZEPAM	Benzodiazepine
METHYLPHENIDATE HCL	Stimulant
OXYCODONE HCL	Opioid
OXYCODONE HCL / ACETAMINOPHEN	Opioid
TRAMADOL HCL	Opioid
ZOLPIDEM TARTRATE	Benzodiazepine

Table 8. Top Ten Opioids Dispensed (Generic Name), 2014 – 2016.

Rank (2016)	Opioid Generic Name	2016 (Jan 1- Oct 31)	% Change (2015 – 2016)	2015 (Jan 1-Oct 31)	% Change (2014 – 2015)	2014 (Jan 1-Oct 31)
1	OXYCODONE HCL	789,323	+1.36	778,730	+7.20	726,438
2	OXYCODONE HCL /ACETAMINOPHEN	598,420	-9.71	662,779	-6.79	711,067
3	TRAMADOL HCL*	565,117	-1.61	574,379	+238.52	169,674
4	HYDROCODONE/ ACETAMINOPHEN	523,092	-11.88	593,635	-19.95	741,557
5	ACETAMINOPHEN WITH CODEINE	219,184	-1.49	222,504	+1.78	218,605
6	BUPRENORPHINE HCL / NALOXONE HCL	205,503	+5.59	194,629	+2.24	190,358
7	MORPHINE SULFATE	187,374	+3.12	181,706	+6.73	170,247
8	HYDROMORPHONE HCL	84,618	-11.83	95,971	-5.37	101,417
9	FENTANYL	75,020	-4.34	78,424	-2.94	80,796
10	METHADONE HCL	61,042	-5.43	64,550	-8.50	70,549
Total		**3,308,693**	**-4.02**	**3,447,307**	**+8.38**	**3,180,708**

* Tramadol was not scheduled until partway through 2014

Table 9. All Opioid Prescriptions Dispensed by Age Group (2014 – 2016).

Age Group	2016 Rank	2016 (Jan 1-Oct 31)	% Change (2015 – 2016)	2015 (Jan 1-Oct 31)	% Change (2014 – 2015)	2014 (Jan 1-Oct 31)
0 - 9	10	15,225	+6.15	14,343	+13.46	12,641
10 - 19	8	68,615	-9.19	75,559	+1.30	74,592
20 - 29	6	271,634	-12.58	310,731	-3.60	322,319
30 - 39	4	466,453	-4.93	490,648	+2.30	479,636
40 - 49	3	603,664	-8.31	658,385	-0.57	662,133
50 - 59	1	910,186	-2.88	937,194	+9.10	859,023
60 - 69	2	633,673	+2.80	616,391	+18.01	522,310
70 - 79	5	299,980	+0.13	299,589	+22.66	244,248
80 – 89	7	137,748	-2.94	141,925	+31.23	108,149
90 - 99	9	31,628	-1.52	32,115	+44.86	22,170
100+	11	2,340	+6.50	2,199	+238.83	649
Unknown	N/A	281	-30.10	402	+99.01	202

Table 10. Top Ten Benzodiazepines Dispensed (Generic Name), 2014 – 2016.

Rank (2016)	Benzodiazepine Generic Name	2016 (Jan 1-Oct 31)	% Change (2015 – 2016)	2015 (Jan 1-Oct 31)	% Change (2014 – 2015)	2014 (Jan 1-Oct 31)
1	ALPRAZOLAM	556,279	-0.74	560,414	-1.68	565,784
2	CLONAZEPAM	362,716	-0.74	365,412	+0.22	361,937
3	LORAZEPAM	313,435	-1.27	317,479	-1.36	317,759
4	DIAZEPAM	192,851	-2.91	198,622	-6.40	206,033
5	TEMAZEPAM	36,308	-2.15	37,107	-3.30	37,547
6	TRIAZOLAM	10,325	-4.29	10,788	-9.65	11,428
7	CHLORDIAZEPOXIDE HCL	8,751	+4.10	8,406	-0.01	8,752
8	CLORAZEPATE DIPOTASSIUM	4,753	-15.62	5,633	-25.64	6,392
9	CLOBAZAM	4,555	+18.65	3,839	+33.11	3,422
10	OXAZEPAM	2,868	-12.29	3,270	-19.14	3,547
Total		**1,492,841**	**-1.20**	**1,510,970**	**-0.76**	**1,522,601**

Table 11. All Benzodiazepine Prescriptions Dispensed by Age Group (2014 – 2016).

Age Group	2016 Rank	2016 (Jan 1-Oct 31)	% Change (2015 – 2016)	2015 (Jan 1-Oct 31)	% Change (2014 – 2015)	2014 (Jan 1-Oct 31)
0 - 9	10	11,072	-2.73	11,383	+7.03	10,635
10 - 19	8	26,836	-2.97	27,657	+1.32	27,296
20 - 29	6	112,232	-3.65	116,479	-5.43	123,171
30 - 39	4	198,877	+1.06	196,796	-1.08	198,939
40 - 49	3	255,803	-4.60	268,144	-5.83	284,752
50 - 59	1	361,893	-2.56	371,385	-1.43	376,762
60 - 69	2	279,399	+3.09	271,022	+3.63	261,539
70 - 79	5	148,450	+0.54	147,650	+2.14	144,562
80 – 89	7	80,400	-1.57	81,685	+3.04	79,276
90 - 99	9	20,103	-6.35	21,466	+13.36	18,936
100+	11	847	+26.61	669	+4.53	640
Unknown	N/A	235	-29.43	333	+80.98	184

Table 12. Top Ten Stimulants Dispensed (Generic Name), 2014 – 2016.

Rank (2016)	Stimulant Generic Name	2016 (Jan 1-Oct 31)	% Change (2015-2016)	2015 (Jan 1-Oct 31)	% Change (2014-2015)	2014 (Jan 1-Oct 31)
1	DEXTROAMPHETAMINE / AMPHETAMINE	465,741	+12.24	414,946	+10.65	374,994
2	METHYLPHENIDATE HCL	269,835	+0.99	267,179	+1.96	262,047
3	LISDEXAMFETAMINE DIMESYLATE	211,460	+9.64	192,861	+6.02	181,904
4	DEXMETHYLPHENIDATE HCL	71,657	-8.38	78,213	-1.06	79,053
5	DEXTROAMPHETAMINE SULFATE	15,775	-0.60	15,870	+0.88	15,731
6	MODAFINIL	15,706	-5.65	16,647	+0.03	16,642
7	ARMODAFINIL	8,718	-33.26	13,062	-1.07	13,203
8	METHYLPHENIDATE	4,350	-50.01	8,702	-16.75	10,453
9	AMPHETAMINE SULFATE	1,627	+201.86	539	+539	0
10	BENZPHETAMINE HCL	587	-1.18	594	-6.90	638
Total		**1,065,456**	**+5.64**	**1,008,613**	**+5.65**	**954,665**

Table 13. All Stimulants Prescriptions Dispensed by Age Group (2014 – 2016).

Age Group	2016 Rank	2016 (Jan 1-Oct 31)	% Change (2015-2016)	2015 (Jan 1-Oct 31)	% Change (2014-2015)	2014 (Jan 1-Oct 31)
0 - 9	4	135,176	-4.32	141,272	-1.51	143,432
10-19	1	318,050	+0.84	315,391	+0.58	313,566
20 - 29	2	196,401	+7.24	183,143	+7.56	170,277
30 - 39	3	160,656	+18.78	135,254	+17.97	114,656
40 - 49	5	112,892	+10.46	102,198	+9.35	93,460
50 - 59	6	90,693	+7.58	84,300	+9.07	77,288
60 - 69	7	41,815	+10.33	37,900	+13.53	33,383
70 - 79	8	7,950	+14.09	6,968	+6.19	6,562
80 - 89	9	1,928	-4.70	2,023	+0.95	2,004
90 - 99	10	318	-16.32	380	+25.83	302
100+	11	0	-100.00	26	+100.00	13
Unknown	N/A	8	+33.33	6	-25.00	8

Table 14. All Buprenorphine-containing Prescriptions Dispensed by Drug Name and Formulation (2014 – 2016).

Drug Name and Formulation	2016 (Jan 1-Oct 31)		% Change (2015 – 2016)	2015 (Jan 1-Oct 31)		% Change (2014 – 2015)	2014 (Jan 1-Oct 31)	
	Rx Count	% of Total		Rx Count	% of Total		Rx Count	% of Total
BELBUCA	553	0.24	N/A	0	0.00	N/A	0	0.00
BUNAVAIL	257	0.11	+66.88	154	0.07	N/A	0	0.00
BUPRENEX	7	0.00	-80.00	35	0.02	+29.63	27	0.01
BUPERENORPHINE - NALOXONE	25,537	10.92	-7.72	27,674	12.47	-55.37	62,007	28.40
BUPRENORPHINE VIAL	14	0.01	+1,300.00	1	0.00	-66.67	3	0.00
BUPRENORPHINE TABLETS	20,435	8.74	+2.92	19,855	8.94	-2.46	20,356	9.32
BUPRENORPHINE POWDER	343	0.15	-6.54	367	0.17	+19.54	307	0.14
BUTRANS	6,970	2.98	-1.68	7,089	3.19	-2.29	7,255	3.32
PROBUPHINE	1	0.00	N/A	0	0.00	N/A	0	0.00
SUBOXONE FILM	147,349	63.01	-7.80	159,813	72.00	+28.09	124,770	57.15
SUBOXONE TABLET	6	0.00	-14.29	7	0.00	-75.86	29	0.01
ZUBSOLV	32,393	13.85	+364.02	6,981	3.14	+96.54	3,552	1.63
Total	**233,865**	**100.00**	**+5.36**	**221,976**	**100.00**	**+1.68**	**218,306**	**100.00**

Table 15. All Buprenorphine-containing Prescriptions Dispensed by Treatment Indication, (2014 – 2016).

Indication*	2016 (Jan 1-Oct 31)		% Change (2015 – 2016)	2015 (Jan 1-Oct 31)		% Change (2014 – 2015)	2014 (Jan 1-Oct 31)	
	Rx Count	% of Total		Rx Count	% of Total		Rx Count	% of Total
Pain Treatment	7,887	3.37	+5.27	7,492	3.38	-1.32	7,592	3.48
Substance Use Disorder Treatment	225,978	96.63	+5.36	214,484	96.62	+1.79	210,714	96.52

* Indication was determined based on FDA indication for approved indices for either the treatment of pain or treatment of substance use disorders. 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 a meaningful proxy was used.

UNSOLICITED REPORTING DATA ANALYSES

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. States vary on the types of PDMP users to whom PDMP data or notifications may be proactively disseminated and what types of questionable patterns identified by the Program may be used to generate notifications. Proactive reporting to prescribers and dispensers allows the Program to better support clinical decision-making around prescribing controlled dangerous substances, improving legitimate patient access to pharmaceutical care, and assist prescribers and dispensers in identifying prescription drug diversion. Chapter 651 (HB 1296, An Act concerning Prescription Drug Monitoring Program – Review and Reporting of Possible Misuse or Abuse of Monitored Prescription Drugs) was passed during the 2014 Legislative Session and amended the original PDMP statute, in line with action taken by 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, and 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 (TAC) was required to review the prescription drug monitoring data prior to it being released to the prescriber or dispenser of a controlled dangerous substance.

Effective October 1, 2016 (HB437 / Chapter 147, 2016), analysis of PDMP data for possible violations of law and possible breaches of professional standards by prescribers and pharmacists is authorized to inform proactive notification to prescribers and pharmacists for educational purposes.

Implementation of the original unsolicited reporting authority (under HB1296 / Chapter 651, 2014) occurred in 2016. PDMP is using a standard approach deployed by many states to identify patients receiving prescriptions from the greatest number of prescribers and filled at the greatest number of pharmacies over specified time periods. The Technical Advisory Committee currently reviews all data reports generated from this analysis and provides clinical guidance and interpretation of those data for a final decision about whether to conduct outreach to the prescriber. Providers identified as having prescribed a controlled substance prescription to that patient during the time period receive a notification

that the patient met or exceeded the set threshold. Table 14 contains information on unsolicited reporting thresholds and notifications generated to date. PDMP staff are currently working with CRISP to match unsolicited reporting notification recipients with information about their PDMP registration and access status to evaluate impact of these notifications on registration for and use of the PDMP; these data will be included in future PDMP reports once this methodology is finalized. In addition, it is intended that future PDMP Annual Reports will include analyses looking at short- and long-term changes to prescribing behavior by prescribers and changes in behavior of patients who triggered unsolicited reporting thresholds.

Table 16. Unsolicited Reporting Prescriber Notifications Generated, 2016.

Date Range (3 Months)	Threshold (# Prescriber / # Pharmacy)	Unsolicited Prescriber Notifications Generated
Jul – Sep 2016	10/8	165*
Jun – Aug 2016	10/8	144
May – Jul 2016	15/15	16
Apr – Jun 2016	15/15	41
Total		**366**

* Preliminary number as of November 8, 2016.

Recommendations on Modification or Continuation of the Program

Interstate Data Sharing:

Chapter 92 (SB0296, An Act concerning Prescription Drug Monitoring Program – Sunset Extension and Program Evaluation) was passed during the 2014 Legislative Session. Among other things, the bill authorized disclosure of PDMP data by the Program to other state PDMPs and permitted 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 established an agreement on December 19, 2014 with the National Association of Boards of Pharmacy (NABP) for use of their interstate data sharing platform, PMP InterConnect (PMPi). Because of Maryland's unique integration within CRISP, significant development was required by CRISP's vendor in order to connect to the PMPi data sharing hub, process requests, and display interstate PDMP data within CRISP. Connections to the PMPi hub were created and extensively tested by both CRISP, who handles requests by Maryland PDMP users for other state PDMP data, and by PDMP vendor, HID, who handles requests by other states for Maryland PDMP data. The Maryland PDMP went live with its connection to Virginia through the PMPi hub on August 3, 2015 and has since added West Virginia, Connecticut, and Arkansas. The Program has been working to establish connectivity with other PMPi-participating states, but has encountered a barrier in regulations. Maryland regulation limits clinical users to only redisclose PDMP data to another licensed healthcare practitioner for the medical treatment of a patient. This regulation is more restrictive than the re-disclosure language in many other state statutes and regulations, and PDMP staff, in consultation with legal counsel and the PDMP Advisory Board, are investigating possible solutions to expand clinical user interstate data sharing.

Table 17. Interstate Data Sharing Connections to date, reports exchanged July – Sept 2016.

State	Date Connected	# Reports Sent to Clinical Users in Other State	# Reports Received By Maryland Clinical Users
Virginia	8/3/2015	39,518	35,040
West Virginia	9/25/2015	1,092	34,215
Connecticut	11/23/2015	1,390	407
Arkansas	2/8/2016	155	147

Legislation / Regulations:

SB757 was signed into law by the Governor (Chapter 381, 2015) on May 12, 2015. This bill adjusted language describing the subpoena requirement of Licensing Boards authorized to request PDMP data for existing investigations to be consistent with the Board of Physicians processes, allowing them to now legally make investigative requests of the PDMP. Additionally, the bill expanded the listed entities

to whom the Program is authorized to disclose PDMP data to include state and local mortality review teams/committees, and medical review committees. These entities may request PDMP data to further existing, individual, bona fide case reviews conducted by the committees/teams. Policies and procedures for implementation of this new allowable data disclosure are being developed by the Program. Regulations required by the statutory amendment were promulgated June 8, 2016.

During the 2016 General Session, HB437 was passed and made a number of changes to the Program. A first round of regulations required under HB437 have been written and approved by the PDMP Advisory Board and are continuing through the official review and promulgation pathway.

Expanded Data Analysis and Reports:

Under the original legislation for the Program (Section 21-2A of the Health-General Article) the PDMP is authorized to disclose de-identified data for research and public education purposes. PDMP has obtained a monthly cut of PDMP data from our data collection vendor, Health Information Designs, and contracted with a team at University of Maryland School of Pharmacy who wrote code to clean the data and prepare research-ready datasets. The Program has taken great strides recently to obtain the staffing, software, and data access needed to produce data reports, summary statistics, and information about CDS dispensing and PDMP use across the state. Examples of the actionable data the Program are able to report out on are included in this report.

A grant award funded in Fall 2016 from the Substance Abuse and Mental Health Administration (SAMHSA) will be used in part to leverage the existing Statewide Epidemiologic Outcomes Workgroup (SEOW), a partnership between BHA and University of Maryland School of Pharmacy, and other existing infrastructure to analyze PDMP data and create robust reports for local health departments and other stakeholders to take action at the local level to reduce overdoses, impact opioid prescribing, increase access to treatment, and improve patient care.

Another grant, awarded in Fall 2015 from the Department of Justice, Bureau of Justice Assistance, is allowing the Program to create a predictive risk model tool for opioid-related morbidity and mortality in partnership with the Johns Hopkins Bloomberg School Center for Population Health Information Technology, a leader in predictive risk modeling in health.

Finally, the Centers for Disease Control and Prevention (CDC) Prevention for States (PfS) grant awarded in Spring 2016 allows the Department to achieve multiple goals related to not only clinical user experience with the PDMP but also development of surveillance reporting capabilities and prescriber education using PDMP data analyses. The CDC grant also funded a new Overdose Prevention Epidemiologist, hired Summer 2016, with an initial primary focus on PDMP data analyses and linking with overdose fatality data.

The Lt. Governor's Emergency Heroin and Opioid Task Force funded two new PDMP positions, a Database Specialist for maintaining the in-house PDMP database we now have in our possession, preparing internal and research-ready datasets, and a Data Quality Specialist who will address data quality and completeness. PDMP data are only as useful as they are complete and accurate, and thus this

is an important new piece of the PDMP.

Task Force funding has also enabled a key project aimed at identifying best practices by prescriber and pharmacists, and then applying flags to PDMP data in order to identify deviations from appropriate practice. Partners at the University of Maryland School of Pharmacy convened a consensus panel of prescribers and pharmacists to review established best practices and guidelines around CDS prescribing and dispensing. Using established, vetted, criteria for identifying high-risk behavior, "flags" were developed that indicate high risk deviation from the best practices. These "flags" are being turned into code that will be applied to the PDMP and allow the Program to identify high-risk prescriber, dispenser, and patient behavior. Clinicians flagged will receive an unsolicited report, and will be offered educational resources. The goal is to alert providers to high-risk behavior and create pathways to behavior modification to decrease these risks.

Program Evaluation:

The Department entered into an agreement with the University of Maryland, School of Pharmacy, who, along with research colleagues at the Johns Hopkins School of Public Health, conducted an evaluation of the Maryland PDMP, including the landscape of prescribing at Program implementation, physician impressions of PDMP, and other foundational data analyses.

The final evaluation's scope of work addressed the following needs:

- Need 1: Conduct a prescriber-level study of the adoption, implementation, and maintenance of the Maryland PDMP through a physician survey and physician focus group interviews.Assess: a) barriers and facilitators to PDMP use; b) retention and/or adaptation of key features and uses of the PDMP, and c) capacity-building for successful program implementation in key settings.
- Need 2: Identify pre and post-PDMP implementation prescribing and dispensing patterns for pharmaceutical controlled substances with a focus on opioids and benzodiazepines.
- Need 3: Measure, from a population health perspective, pre and post-PDMP implementation shifts in: a) rates of hospital inpatient stays for poisoning related to pharmaceutical controlled substances; b) emergency department (ED) visits for poisoning related to pharmaceutical controlled substances; c) poisoning deaths related to pharmaceutical controlled substances; and d) access to / 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 were designed to meet the statutory requirement for ongoing evaluation of the Program under §21-2A-05(4)(iii) and will inform impact of the Program on patient access to pharmaceutical care and on curbing prescription drug diversion in the State.

This project was completed September 30, 2016. A final report including a significant quantity of qualitative and quantitative analyses are currently being digested by PDMP staff for future action.

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, OSCA, and other agencies that oversee CDS 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 IT 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 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 implementing new Program activities, grants, and collaborations, increasing visibility and uptake of the Program, enhancing Program capabilities through legislative and regulatory pathways, and continues 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 A

Advisory Board on Prescription Drug Monitoring – Membership

Chair (October 5, 2016 - present)

Kim Leah Bright, MD
Secretary designee, Department of Health and Mental Hygiene
Medical Director, Behavioral Health Administration

Interim Chair (September 11, 2015 – August 5, 2016)

Gayle Jordan-Randolph, MD
Secretary designee, Department of Health and Mental Hygiene
Deputy Secretary, Behavioral Health Administration

Members

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

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

Dale Baker, CPRS/RPS
Certified Peer Recovery Specialist

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

Richard A. DeBenedetto, PharmD, MS, AAHIVP
Assistant Professor, University of Maryland Eastern Shore School of Pharmacy & Health Professions

Rimple Gabri, RPh
Community Retail Pharmacist

Vinu Ganti, MD
Primary Care Physician, Private Practice

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

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

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

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

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

Orlee Panitch, MD
Physician, Medical Emergency Professionals

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

Thelma B. Wright, MD
Assistant Professor, Department of Anesthesiology, University of Maryland School of Medicine
Professor, Department of Pediatrics, Johns Hopkins University School of Medicine