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 - Van T. Mitchell, Secretary
Gayle Jordan-Randolph, M.D., Deputy Secretary – Barbara Bazron, Ph.D., Executive Director

December 8, 2015

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) - 2015 Annual Report 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.

In addition, in a letter dated February 10, 2015 (enclosed) Chairman Hammen requested that DHMH include analysis of the desirability and feasibility of implementing mandatory use of the PDMP by prescribers and/or dispensers of controlled substances. The Board created a sub-committee to address this request and their response is included in the Annual Report.

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,

Gayle Jordan-Randolph, M.D.
Interim Chair, Advisory Board on Prescription Drug Monitoring

Enclosures

Cc: The Honorable Thomas M. Middleton
The Honorable Peter A. Hammen
Albert A. Zachik, M.D.
Allison Taylor, J.D., M.P.P.
Kate Jackson, M.P.H.
Rianna Brown, J.D.
The Honorable Sally Y. Jameson
Barbara Bazron, Ph.D.
Van T. Mitchell
Simon Powell
David Smulski
Linda Stahr
Sarah Albert, DLS, MSAR # 8632
Michael Baier
HGO Committee Members
Kathleen Rebbert-Franklin

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 15 times 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 2015 Annual Report is submitted pursuant to this requirement.

PDMP Implementation and Operations Update

In the two 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. On December 20, 2013, Chesapeake Regional Information System for our Patients (CRISP), the state-designated health information exchange (HIE) and the Department's PDMP information technology provider, opened general registration to healthcare providers to access PDMP data through the online HIE query portal. Prescriber and dispenser access was initially granted to a pilot group of users in September 2013. In February 2014, the Program began training and registering a pilot group of local law enforcement users to submit data requests using a separate online system. Processing of law enforcement data requests (pursuant to subpoena) began in March. The Program has also trained and registered investigators from licensing entities and units of the Department that are authorized to request data. CRISP has implemented a number of upgrades to the Patient Query Portal to enhance the usability and timeliness of the system for clinical users.

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

As of November 1, 2015 there are 14,258 Prescribers, Dispensers, Prescriber Delegates, and Dispenser Delegates registered to use the PDMP. Of these, 8,675 are active users, having accessed the system within the last 90 days. 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)
Prescriber (incl. physicians, physician assistants, nurse practitioners, dentists, podiatrists)	9,718	6,203 (63.83%)
Prescriber Delegate (incl. nurses without prescriptive authority, social workers, psychologists, professional therapists and counselors, etc.)	1,767	1,151 (65.14%)
Dispenser (pharmacists)	2,656	1,236 (46.55%)
Dispenser Delegate (pharmacy technicians and interns)	117	85 (72.65%)
Total	**14,258**	**8,675 (64.36%)**

Figure 1 shows the increase in active users and total clinical PDMP queries since clinical user access was opened, December 20, 2013, through November 1, 2015. Clinical users are averaging approximately 20,000 weekly queries, up from an average of 13,500 weekly queries in October/November 2014. Dips in the number of active user accounts occur when CRISP de-activates

accounts due to inactivity within the last 90 days. There were a limited number of pilot clinical users who assisted with testing the system from September 26, 2013 until full clinical user registration was opened December 20, 2013.

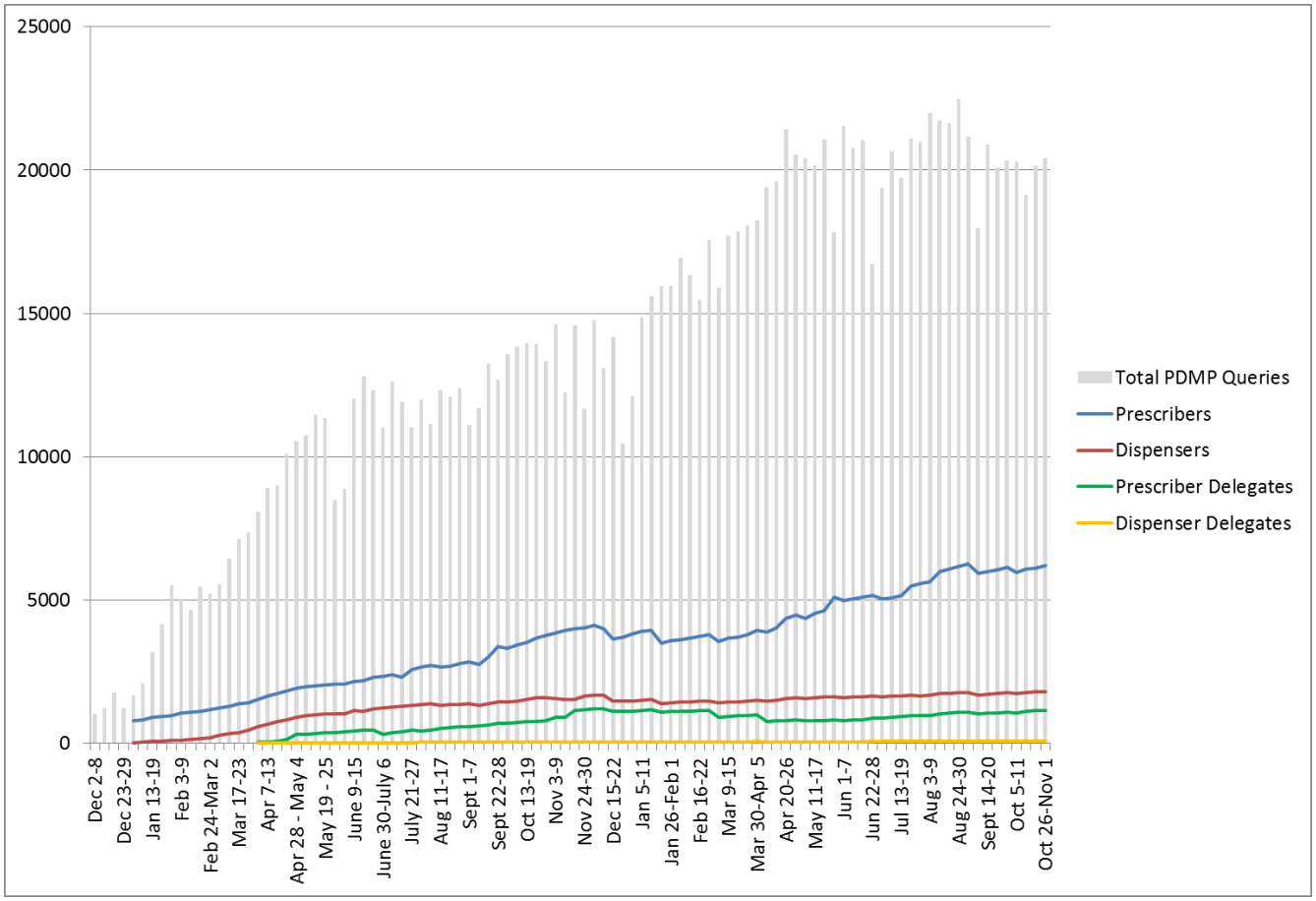


Figure 1. Active Clinical User Accounts, by User Type, and Total Clinical PDMP Queries, December 2, 2013 – November 1, 2015.

Figure 2 shows the increase in registered clinical users since clinical user access was opened through November 1, 2015. In calendar year 2015 through November 1, there has been an 88.66% increase in Prescriber accounts, a 32.67% increase in Dispenser accounts, a 77.27% increase in Prescriber Delegate accounts, and a 45.91% increase in Dispenser Delegate accounts.

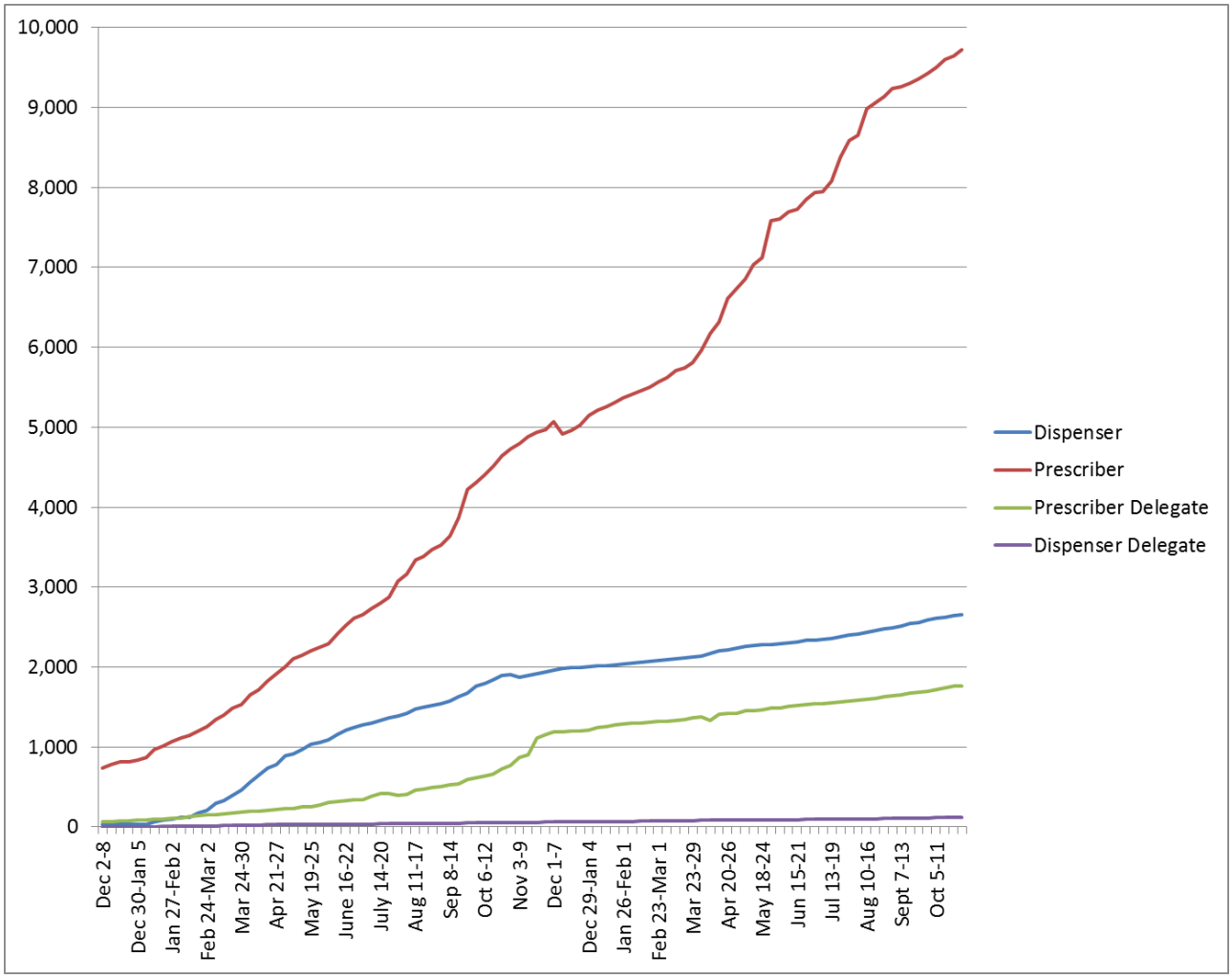
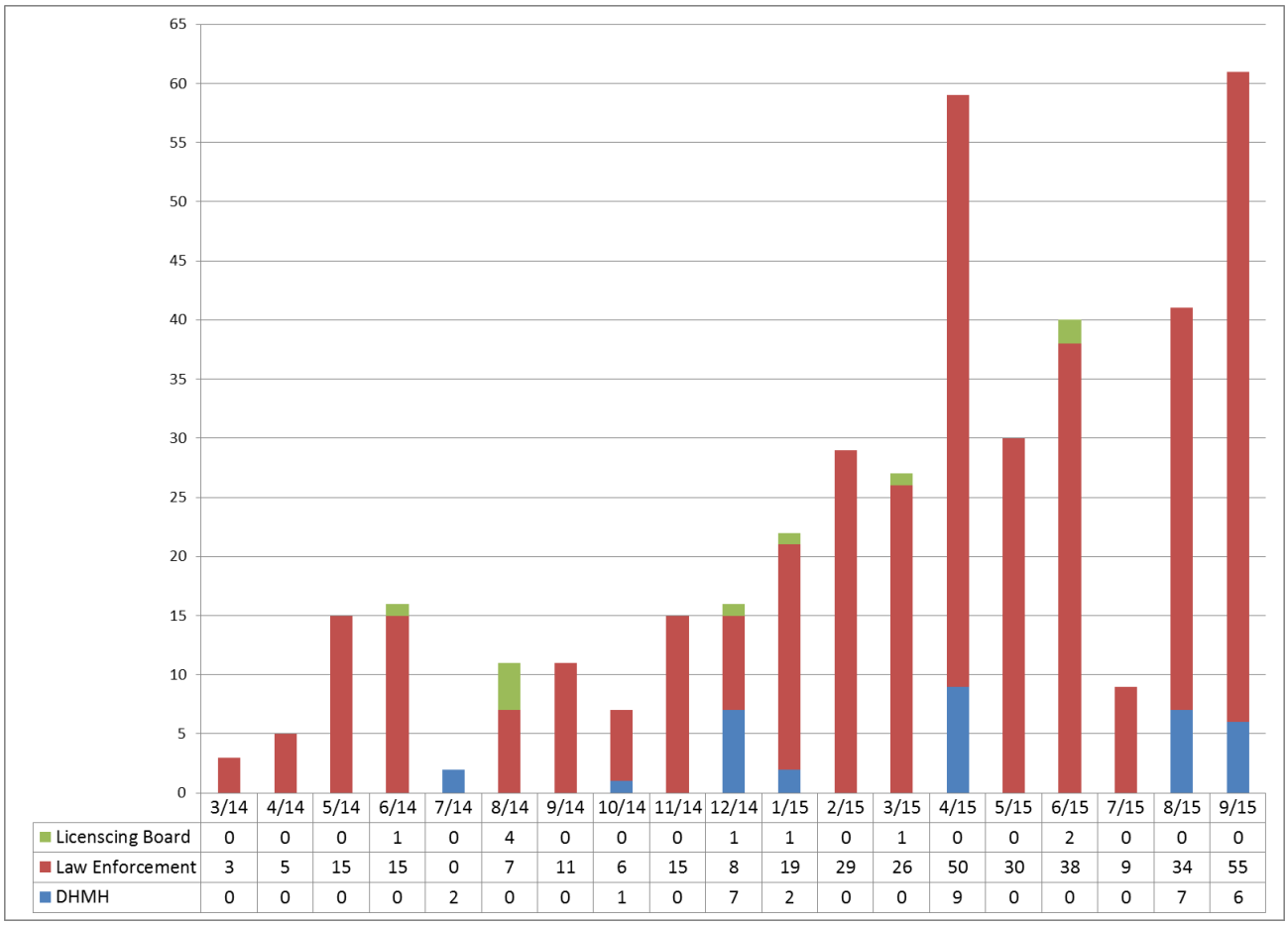


Figure 2. Clinical User Registration, by User Type, December 2, 2013 – November 1, 2015.

Between March 21, 2014, when the investigative data requesting functionality was initiated, and September 30, 2015, there have been 419 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 Division of Drug Control), in order to further existing, bona fide, individual investigations. Accounting for these investigative requests is a total of 130 registered investigative users with active accounts as of November 1, 2015. Table 2 shows the breakdown of currently active investigative user accounts and total number of valid investigative data requests by user type: local, state, or federal law enforcement, licensing board, or DHMH agency. Since this Program activity was implemented, a total of 148 individual 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 3 shows monthly requests, by requestor type submitted to the Maryland PDMP since program implementation.

Table 2. Total Number of Investigative User Accounts Requests Submitted to Maryland PDMP, 3/21/2014 – 9/30/2015.

Investigative Agency Type	# of Active Registered Users	# of Requests
Federal, State, Local Law Enforcement	70	375
Licensing Board	33	10
DHMH Agency	27	34
Total	**130**	**419**



	3/14	4/14	5/14	6/14	7/14	8/14	9/14	10/14	11/14	12/14	1/15	2/15	3/15	4/15	5/15	6/15	7/15	8/15	9/15
Licenscing Board	0	0	0	1	0	4	0	0	0	1	1	0	1	0	0	2	0	0	0
Law Enforcement	3	5	15	15	0	7	11	6	15	8	19	29	26	50	30	38	9	34	55
DHMH	0	0	0	0	2	0	0	1	0	7	2	0	0	9	0	0	0	7	6

Figure 3. Investigative Data Requests by Requestor Type, 3/21/2014 – 9/30/2015.

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 is 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 2015. In calendar year 2016, the Program intends to review available data to determine whether PDMP activities, such as dispenser reporting, prescriber and dispenser access to PDMP data, law enforcement and other requestor utilization of data reports, and unsolicited reporting activities, have affected patients' ability to legitimately access pharmaceutical care or altered existing drug diversion trends. As the Program is gaining greater understanding of the data in the PDMP, it is now in the place to work with its vendor, Health Information Designs® (HID), to develop a standardized set of comprehensive data reports for inclusion in future Annual Reports. The Program will work with the Advisory Board to ensure that the reported data are programmatically and clinically relevant, and provide context to the analysis of the PDMP's impact on patient access to controlled substances and on curbing prescription drug diversion.

The number of total controlled substance, opioid, and benzodiazepine prescriptions dispensed in or into Maryland and reported to the PDMP in corresponding time periods of 2014 and 2015 (January 1 – September 30 of each year) are shown in Table 3 below. Prescriptions reported to the PDMP were dispensed in or into Maryland, but could have been prescribed by a provider who practices outside of Maryland, and recipients of prescriptions reported to the PDMP may reside in or outside of Maryland. The sole requirement is that the prescription location of dispensing was in Maryland or as mail-order to a Maryland address.

The counts for total controlled substance prescriptions reported to the PDMP may contain non-controlled substances submitted to the PDMP by dispensers. The Program is in the process of removing non-controlled substance prescriptions from the PDMP, but does not have the capability to differentiate between controlled and non-controlled substances using currently available queries. 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 prescriptions in 2015 were required to be reported to the PDMP. There was a 377% increase in tramadol-containing prescriptions reported to the PDMP between 2014 (118,025 prescriptions) and 2015 (563,855 prescriptions).

[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 3. Total Prescription Counts for All Controlled Substances, Opioids, and Benzodiazepines reported to the Maryland PDMP, January 1 – September 30 for 2014 and 2015.

All Controlled Substance Prescriptions		Opioid Prescriptions		Benzodiazepine Prescriptions	
2014	**2015**	**2014**	**2015**	**2014**	**2015**
6,903,290	6,990,404	3,088,102	3,417,855	1,436,543	1,439,908
% Change	+1.26%	% Change	+10.67%	% Change	+0.23%

Also in the 2014 Report, the Program anticipated expanding activities through the unsolicited reporting authority granted during the 2014 General Legislative Session, enabling the Program to proactively send prescribers and dispensers information about potentially inappropriate patient prescription use around CDS (see Recommendations on Modification or Continuation of the Program sub-section on 'Unsolicited Reporting' for more details on this activity). Because of delays in adoption of associated regulations, unsolicited reporting activities will not begin until fourth quarter of 2015, and therefore data from this activity is not yet available. Analysis of unsolicited reporting activities should provide a rich understanding of the impact of the Program on key operational goals, such as correlating PDMP use with changes in prescribing patterns of users in 2016.

Additional analysis of PDMP impact will be included in the final report issued by the Department-funded Program evaluation currently underway by the University of Maryland, School of Pharmacy and the Johns Hopkins Bloomberg School of Public Health (see "Program Evaluation," below).

Recommendations on Modification or Continuation of the Program

Unsolicited Reporting:

In Maryland, unsolicited reporting is the proactive dissemination of PDMP data or notification of clinical PDMP users about questionable or deviant prescription patterns that may indicate the presence of patient abuse or misuse of controlled dangerous substances. States vary on the types of PDMP users to whom PDMP data or notifications may be proactively disseminated and whether questionable patterns identified by the Program may include indications of inappropriate prescribing or dispensing. Unsolicited reporting is considered a best practice by the Department of Justice, BJA's Prescription Drug Monitoring Program Center of Excellence at Brandeis University, and has been or is currently being adopted by a majority of states. Proactive reporting to prescribers and dispensers will allow the Program to better support clinical decision-making around prescribing controlled dangerous substances, improving legitimate patient access to pharmaceutical care, and assist prescribers and dispensers in identifying prescription drug diversion. Chapter 651 (HB 1296, Prescription Drug Monitoring Program – Review and Reporting of Possible Misuse or Abuse of Monitored Prescription Drugs) of the Acts of 2014 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) must review the prescription drug monitoring data prior to it being released to the prescriber or dispenser of a controlled dangerous substance.

Unsolicited Reporting regulations were developed by the Program, as directed by Chapter 651. Adoption of regulations related to this legislative change took longer than expected due to a hold on the regulation by the Joint Committee on Administrative, Executive, and Legislative Review (AELR). Regulations were formally adopted on June 8, 2015 and the Program drafted policies and procedures for pilot implementation of this activity, which were reviewed and approved by the PDMP Advisory Board at its September 10, 2015 quarterly meeting. Pilot implementation will identify the top few patients receiving prescriptions from the greatest number of prescribers and filled at the greatest number of pharmacies over specified time periods. Providers identified as having prescribed a controlled substance prescription to that patient during the time period will receive a notification that the patient met or exceeded the set threshold; this method of implementing unsolicited reporting activity is the most commonly used among other states with similar legislative authority. The Program intends to begin pilot implementation in the fourth quarter of 2015 and slowly expand activities upon careful evaluation of activity implementation and impact, and contingent on allocation of additional resources to conduct in-house analyses of PDMP data. Currently, PDMP staffing is inadequate to develop and analyze a copy of the PDMP database within the Department. The Program relies on a query tool provided by PDMP vendor, Health Information Designs (HID), which allows the Program to run only basic reports on Maryland PDMP data. The ability to conduct more in-depth analyses of indicators of misuse and abuse will be necessary to expand unsolicited reporting activities beyond basic 'doctor/pharmacy shopping' criteria. An over-the-target request was submitted for FY2017 to appropriate staff this portion of the PDMP, though no decision has been made on this request at the time of report submission.

Interstate Data Sharing:

Chapter 92 (HB255, Prescription Drug Monitoring Program – Sunset Extension and Program Evaluation) of the Acts of 2014, among other things, 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 MOU 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 added West Virginia on September 25, 2015. The Program is currently working to establish connectivity with border and neighboring states, with the goal of eventually connecting with all PMPi-participating states whose laws, regulations, and policies allow for data sharing with Maryland.

In conjunction with establishing interstate data sharing, PDMP worked with CRISP to develop and deploy an enhanced PDMP user interface. The Board provided feedback on the design of the new user interface, is supportive of the interoperability efforts, and has reviewed the Program's intended interoperability expansion plans. The PDMP Manager is a member of the NABP PMPi Steering Committee and attending the annual in-person Steering Committee Meeting, held July 15 – 16, 2015 in Northbrook, IL.

Legislation / Regulations:

Regulations dictated by Chapter 651, HB1296 and by Chapter 92, HB 255, both passed and signed into law during the 2014 Legislative Session have been adopted as of June 8, 2015. The regulatory changes establish the authority for the review of prescription drug monitoring data for indications of possible misuse or abuse of a monitored prescription drug and allow reporting of possible misuse or abuse to prescribers and dispensers registered with the program. These regulations also require the PDMP Technical Advisory Committee (TAC) to review prescription drug monitoring data prior to being released to a prescriber or dispenser of a monitored prescription drug. The regulations specify when data can be shared for the purpose of individual investigations. Finally, they expand the number of fatality review teams that can receive re-disclosed PDMP data, and remove language not required by statute.

During the 2015 Legislative Session, HB3 was proposed to mandate prescribers and dispensers check the PDMP prior to prescribing or dispensing any controlled substance prescription. This bill received an unfavorable report by the House Health and Government Operations (HGO) Committee and subsequently HGO Committee Chair Hammen wrote a letter to DHMH Secretary Mitchell on February 10, 2015 requesting that the Advisory Board on Prescription Drug Monitoring research and report on the desirability and feasibility of moving toward mandatory registration and/or use. The Advisory Board created a sub-committee to address this request, and their recommendations are found in the 'Analysis of the Desirability and Feasibility of Mandatory Registration and/or Use' section of this report.

SB757 was signed into law by the Governor (Chapter 381) 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 submitted for public comment and adoption in September 2015.

Expanded Data Requests:

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. In addition, the PDMP is authorized to release to prescribers of controlled substances a report of prescriptions in the PDMP attributed to them as the prescriber. Procedures and request processes for both of these program activities were developed and implemented during 2015.

Program Evaluation:

The Department has 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, are conducting an evaluation of PDMP impact and outcomes. The evaluation's scope of work will address the following needs:

- Need 1: Conduct a prescriber-level study of the adoption, implementation and maintenance of the Maryland PDMP. Document and evaluate the uptake of the PDMP by prescribers in key clinical settings, including hospitals, ED's, urgent care clinics, pain management clinics, behavioral health treatment providers, etc. 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 baseline and post-PDMP implementation prescribing and dispensing patterns for pharmaceutical controlled substances with a focus on opioids and benzodiazepines.
- Need 3: Measure the effectiveness of the Maryland PDMP, from a population health perspective, by analyzing longitudinal data to assess the effect of the program on: 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 and use of treatment and recovery services for individuals with prescription drug-related substance use disorders.
- Need 4: Evaluate whether the Maryland PDMP has had unintended consequences, including reducing legitimate access to pharmaceutical care and uptake in use of illicit substances.

Evaluation activities are designed to meet the statutory requirement for ongoing evaluation of the Program under Health-General §21-2A-05(f)(4)(iii) and will inform impact of the Program on patient access to pharmaceutical care and on curbing prescription drug diversion in the State. The Program reports regularly to the Advisory Board on progress of this project.

Education Initiatives:

The Department has worked with the Board and diverse stakeholder organizations to increase knowledge of the Program throughout the State. BHA has engaged with the Boards of Pharmacy and Physicians, DDC, and other agencies that oversee 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 PDMP Manager, CRISP personnel and Board members have continued to give in-person presentations on the PDMP to a number of audiences/organizations throughout the State. The PDMP Manager has given multiple trainings that meet the Board of Physicians' requirement for continuing medical education (CME) around opioid prescribing through MedChi, and has spoken at events geared

toward both medical and law enforcement audiences. Program staff attended conferences, including the National Prescription Drug Abuse Summit, held April 6 – 9, 2015 in Atlanta, GA, and the National Association of State Controlled Substances Authorities (NASCSA) Annual Conference, held October 20 – 23, 2015 in Scottsdale, AZ. Department staff attended the Appalachian Opioid Abuse Summit, held September 23 – 24 in Wise, VA.

The Department announced creation of the Opioid Misuse Prevention Program (OMPP) on October 17, 2014, funding a total of 22 local jurisdictions to address the opioid crisis in their community. The purpose of this funding initiative is to reduce opioid misuse, overdoses, and overdose fatalities by supporting the implementation of effective and sustainable prevention strategies in Maryland jurisdictions. Grant funding is being used to strengthen the jurisdictions' local overdose prevention plans and to implement the evidence-based opioid misuse prevention strategies contained in those enhanced plans. OMPP requires the grantees to conduct a needs assessment and propose a strategic plan that includes educational outreach. Most jurisdictions have chosen to conduct outreach at least in part around PDMP use by clinicians in their community. In addition, OMPP was the first major public health program to exercise their legal authority to request aggregate, deidentified data from the PDMP. This data sharing partnership, in which PDMP will continue to provide datasets every six months to OMPP grantees, will enhance the ability of jurisdictions to analyze the scope of the problem in their community and monitor changes in these indicators over time. The Department continues to deploy an overdose response media campaign started in Summer 2014, and is working with local authorities to provide educational materials that can be distributed to community healthcare providers and the general public.

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.

Analysis of the Desirability and Feasibility of Mandatory Registration and/or Use

Summary Recommendations:
The Advisory Board on Prescription Drug Monitoring formed a sub-committee to investigate and report on the desirability and feasibility of mandatory registration and/or use of the PDMP by prescribers and/or dispensers. Participation in this sub-committee included the following Board members:

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

- Rimple Gabri, RPh
  Community Retail Pharmacist

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

- Celeste M. Lombardi, MD
  Physician Advisor, Office of Quality, Safety & Improvement Director,
  Interventional Pain Service, Department of Neurology/Pain Management

- Orlee Panitch, MD
  Physician, Medical Emergency Professionals

- David Sharp, Ph.D.
  Director, Center for Health Information Technology & Innovative Care Delivery
  Maryland Health Care Commission

Mandatory registration statutes require that prescribers who meet specified criteria (e.g. have an active DEA number or a state CDS license) create an account with the PDMP, including completion of any associated registration process and training. Mandatory use laws require that certain prescribers and in some cases dispensers access the PDMP and check CDS prescription data for a patient in a specifically defined situation.

The Advisory Board found desirability in moving toward mandatory registration and then mandatory use of the PDMP under specific, data-driven, clinical situations in a controlled, step-wise fashion. The Advisory Board cautioned against rushing into any use mandate without having in place the appropriate health information technology and operational infrastructure to handle the impact of a mandate on the system. This recommendation is largely consistent with lessons learned from some of the first states to adopt mandatory use legislation.[2] The Department of Justice (DOJ) Bureau of Justice Assistance (BJA)

[2] Prescription Drug Monitoring Program Center of Excellence at Brandeis, Mandating PDMP participation by medical providers: current status and experience in selected states (Revision 2, October 2014) see

funded PDMP Center of Excellence (COE) at Brandeis University published a briefing on the experience of early adopter states in implementing PDMP use mandates. The states reviewed in this briefing were: Kentucky, Tennessee, New York, and Ohio. The briefing concluded that "efforts to facilitate provider enrollment and easy access to PDMP data, without compromising data security, will help ensure a mandate's acceptance and help make provider use of PDMP data a standard of care."[3]

The need for a step-wise implementation strategy toward mandatory use cannot be overstated to ensure information available in Maryland's PDMP provides the greatest value to prescribers, dispensers, and consumers. The COE briefing stated that "mandates in these states necessitated the expansion and enhancement of their PDMPs in order to meet the increased demand for patient reports … [requiring] increased staff and IT resources for planning and implementing the enhancements, including automated enrollment systems."[4]

Staff increases reported to handle mandatory use in other states[5]:
Kentucky: HelpDesk increased from one to four full-time staff, PDMP administrators increased from two to three full time staff, and four temporary staff brought on to process account registrations and answer administrative program emails and phone calls.
Tennessee: Added another project manager and two additional administrative support staff.
New York: Added five programmers, obtained a consultant pharmacist with IT expertise, and transferred two Medicaid staff members full-time to the PDMP.

Limited voluntary use of state PDMPs by clinicians is most often attributed to lack of clinical workflow integration, slow or cumbersome data access, and poor data format display.[6] Introducing a mandate without addressing these real barriers to PDMP use may result in a 'chilling effect' on controlled substance prescribing or dispensing. The Advisory Board recommends that specific PDMP enhancements occur prior to implementation of any mandate in order to help mitigate any possible 'chilling effect.' These include: 1) streamline user registration, 2) educate providers and the public about the PDMP and its use, 3) support provider workflow integrations, 4) improve system information technology capacity to handle increased user load, 5) improve system administrative capacity to address user and policy questions, and 6) improve data quality. These enhancements are discussed within the report below.

The Advisory Board proposes that a reasonable timeline for implementation of a registration mandate is two years after passage of legislation, and a use mandate could be implemented within one year after a registration mandate went into effect. This timeline is contingent on satisfactory completion of the abovementioned PDMP system enhancements.

The potential contribution that a required query could make to preventing drug abuse and misuse:

---

http://www.pdmpexcellence.org/sites/all/pdfs/COE_briefing_mandates_2nd_rev.pdf accessed October 6, 2015. (COE Briefing, Revision 2, October 2014)

[3] COE Briefing, Revision 2, October 2014
[4] COE Briefing, Revision 2, October 2014
[5] Reporting on Ohio did not mention whether additional staffing resources were required to implement their mandate.
[6] Green, Sherry L. Policy Brief: Mandates to Use State Prescription Drug Monitoring Programs (PMPs): Implications for Health Care Providers, June 19, 2015.

The Maryland PDMP began collecting prescription information on August 20, 2013 and opened up clinical data access on December 20, 2013. As was discussed in the 'Analysis of PDMP Impact on Patient Access to Pharmaceutical Care and on Curbing Prescription Drug Diversion' section of this report, year over year increases in all controlled substances and specifically opioids dispensed in Maryland from 2014 to 2015 have been modest. In less than two years of operations, it is unlikely that Maryland would see a prescription decline as has borne out from other states' experiences. Registration with and utilization of the PDMP by prescribers and dispensers has been steadily increasing, but a minority of prescribers and dispensers in the state currently access PDMP data. In contrast, rapid increases in utilization and decreases in dispensing of target controlled substances, such as opioids and benzodiazepines, have been seen after implementation of use mandates.[7,8]

If a required query could make a contribution to preventing drug abuse and misuse, ways the requirement could be targeted to be most useful, such as targeting certain classes of drugs, certain prescribers or dispensers, or just initial prescribing of a drug:

Because states have implemented a wide range of registration and use mandate statutes, there is the opportunity to learn which types of mandates yield clinically relevant, positive results. As of yet, no rigorous studies have been conducted to establish the most effective types of requirements to reduce overdose, excessive opioid prescribing, dangerous polypharmacy, and diversion. However, there are some lessons to be learned from other states and from the clinical experience of Board members.

Ohio's implementation of a use mandate was introduced in conjunction with emergency room and long-term opioid treatment prescribing guidelines, and legislation was developed in a collaborative spirit.[9] Specifics of the exact clinical scenarios requiring PDMP checks as well as defined exception to the mandate were amended throughout the legislative process as a result of input from a variety of stakeholders. The end product was a compromise that reflected actual clinical practice standards and processes, making it agreeable to most parties, and thus resulted in quick adoption by clinicians.

The Advisory Board recognizes that there are specific high-risk or high-prescribing clinical settings, such as the emergency department, pain clinics, opioid treatment programs, or workers' compensation care. These clinical areas are particularly important for implementation of a use mandate, but present unique information technology and logistical difficulties. Blanket mandates may require a prescriber or dispenser to check the PDMP when it may not otherwise be clinically indicated.[10,11] At least in the emergency department setting, it has been suggested that a physician's decision about voluntary PDMP use is driven by practical workflow and ease of access considerations as opposed to imposed policy. When emergency physicians practiced in a state with a well-functioning, easy to access PDMP, those physicians were more

---

[7] COE Briefing, Revision 2, October 2014

[8] Kentucky House Bill 1 Impact Evaluation Prepared for The Kentucky Cabinet for Health and Family Services, March 2015. http://www.chfs.ky.gov/NR/rdonlyres/8D6EBE65-D16A-448E-80FF-30BED11EBDEA/0/KentuckyHB1ImpactStudyReport03262015.pdf accessed October 6, 2015

[9] COE Briefing, Revision 2, October 2014

[10] Haffajee, R., Anupaum B.J., and Wiener S.G. Mandatory Use of Prescription Drug Monitoring Programs. JAMA 2015; 313:9, 891-2.

[11] Smith, Robert J., et al. How, and for Whom Do Emergency Medicine Providers Use Prescription Drug Monitoring Programs? Pain Medicine 2015; 16: 1122-1131.

likely to utilize the PDMP and spoke more highly of their experience with the PDMP.[12] Ensuring that significant stakeholder involvement occurs for these high-risk or high-prescribing clinical settings will provide the opportunity to identify and address challenges related to health information technology and workflows.

Piloting the use mandate before expanding out to all applicable prescribers and dispensers will provide the opportunity to collect lessons learned and time to work out any unexpected glitches. The Advisory Board suggests making a legislative change that would require the major academic medical institutions participate in use-case pilots within their hospital systems. The Advisory Board envisions this pilot lasting approximately 12 months and could be implemented in a variety of care settings within different academic medical institutions, providing a wide variety of lessons learned about barriers and facilitators to successful implementation of a use mandate. It will be essential to convene appropriate stakeholders to provide input on any use mandate pilot. This will ensure that appropriate information technology and operational steps are addressed for each provider population under the pilot mandate. Gathering stakeholders will allow the Program to be confident that these pilot provider groups are appropriately supported to comply with the use mandate in the course of their regular practice activities, and a 'chilling' effect is not seen as a result of the mandate. Advisory Board members stressed the importance of making all necessary enhancements to the PDMP data and Chesapeake Regional Information System for our Patients (CRISP) clinical user access prior to implementing a use mandate, even as a pilot.

Regardless of any pilot deployments, it will be necessary to create a robust educational campaign for prescribers and dispensers. This campaign should address the benefits and use of PDMP, how to interpret findings in the PDMP, and available resources in the community to address any issues of abuse, diversion or inadequate patient management discovered through PDMP use. States often partner with professional societies, give presentations to a wide variety of audiences, and/or create online modules or web content. Engaging stakeholders to advise on the best way to deliver this educational campaign will be essential to prepare providers, garner support, and ensure a smooth implementation of any mandate. In addition to educating prescribers and dispensers, the Board recognizes the need to conduct a broader public education campaign to inform patients about the existence of the PDMP and how the data are used. Also, patients should be educated about the fact that they may opt out of having their medical information displayed in CRISP but do not have a legally authorized option to opt out of display of PDMP data within CRISP.

The experience of states that require a query of their PDMP before prescribing or dispensing a monitored prescription drug:

The importance of having in place appropriate staffing, health information technology, data quality, clinical workflow integration, and an automated registration process prior to implementation of a use mandate cannot be overstated. Early adopter mandatory use states, including Kentucky, Tennessee, New York, and Ohio, all report requiring significant increases in PDMP staffing to implement mandatory access legislation in a timely manner. Automation of the registration process was cited as another important piece to address before a mandate. Automation or streamlining of the registration process will not only ease provider frustration with the system, but will also reduce the number of new staff required within the PDMP

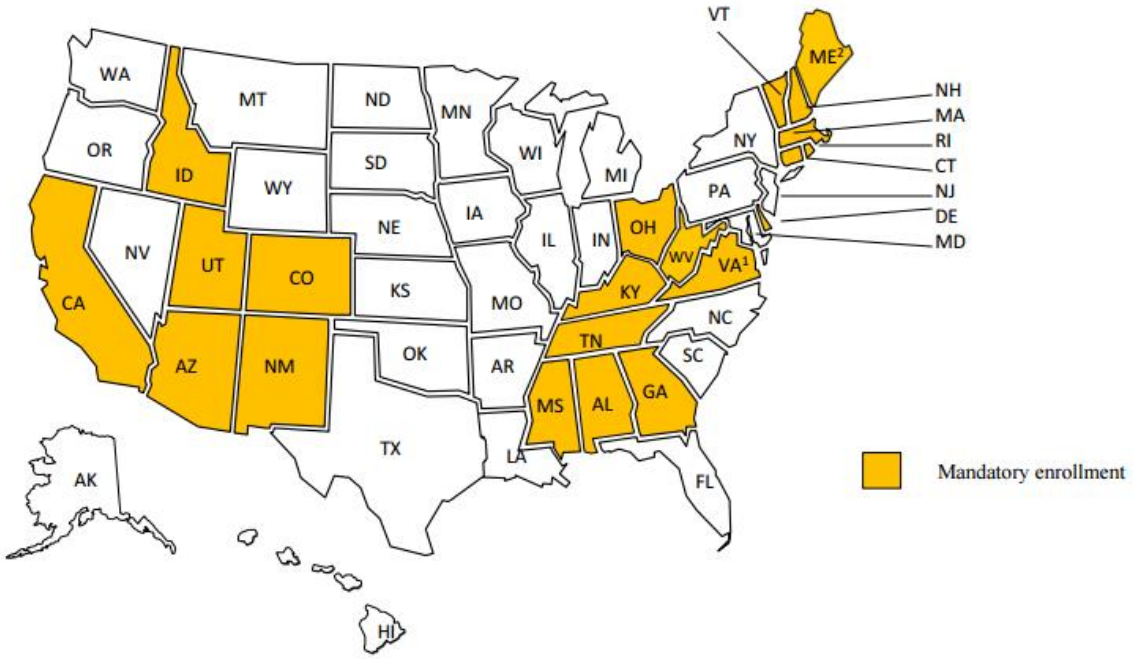
[12] Smith, Robert J., et al. How, and for Whom Do Emergency Medicine Providers Use Prescription Drug Monitoring Programs? Pain Medicine 2015; 16: 1122-1131.

and at CRISP. In addition to registering individuals, staff will be required to address data quality (described below) and the PDMP will need to devote staff resources to ensure enforcement of the mandate; additional staff at licensing boards may also be required to address sanctions related to non-compliance.

Mandatory Registration:

The following map shows all states that require prescribers and/or dispensers to have a registered user account with the state PDMP as of December 2014, prior to the last legislative session for many states.[13]

States that Require All Licensed Prescribers and/or Dispensers to Register with PMP Database*



* Many states require that persons requesting access to the state PMP database first register as an authorized user. This map and the memorandum located on the NAMSDL website are concerned with only those states that require all practitioners licensed in the state to also register to use the PMP database.
[1] The Virginia provision goes into effect on July 1, 2015. [2] Practitioners in Maine will be automatically registered with the PMP upon obtaining or renewing their professional license.

Currently, 24 states (including Guam) have a statutory or regulatory requirement for prescribers and/or dispensers to register for a user account with their state PDMP.[14] Of those 24 states:

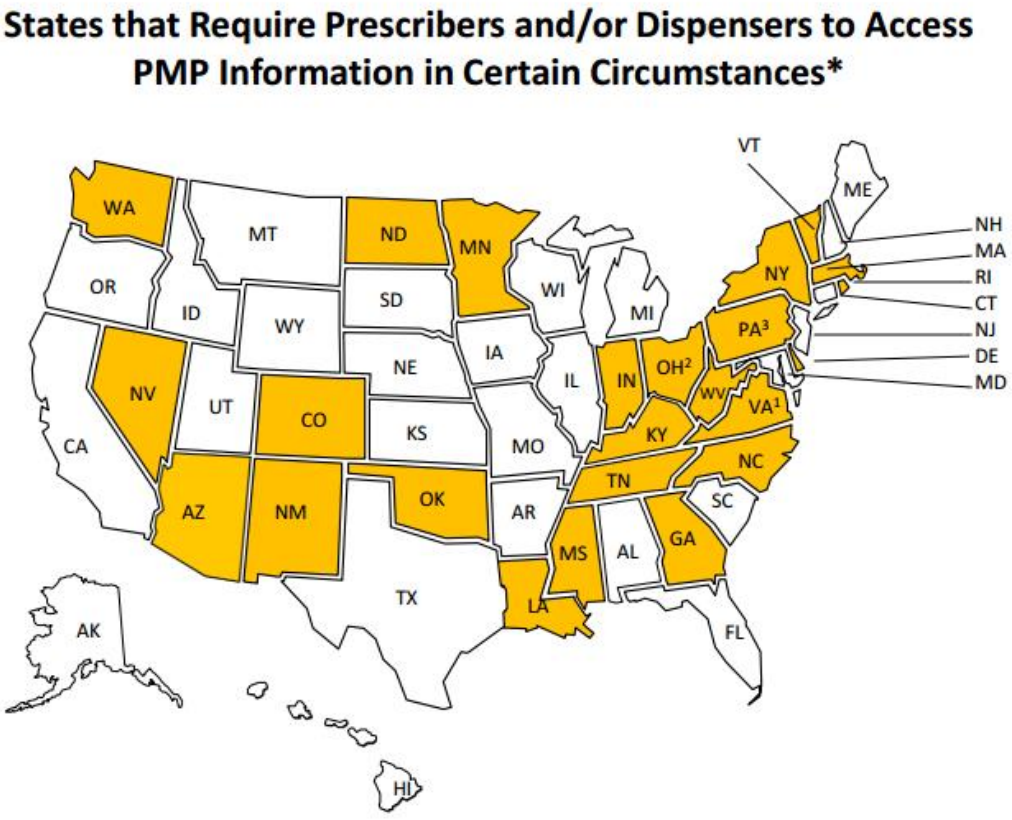
Number of States	Registration Mandate
7	require only Prescribers to register with the PDMP
2	require only Dispensers to register with the PDMP
15	require both Prescribers and Dispensers to register with the PDMP

[13] The National Alliance for Model State Drug Laws (NAMSDL), States that Require All Licensed Prescribers and/or Dispensers to Register with the State Prescription Monitoring Program. Map (December 2014). http://www.namsdl.org/library/99D1512E-C3D3-D54B-1D3DFEF57FE47F77/ accessed October 8, 2015.
[14] Email correspondence between Kate Jackson and the PDMP Center of Excellence at Brandeis University Training and Technical Advisory Center (TTAC), August 14, 2015.

Registration mandates can be found in conjunction with use mandates or as stand-alone requirements for providers. Some states may choose to only enact a use mandate, though this action necessarily imposes a requirement to register for PDMP access on those providers who fall under a use mandate. The Advisory Board recommends that both prescribers and dispensers should be required to register with the Maryland PDMP. Registration should be a requirement for approval of a new or continuing state controlled dangerous substance (CDS) permit issued and maintained by the Division of Drug Control (DDC). All individual practitioners obtaining a CDS permit would be subject to the prescriber and dispenser PDMP registration mandate, so tying these processes together should result in efficiency for the applicant and both the PDMP and DDC.

Mandatory Use:

The following map shows states that require prescribers and/or dispensers to access the PDMP in defined clinical situations as of December 2014, prior to the most recent legislative session for some states.[15]



* Please see the accompanying memorandum for specifics as to the circumstances under which a prescriber and/or dispenser is obligated to access the PMP database in each state.
[1] The Virginia provision goes into effect on July 1, 2015. [2] A number of the Ohio provisions go into effect on April 1, 2015. [3] The Pennsylvania provision goes into effect on June 30, 2015.

[15] The National Alliance for Model State Drug Laws (NAMSDL), States that Require Prescribers and/or Dispensers to Access PMP Database in Certain Circumstances. Map (December 2014). http://www.namsdl.org/library/99E15A79-F594-42AA-8F8E61AF2C512CB4/ accessed October 8. 2015.

Currently, 26 states (including Guam) have a statutory or regulatory requirement for prescribers and/or dispensers to access their state PDMP under certain circumstances.[16] Of these 24 states:

Number of States	Use Mandate
18	require only Prescribers to access the PDMP under a use mandate
0	require only Dispensers to access the PDMP under a use mandate
8	require both Prescribers and Dispensers to access the PDMP under a use mandate

The registration and use mandates are implemented in a number of different combinations. Of the 33 states that have in place a registration and/or use mandate:[17]

Number of states	Mandate
6	Registration Mandate ONLY
9	Use Mandate ONLY
18	BOTH Registration and Use Mandates

Statutory language varies widely between states, though the laws can be roughly grouped into two main approaches: requiring providers to access the PDMP upon suspicion that a patient is 'doctor shopping,' misusing or diverting controlled substances, or requiring providers to check the PDMP when placed in specific, objective prescribing or dispensing situations.[18] For the latter category of use statutes, a spectrum of scenarios prompting a requirement to access the PDMP exist. Some states require PDMP checks for prescribers only in certain clinical settings, while others target the act of prescribing certain types of controlled substances regardless of setting.

Kentucky implemented a use mandate that targeted prescribing of Schedule II opioids and hydrocodone-containing Schedule III substances (this was prior to the rescheduling of hydrocodone as a Schedule II controlled substance at the federal level). An impact evaluation showed the first decrease in opioid and benzodiazepine dispensing since PDMP introduction occurred after implementation of the use mandate, while stimulant prescription numbers continued to increase.[19] The evaluators concluded that targeting specific schedules of medications of concern for mandatory PDMP check before prescribing did not have a universal 'chilling effect' on all controlled substance prescribing. Blanket mandates could result in providers being required to check the PDMP when it is not clinically indicated.[20]

Even with a highly efficient and usable system, providers will necessarily need to take time out of a visit to check the PDMP. Mandates should address medications and prescribing situations most likely to result in misuse, abuse, or diversion. Time spent checking the PDMP is uncompensated time, and therefore it has been suggested that innovative approaches to incentivize PDMP use through pay-for-performance or

[16] Email correspondence between Kate Jackson and the PDMP Center of Excellence at Brandeis University Training and Technical Advisory Center (TTAC), August 14, 2015.
[17] Email correspondence between Kate Jackson and the PDMP Center of Excellence at Brandeis University Training and Technical Advisory Center (TTAC), August 14, 2015.
[18] COE Briefing, Revision 2, October 2014
[19] Kentucky House Bill 1 Impact Evaluation Prepared for The Kentucky Cabinet for Health and Family Services, March 2015. http://www.chfs.ky.gov/NR/rdonlyres/8D6EBE65-D16A-448E-80FF-30BED11EBDEA/0/KentuckyHB1ImpactStudyReport03262015.pdf accessed October 6, 2015 (Kentucky HB1 Impact Evaluation, 2015)
[20] Haffajee, R., Anupaum, B.J., and Wiener, S.G. Mandatory Use of Prescription Drug Monitoring Programs. JAMA 2015; 313:9, 891-2.

third party reimbursement should be considered by states; the Board is unaware if this has been attempted by any state yet.[21]

Early adopter states reported significant increases in user account registration and data query immediately after implementation of use mandates. Some states have demonstrated declines in dispensing of controlled substances, drugs within the opioid therapeutic class, or with specific opioids of concern.[22, 23] The Advisory Board recommends a use mandate be implemented for both prescribers and dispensers. Statutory language defining specifics of the use mandate should be minimal and instead allow for stakeholders to provide significant input into exact use mandate situations to be outlined in regulations. This will allow stakeholders across professions and care settings to implement varying, clinically-relevant use mandates applicable to their specific medical practice.

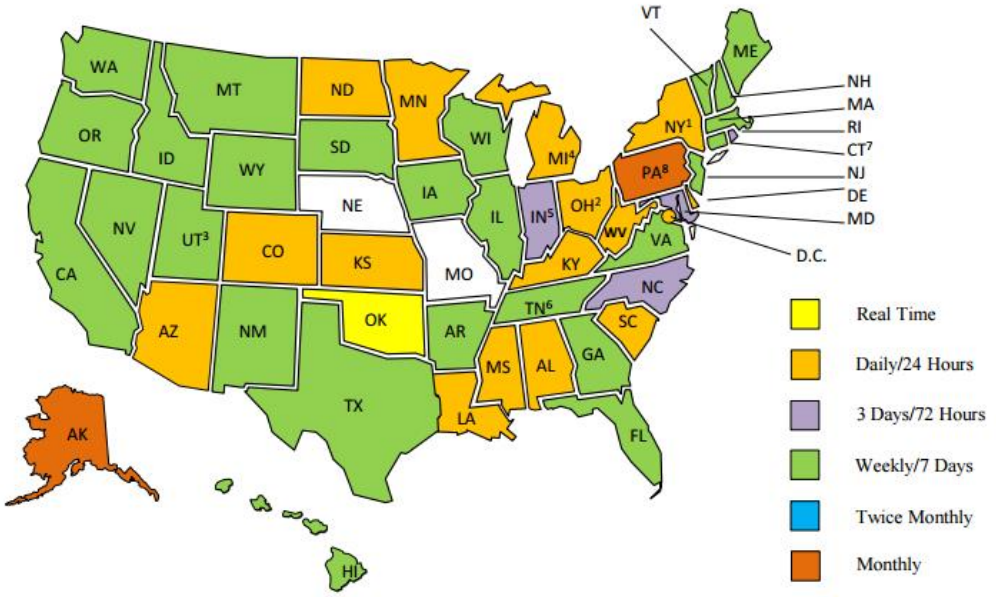
How weaknesses in the PDMP reported by users can be overcome:

1) **Real-time data reporting:** The PDMP regulations currently require dispensers (retail and outpatient hospital pharmacies as well as practitioners that dispense CDS in their practice) to report all CDS prescriptions dispensed to a patient or patient's agent in Maryland within three business days of dispensing. Many chain or larger independent pharmacies report records to the PDMP on a daily basis. The following map identifies reporting intervals required in other states, with known updates summarized in the table below.[24]

Reporting Interval	Number of States
Real-time (within 5 minutes)	1
Daily (within 24 hours)	17
Three Days / 72 hours	4 (including MD, which requires within 3 business days)
Weekly	25
Monthly	1

[21] Green, Sherry L. Policy Brief: Mandates to Use State Prescription Drug Monitoring Programs (PMPs): Implications for Health Care Providers, June 19, 2015.
[22] COE Briefing, Revision 2, October 2014
[23] Kentucky HB1 Impact Evaluation, 2015
[24] National Alliance for Model State Drug Laws (NAMSDL), Data Collection Interval, Map (December 2014). See http://www.namsdl.org/library/F24061BF-03E6-9613-F219115C9737BD9E/ accessed on October 7, 2015. There may have been changes in state data collection intervals since this map was last updated.

Data Collection Interval



[1] New York requires the submission of data in real time by statute, but that has been interpreted by regulation to mean no later than 24 hours after the substance is delivered. [2] Ohio requires submission of data from pharmacies daily and from wholesalers monthly. [3] Utah requires submission weekly, but for those participating in the statewide pilot program, submission is required daily. [4] Michigan requires daily reporting for online reporting of dispensing information and weekly for mail-in submission of data. [5] Indiana will begin requiring the submission of data within 24 hours by January 1, 2016. [6] Tennessee will begin requiring daily submission on January 1, 2016. [7] Connecticut requires marijuana dispensaries to report marijuana dispensing to the PMP daily. [8] Pennsylvania will begin requiring submission of information within 72 hours on June 30, 2015.

PDMP vendor, Health Information Designs (HID) manages dispenser reporting in Maryland. HID completes basic data standardization and transfers new or corrected records to CRISP every 4 hours, 24 hours a day, 7 days a week. Therefore, the time between when a record is submitted to the Maryland PDMP and when it is accessible in CRISP is minimal. Many states implemented PDMPs with a collection interval of weekly and are now evaluating the desirability of shortening the interval. Daily, or within 24-hour, reporting by dispensers would remove the majority of the current small lag-time between dispensing and record availability in the PDMP. However, if a patient is 'ER hopping' or 'doctor shopping' at multiple locations within one day, this activity may not be reflected when a provider views the PDMP even with daily reporting. The shorter the window between dispensing and record availability within the PDMP, the more accurate of a patient CDS history a provider has at his/her disposal when making a prescribing or dispensing decision. Real-time reporting is of most use in the emergency department and urgent care facility care settings, where patients seeking to misuse or divert CDS can visit multiple locations within one day. However, the move to 'real-time' reporting has only been successfully attempted by one state thus far, likely in part because "the technical and logistical obstacles to such reporting are formidable."[25] The Advisory Board recommends that the reporting requirement be modified from 3 business days after dispensing occurs to within 24 hours after dispensing occurs; this change will serve to provide data in a more timely fashion, but will still be a reasonable timeline with which dispensers should be able to comply.

[25] The Prescription Monitoring Program Center of Excellence at Brandeis University, Notes From the Field (NF 3.1), Real Time Reporting: Oklahoma's Pioneering PMP. (January 2012). http://www.pdmpexcellence.org/sites/all/pdfs/ok_real_time_data_nff_11912.pdf accessed on October 7, 2015.

2) Clinical workflow integration:

The need to ensure PDMP data can be easily and quickly accessed within the practitioner's existing clinical workflow has been demonstrated across state PDMPs. Other states and reports published on PDMPs consistently cite that one of the most significant barriers to PDMP use, even where statutory use mandates exist, is a lack of workflow integration. The Board agrees that this issue must be addressed prior to implementation of any mandate. Despite significant enhancements by CRISP, workflow integration barriers remain.

When the PDMP was first implemented, user feedback identified specific issues with CRISP that impeded easy, fast access to PDMP and other clinical data. CRISP has made significant enhancements to the Patient Query Portal infrastructure over the past year that reduced sign-on and data load times, reduced the frequency of system time-outs, and improved patient record linking. The PDMP evaluation being conducted by researchers at the University of Maryland, School of Pharmacy and the Johns Hopkins Bloomberg School of Public Health includes a physician survey and physician focus groups. The goal of these evaluation activities is to better understand current physician views about the PDMP, including barriers to and facilitators of PDMP use. The results of the survey and focus groups will inform future development projects for CRISP to continue improving the user experience. This evaluation project is slated for completion in second quarter 2016.

Currently, PDMP law only allows licensed healthcare providers to be delegated access to PDMP data by a prescriber or dispenser. Unlicensed healthcare staff members (e.g. medical assistants, ER scribes) typically pull other health reports for providers. Enabling these staff members to access PDMP data facilitates integration of PDMP use into established clinical workflows across care setting (ambulatory practice, ED, etc.). Many states have expanded delegate accounts to include unlicensed clinic staff. Of the 35 states that currently allow delegate accounts, at least 25 allow both licensed and unlicensed delegates to access PDMP data.[26]

Interstate data sharing was implemented in August 2015, with connections currently active between Maryland and both Virginia and West Virginia. CRISP PDMP users are only able to look at the PDMP history for patients that have existing Patient Profiles in CRISP. Patient Profiles are created when PDMP or other Maryland-based clinical data feeds provide records for a specific patient. However, there will be occasions where a patient may not have had a prescription filled or been seen at an organization contributing data to CRISP and therefore have no Patient Profile. There may be clinical circumstances in which a CRISP user will want to query out-of-state PDMP history for a patient without a Patient Profile. CRISP will need its infrastructure IT vendor to complete additional system development to allow providers to query out-of-state patients with no clinical or Maryland PDMP information via the currently established interstate data sharing hub, PMP InterConnect (PMPi).

3) Data inaccuracies:

[26] National Alliance for Model State Drug Laws (NAMSDL). States that Allow Prescribers and/or Dispensers to Appoint a Delegate to Access the PMP, Map December 2014. http://www.namsdl.org/library/BBB38C95-A57D-76AF-8DB22F9D99EFBA4C/ accessed September 30, 2015.

PDMP vendor Health Information Designs (HID) provides standard reports to assist PDMP staff with addressing dispenser reporting compliance, including whether dispensers required to report to the PDMP are doing so and whether errors are flagged in the data that has been reported. HID does not conduct error resolution, and therefore this task is the sole responsibility of the PDMP staff. Currently, the Program has prioritized ensuring that all dispensers comply with the mandate to report CDS dispensing or attest to their exempted status, but does not have adequate staffing to address all aspects of data quality. However, optimal data quality review involves significantly expanded activities, including: reviewing reports for gaps in data submissions by pharmacies and dispensing practitioners, following up with dispensers for error resolution, and addressing errors noted and reported to the PDMP by patients and clinical PDMP users. The Program would need to hire a Database Specialist to complete programming using PDMP data and compliance reports from HID in order to appropriately audit the quality of the PDMP data. This Database Specialist would be responsible for ongoing data quality analysis and trend review.

An additional staff member who is in charge of quality compliance outreach would work with pharmacies and dispensers' health information technology vendors to resolve any data errors or gaps in data transmission. This position would also allow the Program to be more adequately staffed to handle the anticipated increased volume of inquiries about how to access and utilize the PDMP by prescribers, dispensers, health systems and other stakeholders upon implementation of a registration and/or use mandate. We also anticipate that the program would receive contacts about data errors noted by stakeholders, including clinicians, pharmacists, and patients.

How to reduce costs, such as piggybacking on existing health information technology or phasing in a PDMP query requirement:

Mandating registration as a condition of obtaining CDS Permit application and/or renewal will provide incentive for compliance with the mandate and increased opportunity for direct outreach to providers about both the mandate and the utility of the PDMP. The mandate could be implemented as a condition of CDS permit, professional license, or independent requirement. The PDMP Advisory Board advises having a functional, streamlined registration process before mandating registration.

Currently, providers conduct most clinical work within their health system's electronic health record (EHR), and must log in separately to the CRISP portal in order to access the health information exchange's (HIE's) data feeds, including PDMP. Single sign-on allows a provider to log in to their health system's EHR and access CRISP data through that EHR (usually by clicking a specific 'CRISP' button) without opening a new screen and completing an additional log in process. CRISP currently offers single sign-on services at no cost to the end user, though expanded use of this service could alter this arrangement. Integration with chain pharmacy systems is also essential, and should be considered in this single sign-on effort. Multiple states have implemented integration projects with major pharmacy chains independently or through PMP Gateway, a sister product to the interstate data sharing hub; PMP InterConnect, supported by the National Association of Boards of Pharmacy (NABP); and Appriss®; and utilized by the Maryland PDMP. Cost-sharing opportunities may exist.

As previously discussed, one of the most significant barriers to PDMP use, voluntary or compulsory, is the ability of the provider to access the PDMP data at the point of care. While some practices may solve this issue by enlisting delegates to pull reports of the data for providers in advance of appointments, many providers may still want or need the ability to view PDMP data alongside other patient

health information in the EHR. Health systems should be supported to provide PDMP data feeds directly to prescribers with the goal of enabling real-time review of PDMP data and CDS prescribing decision-making. This could be implemented in unique ways by each interested health systems using IT solutions that fit both the unique health IT landscape of their practice settings and practitioner needs. This type of action would not serve as a replacement for prescriber and/or dispenser use mandates, but could serve to better support the feasibility of practitioner compliance with a mandate. For example, hospital EDs may choose an approach applied in some other states where PDMP data alerts automatically populate in the ED EHR when a patient's drug utilization history meets an established threshold level. Especially in this fast-paced care environment, push messages based on agreed upon thresholds could provide desired clinically relevant information without compromising efficiency of ED staff. There could be the opportunity to partner with CRISP, the Maryland Health Care Commission (MHCC), and professional organizations representing emergency physicians or hospitals, to develop, pilot and expand a unified IT approach.

Feedback from providers who access PDMP data through CRISP in a variety of care settings report that some health care facilities in Maryland are better able to support CRISP than others. Antiquated hardware and software, firewalls, lack of access to computer terminals or tablets at the point of care, and other health information technology or infrastructure limitations impact usability of the PDMP in the clinical setting. For example, despite upgrades by CRISP, some users still experience delays and are 'timed out' of CRISP due to system constraints in one practice setting, but will have no issue accessing CRISP at a different practice site. Recently, the Maryland Hospital Association has engaged with the PDMP and CRISP to better understand how to support PDMP use in the hospital setting. Outreach and technical assistance should occur with all care settings so that providers have the IT set-up and institutional support to be able to reliably access PDMP data.

Other items:

A comprehensive Interim Report on PDMP Mandatory Registration and Use Implementation was created by the Department at the request of Delegate Hammen. The Interim Report outlines Department-identified barriers to implementation of a registration or use mandate for the PDMP and solutions to address these barriers, including timelines and legislative, operational and fiscal needs. A copy of the Interim Report is enclosed with this Annual Report and has been reviewed by the full Advisory Board on Prescription Drug Monitoring.

Conclusion

During the past year, the Department made substantial progress with fully implementing the PDMP, increasing visibility and uptake of the Program, enhancing Program capabilities through legislative and regulatory pathways, and 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 (through September 11, 2015)
Mona K. Gahunia, DO
Chief Medical Officer, Department of Health and Mental Hygiene

Interim Chair (September 11, 2015 – present)
Gayle Jordan-Randolph, MD
Deputy Secretary, Behavioral Health Administration, Department of Health and Mental Hygiene

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

Daniel M. Ashby, M.S., FASHP
President 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

Shirley Devaris, RN, JD
President designee, Maryland Board of Nursing
Director, Policy Analysis and Legislation, Maryland Board of Nursing

J. Ramsay Farah, MD, MPH – on leave
Regional Medical Director, Clinical Services, UnitedHealthcare
Medical Director, Phoenix of Health, LLC

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, MPH
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

Orlee Panitch, MD
Physician, Medical Emergency Professionals

David Sharp, Ph.D.
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

Attachment B

Official Correspondence Regarding Mandatory Registration / Use Report from the Advisory Board on Prescription Drug Monitoring

PETER A. HAMMEN
46th Legislative District
Baltimore City

Chair
Health and Government
Operations Committee

Annapolis Office
The Maryland House of Delegates
6 Bladen Street, Room 241
Annapolis, Maryland 21401
410-841-3770 · 301-858-3770
800-492-7122 *Ext.* 3770
Peter.Hammen@house.state.md.us

District Office
821 S. Grundy Street
Baltimore, Maryland 21224
410-342-3142

THE MARYLAND HOUSE OF DELEGATES
ANNAPOLIS, MARYLAND 21401

February 10, 2015

Van T. Mitchell
Secretary
Department of Health and Mental Hygiene
201 W. Preston Street
Baltimore, MD 21201

Dear Secretary Mitchell:

House Bill 3 "Prescription Drug Monitoring Program – Prescribers and Dispensers – Required Query" would require a prescriber and a dispenser, except under certain circumstances, to query the Prescription Drug Monitoring Program (PDMP) to review a patient's prescription monitoring data before prescribing or dispensing a monitored prescription drug. Under current law, a dispenser must report to the PDMP the dispensing of a monitored prescription drug. However, the choice of whether or not to query the PDMP is voluntary on the part of both the prescriber and dispenser.

With the swelling incidence of opioid abuse across the country, several states, including Kentucky, Tennessee, and New York, have acted to require prescribers and/or dispensers to query their state's PDMP before prescribing or dispensing certain controlled dangerous substances or other drugs. Kentucky requires prescribers to query the PDMP when initially prescribing a patient a Schedule II drug or any Schedule III drug containing hydrocodone, check the PDMP every 3 months for that patient, and review the information before prescribing refills or any additional Schedule II drug or Schedule III drug containing hydrocodone for that patient. Several exceptions apply. In Tennessee, prescribers, must check the database when first prescribing opioids and benzodiazepines for more than 7 days and at least annually thereafter if prescribing continues. Again, there are exceptions to the law. In New York, practitioners must consult the PDMP when prescribing or dispensing controlled substances in Schedules II – IV, with some exceptions.

The House Health and Government Operations Committee held a hearing on the bill on February 5, 2015. At the hearing, while all the witnesses expressed general support for the PDMP as a helpful tool in identifying individuals who may be abusing or misusing controlled dangerous substances, almost all opposed the bill or recommended major amendments. A common theme among the witnesses was the need to improve system capacity and reliability before imposing additional requirements. The fiscal note of $1,723,200 in the first year of implementation and approximately $700,000 in each subsequent year presents another obstacle, particularly as the PDMP does not yet have a dependable funding source.

In short, House Bill 3, while laudable for what it seeks to achieve, is not yet feasible. I am requesting that the Advisory Board on Prescription Drug Monitoring, as part of its statutory charge to "provide ongoing advice and consultation on the implementation of the program," review the feasibility and desirability of requiring prescribers and/or dispensers to query the PDMP before prescribing or dispensing monitored prescription drugs. The review should include:

- The potential contribution that a required query could make to preventing drug abuse and misuse;
- If a required query could make a contribution to preventing drug abuse and misuse, ways the requirement could be targeted to be most useful, such as targeting certain classes of drugs, certain prescribers or dispensers, or just initial prescribing of a drug;
- The experience of states that require a query of their PDMP before prescribing or dispensing a monitored prescription drug;
- How weaknesses in the PDMP reported by users, such as the lack of real-time data, the length of time required to query the PDMP for each patient, and the inaccuracy of prescriber information, can be overcome;
- How to reduce costs, such as piggybacking on existing health information technology or phasing in a PDMP query requirement; and
- Any other item the Department or the Advisory Committee considers important.

I would appreciate a report from the Advisory Committee on its findings and recommendations by December 1, 2015. Please direct any questions or comments to Linda Stahr, committee analyst, at 410-946-5477 or linda.stahr@mlis.state.md.us. Thank you for the fine work that the PDMP has accomplished to-date.

Sincerely,

Peter A. Hammen

Peter A. Hammen

Cc: HGO Committee Members
The Honorable Sally Y. Jameson

STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
Lawrence J. Hogan, Jr., Governor – Boyd K. Rutherford, Lt. Governor – Van T. Mitchell, Secretary

March 4, 2015

The Honorable Peter A. Hammen
Chairman, Health and Government Operations
241 House Office Building
Annapolis, MD 21401

Dear Chair Hammen,

The Department of Health and Mental Hygiene is committed to continued expansion and enhancement of the Prescription Drug Monitoring Program (PDMP). We appreciate your thorough evaluation and careful consideration of the information provided through testimony around and the fiscal note for proposed House Bill 3 "Prescription Drug Monitoring Program – Prescribers and Dispensers – Required Query." We also appreciate and share your commitment to addressing the problem of opioid abuse in Maryland.

In your letter dated February 10, 2015, you requested that the Advisory Board of Prescription Drug Monitoring to conduct a review of "the feasibility and desirability of requiring prescribers and/or dispensers to query the PDMP before prescribing or dispensing monitored prescription drugs." The Advisory Board will conduct this review – to include the items specified in your letter – and incorporate its findings into its Annual Report to the Governor and The General Assembly. We will make sure that you and the members of the Health and Government Operations Committee receive this report by December 1, 2015.

If you have any questions about this, please contact Allison Taylor, Director of Governmental Affairs, at (410) 260-3190.

Sincerely,

Van T. Mitchell
Secretary

cc: Allison Taylor
Mona Gahunia
Gayle Jordan-Randolph
Kate Jackson