



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

201 W. Preston Street • Baltimore, Maryland 21201

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

JUL 18 2012

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)(i) - 2012 Report on the Analysis and Recommendations of the Advisory Board on Prescription Drug Monitoring

Dear President Miller and Speaker Busch:

Pursuant to Health - General Article, Section 21-2A-05(f)(3)(i), the Advisory Board on Prescription Drug Monitoring (Advisory Board) submits this report on the analysis and recommendations of the Advisory Board relating to the design and implementation of the Prescription Drug Monitoring Program in the Department of Health and Mental Hygiene. Senate Bill 883 of 2012 established a Prescription Drug Monitoring Program to assist prescribers, dispensers, and public health provisions in identifying and preventing prescription drug abuse, as well as identifying and investigating unlawful prescription drug diversion.

I hope this information is useful. If you have questions regarding this report, please contact Ms. Marie Grant, Director of the Office of Governmental Affairs at the Department of Health and Mental Hygiene, at (410) 767-6480.

Sincerely,

Laura Herrera, M.D.
Chair, Advisory Board on Prescription Drug Monitoring

Enclosure

cc: Michael Baier
Marie L. Grant, J.D.
Joshua M. Sharfstein, M.D.
Sarah Albert, MSAR #8631

Introduction

Title 21, Subtitle 2A of the Health-General Article (enacted by Senate Bill 883, Chapter 166 of the Acts of 2011) requires the Department of Health and Mental Hygiene (Department) to create a Prescription Drug Monitoring Program (PDMP) to reduce the adverse consequences of the misuse, abuse and diversion of prescription drugs throughout the State. The duties of the PDMP, as outlined in the PDMP law, include:

- monitoring the prescribing and dispensing of prescription drugs designated by law as “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.

Additionally, the PDMP will build upon the interest in and use of the database to develop a collaborative, interagency and interdisciplinary strategy to treat and prevent drug abuse, improve the quality of pain management and educate stakeholders and the general public on how to reduce the threat across the State. The Secretary of the Department has assigned responsibility for programmatic development of the PDMP to the Alcohol and Drug Abuse Administration (ADAA) 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 membership is attached. The Board has convened three times since its first meeting in October, 2011, and has provided feedback and recommendations on a number of topics, including regulations, information technology (IT), program evaluation, funding and educational initiatives.

Section 21-2A-05(f)(3)(i) of the Health-General Article also requires the Board to provide, within 180 days of its first meeting, a report setting forth the Board’s analysis and recommendations relating to the design and implementation of the PDMP, regulations for the PDMP, legislation for the PDMP, and sources of funding for the PDMP. This Interim Report is submitted to the General Assembly pursuant to this requirement.

Recommendations for Program Design & Implementation

General Program Design

Maryland is in the fortuitous position of having a wealth of PDMP-related knowledge and expertise at its disposal. Developments within the world of health information technology point the way to promising, alternative approaches to prescription monitoring, primarily through integration with the

statewide Health Information Exchange (HIE).¹ The HIE employs IT that provides similar functionality to that required by electronic PDMPs and often features significant enhancements over currently operational programs. For this reason, the Board recommends that the PDMP not develop a stand-alone, “siloeed” system and, specifically, that the Department leverage, to the greatest extent possible, the enormous investment the State has made in developing the HIE to maximize the operational efficiency, utilization and overall effectiveness of the PDMP. Successful implementation of this design would put Maryland at the forefront of PDMP innovation and enable program enhancements currently being promoted by subject matter experts and federal agencies as essential for the future of effective prescription drug monitoring.

Recommendation: The Department should pursue integration between the PDMP and the IT infrastructure of the HIE to the greatest extent possible.

The Department intends to divide responsibility for implementing each of the major PDMP components as follows:

- **ADAA, in consultation with the Board:** Policy development and administrative support; oversight of educational initiatives; database hosting and disclosure to law enforcement, licensing boards and their practitioner rehabilitation programs, units of the Department, patients, other states’ PDMPs (non-automated requests) and researchers;
- **The Maryland Health Care Commission (MHCC), through its oversight of the HIE:** Data processing/analysis; database hosting, data disclosure, training and technical assistance services and authentication/credentialing for clinical end-users; data disclosure to other states’ PDMPs (automated requests); and
- **Vendor** (to be selected through a competitive procurement process): Data collection and processing; training and technical assistance (T/TA) for dispenser reporting; possible data disclosure to dispensers.

The tentative timeframe for establishing a minimally operational PDMP is the third quarter of FY2013, though unforeseen issues in IT implementation or the inability to secure adequate program funding may cause delays. A detailed review of this design, broken down by program component, is provided below.

Data Collection

The PDMP law allows the Secretary to determine the reporting deadline in regulations. Regardless of the specific deadline that is ultimately adopted, the Board recommends that the Department develop a system that allows for real-time, transaction-based reporting for most, if not all, qualifying

¹ In Maryland, funding made available through the Health Services Cost Review Commission and the federal Health Information Technology for Economic and Clinical Health Act has supported the development of the statewide HIE by Chesapeake Regional Information System for Out Patients (CRISP), a not-for-profit membership corporation whose organizational members are Erickson Retirement Communities, Johns Hopkins Medicine, MedStar Health and the University of Maryland Medical System. CRISP was designated as Maryland’s statewide HIE following a competitive process overseen by MHCC.

dispensing of CDS to increase interest in and utilization of the PDMP, integrate reporting procedures more closely with the existing data entry practices of dispensers and provide a foundation for future program enhancements. Given the inherent difficulties with building a data collection system from the ground up, the Department intends to issue an RFP and select a vendor to provide, at a minimum, data collection services for the PDMP. Responders should be allowed to propose other services beyond the minimum CDS data collection requirement, including the collection of additional data on CDS dispensing beyond that required by regulations, collection of data on non-CDS dispensing and providing the means to make alerts or PDMP reports available within dispenser practice management systems.

Recommendation: The Department should issue an RFP for IT capable of supporting real-time data collection from dispensers.

Data Processing/Analysis

As the utility of PDMP data is to a great extent dependent on the quality of the data submitted by dispensers, the Department's RFP should require the data collection vendor to identify and reject incomplete or inaccurate dispenser reports to ensure that data collected by the Program meets a minimum threshold for accuracy. Reporting will also be conducted using data standards and file transfer protocols that are commonly used and accepted in the pharmacy industry, and data will be encrypted at a level sufficient to ensure that personal health information is not improperly disclosed or intercepted.

In order to accurately identify unique patients within the dataset, the Department should utilize the Master Patient Index (MPI) component of the HIE. The ability of the MPI to identify the correct patient increases with access to each new dataset; likewise, the addition of prescription data to its analysis engine will increase the accuracy of PDMP data far beyond what would be possible using another software product. Use of the MPI will be a major "value added" component of integration with the HIE which will also allow the Department to avoid the necessity of procuring redundant services and technology.

Lastly, the data collection vendor, the HIE and any other entity that supports PDMP data processing should be required to keep logs of data reporting, system access and disclosure to end users. These logs must be available for audit by the Department on a periodic basis and in response to patient requests, court orders or other quality assurance inquiries.

Recommendation: The data collection vendor must have the ability to reject incomplete or inaccurate dispensers reports, and the PDMP should use the HIE's Master Patient Index to identify unique patients in the database.

Database Hosting

Once dispensing reports have been cleaned and stamped with a unique patient identifier by the MPI, the HIE should store the information in a database optimized for handling electronic queries from

prescribers, dispensers and Program personnel. The Department is currently working to identify the technical requirements for database security and has not yet determined what entity will host the database.

Data Disclosure

The PDMP law enumerates the individuals and entities that may request or otherwise access PDMP data and the circumstances under which disclosure is permissible. Upon request, PDMP data shall be disclosed to CDS prescribers and dispensers if they have a legitimate medical relationship with the patient about whom data is being requested. Recognizing that timely access to prescription data at the point-of-care has significant clinical utility for physicians, nurses, pharmacists and other providers, the Department should adapt the existing HIE web portal and end-user authentication/credentialing procedures to support PDMP data disclosure. Much like the use of the MPI for unique patient identification, adaptation of these HIE technologies will eliminate the procurement of redundant services. Importantly, PDMP data disclosure through the HIE will add to the wealth of patient health information available through the exchange and provide essential clinical context for CDS prescription data.

Due to the PDMP law's restrictions on access by authorized requesters other than prescribers and dispensers, the Department does not envision that automated request and disclosure processes can be established for law enforcement, licensing boards and their practitioner rehabilitation programs, units of the Department, patients and researchers.² Additionally, the PDMP law requires that the Technical Advisory Committee (TAC)³ have the opportunity to review most of these requests. For these reasons, these requests should be delivered directly to Program staff and include all required forms and documentation.

In keeping with legislative authorization and best practices in prescription drug monitoring, the Department should pursue interoperability with other states PDMPs, especially those operating in neighboring states, to assist all stakeholders in reducing cross-border "doctor shopping" and diversion. The Department has not established which interstate exchange solution it will utilize, and this decision is unlikely to be made until program implementation is further along. Regardless, it is important to note that the PDMP law currently requires TAC review of every request from another state's PDMP, meaning that requests from out-of-state health care providers must be reviewed even though in-state provider requests are not. Given that current interoperability solutions seek to automate, at a minimum, interstate requests from prescribers and dispensers, the inclusion of TAC review in the process poses a significant barrier to interoperability implementation.

² The PDMP law requires a subpoena for disclosure to law enforcement or the licensing boards and an existing investigation for units of the Department (including Maryland Medical Assistance, the Office of Health Care Quality, the Office of the Inspector General and the Office of the Chief Medical Examiner). Requests for research, education and public reporting purposes will likely require approval by the Department's Institutional Review Board.

³ As required by law, the TAC will be composed of four specialist physicians and a pharmacist appointed by the Secretary from a pool of candidates nominated by certain health professional societies who will provide clinical guidance and interpretation of the data requested to the Secretary and the data recipient. The Department intends to conduct this appointment process for the TAC once the Program is closer to becoming operational.

Recommendation: The PDMP should use the HIE’s web portal and authentication/credentialing procedures to facilitate electronic data disclosure to prescribers and dispensers. Disclosure requests from law enforcement, licensing boards, units of the Department, patients and researchers must be individually processed by PDMP personnel, and legal barriers to interoperability with other states’ PDMPs must be removed.

Training and Technical Assistance

Training and technical assistance must be made available primarily for dispensers required to report to the PDMP and authorized requesters of PDMP data. The data collection vendor should be required to provide T/TA services to dispensers, including easily accessible and intelligible instructional materials, direct support for any necessary software products and “help desk” services when dispensers encounter technical problems. For T/TA to support prescriber and dispenser registration and use of the system, the Department should leverage the existing services provided by the HIE. This will allow registration drives and other initiatives aimed at increasing provider utilization undertaken by MHCC, CRISP or ADAA to benefit both projects.

Recommendation: The PDMP data collection vendor must provide T/TA to reporting dispensers and the HIE must do so for clinical end-users.

Recommendations for Regulations

As the PDMP law left some of the detailed requirements for program operations to be determined in regulations, these issues required extensive deliberation before a consensus was reached. Many other issues, however, tracked closely with the pre-determined requirements of the legislation and commonly accepted practices in prescription drug monitoring and were therefore less controversial. Below is an overview of the Board’s recommendations, as reflected in the current draft, on some of the key issues. The Department will publish the proposed regulations for public comment in June.

Deadline for Dispenser Reporting

As mentioned above, the Department should seek to implement a novel IT infrastructure that makes real-time data reporting and collection a practical possibility for most if not all CDS dispensing. The Board was concerned, however, that including a real-time reporting requirement in regulations could prove too costly and burdensome for dispensers should the IT design proposed by the Department not be viable or function as envisioned. After much discussion, a consensus was reached on “3 business days”⁴ as the deadline for both initial dispenser reporting as well as resubmission of reports following notification by the Department that the original report was incomplete or inaccurate. The Board believes

⁴ A “business day” is defined as “any day except Saturday, Sunday, or a holiday on which State offices are closed.”

that this deadline would strike an acceptable balance between the need for timely data and the costs of reporting for dispensers.

Lastly, the Board determined that it would be appropriate to include a process for dispensers to apply for a waiver from the reporting requirement should they experience an unforeseen problem that makes reporting impossible even though dispensing is still taking place. It is important to note, however, that this does not allow dispensers to apply for a blanket waiver from meeting the reporting deadline for all dispensing; the waiver only applies to an individual instance or situation. Waiver requests must describe in detail the circumstances that prevent reporting and may be approved at the Secretary's discretion.

Recommendation: The deadline for dispenser reporting to the PDMP should be 3 business days.

Means of Data Reporting

The Board supports the Department's recommendation that the precise means of data reporting, including the data standard and transfer protocol, should not be specified in regulations. Given the rapidly changing HIT environment, it would be inappropriate to lock the PDMP into an IT approach that may be functionally obsolete by the time regulations are promulgated. Continuing discussions with HIT experts and feedback through the procurement process could uncover previously unknown approaches that could greatly improve the operations of the Program. The Department, therefore, should retain the discretion to specify the precise means of electronic reporting and the standards and protocols to be used.

The PDMP law gives the Secretary discretionary authority to allow for non-electronic reporting. The Board believes that allowing these reporting procedures would run counter to the goal of developing a state-of-the-art PDMP while imposing a cost in personnel time and effort on the Department that exceeds any benefit to system users or dispensers. Consultation with neighboring states' PDMP administrators and pharmacy representatives in Maryland indicates that few if any dispensers are completely without the means of electronic reporting. The Board recommends, therefore, that only electronic reporting should be allowed.

Recommendation: Regulations should not specify the means of data reporting nor should they allow non-electronic reporting methods.

Responsibility of a Prescriber or Dispenser that Delegates PDMP Access to a Licensed Health Care Practitioner

The PDMP law allows prescribers and dispensers to authorize licensed health care practitioners to request PDMP data on their behalf. Consultation with other states' PDMP administrators indicates that this delegation authority is a useful tool that allows physicians, nurse practitioners, physician assistants, pharmacists, dentists, etc., working in busy practices to avoid the time consuming and disruptive process of logging in, requesting and reviewing PDMP themselves, an activity that may be better left to other

practitioners. However, expanding direct access to PDMP data beyond prescribers and dispensers increases the risks of unlawful data access and use which must be balanced against the benefits of increased system utilization. To mitigate these risks, the Board recommends inclusion of language requiring prescribers and dispensers who delegate access to “make every reasonable effort, including regularly reviewing and auditing any available logs of system access and use, to ensure the authorized practitioner is requesting disclosure of, re-disclosing, or otherwise accessing prescription monitoring data in clear compliance with” the PDMP and all other applicable state and federal laws. Also, the current regulations will require prescribers and dispensers to notify both the Department and the relevant licensing board if they suspect that the confidentiality of prescription monitoring data or the security of the program has been compromised by an authorized practitioner.

Recommendation: Regulations should require prescribers and dispensers who delegate PDMP access to a licensed health care practitioner to monitor their delegate’s use of the system and report any suspected unlawful use to the delegate’s relevant licensing board and the PDMP.

Technical Advisory Committee Review

Regulations governing the TAC review process must balance the benefit of the TAC’s clinical advice and interpretation with the necessity of providing PDMP data to authorized requesters in a timely and efficient manner. A lengthy and cumbersome review process could make data so difficult to obtain for investigative purposes and would negate the utility of authorizing requests by these agencies. Therefore, the Board supports the Department’s recommendation that the TAC be given 10 business days from submission of the request to the Committee’s response. After the allotted time has expired, the Secretary may use his discretion in responding to the request. The current draft regulations require the Program to implement a means of communication with the TAC that both protects the confidentiality of PDMP and expedites the process.

Recommendation: Regulations should allow the Technical Advisory Committee 10 business days to review and respond to disclosure requests.

Notice to Patients

Many states require prescribers or dispensers who intend to access PDMP data to provide notice to patients (by posting a sign, providing written material or other method) of both the existence of the PDMP and their intent to request patient history reports. Some Board members expressed the opinion that requiring notice may provide a minimum level of deterrence of doctor or pharmacy shopping while also avoiding patient confusion that might arise when notice is displayed or inconsistently provided. However, pharmacist representatives were concerned that the requirement may place an additional cost and liability burden on pharmacies. Therefore, the Board concluded that patient notification practices should be referenced in regulations but not be required.

Recommendation: Regulations should not mandate that prescribers and dispensers notify patients of their intent to access PDMP data.

Re-disclosure of PDMP Data

The PDMP law explicitly leaves the issue of allowable re-disclosure of PDMP data to regulations. The current draft regulations specify that re-disclosure “is prohibited unless intended to facilitate the treatment of a patient and is consistent with all other State and federal laws and regulations governing the security and confidentiality of protected health information and personal medical records.” The Board believes that only allowing re-disclosure for treatment purposes parallels both legislative intent and commonly accepted practice. The Board’s local law enforcement representative indicated that information obtained through a subpoena is often shared between law enforcement agencies that are coordinating efforts on a particular case. However, the representative does not believe that the current limitation contained in the draft regulations will adversely affect law enforcement’s ability to use PDMP data for investigative purposes.

Recommendation: Regulations should only allow for re-disclosure of PDMP data for treatment purposes.

Recommendations for Legislation

As the PDMP is not yet operational, the Board cannot make recommendations based on direct knowledge and experience of what aspects of the authorizing legislation are appropriate and which present obstacles to the development of an optimized Program. However, initial deliberations have identified one amendment that the General Assembly should consider before the program becomes operational: authorization for the Division of Drug Control (“DDC”) to request PDMP data. The PDMP law allows four units of the Department to request PDMP data to support investigations, but DDC is not among them. DDC is responsible for issuing permits to all individuals and entities that manufacture, distribute, import, export, prescribe, dispense or research CDS in the State. DDC inspects pharmacies, clinics, wholesalers and other permit holders to ensure that their business and record keeping practices are in compliance with law and regulation. When conducting an investigation, DDC often requires that permit holders provide copies of the original prescription records on which electronic PDMP reports are based. However, review of paper records is an extraordinarily time consuming and inefficient process. Allowing DDC to request PDMP reports to aid investigations in a manner similar to other departmental agencies (with the approval of the Secretary) would significantly improve the operations of DDC and the Department’s ability to use every tool at its disposal to deal effectively with prescription drug abuse and diversion.

Recommendation: The PDMP statute should be amended to allow the Division of Drug Control to request PDMP data pursuant to an existing bona fide individual investigation.

Recommendations for Funding

In light of the fiscal constraints imposed on governments at all levels in recent years, states have struggled to identify sources of funding for PDMPs. However, as current data from public health and public safety authorities indicates ongoing increases in the social costs of prescription drug abuse and diversion, it is imperative that policymakers continue to find ways to support the implementation and enhancement of PDMPs while there is still an opportunity to significantly change the trajectory of this epidemic. The Department has been diligent in pursuing funding available through federal grant programs, but sustainable sources of funding must be found to ensure that the Program has an opportunity to fulfill its legislative mandate. Below is an estimate of Program costs through the implementation period (FY2012-FY2014) and an overview of funding the Department has secured to date. The Board is currently investigating possible sources of sustainable funding and will reserve its recommendations in this area for the first annual report, to be submitted in October, 2012.

Funding Secured to Date

Following passage of the PDMP law, the Governor's Office of Crime Control and Prevention (GOCCP) pledged \$500,000 from its annual Edward J. Byrne Memorial Justice Assistance Grant (BJAG)⁵ allocation from the Bureau of Justice Assistance (BJA) to support initial implementation. ADAA began incurring costs under BJAG beginning in July, 2011. GOCCP also applied for, and was awarded in September, 2011, a FY2011 Harold Rogers Prescription Drug Monitoring Program Implementation Grant (HRPDMP) from BJA, receiving the maximum award amount of \$400,000.⁶ Both the BJAG and HRPDMP grants have been made available to ADAA on a quarterly reimbursement basis. In May, 2012, ADAA submitted an application for another \$400,000 FY2012 HRPDMP Implementation Grant. It is important to note that HRPDMP grants are not designed to support basic program operations indefinitely, and only applicants that propose to enhance or expand existing PDMP capabilities are likely to be awarded funding. Unfortunately, Congress has not appropriated any funding in 2011 or 2012 for the Department of Health and Human Services National All Schedules Prescription Electronic Reporting grant program, the only other significant source of federal PDMP funding. Assuming that ADAA is awarded a full FY2012 HRPDMP grant, the Department will have a total of \$1.3 million in secured funding for the PDMP through FY2014, averaging approximately \$433,000 per year for all program costs.

⁵ BJAG is a combination formula and block grant that is the largest source of direct funding that the Department of Justice (DOJ) provides to state criminal justice coordinating agencies on an annual basis. Due to federal budget cuts, DOJ has significantly reduced each state's BJAG allocation, making it unlikely that GOCCP will be able to provide additional funds to support the PDMP.

⁶ HRPDMP is the primary federal grant program supporting the state PDMPs. States are eligible to apply annually for grants under the categories of Planning, Implementation and Enhancement. The Department received a \$50,000 Planning grant in 2009 to support Advisory Council activities.

Estimated Implementation Costs

Because the Department proposes a novel approach to developing the PDMP IT infrastructure, it is difficult at this time to estimate the total funding needed to support implementation. Mindful of funding constraints, the Department believes that the decision to utilize the existing HIE infrastructure to support a number of essential PDMP components will, in addition to the programmatic benefits outlined above, produce significant cost savings in out-years even if up-front implementation costs are more than what would be needed to procure a stand-alone system. Regardless, the Department estimates that personnel costs related to 3 Program positions will be roughly \$540,000 through the end of FY2014, leaving less than \$750,000⁷ to cover other program costs, including IT support, educational initiatives and program evaluation. Given the many uncertainties related to IT, the Department estimates that the cost of procuring a data collection vendor and adapting HIE infrastructure will be between \$1 million and \$2 million for a fully operational data reporting, analysis, hosting and disclosure system. Assuming the remaining \$750,000 can be used to fund essential IT support, the Department will need between \$250,000 to \$1.25 million more to ensure minimal program implementation.

Conclusion

Given adoption of the recommendations outlined above, the Board is confident that the Department will be able to implement a state-of-the-art PDMP that will have a direct, positive impact on prescription drug abuse and diversion. Over the next six months, the Board will continue to provide its advice and recommendations on the development of the PDMP IT infrastructure, including a review of the procurement strategy, and also on the design of a program evaluation component that can track the long-term impact of the PDMP. The Board will also investigate potential sources of sustainable funding for the program and make recommendations to the General Assembly in the Board's first annual report. Finally, the Board will assist the Department with the development and implementation of educational programs for health care providers and other PDMP stakeholders designed to increase knowledge and improve practice in the area of controlled substance prescribing and dispensing.

⁷ This figure excludes currently budgeted costs for travel and office equipment.

Attachment

Advisory Board on Prescription Drug Monitoring - Membership

Chair

Laura Herrera, MD, MPH

Chief Medical Officer, Maryland Department of Health and Mental Hygiene

Paul T. Elder, MD

Chair, Maryland Board of Physicians

Anesthesiologist, Anne Arundel Medical Center

Michael Souranis

President, Maryland Board of Pharmacy

Pharmacist, Bayview Pharmacy

Nancy D. Adams, MBA, RN

President, Maryland Board of Nursing

Senior Vice President/Chief Nurse Executive, Western Maryland Health System

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