

Department of Legislative Services
 Maryland General Assembly
 2016 Session

FISCAL AND POLICY NOTE
 First Reader

House Bill 456 (The Speaker, *et al.*) (By Request - Administration)
 Health and Government Operations

Prescription Drug Monitoring Program - Revisions

This Administration bill requires certain prescribers and all pharmacists to register with the Prescription Drug Monitoring Program (PDMP). Prescribers and pharmacists must also request and assess prescription monitoring data in a specified manner, except under specified circumstances. Prescribers and pharmacists are subject to disciplinary action by the appropriate licensing entity for failure to comply with the bill’s mandatory registration and use requirements.

Fiscal Summary

State Effect: General fund expenditures for PDMP increase by an estimated \$502,100 in FY 2017 for personnel and contractual services to implement and enforce the bill. Revenues are not affected. Future years reflect annualization, inflation, and elimination of one-time costs. The Governor’s proposed FY 2017 budget includes \$522,000 for implementation of mandatory PDMP registration and use.

(in dollars)	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	502,100	234,500	231,900	170,700	177,300
Net Effect	(\$502,100)	(\$234,500)	(\$231,900)	(\$170,700)	(\$177,300)

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

Local Effect: Meaningful operational impact on local health departments that provide direct medical services. Potential meaningful fiscal impact to the extent additional personnel or technology is needed to comply with the bill.

Small Business Effect: The Administration has determined that this bill has minimal or no impact on small business (attached). The Department of Legislative Services disagrees with this assessment as discussed below.

Analysis

Bill Summary: An authorized provider who prescribes a controlled dangerous substance (CDS) in Schedules II through V must register with PDMP before obtaining a new or renewal CDS registration from the Department of Health and Mental Hygiene (DHMH) or by July 1, 2017, whichever is sooner. Likewise, a pharmacist must be registered with PDMP by July 1, 2017.

Beginning July 1, 2018, a prescriber or pharmacist must (1) request at least the prior six months of prescription monitoring data for a patient before initiating a course of treatment that includes prescribing or dispensing an opioid or a benzodiazepine; (2) request prescription monitoring data for the patient at least every 90 days until the course of treatment has ended; and (3) assess prescription monitoring data before deciding whether to prescribe or dispense or continue prescribing or dispensing an opioid or benzodiazepine. Specified documentation by a prescriber in the patient's medical record is required.

A prescriber or pharmacist may authorize a delegate to request prescription drug monitoring data if (1) the prescriber or pharmacist takes reasonable steps to ensure that the delegate is competent in the use of PDMP; (2) the prescriber or pharmacist is responsible for ensuring that access to PDMP is limited to lawful purposes and confidentiality is protected; and (3) the decision to prescribe or dispense a monitored drug remains with the prescriber or pharmacist and is reasonably informed by the data obtained.

A prescriber or pharmacist is not required to request prescription monitoring data from PDMP if the opioid or benzodiazepine is prescribed or dispensed to specified individuals and in other specified circumstances. Specified documentation by a prescriber in the patient's medical record is required.

The Secretary of Health and Mental Hygiene may identify and publish a list of monitored prescription drugs that have a low potential for abuse by individuals. The Secretary, in consultation with the Maryland Health Care Commission and the PDMP advisory board, must educate pharmacists, prescriber delegates, and pharmacist delegates about the purpose and operation of PDMP.

The prohibition on using prescription monitoring data as the basis for imposing clinical practice standards is repealed, and a licensing entity is authorized to adopt regulations that establish standards of practice for the review of prescription drug monitoring data.

Current Law: Chapter 166 of 2011 established PDMP in DHMH to assist with the identification and prevention of prescription drug abuse and the identification and investigation of unlawful prescription drug diversion. PDMP must monitor the prescribing and dispensing of Schedule II through V CDS.

When a dispenser fills a prescription for a monitored drug, the dispenser must electronically submit to PDMP identifying information for the patient, prescriber, dispenser, and drug within three business days of dispensing. Dispensers include pharmacies (including nonresident pharmacies) as well as physicians, podiatrists, and dentists holding a dispensing permit from their respective licensing board. A dispenser who knowingly fails to submit prescription monitoring data to PDMP is subject to a civil penalty of up to \$500 for each failure to submit required information.

Prescribers (physicians, physician assistants, nurse practitioners, dentists, and podiatrists) are not required or obligated to access or use prescription monitoring data. They may register to access their patients' prescription information for treatment purposes. Nonprescribing practitioners (nurses, psychologists, professional counselors/therapists, and social workers) may also register for delegated access under a prescribing practitioner. Pharmacy technicians may also be delegated access by a licensed pharmacist.

A person who knowingly discloses, uses, obtains, or attempts to obtain by fraud or deceit prescription monitoring data 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 unlawfully uses prescription monitoring data is subject to disciplinary action by the appropriate licensing board.

A person must obtain and maintain a CDS registration before the person (1) manufactures, distributes, or dispenses CDS; (2) conducts research or instructional activities with Schedule II through V CDS; (3) conducts research or instructional activities with a Schedule I CDS; or (4) conducts a chemical analysis with any CDS. A registration may not be renewed for more than three years.

Background: In February 2015, Governor Hogan established, by executive order, the Heroin and Opioid Emergency Task Force. The [Final Report of the Heroin and Opioid Emergency Task Force](#), issued in December 2015, noted that 33 states have laws or regulations that require health care practitioners to either register with the state PDMP in order to query data (mandatory registration) and/or to query PDMP data at specific times, such as when first prescribing CDS to a patient (mandatory use). States that mandate comprehensive PDMP use, such as New York, Ohio, Kentucky, and Tennessee, have experienced decreases in prescribing of commonly abused CDS and decreased doctor shopping. The final report included a recommendation to require mandatory registration and querying of PDMP. This bill implements that recommendation.

State Expenditures: As of November 2015, PDMP had 14,258 registered users, including 8,675 active users who had accessed the system within the last 90 days. **Exhibit 1** displays the number of anticipated new registered users under the bill. In addition, PDMP currently averages approximately 21,000 weekly queries; under the bill, PDMP anticipates weekly queries will increase to 137,000.

Exhibit 1
Estimated Additional Registered Users Under the Bill

Registrant Type	Total Estimated Providers	Current Registrations¹	Estimated Additional Registrations
Prescribers ²	37,153	9,718	27,435
Prescriber delegates ³	74,306	1,767	72,539
Pharmacists ⁴	10,505	2,656	7,849
Pharmacist delegates ⁵	9,043	117	8,926
Total	131,007	14,258	116,749

¹ As of November 1, 2015.

² Number of providers with an active controlled dangerous substance permit as of September 22, 2015.

³ Assumes each prescriber designates two delegates to access the program on his or her behalf.

⁴ Number of licensed pharmacists as of May 20, 2015.

⁵ Number of licensed pharmacy technicians as of May 20, 2015. It is assumed that licensed pharmacy technicians will serve as pharmacist delegates under the bill.

Source: Prescription Drug Monitoring Program; Department of Health and Mental Hygiene

Mandatory registration and use requirements are expected to significantly increase the number of registered PDMP users and weekly inquiries, which will require additional information technology (IT) infrastructure to enroll as many as 116,749 new users by the July 1, 2017 deadline, a process that requires credentialing and verification of identity for each prescriber, pharmacist, or delegate. Furthermore, as the bill requires prescribers and pharmacists to be subject to disciplinary action for failure to comply with the bill's mandates, PDMP will need to ensure data quality, audit clinical PDMP access, and work with health occupations boards to ensure enforcement.

General fund expenditures for PDMP increase by an estimated \$502,092 in fiscal 2017, which accounts for the bill's October 1, 2016 effective date. This estimate reflects the cost of increased contractual services to provide the IT infrastructure necessary to implement mandatory registration by July 1, 2017, and the mandatory use requirement by July 1, 2018, as well as the cost to hire two personnel (one full-time grade 19 database specialist and one full-time grade 15 administrative officer) to ensure data quality and enforce the mandates.

It includes contractual expenses (including software programming and enrollment of new users), salaries, fringe benefits, a communications campaign to educate prescribers and pharmacists about the registration and use mandates, one-time start-up costs, and ongoing operating expenses.

Positions	2
Contractual expenses	\$325,489
Salaries and fringe benefits	113,674
Communications campaign	50,000
One-time start-up expenses	8,726
Ongoing operating expenses	<u>4,203</u>
Total FY 2017 State expenditures	\$502,092

Future years reflect full salaries with annual increases and employee turnover as well as annual increases in ongoing operating expenses. Contractual expenses decline significantly in fiscal 2018 and 2019 and are eliminated in fiscal 2020 as most IT infrastructure changes are of a one-time-only or short-term nature.

Small Business Effect: Small business health care practices and pharmacies must register prescribers and pharmacists with PDMP, including delegates. Prescribers and pharmacists must also access and assess PDMP data, which will alter workflow. Although the ability to designate delegates to access PDMP may mitigate this impact, to the extent additional personnel or technology is needed, the bill has a potential meaningful fiscal impact.

Additional Information: House Bill 437/Senate Bill 537 of 2016 is a substantially similar bill. Although PDMP is subject to evaluation and reestablishment (with a termination date of July 1, 2019), this analysis assumes the program is maintained after its next full evaluation (which will be conducted in 2017).

Additional Information

Prior Introductions: Similar legislation, HB 3 of 2015, would have required prescribers and dispensers, except under specified circumstances, to query PDMP before prescribing or dispensing a monitored prescription drug. HB 3 received an unfavorable report from the House Health and Government Operations Committee.

Cross File: SB 382 (The President, *et al.*) (By Request - Administration) - Finance.

Information Source(s): Office of the Attorney General, Governor's Office of Crime Control and Prevention, Department of Health and Mental Hygiene, Department of State Police, Department of Legislative Services

Fiscal Note History: First Reader - February 17, 2016
kb/ljm

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ANALYSIS OF ECONOMIC IMPACT ON SMALL BUSINESSES

TITLE OF BILL: Prescription Drug Monitoring Program - Revisions

BILL NUMBER: SB382/HB456

PREPARED BY: Department of Health and Mental Hygiene

PART A. ECONOMIC IMPACT RATING

This agency estimates that the proposed bill:

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

Small medical practices would need to include this querying the PDMP mandate in to the workflow of serving patients. The inclusion of prescriber and pharmacist delegates in the bill should alleviate any possible workflow issues experienced by prescribers and pharmacists.