MARYLAND
Department of Health

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

September 18, 2017

The Hon. Thomas M. Middleton, Chair
Senate Finance Committee
3 East Miller Senate Office Building
Annapolis, Maryland 21401

The Hon. Shane E. Pendergrass, Chair
House Health & Government Operations Committee
241 House Office Building
Annapolis, Maryland 21401

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

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

Re: HB 437, Chapter 147 (2016), Section 5(2)—Report on the Implementation and Use of the Prescription Drug Monitoring Program

Dear Chairs Middleton, Pendergrass, Klausmeier, and Bromwell:

Pursuant to HB 437, Chapter 147 (2016), Section 5(2), the Maryland Department of Health (Department) submits this report on the implementation and use of the Prescription Drug Monitoring Program (PDMP) and specifically on:

(1) the status of the implementation of providing education and notice of a possible violation of law or a possible breach of professional standards to prescribers and pharmacists, as authorized under § 21–2A–06(d) of the Health-General Article; and

(2) a recommendation on whether the authority of the PDMP to report possible violations of law or possible breaches of professional standards should be expanded to allow reporting to law enforcement agencies, licensing boards, or units of the Department.

This report follows the report submitted on January 13, 2017, in response to HB 437, Chapter 147(2016), Section 5(1).

Program Update

The Maryland PDMP collects controlled dangerous substance (CDS) prescription dispensing information and enables authorized users access to this data for the purpose of improving the health and safety of Maryland patients and the public. The PDMP is an electronic database that contains

CDS Schedule II–V prescriptions dispensed in Maryland and can be disclosed as permitted by statute.

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

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

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

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

Numerous other operational initiatives are in progress. As of early September 2017, approximately 73% of all prescribers have registered with the PDMP. In addition, preliminary data analysis shows a decrease in the total opioid prescriptions dispensed since 2015, as shown in Table 1.

Table 1. Total Opioid Prescriptions Dispensed*, 2015 – 2017 year to date.

Year (Jan 1 – Aug 31)	Prescription Count	% Change (Year to Year)
2015	2,849,972	N/A
2016	2,759,979	-3.16%
2017	2,527,379	-8.43%

*Total Opioids include all prescriptions containing a medication in the opioid class of drugs, with the exception of medication containing an opioid in a formulation indicated for the treatment of opioid use disorder. 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. Prescriptions were included regardless of whether the prescription recipient (patient) or the prescriber was associated with a Maryland or non-Maryland address.

Attestation of consultation with the Advisory Board on Prescription Drug Monitoring

The Advisory Board on Prescription Drug Monitoring (PDMP Advisory Board) has been consulted throughout the development and deployment of all unsolicited reporting activities conducted by the PDMP. On July 17, 2017, the PDMP Advisory Board was presented with the analytic methods and program plans for expansion of unsolicited reporting activities to include analysis of PDMP data for possible violations of law and breaches of professional standards.

The PDMP intends to continue consultation with the PDMP Advisory Board as these methods, policies, and procedures are further developed. Board members present concurred with the recommendation to focus attention on policies and procedures of the current legal authority to analyze PDMP data for indicators of possible violations of law or breaches of professional standards, and to conduct outreach and education to prescribers and dispensers based on these analyses.

Status of education and notice implementation

A new training video was added as part of the registration process for CDS prescribers along with step-by-step registration guidelines. The Office of Controlled Substance Administration has developed community outreach programs that are targeted to the medical, law enforcement, government, educational, and public stakeholders and are focused on reduction of CDS abuse, misuse, addiction, and overdoses.

As part of this effort, education programs have been provided on opioid history, structural compounds, interactions with the body, side effects and usage standards, and alternatives to opioids through social media, website updates, and written alerts.

The Department currently identifies patients with multiple provider episodes ("doctor shopping") as a key indicator of misuse or abuse to inform unsolicited reporting notifications the PDMP sends to prescribers. This activity has been ongoing since January 2016. Development of analytic tools was necessary to implement the expanded unsolicited reporting authority to identify potential violations of law or potential breaches of professional standards. As previously reported, the PDMP undertook analytic capacity-building projects with support from a federal Centers for Disease Control and Prevention Prescription Drug Overdose Prevention for States grant, additional funding by the Governor's Heroin and Opioid Emergency Task Force, and gift funds from Chesapeake Employers Insurance Company.

Red Flags Project Update

The PDMP continues work with partner academic researchers at the University of Maryland, School of Pharmacy who have experience in development and operation of drug utilization review programs to develop analytic tools to identify high-risk opioid prescribing with PDMP data. The research team conducted an extensive literature review of national, state, professional organizations, and other sources of clinical practice guidelines around appropriate management of patients receiving opioids and other CDS medications of interest. The team convened a consensus panel of prescribers and pharmacists with expertise in addiction medicine, pain management, internal medicine, pharmacy, and other relevant practice areas to evaluate the literature, review results, and identify specific criteria for identifying high-risk behavior.

Flags that have been reported on previously have been generated based upon the identified evidence-based criteria. An initial version of statistical coding has been developed to translate these flags into an analytics tool to identify possible violations of law or breaches of professional standards by prescribers and pharmacists. The statistical code is currently being reviewed and tested on the PDMP data at present.

Once the code is finalized, PDMP will be able to identify high-risk prescriber, dispenser, and patient behavior. Flagged clinicians will be reviewed by the PDMP Technical Advisory Committee and may receive an unsolicited reporting notification and be offered educational resources. The goal is to alert providers to high-risk behavior and create pathways to behavior modification through educational outreach and assistance to decrease these risks. Development of policies and procedures for Technical Advisory Committee review of flagged clinicians, outreach methods, and educational offerings will occur upon completion of statistical code.

The Technical Advisory Committee is statutorily required to review PDMP data indicating possible violations of law or breaches of professional standards, and provide its clinical guidance and interpretation of the data to the PDMP *before* unsolicited reports are sent to a prescriber or

dispenser about their professional practice. The Technical Advisory Committee review supplements quantitative data analysis tools and methods that the PDMP employs to identify potentially illegal or inappropriate prescribing or dispensing. The Technical Advisory Committee's guidance will inform the PDMP's determination on whether or how to engage a prescriber.

Recommendation on reporting to law enforcement agencies, licensing boards, or units of the Department

The PDMP is not authorized by statute to report possible violations of law or breaches of professional standards to law enforcement, licensing boards, or other regulatory authorities. The PDMP is authorized to report these issues only to the prescribers or pharmacists themselves for the purpose of education. At the current moment, and in accordance with the mandatory registration and use deadlines, the PDMP continues to prioritize development and implementation of these activities.

The January 13, 2017, PDMP status report included an assessment of factors to consider when analyzing whether, when, and how the expanded authority to report to enforcement agencies should be implemented. The goal is to maximize the benefits of enhanced monitoring while reducing the risk of imposing unnecessary costs or consequences on patients, practitioners providing legitimate medical care, government agencies, and private organizations.

For the next 12 months, the Department intends to focus on fulfilling its three primary initiatives, as noted above: (1) achieving 100% compliance with the July 1, 2017, PDMP mandatory registration requirement of CDS prescribers and pharmacists as a collaborative effort between PDMP and the Office of Controlled Substance Administration; (2) continuing outreach and education efforts on CDS prescriptions to lower the number of unnecessary or inappropriate prescriptions in Maryland; and (3) preparing for and achieving compliance with the July 1, 2018, PDMP use and dispensing mandate.

In addition to the technical and operational progress that the Department intends to achieve within PDMP, the bulk of the second half of 2017 and early 2018 CDS enforcement efforts will lie with OCSA. HB 437, Chapter 147 (2016), and the Heroin and Opioid Prevention Effort (HOPE) and Treatment Act of 2017, HB 1329, Chapter 571, SB 967, Chapter 572, increased the authority and flexibility of OCSA to deny, suspend, revoke, or refuse to renew a CDS registration. See generally Criminal Law Article § 5–301.

In Spring 2017, the Office of Controlled Substance Administration submitted an opioid/CDS enforcement expansion plan to the Governor's Opioid Operational Command Center and received funding to expand its enforcement efforts. The Office of Controlled Substance Administration's enforcement efforts are structured to focus on hiring additional inspectors, analysts, and technical specialists to allow the Department to identify CDS non-compliance, provide data analysis, and to conduct case investigations that may result in action against a registrant's CDS registration. As provided by statute, these actions may include disciplinary actions, such as educational awareness warnings, corrective action plans, CDS restrictions, revocation of registration, and referral for action by the Department Office of the Inspector General, Medicaid Fraud Office, Office of the Attorney General, Drug Enforcement Administration, and other relevant entities. The Office of Controlled Substance Administration implemented the necessary organizational changes in July 2017 to begin the hiring of new staff, including clinical pharmacists, inspectors, and administrative staff.

Should the Maryland General Assembly decide to make any policy changes to unsolicited reporting, the Department will adjust its operations at that time. Given the considerations in the January 13, 2017, report and in light of the statutory and operational expansion of the Office of Controlled Substance Administration's enforcement efforts, the Department recommends a careful and deliberative approach to any potential changes in PDMP authority during the 2018 legislative session. The Department intends to continue fulfilling PDMP's primary initiatives, enhancing the operational coordination and effectiveness of both the Office of Controlled Substance Administration and PDMP, and bringing about the necessary actions to ensure that the Office of Controlled Substance Administration is able to carry out its statutory enforcement responsibilities. The Department intends to continue its ongoing updates via briefings and periodic reports as necessary to your respective committees.

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

Sincerely,

Dennis R. Schrader
Secretary

cc:

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