HB 918

Department of Legislative Services

Maryland General Assembly
2010 Session

FISCAL AND POLICY NOTE

House Bill 918 (Delegate Kullen)
Health and Government Operations

Prescription Drug Monitoring Program

This bill establishes a prescription drug monitoring program (PDMP) in the Department of Health and Mental Hygiene (DHMH), that monitors the prescribing and dispensing of all Schedule II through V controlled dangerous substances. The program must be designed to be compatible with the requirements of a health information exchange (HIE) for the electronic submission and disclosure of data. The Secretary of Health and Mental Hygiene, in consultation with the newly established Advisory Board on Prescription Drug Monitoring, must adopt regulations to carry out the bill's provisions. The implementation of the program is subject to the availability of funds.

Fiscal Summary

State Effect: General fund expenditures increase by $764,500 in FY 2011, including a one-time cost of $500,000 to design and implement the database system. Maryland Health Care Commission (MHCC) special fund expenditures increase by $300,000 in FY 2011 for contractual staff to design and implement the necessary HIE infrastructure to support a PDMP. Special fund revenues from user fees in MHCC may increase in FY 2011. Future year estimates reflect additional administrative staff, annualization, and inflation. General fund revenues and expenditures are not significantly affected by the criminal penalty provisions of the bill.

(in dollars)	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
SF Revenue	$300,000	$0	$0	$0	$0
GF Expenditure	$764,500	$690,500	$684,100	$715,200	$747,800
SF Expenditure	$300,000	$0	$0	$0	$0
Net Effect	($764,500)	($690,500)	($684,100)	($715,200)	($747,800)

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 significantly affect local finances or operations.

Small Business Effect: Potential meaningful. Small business pharmacies could incur additional costs to transmit required data to PDMP.

Analysis

Bill Summary: 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 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 is disclosed to authorized recipients and others;
- identify the circumstances under which an authorized recipient may disclose prescription monitoring data received under the program;
- identify the circumstances and process under which federal, State, or local law enforcement agencies, or a licensing entity that has received prescription monitoring data, must consult with the multidisciplinary consultation team about the interpretation of the data;
- establish requirements for program retention of prescription monitoring data; 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 duties. The board must make recommendations regarding 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 board, must establish a web site for the program and educate dispensers, prescribers, and consumers regarding the purpose and operation of the program.

The Secretary of Health and Mental Hygiene must appoint members to the board, including members representing the perspective of prescribers, dispensers, licensing entities, health care practitioners, law enforcement, and pain patients. In addition, the Secretary must designate the chair of the board, determine the terms of board members, fill vacancies on the board, and provide staff support for the board. A member of the board may not receive compensation but is entitled to reimbursement for expenses under State travel regulations.

Use of Prescription Monitoring Data

The Secretary of Health and Mental Hygiene must appoint a multidisciplinary consultation team comprising prescribers and dispensers engaged in active practice. The team must assist federal, State, or local law enforcement agencies, or a licensing entity that has received prescription monitoring data from the program with interpreting the data and considering whether the data, along with the nature of a prescriber's or dispenser's practice, a patient's medical condition, or any other relevant facts, suggest the need for further investigation or additional education for the prescriber or dispenser.

Prescription monitoring data are confidential and privileged and may not be disclosed to any person other than "authorized recipients." Prescription monitoring data are not public records and are not subject to discovery, subpoena, or other means of legal compulsion in civil litigation.

The program may disclose prescription 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 of research. Furthermore, the Office of the Attorney General may seek appropriate injunctive or other relief to maintain the confidentiality of prescription monitoring data.

Penalties and Liabilities

A dispenser who knowingly fails to submit prescription monitoring data is subject to a civil penalty of up to $500 for each failure to submit required information. An authorized

recipient who knowingly discloses or uses 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. In addition, a prescriber or dispenser who knowingly violates any provision of the bill is liable for actual damages and reasonable attorney fees and is subject to further disciplinary action by the appropriate licensing entity.

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. 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.

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 hyrocodone 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.

MHCC and the Health Services Cost Review Commission (HSRC) were required to design a health information exchange by October 1, 2009. The commissions selected the Chesapeake Regional Information System for our Patients (CRISP), a nonprofit organization to build the statewide HIE, and efforts are currently underway to implement a private and secure statewide HIE. HIE is a statewide infrastructure that provides organizational and technical capabilities to enable the electronic exchange of health information between health care providers and other health services organizations authorized by MHCC.

MHCC is required to post a report for public comment on its web site before January 1, 2011, and to submit a report to the Governor, and designated committees on the development of a coordinated public-private approach that improves the State's health information infrastructure; any changes in state laws that are necessary to protect the privacy and security of health information stored in electronic health records (EHRs) or exchanged through HIE; any changes in State laws that are necessary to provide for the effective operation of an HIE; any actions that are necessary to align funding opportunities under the American Recovery and Reinvestment Act of 2009 (ARRA) with other State and private-sector initiatives related to health information technology; and the recommended language for the EHR adoption incentive regulations.

Background: Prescription drug abuse is a growing problem in the United States. The National Institutes of Health (NIH) estimated that 48 million people (ages 12 and older) have used prescription drugs for nonmedical reasons within their lifetime. This accounts for approximately 20% of the U.S. population. NIH hypothesizes 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.

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's name, and other relevant information. Medical professionals can use this information to prevent abusers from obtaining prescriptions from multiple prescribers.

To date, 33 states have operating PDMPs; another six states and one U.S. territory (Guam) 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 based on the council's recommendations. In addition, the report noted the HIE is currently under development and is well suited to support a PDMP. The HIE provides an efficient approach to implementing a secure system that prevents abuse, trafficking, and diversion of controlled substances; and is an invaluable information source for providers and the public of trends in the use and abuse of prescription drugs. In addition the HIE is capable of connecting with the existing 47 acute care hospitals, 7,914 physician practices, and 1,628 pharmacies throughout Maryland.

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, or enhance a PDMP. 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 has 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 2010 authorization, which could be used in fiscal 2011. It is important to note, the federal fiscal 2011 budget *does not* include funding for the program.

Maryland Health Care Commission

MHCC develops and carries out new health policies, including developing a database on all nonhospital health care services; developing the comprehensive standard health benefit plan for small employers; monitoring the fiscal impact of State-mandated benefits; developing quality and performance measures for health maintenance organizations, hospitals, ambulatory care facilities, and nursing homes; overseeing electronic claims clearinghouses; directing and administering State health planning functions to produce the State Health Plan for Facilities and Services; and conducting the Certificate of Need Program for regulated entities. MHCC is special funded by user fees imposed on payors and providers. Fees are used exclusively to cover the costs of fulfilling the statutory and regulatory duties of the commission.

State Fiscal Effect: MHCC special fund expenditures increase by $300,000 for contractual services to implement the necessary HIE infrastructure to facilitate a PDMP in fiscal 2011. Special fund revenues from user fees may increase by $300,000 to match expenditures to help cover MHCC operations; however, the commission advises raising fees imposed on payors to cover costs associated with the bill is not feasible.

DHMH general fund expenditures increase by $764,477 in fiscal 2011, which accounts for the bill's October 1, 2010 effective date. Since the federal fiscal 2011 budget does not include funding for state PDMP programs, it is assumed federal funds will not be used to support the program. However, if the State applies for federal funding by April 2010, it would be eligible for up to $400,000, which would be awarded in fiscal 2011, offsetting State expenditures by up to $400,000.

This estimate reflects a one-time $500,000 cost for designing and implementing a database system, and implementing the necessary infrastructure within the HIE to support a PDMP. It reflects the costs of four new positions to oversee the program, handle database changes, and coordinate with authorized recipients of monitored prescription drug data. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Positions	4
Salaries and Fringe Benefits	$187,512
One-time Database Implementation Cost	500,000
Other Operating Expenses	76, 965
Total FY 2011 DHMH Expenditures	**$764,477**

For the purposes of this analysis, it is assumed that the collection and analysis of data would begin in fiscal 2012. Therefore, future year expenditures reflect an additional six employees to handle database changes; implement a web site; monitor, verify, and interpret information submitted to the program; and coordinate with authorized data recipients. Future year expenditures reflect full salaries for all 10 positions with 4.4% annual increases, 3% turnover, and 1% annual increases in ongoing operating expenses.

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

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. There are insufficient data at this time to reliably estimate any savings to enforcement agencies.

Additional Information

Prior Introductions: 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: None.

Information Source(s): U.S. Government Accountability Office, National Institutes of Health, U.S. Department of Justice, Harford and St. Mary's counties, Office of the Attorney General, Department of Health and Mental Hygiene, Judiciary (Administrative Office of the Courts), Department of State Police, University of Maryland Medical System, Department of Legislative Services

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