SB 883

Department of Legislative Services

Maryland General Assembly
2011 Session

FISCAL AND POLICY NOTE
Revised

Senate Bill 883 (The President)(By Request - Administration) and Senator Forehand

Finance Health and Government Operations

Prescription Drug Monitoring Program

This Administration bill establishes the Prescription Drug Monitoring Program (PDMP) in the Department of Health and Mental Hygiene (DHMH), to monitor the prescribing and dispensing of Schedule II through V controlled dangerous substances. The Secretary of Health and Mental Hygiene, in consultation with an Advisory Board on Prescription Drug Monitoring established in the bill, must adopt regulations to carry out the bill's provisions. Implementation of the program is subject to the availability of funds.

Fiscal Summary

State Effect: Federal fund revenues increase from additional grant funding to the State for PDMP. Federal fund expenditures increase by $344,000 in FY 2012, including a one-time expense of $210,000 to contract with a vendor to design and implement a database system. Future year estimates reflect one additional administrative position, annualization, and inflation. General fund revenues and expenditures are not materially affected by the criminal penalty provisions of the bill.

(in dollars)	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
FF Revenue	-	-	-	-	-
FF Expenditure	$344,000	$328,900	$336,000	$347,100	$358,900
Net Effect	($344,000)	($328,900)	($336,000)	($347,100)	($358,900)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: The criminal penalty provisions of the bill are not expected to materially affect local finances or operations.

Small Business Effect: The Administration has determined that this bill has minimal or no impact on small business (attached). Legislative Services disagrees with this assessment as discussed below. (The attached assessment does not reflect amendments to the bill.)

Analysis

Bill Summary: The mission of the program is to (1) assist prescribers, dispensers, and public health professionals in the identification and prevention of prescription drug abuse and the identification and investigation of unlawful prescription drug diversion; and (2) promote a balanced use of prescription drug monitoring data. The program must monitor the prescribing and dispensing of drugs that contain a substance listed in Schedules II through V. For each monitored prescription drug dispensed, a dispenser must electronically submit data to PDMP in accordance with regulations adopted by the Secretary of Health and Mental Hygiene. Under certain circumstances, a dispenser may submit data by other means. Regulations must:

- specify the prescription monitoring data required to be submitted;
- specify the electronic or other means by which information is to be submitted;
- specify that the program must provide the software to dispensers to upload prescription monitoring data and may not impose any fees or assessments on prescribers or dispensers to support the operation of the program;
- specify that a prescriber or dispenser is not required or obligated to access or use prescription monitoring data available under the program;
- identify the mechanism by which prescription monitoring data are disclosed;
- identify the circumstances under which a person may disclose prescription monitoring data received under the program;
- establish requirements for program retention of prescription monitoring data for three years; and
- require that confidential or privileged patient information be kept confidential and filed in a manner that does not disclose the identity of the person protected, except for the disclosures permitted under the bill.

Advisory Board on Prescription Drug Monitoring

The bill establishes an Advisory Board on Prescription Drug Monitoring within DHMH and specifies board membership and duties. The board has to meet at least three times a year and must make recommendations to the Secretary of Health and Mental Hygiene relating to the design and implementation of the program, including regulations, legislation, and sources of funding, in particular, grant funds under the Harold Rogers Prescription Drug Monitoring Program and other sources of federal, private, or State funds. Within 180 days of the board's first meeting, an interim report must be submitted to the General Assembly regarding the design, implementation, and funding of the program. In addition, the board must report annually to the Governor and the General Assembly on specified issues, and otherwise provide oversight of the program.

The Secretary of Health and Mental Hygiene, in consultation with the Maryland Health Care Commission and the board, must determine the appropriate technology to support the operation of the program and educate dispensers, prescribers, and consumers regarding the purpose and operation of the program. The Secretary must grant a waiver from reporting to the program to a pharmacy that dispenses to an inpatient hospice under specified circumstances.

The Secretary of Health and Mental Hygiene must designate the chair of the board. The term of a member appointed by the Secretary is three years. A member of the board may not receive compensation but is entitled to reimbursement for expenses under State travel regulations. The Secretary and the board must consult with stakeholders and professionals knowledgeable about prescription drug monitoring programs as appropriate to obtain input and guidance about implementation of the program.

Use of Prescription Monitoring Data

Prescription monitoring data are confidential and privileged, and are not subject to discovery, subpoena, or other means of legal compulsion in civil litigation. Prescription monitoring data are not public records and may not be disclosed to any person except as specifically authorized under the bill. The program must disclose prescription monitoring data, in accordance with regulations adopted by the Secretary of Health and Mental Hygiene, to:

- a prescriber, or a licensed health care practitioner authorized by the prescriber, in connection with the medical care of a patient;
- a dispenser, or a licensed health care practitioner authorized by the dispenser, in connection with the dispensing of a monitored prescription drug;
- a federal, State, or local law enforcement agency, on issuance of a subpoena, for an existing *bona fide* individual investigation;
- a licensing entity, on issuance of an administrative subpoena voted on by a quorum of the board of the licensing entity, for purposes of a *bona fide* individual investigation;
- a rehabilitation program under a health occupations board on issuance of an administrative subpoena;
- a patient with respect to prescription monitoring data about the patient;
- an authorized administrator of another state PDMP;
- specific units of DHMH on approval of the Secretary of Health and Mental Hygiene for the purpose of furthering an existing *bona fide* individual investigation; or
- the technical advisory committee of the program.

A person who receives prescription drug monitoring data from the program may not disclose the data, except as provided by regulations adopted by the Secretary.

The program may disclose prescription drug monitoring data for research, analysis, public reporting, and education after redaction of all information that could identify a patient, prescriber, dispenser, or other individual, and in accordance with regulations adopted by the Secretary of Health and Mental Hygiene. Prior to disclosing data for such purposes, the Secretary may require the submission of an abstract explaining the scope and purpose of the research. Furthermore, the Office of the Attorney General may seek appropriate injunctive or other relief to maintain the confidentiality of prescription monitoring data.

The program may provide prescription drug monitoring data to and request and receive prescription drug monitoring data from another state's PDMP in a manner consistent with the bill. Prescription monitoring data may not be used as the basis for imposing clinical practice standards.

Technical Advisory Committee

The technical advisory committee, which comprises specified members appointed by the Secretary of Health and Mental Hygiene, must review certain requests for information from the program. Before the program discloses information to law enforcement, a licensing entity, a rehabilitation program under a health occupations board, an authorized administrator of another state's PDMP, or to a specific unit of DHMH, the technical advisory committee must review the requests for information and provide clinical guidance and interpretation to assist the authorized recipient of the information and to assist in the Secretary's decision on how to respond to a request.

Penalties and Liabilities

A dispenser who knowingly fails to submit prescription monitoring data to the program is subject to a civil penalty of up to $500 for each failure to submit required information. A person who knowingly discloses, uses, obtains, or attempts to obtain by fraud or deceit, prescription monitoring data in violation of the bill is guilty of a misdemeanor and subject to maximum penalties of one year imprisonment and/or a $10,000 fine. A prescriber or dispenser who knowingly discloses or uses prescription monitoring data in violation of the bill is subject to disciplinary action by the appropriate licensing entity. The release of prescription monitoring data by a prescriber or dispenser to a licensed health care professional solely for treatment purposes in a manner otherwise consistent with State and federal law is not a violation of the bill's provisions.

With respect to the administration and operation of the program, DHMH and its agents and employees are not subject to liability arising from inaccuracy of any information or the unauthorized use or disclosure of prescription monitoring data by a person to whom the program was authorized to provide such data. A prescriber or dispenser, acting in good faith, is not subject to liability arising solely from requesting or receiving, or failing to request or receive data from the program, or acting or failing to act on the basis of data provided by the program.

Program Review

The bill subjects the program to periodic review under the Maryland Program Evaluation Act, establishing an evaluation date of July 1, 2015, and a termination date of July 1, 2016.

Uncodified Language and Reporting Requirement

Uncodified language requires the program to develop a mechanism to allow a patient or the patient's prescriber to correct erroneous data reported to the program relating to the patient's prescription history. Uncodified language also states that it is the intent of the General Assembly that the Secretary of Health and Mental Hygiene, in adopting regulations to implement the program, must ensure that the technology used by the program to report prescription monitoring data to authorized recipients is not subject to manipulation by the recipients.

By December 1, 2012, DHMH and the advisory board must report to the Governor and specified committees of the General Assembly on the status and funding of the program, feedback from stakeholders on the operations of the program, any recommendations from DHMH and the advisory committee to improve the operations of the program, and whether a legislative safe harbor provision is recommended to address any access issues experienced by patients after implementation of the program.

Current Law: The federal Controlled Substances Act of 1970 (CSA) authorizes federal regulation of the manufacture, importation, possession, and distribution of certain drugs. Under CSA, various drugs are listed on Schedules I through V, and generally involve drugs that have a high potential for abuse. Morphine and amphetamines (such as Adderall) are examples of Schedule II drugs; anabolic steroids and hydrocodone are examples of Schedule III drugs; and benzodiazepines (such as Valium or Xanax) are Schedule IV drugs. Schedule V drugs include cough suppressants containing small amounts of codeine, and the prescription drug Lyrica, an anticonvulsant and pain modulator. Schedule I drugs are not prescribed and are therefore excluded from the requirements of the bill.

Maryland Program Evaluation Act

The Maryland Program Evaluation Act specifies about 70 regulatory entities and activities that are subject to periodic evaluation. The Act establishes a process better known as "sunset review" as most entities evaluated are also subject to termination. The sunset review process begins with a preliminary evaluation conducted by the Department of Legislative Services (DLS) on behalf of the Legislative Policy Committee (LPC). LPC decides whether to waive an entity from further (or full) evaluation. If waived, legislation to reauthorize the entity typically is enacted. Otherwise, a full evaluation usually is undertaken the following year.

Background: Prescription drug abuse is a growing problem in the United States. The National Institutes of Health (NIH) has estimated that 48 million people (ages 12 and older) have used prescription drugs for nonmedical reasons within their lifetime. This comprises approximately 20% of the U.S. population. NIH hypothesizes that the growth of prescription drug abuse can partially be attributed to the increased availability of prescription drugs. NIH indicates older adults, adolescents, and women are at the greatest risk for prescription drug abuse.

According to the Alcohol and Drug Abuse Administration (ADAA) within DHMH, during the first quarter of fiscal 2011, more than one in every five admissions to an ADAA-funded treatment program involved prescription drug problems. From fiscal 2007 through the first quarter of fiscal 2011, the percentage of prescription drug-related admissions doubled, primarily due to the growing problem of opiate-painkiller abuse. Treatment data indicate that abusers of prescription substances are more likely to be white, female, living in more suburban and urban parts of the State, and exhibit co-occurring mental health problems.

Prescription Drug Monitoring Programs

State prescription drug monitoring programs address this issue by requiring pharmacies to log each prescription they fill. The reports created are stored in a state electronic database that typically includes the patient's name, address, type and amount of drug, prescribing physician, and other relevant information. Medical professionals can use this information to prevent abusers from obtaining prescriptions from multiple prescribers.

As of August 2010, 34 states have operating PDMPs, including Pennsylvania, Virginia, and West Virginia. An additional nine states (including Delaware) have enacted legislation to establish a PDMP, but their programs are not fully operational yet. In order to expand state monitoring efforts, a pilot interstate prescription monitoring information exchange (PMIX) program took place between California and Nevada in 2007. Through the program, the two states were successfully able to share PDMP data, which will allow

each state to monitor prescription drug abuse more effectively. Since the implementation of the program, a number of other states have implemented, or are planning to implement, PMIX programs.

Advisory Council on Prescription Drug Monitoring

Chapter 276 of 2008 established an Advisory Council on Prescription Drug Monitoring. The council met for two years and submitted the *Maryland Advisory Council on Prescription Drug Monitoring Legislative Report,* to the Governor and the General Assembly on December 29, 2009. This bill is largely based on the council's recommendations.

Federal Funding

Federal grant funds for PDMPs are both competitive and limited; therefore, funding is not guaranteed. Since 2002, the U.S. Congress has appropriated funds to the U.S. Department of Justice to support the Harold Rogers Prescription Drug Monitoring Program. This federal program has assisted states through grants as they plan, implement, and enhance PDMPs. DHMH applied for a $50,000 Harold Rogers Planning Grant for fiscal 2009 but was not awarded the grant. In February 2009, the department reapplied and received the $50,000 planning grant, which in part allowed the Advisory Council on Prescription Drug Monitoring to fulfill its mandate. Obtaining an additional grant through this program is contingent on passing legislation establishing a PDMP. If legislation goes into effect, the State would be eligible for up to $400,000 in federal funds from the federal fiscal 2011 authorization, which could be used in fiscal 2012.

The National All Schedules Prescription Electronic Reporting Act (NASPER), administered by the U.S. Department of Health and Human Services enables states to establish or enhance a PDMP database. To be eligible, states must have enacted legislation or regulations to permit the implementation of the state controlled substance monitoring program and the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained in such a program. Additional requirements include budget cost estimates, interoperability standards, uniform electronic formats, access to information, penalties for unauthorized disclosures, and other issues. NASPER grants were first awarded in federal fiscal 2009. Total appropriations have been $2 million annually.

State Fiscal Effect: DHMH and the Governor's Office of Crime Control and Prevention indicate that a combination of Harold Rodgers and NASPER grants will be used to fund the program and that an additional $500,000 in federal Edward J. Byrne Justice Assistance Grant Program funding (Byrne grants) will be available to the program in fiscal 2012. Byrne grants allow states and local governments to support a broad range of

programs to prevent illegal drug activities, control violent crime, and improve the criminal justice system. DLS assumes that federal funding will be used to fund the program beginning in fiscal 2012. Federal revenues under the Harold Rodgers grant are estimated to be approximately $210,000 per year in fiscal 2012 and 2013 and $400,000 in fiscal 2014, if the State is successful in attaining the grants.

In past years, DHMH and DLS assumed that any State PDMP would be created and maintained by DHMH. However, as the number of PDMPs has grown nationally, vendors are now available to create and host the database and provide training and technical support to program participants. Therefore, estimated expenditures are less under this bill than in previous years.

DHMH federal fund expenditures increase by $344,000 in fiscal 2012, which accounts for the bill's October 1, 2011 effective date. This estimate reflects the costs of two new positions, a program administrator and an administrative specialist, to staff the new advisory board; develop an interim report to the General Assembly regarding regulations, legislation, and funding relating to the program; and contract with a vendor to design the software and data collection mechanism. It includes salaries, fringe benefits, one-time start-up costs, ongoing operating expenses, and a one-time $210,000 cost to contract with a vendor to design and implement a database system.

Once the PDMP is operational in fiscal 2013, one additional administrative specialist will be required to provide support to prescribers and dispensers and assist other staff with annual reporting and analysis of the impact of the program.

	FY2012	**FY2013**
New Permanent Positions	2	1
Salaries and Fringe Benefits	$88,390	$170,405
One-time Vendor Cost to Implement Database	210,000	0
Vendor Maintenance Contract	0	147,056
Other Operating Expenses	45,610	11,484
Total FY 2012 DHMH Expenditures	**$344,000**	**$328,945**

Future year expenditures reflect full salaries for all three positions with 4.4% annual increases, 3% turnover, and 1% annual increases in ongoing operating expenses.

The criminal penalty provisions of the bill are not expected to materially affect State revenues or expenditures.

Small Business Effect: Under the bill, small business pharmacies and health care providers that dispense prescription drugs must submit certain data to PDMP. DLS advises that these entities may incur potentially meaningful costs to collect and transmit the required data to PDMP.

Additional Comments: To the extent PDMP reduces illegal activity and/or substance abuse, federal, State, and local law enforcement and public health care costs could decrease. According to the U.S. Government Accountability Office (GAO), states with monitoring programs have experienced considerable reduction in the time and effort required by law enforcement and regulatory investigators to explore leads and the merits of possible drug diversion cases. GAO also found that the presence of a monitoring program in a state may help to reduce illegal drug diversion there; however, diversion activities could increase in contiguous states that do not have such programs. A national evaluation of PDMPs conducted in 2006, which focused primarily on Schedule II controlled substances, suggests that PDMPs reduce the per capita supply of prescription pain relievers and stimulants and in so doing reduce the probability of abuse for these drugs. There are insufficient data at this time to reliably estimate any savings to enforcement agencies.

Additional Information

Prior Introductions: Similar legislation, HB 918 of 2010, was heard by the House Health and Government Operations Committee, but no further action was taken. HB 525 of 2008, as introduced, would have established a PDMP; the bill was amended to create the Advisory Council on Prescription Drug Monitoring. Similar bills, SB 333 and HB 1287 of 2006, were adopted by the General Assembly and subsequently vetoed by the Governor due to fiscal and policy concerns.

Cross File: HB 1229 (The Speaker)(By Request - Administration) - Health and Government Operations.

Information Source(s): *An Evaluation of Prescription Drug Monitoring Programs*, Simeone and Associates, September 2006; National Alliance for Model State Drug Laws; National Institutes of Health; U.S. Department of Justice (Drug Enforcement Administration); U.S. Government Accountability Office; Governor's Office of Crime Control and Prevention; Department of Health and Mental Hygiene; Maryland Insurance Administration; Department of State Police; Department of Legislative Services

Fiscal Note History: First Reader - March 16, 2011
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ANALYSIS OF ECONOMIC IMPACT ON SMALL BUSINESSES

TITLE OF BILL: **Prescription Drug Monitoring Program**

BILL NUMBER: SB 883/HB 1229

PREPARED BY: Michael Wajda, Deputy Director, Laboratories Administration

PART A. ECONOMIC IMPACT RATING

This agency estimates that the proposed bill:

__X__ WILL HAVE MINIMAL OR NO ECONOMIC IMPACT ON MARYLAND SMALL BUSINESS

OR

___ WILL HAVE MEANINGFUL ECONOMIC IMPACT ON MARYLAND SMALL BUSINESSES

PART B. ECONOMIC IMPACT ANALYSIS

The proposed legislation will have no impact on small business in Maryland.

There may be a minimal fiscal impact on pharmacies that operate independently of the chain pharmacies and for dispensing health care providers specifically physician offices because of manual data collection and submission. While this fiscal impact is unquantifiable, the bill allows the Secretary, for good cause shown, to authorize a dispenser to submit data by an alternative form of submission.