STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Dennis R. Schrader, Secretary

January 13, 2017

The Honorable Thomas M. Middleton
Chair
Senate Finance Committee
3 East Miller Senate Office Building
Annapolis, MD 21401-1991

The Honorable Shane E. Pendergrass
Chair
House Health and Government Operations Committee
241 House Office Building
Annapolis, MD 21401-1991

The Honorable Katherine Klausmeier
Chair
Joint Committee on Behavioral Health and Opioid Use Disorders
James Senate Office Building, Room 103
Annapolis, MD 21401-1991

RE: HB437 (Chapter 147, 2016), Section 5 - Report on the Capacity of the Maryland Prescription Drug Monitoring Program to Identify & Report Possible Illegal or Inappropriate Prescribing & Dispensing

Dear Chairpersons Middleton, Klausmeier and Pendergrass:

Pursuant to HB437 (Chapter 147, 2016), Section 5, the Prescription Drug Monitoring Program (PDMP) submits this report on the analysis of the capacity of the Maryland PDMP to identify and report on possible violations of law and possible breaches of professional standards by controlled dangerous substance prescribers and pharmacists. A second report on this topic will be submitted as required under Section 5, on or before September 1, 2017.

Thank you for your consideration of this information. If you have any questions regarding this report, please contact Webster Ye, Director of Governmental Affairs, at (410) 767-6480 or at Webster.ye@maryland.gov.

Sincerely,

Dennis R. Schrader
Secretary

Enclosure

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Report on the Capacity of the Maryland Prescription Drug Monitoring Program to Identify and Report Possible Illegal or Inappropriate Prescribing and Dispensing Department of Health and Mental Hygiene

Executive Summary

Chapter 147, 2016 (HB437) requires the Department of Health and Mental Hygiene (DHMH) to report on the technical capacity of the Prescription Drug Monitoring Program (PDMP) to identify possible violations of law and possible breaches of professional standards by controlled dangerous substance (CDS) prescribers and dispensers and analyze the possibility of reporting possible violations/breaches to law enforcement agencies, licensing entities, or units of DHMH.

The PDMP currently has the capacity to identify a limited number of potential violations/breaches, including high volume CDS prescribing or dispensing, prescribing or dispensing to many patients receiving prescriptions from multiple other providers, and prescribing or dispensing to many individuals living at the same residence. The PDMP is working with academic partners and medical experts to develop more sophisticated data analysis tools to identify practices that research and consensus expert opinion deem a high-risk for CDS, and specifically opioid, misuse, addiction, overdose or diversion, including maintaining patients on excessively high opioid doses for extended periods of time and co-prescribing opioids and benzodiazepines to individual patients. The PDMP is also investigating approaches to identifying "pill mill" activity and illegitimate practitioner self-prescribing.

The potential for PDMP reporting of possible violations/breaches to investigative authorities must be analyzed in the context of a lack of universally applicable professional standards, the limitations of the types of data available to the PDMP, the Program's ability to analyze and draw conclusions from the data, the potential unintended consequences for legitimate medical practice and patient care, and other factors. Given these issues, legal and policy approaches should be considered that prioritize PDMP notifications to investigative authorities with the capacity, legal authority, and in-house expertise sufficient to: 1) access additional information (including original prescription records for verification of PDMP data accuracy, provider specialty and practice setting, patient medical records, etc.) that provides the necessary context for making informed, objective assessments on the appropriateness of prescribing or dispensing practices, and 2) understand what constitutes "actionable" information for the purposes of initiating formal investigations or pursuing criminal, civil or administrative action. This could include initial notification of DHMH units which are also under the Secretary's authority and currently have the ability to assess PDMP data in context of the specific provider's practice, take appropriate action using their own legal authority and determine whether referral to independent licensing entities or external law enforcement agencies is warranted.

Background

Section 5 of Chapter 147, 2016 (HB437) requires the DHMH to report to the Senate Finance Committee, the House Health and Government Operations Committee, and the Joint Committee on Behavioral Health and Opioid Use Disorders, on: 1) the technical capacity of the PDMP to analyze prescription drug monitoring data for possible violations of law and possible breaches of professional standards by a prescriber or a dispenser; and 2) an analysis of the possibility of reporting possible violations of law or possible breaches of professional standards by a prescriber or a dispenser to law enforcement agencies, licensing entities, or units of DHMH.

This report was prepared by the DHMH Behavioral Health Administration (BHA), which houses the PDMP, in response to this requirement. The report is divided into three sections, including:

1. Defining "Possible Violations of Law" and "Possible Breaches of Professional Standards" Identifiable Through PDMP Data Analysis;
2. Current Technical Capacity of the Maryland PDMP to Analyze Data to Identify Possible Violations/Breaches; and
3. Analysis of the Possibility of Reporting Possible Violations/Breaches to Investigative Authorities.

Defining "Possible Violations of Law" and "Possible Breaches of Professional Standards" Identifiable Through PDMP Data Analysis

It is important to first define which possible violations of law or breaches of professional standards are relevant to the goals of the PDMP and could reasonably be expected to be identified through PDMP data analysis, to appropriately conduct the analysis required by HB437. There are many possible ways in which a physician, nurse practitioner, dentist, pharmacist or other healthcare provider could violate law or breach professional standards when prescribing or dispensing a CDS prescription. However, a full accounting of all potential violations/breaches is beyond the scope of this report as many are not directly relevant to the legislative and policy mandate of the PDMP to address prescription drug misuse and addiction.

Additionally, there are many possible violations/breaches that PDMP data analysis could not reasonably be expected to identify. CDS laws and regulations at both the federal and State level create requirements that are primarily administrative in nature, including rules about practitioner registration with regulatory authorities, documentation and record keeping, CDS purchasing, storage, labelling, etc. Data collected by the PDMP would not indicate whether a pharmacy had stored CDS securely, filed CDS prescriptions separately based on drug schedule or appropriately labelled dispensed medications. PDMP data would also not indicate whether a prescriber had included all required information in the prescription.

However, criminal, civil, or administrative penalties authorized by these laws could be imposed not only for violations of administrative requirements, but also for conduct deemed to constitute illegitimate medical practice. This is true even though these laws do not explicitly define acceptable medical practice in CDS prescribing or dispensing. For instance, 21 CFR §1306.04, authorized under the federal Controlled Substances Act (CSA), states that "a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." DEA's "Practitioner's Manual" notes that "Federal courts have long recognized that it is not possible to expand on the phrase 'legitimate medical purpose in the usual course of professional practice' in a way that will provide definitive guidelines to address all the varied situations physicians may encounter… Each case must be evaluated based on its own merits in view of the totality of circumstances particular to the physician and patient."[1]

Therefore, violations of professional practice standards could be judged to constitute a violation of law. Identifying what standards may apply, however, is not straightforward given the lack of a single authoritative source. Professional standards are generally understood to address what constitutes appropriate medical care provided by a competent practitioner. Standards could be derived from consensus statements or practice guidelines issued by authoritative bodies, including medical professional societies, government agencies, commissions and other organizations. They may be specific to certain specialty areas, practice settings, conditions or patient groups, and therefore may not uniformly apply to all healthcare providers. As the research, pace of knowledge diffusion, and norms of medical practice are all continually evolving, what is considered the standard may change over time and differ even among authorities in the same practice area. Finally, the PDMP's lack of access to patient medical records, practitioner specialty information, and other data that could provide context for CDS dispensing data presents additional challenges for identification of illegal or inappropriate practice.

Despite the inherent ambiguities in identifying violations of law or breaches of professional standards through PDMP data analysis, there are a number of practices that PDMPs have or could potentially identify. These include:

1. **"Pill mill" activity**: Although "pill mill" is not explicitly defined in federal or state law, the term is commonly used to describe a medical practice where high volumes of opioids and other CDS are illegitimately prescribed and/or dispensed to individuals who are not using the medication for its intended purpose. It is often assumed that the practitioners are knowingly prescribing/dispensing medication in manner that deviates from professional standards and that the patient population largely consists of individuals who are addicted to or diverting

[1] DEA Practitioner's Manual, 2006 Edition: https://www.deadiversion.usdoj.gov/pubs/manuals/pract/ (Accessed November 16, 2016)

prescription drugs. However, practices that are owned and operated by non-practitioners may employ a rotating cast of prescribers with high turnover rates, potentially due to practitioner discomfort or outright disagreement with practice policies and norms that only become apparent with time, rather than deliberate malfeasance by the practitioners. Similarly, the patient population may include not only addicted individuals and those engaging in illicit diversion, but also people with multiple, complex somatic and behavioral health issues that, for a multitude of reasons, are unable or unwilling to seek or access appropriate and comprehensive medical care.

DEA and other CDS regulatory agencies have developed "red flag" lists to assist pharmacists, other healthcare providers and public health and safety authorities with identifying practices or practitioners that are engaged in potentially illegitimate medical practice. The lists typically include factors such as:

- Patients who request specific brand name drugs and use slang terms associated with illicit sale;
- Multiple patients of a single practice or practitioner being issued, or presenting at a pharmacy, prescriptions for the same drugs, and in the same or similar quantities, indicating prescribing decisions that are not tailored to the individual patient need;
- A significant proportion of patients who travel long distances to the prescriber, pharmacy or both, particularly when the patients are not regular customers of the pharmacy or other pharmacies and prescribers are available in closer proximity to the patient's residence;
- Multiple patients of the practice receiving similar prescriptions and having the same address or who are likely family members;
- High number of patients of the practice going to multiple other prescribers or pharmacies;
- High number of patients paying cash for office visits or dispensed medications, especially when they have insurance that includes a pharmacy benefit;
- Practitioners issuing large numbers of CDS prescriptions who have previously been sanctioned by licensing authorities for CDS-related standard of care violations;
- Practitioners issuing CDS prescriptions without routinely conducting patient physical examinations;
- Practitioners instructing patients to fill prescriptions at a specific pharmacy or multiple pharmacies, or pharmacies that appear to be filling large numbers of CDS prescriptions from a small number of prescribers whose patients don't typically go to other pharmacies;
- Practitioners issuing prescriptions for CDS drugs that are not indicated for the patients' condition, or pharmacies that routinely dispense prescriptions to these patients; and

- Practitioners issuing prescriptions to patients known to have engaged in illegal drug diversion, or pharmacies routinely dispensing to these patients.

DEA cautions that the existence of any one of these factors is not dispositive of illegal or inappropriate medical practice and advises that these and other potential factors should be considered in context of the totality of circumstances relevant to the patients, prescribers, and dispensers.

2. **Self-prescribing:** Although practitioners prescribing controlled substances to themselves is not explicitly prohibited by federal or state law, the practice, particularly when done routinely or not clearly in an emergency situation, is generally considered to be outside the normal scope of professional practice due to the inherent limitation to the practitioner's objectivity and threat of drug misuse.

3. **Chronic high-dose opioid prescribing:** It has been established that higher dosage levels of opioid therapy are directly related to increased overdose risk.[2] Centers for Disease Control and Prevention (CDC) guidelines for prescribing opioids for chronic pain in the primary care setting recommend that opioids are non-preferred for treatment of chronic pain, and if used at all they should be prescribed at the lowest dosage possible for the shortest necessary duration to reduce risks of negative health outcomes.[3]

4. **Co-prescribing opioids and benzodiazepines:** Benzodiazepines, a class of psychoactive drugs that work as a central nervous system (CNS) depressant, are often prescribed in combination with opioids. Benzodiazepines include many medications that are prescribed to treat anxiety, insomnia, and seizures. CDC's opioid prescribing guidelines for chronic pain also recommended that these two classes of drugs not be prescribed in combination. In August 2016, the Food and Drug Administration (FDA) required that stronger 'black box' warnings be placed on the packaging for benzodiazepines and opioid-containing medications because of the significant risk of morbidity and mortality related to concomitant use of benzodiazepines and opioids.[4] While some providers may still be writing prescriptions for both benzodiazepines and opioids for the same patient, many providers may prescribe only an opioid while being unaware that another practitioner has also prescribed a benzodiazepine

[2] Bohnert ASB, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA, Blow FC. Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths. *JAMA.* 2011;305(13):1315-1321. doi:10.1001/jama.2011.370

[3] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1

[4] FDA News Release: FDA requires strong warnings for opioid analgesics, prescription opioid cough products, and benzodiazepine labeling related to serious risks and death from combined use. August 31, 2016. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm (Accessed: November 16, 2016)

for the same patient; PDMP can be used to identify both scenarios and take appropriate alerting and educational approaches to each situation as appropriate.

Current Technical Capacity of the Maryland PDMP to Analyze Data to Identify Possible Violations/Breaches

Existing Data Analysis Capacity

DHMH currently uses a web-based PDMP administrative tool provided by a subcontractor. The tool allows PDMP staff to extract raw data, containing prescriber, dispenser and patient information, based on a number of key parameters that could identify possible violations of law or breaches of professional standards. The tool is currently used to identify patients with multiple provider episodes ("doctor shopping") to inform unsolicited notifications the PDMP sends to their prescribers. Additionally, aberrant prescriber or dispenser activity could be identified using three such methods described below:

1. **High-volume prescribing/dispensing:** Prescribers who are writing the greatest quantity of prescriptions for all CDS or specific classes of drugs, like opioids, can be identified, and a report of prescription-level records can be generated that includes the specific drug name and strength, dose, quantity of doses dispensed and intended days' supply, as well as identifying information about the dispenser and patient and distances between the patient residence, prescriber, and dispenser. The same type of report can be generated for the dispensers filling the greatest quantity of prescriptions.
2. **Prescribing/dispensing to patients with multiple provider episodes:** Providers who prescribe or dispense CDS to patients who are consistently receiving CDS prescriptions from multiple providers can be identified. This activity could indicate insufficient patient screening and risk mitigation strategies that violate the standard of care or, particularly in cases where the provider is treating large numbers of patients with multiple other prescribers, potential complicity in drug diversion.
3. **Prescribing/dispensing to multiple patients at the same residential address:** The tool allows for identification of patient residence addresses that are linked to the highest quantity of CDS prescriptions. High volumes of prescriptions written or dispensed to multiple individuals at a single address may indicate the presence of diversion or other aberrant activity. Prescribers and pharmacies who are significantly contributing to this high volume of prescriptions can be identified using existing queries and analytic methods.

The PDMP is currently reviewing the feasibility and desirability of implementing these potential approaches to provider identification and notification, in accordance with new legal authorities effective October 1, 2016.

It is important to note that current law requires the PDMP's Technical Advisory Committee (TAC) 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 Program before unsolicited reports are sent to a prescriber or dispenser about their professional practice. TAC review supplements quantitative data analysis tools and methods that the PDMP employs to identify potentially illegal or inappropriate prescribing or dispensing. The TAC's guidance will be taken into consideration when the PDMP is determining whether or how to engage a provider about practice issues.

Capacity Building Activities

The PDMP has recently undertaken analytic capacity building projects with support from a federal CDC Prescription Opioid Overdose Prevention for States grant, additional funding recommended by the Governor's Heroin and Opioid Emergency Task Force and gift funds from Chesapeake Employers Insurance Company. These activities can be broken down into investments in PDMP data storage and access, hiring of new staff to conduct data cleaning and analysis, and collaboration with academic partners to develop a more comprehensive methodology for identifying indicators of possible breaches of professional standards.

PDMP Dataset

States engaged in more advanced data analysis activities often choose to maintain an in-house copy of the PDMP dataset for analysis purposes rather than solely using vendor reporting tools. The PDMP is currently working to establish such an in-house file that is regularly updated from the data collection vendor, cleaned and formatted for analysis. For the in-house dataset to be useful for both internal analyses and preparation of research-ready datasets, it was necessary to procure industry-standard data cleaning resources. The PDMP has partnered with the University of Maryland, School of Pharmacy's Pharmaceutical Research Computing (PRC) center to develop methodology and statistical software code for cleaning the dataset variables and also produce de-identified research datasets. PRC delivered code and copies of the research dataset in September, 2016.

Staffing

An epidemiologist was hired to assist coordination of data analytic capacity building, develop and implement analysis tools for identifying high-risk prescribing practices, link PDMP and other relevant data sets, and conduct other data analysis activities. Additionally, the PDMP will hire a database specialist responsible for maintaining the in-house PDMP database, preparing internal and research ready datasets, and working with the epidemiologist to develop analytic methodology consistent with known characteristics of the data variables. The database specialist will also maintain other obtained datasets for use in data linking and analysis, including: PDMP registration and use data files from Chesapeake Regional Information System for our Patients (CRISP), overdose decedents provided by the Office of the Chief Medical Examiner (OCME)

and the Vital Statistics Administration, and behavioral treatment system data from current and legacy sources. The database specialist will be able to generate more comprehensive reports on dispenser compliance with the reporting requirement in order to appropriately audit the quality of the PDMP data.

Analytic Tools

The PDMP has partnered with 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. This activity is funded through additional funding recommended by the Governor's Heroin and Opioid Emergency Task Force. The research team conducted an extensive literature review of national, state, professional organization, 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 will be generated based upon the identified evidence-based criteria; examples include:

- Specific pharmaceutical thresholds (e.g. daily milligrams of morphine equivalency) in the analytic program will be calibrated to identify outlier providers based on provider specialty, types of drugs prescribed, or other relevant factors;
- Potentially dangerous combinations like opioids and benzodiazepines, opioids, and controlled sleep medications ("Z-drugs"), or benzodiazepines and stimulants; and
- Multiple patients receiving CDS prescriptions from the same prescriber or pharmacy residing at the same address.

The consensus panel has completed the work of developing the evidence-based flags. These flags are being translated into statistic coding that will be applied to the PDMP data itself, and once in place will allow the Program to identify high-risk prescriber, dispenser, and patient behavior. Flagged clinicians will be reviewed by the TAC 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.

Predictive Risk Model

The Office of Overdose Prevention is engaged in a separate project that in the future may prove to be an important tool and source of information about clinically-driven risk factors for opioid-related morbidity and mortality. Funded in Fall 2015, a four-year, $750,000 Department of Justice grant is being used to create a predictive risk model for overdose and negative opioid-

related outcomes, which will be integrated into the PDMP. This project is being conducted in collaboration with the Johns Hopkins Center for Population Health Information Technology, a leader in predictive risk modeling in health. At present, agreements are being put in place to enable data access and linking person-level data from PDMP, OCME, Health Services Cost Review Commission (HSCRC), Department of Public Safety and Corrections Services (DPSCS), Department of Juvenile Services, and behavioral treatment data. Individuals who have records across multiple datasets will be matched, and then the dataset will be de-identified and used to create the risk model. No person-identifying information will be disclosed to researchers or fed into the PDMP.

Outcomes from the risk model may highlight clinical practices that increase patient risk. The most fundamental outcome of predictive modeling is to understand key health indicators and their relative weight in contributing to morbidity and mortality. This model will use Maryland-specific datasets and will identify clinically relevant patterns based on the linkage of these datasets. Clinician behavior that may increase patient risk could be analyzed in the PDMP data and with appropriate stakeholder input and regulatory review and might inform clinical practice standards in Maryland in the future.

Analysis of the Possibility of Reporting Possible Violations/Breaches to Investigative Authorities

Currently, the PDMP is not legally authorized to report possible violations of law or breaches of professional standards to law enforcement, licensing boards (LBs) or other regulatory authorities. The PDMP is authorized to report these issues only to the prescribers or dispensers themselves for the purpose of education. The CDC has cited active reporting to "identify inappropriate prescribing trends" as a promising practice for PDMPs.[5] Providing PDMPs with legal authority to report potential violations/breaches to investigative and regulatory authorities augments the utility of these programs as a tool for public health surveillance and intervention and is consistent with research indicating a connection between inappropriate opioid prescribing and elevated patient risk.

However, there are multiple factors to consider when analyzing whether, when, and how such authorities should be implemented in order 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. In addition, if the authority is granted to the Program, it should be discretionary, rather than mandatory, to allow the PDMP to accommodate the complexity of this work and balance resource needs across multiple Program priorities. Given the considerations described below, it would be advisable, and the Program's intention, to take a phased approach to implementation after developing, in

[5] https://www.cdc.gov/drugoverdose/pdmp/states.html

collaboration with the Advisory Board on Prescription Drug Monitoring and other relevant stakeholders, clear policies and procedures.

An analysis of these factors, including proposed methods for addressing them, is provided below:

1. **PDMP Data Accuracy:** Although the PDMP employs data collection procedures to reduce the possibility of inaccurate or incomplete data being reported to and stored by the Program, it is not currently possible to ensure that all data errors are identified and addressed. If possible, PDMP data should be compared to the original prescription records maintained by the dispenser to verify accuracy.

   Investigative authorities with existing legal authority, expertise and established relationships with pharmacies are best positioned to access original prescription records or other supplemental data sources to verify the accuracy of PDMP data. These include the LBs and DHMH units like the Office of Controlled Substance Administration (OCSA), formerly known as the Division of Drug Control, the Office of the Inspector General and Maryland Medical Assistance. Although some law enforcement agencies, including DEA, specialize in investigations involving access to PDMP data and original prescription records, many State or local law enforcement agencies do not routinely conduct these types of investigations.

2. **Patient Context:** As discussed above, the PDMP law only requires reporting of data on dispensed CDS prescriptions. Although the law does not preclude requiring dispensers to report information beyond that which is necessary to identify the drug, patient, prescriber, and dispenser, the practical limitations on current pharmacy data collection, storage and reporting capabilities effectively prevents PDMP from accessing information, including patient medical history, diagnosis, prognosis, etc., necessary to make a fully informed determination of medical legitimacy.

   The PDMP is currently investigating access to patient information from other sources that could improve analysis of the contextual factors. Other sources could potentially include hospital utilization data through HSCRC and/or CRISP, claims for medical services from Medicaid and private payers, and other sources. Clear legal authority to access and use supplemental data sources for PDMP monitoring functions and increased stakeholder involvement and support of these data uses could help the Program overcome these barriers. As the TAC will be an important Program resource for identifying high-risk patients, it would be important to specifically address any ambiguity related to TAC access to non-PDMP data sources to support their statutory responsibilities. This could include clear authority for the TAC to communicate with providers identified through PDMP data analysis to better understand patient context and their rationale for prescribing or dispensing decisions.

3. **Provider Context:** The PDMP has established collaborative relationships with the OCSA, and the Boards of Physicians, Nursing, Pharmacy, Dental Examiners, and Podiatric Medical Examiners to receive periodic updates of licensing records, some of which contain provider specialty and board certification information. This information is being combined with similar data reported by providers as part of the PDMP registration process to create a unified provider registry that will assist both streamlined PDMP registration (currently implemented to support mandatory prescriber and pharmacist registration, as required under HB437, 2016) and improved analysis of prescriber practices.

   However, the PDMP does not currently have an independent way to verify that any prescriber identified through PDMP data analysis is currently practicing a particular medical specialty or in a specialized medical setting. This constrains analyses of prescribing practices that may appear outside of professional standards for certain provider types but not necessarily for others. TAC review and guidance may assist the PDMP with understanding whether the practices at issue could be legitimate for any specialist, but it alone could not remove all uncertainty.

   The PDMP could be provided with supplemental provider information to improve the Program's ability to analyze contextual factors relevant to questions of medical legitimacy. Data that is both current and accurate regarding specialty, certification, and practice setting would be most useful. Similarly, better information on the specific practice or institution where a provider is treating patients with CDS prescriptions would improve the Program's ability to determine whether practice-level factors may be influencing prescribing profiles, particularly if other practitioners within a single practice are routinely prescribing to the patient as well.

4. **Institutional Expertise in Investigations:** As the PDMP is administered by the DHMH BHA, institutional expertise is limited in identifying violations/breaches by providers whose scope of practice falls outside of BHA's regulatory authority over licensed behavioral health treatment providers. This limitation also applies to knowledge of what constitutes "actionable" information for the purposes of initiating investigations and criminal, civil or administrative charges, prosecutions or other case resolution alternatives. Investigative and regulatory authorities that may receive unsolicited notifications from the PDMP about provider activity may have formal policies in place that require some level of review or inquiry to determine whether a formal investigation should take place. Even a modest increase in preliminary investigations may impose significant costs on these investigative entities, particularly if they receive regular PDMP notifications based on established thresholds for provider activity. PDMP notification policies must be attuned to the capabilities of recipient entities to process and act on the notifications.

   There are multiple units within DHMH that have more direct working relationships with external law enforcement agencies and with LBs that, although administratively connected to

the Department, have independent legal authority. A number of these units, including OCSA, OCME, Office of Health Care Quality, Office of the Inspector General and Maryland Medical Assistance, are already authorized to request PDMP data to support existing investigations. At least two of these units have criminal, civil or administrative enforcement authority over both prescribers and dispensers. Prudence would dictate that these units could be primary recipients of PDMP notifications. As these units are all under the authority of the Secretary, Departmental policies could be established to determine specific criteria or thresholds for issuance of PDMP notifications to each unit that balance the need to pursue leads with the availability of scarce resources. These units could conduct initial inquiries into possible violations/breaches to determine whether formal, full investigations were justified. PDMP data could be analyzed in the context of medical claims, patient deaths or other data the units already have access to. Through existing relationships with LBs and law enforcement agencies, these DHMH units could assist with determining when a particular case warrants the attention of external authorities.

5. **Potential Adverse Impact on Legitimate Care:** Investigation and adjudication of charges against healthcare providers may impose significant costs on the provider in terms of fees for legal representation, time away from work, damage to professional reputation and employment prospects, etc. Patients being provided legitimate care by the provider could experience treatment disruptions that put them at higher risk for adverse drug-related events. It is important that units that receive PDMP notifications use it judiciously to inform investigations and implement support systems directly, or through collaborations with other units, to assist providers and patients who may unintentionally be harmed.

   As indicated above, assistance from other units with the expertise and ability to conduct more in-depth inquiries into the practices at issue should help mitigate risks of unintended consequences. In addition to the DHMH units, LBs that receive PDMP notifications could conduct preliminary inquiries and, if a full investigation is warranted, subpoena patients records, conduct interviews with licensees and their patients, submit evidence to independent peer reviewers, and pursue a highly structured adjudication process that provides licensees with appropriate due process rights. Although Board processes tend to move slowly, they provide another external check on PDMP data analyses to determine whether provider conduct warrants referral to, and possible criminal investigation by a law enforcement agency. Boards have also demonstrated, through participation in past collaborations, the legal authority and ability to work in concert with BHA and other DHMH units to provide support services for the patients of sanctioned providers to reduce the risk of gaps in treatment. Revisiting these collaborative efforts would be important if the PDMP is given legal authority to issue unsolicited notifications to investigators.