HB 437

Department of Legislative Services

Maryland General Assembly
2016 Session

FISCAL AND POLICY NOTE
Enrolled - Revised

House Bill 437 (Delegate Barron, *et al.*)
Health and Government Operations Finance

Department of Health and Mental Hygiene - Prescription Drug Monitoring Program - Modifications

This bill requires certain prescribers and all pharmacists to register with the Prescription Drug Monitoring Program (PDMP) by July 1, 2017. 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. PDMP may review prescription monitoring data for indications of a possible violation of law or a possible breach of professional standards by a prescriber or dispenser. If indicated, PDMP may notify and provide education to the prescriber or dispenser after obtaining certain clinical guidance from the technical advisory committee (TAC). The bill also requires the Department of Health and Mental Hygiene (DHMH) to develop and implement an outreach and education plan regarding mandatory registration with PDMP and submit specified reports.

Fiscal Summary

State Effect: General fund expenditures for PDMP increase by an estimated $589,700 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 FY 2017 State budget includes $522,245 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	589,700	306,100	306,400	248,000	257,700
Net Effect	($589,700)	($306,100)	($306,400)	($248,000)	($257,700)

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: Meaningful operational impact and potential meaningful fiscal impact as discussed below.

Analysis

Bill Summary:

Mandatory Registration: Prior to registration with PDMP, a prescriber or pharmacist must complete a course of instruction and training developed by DHMH, including the effective use of the program.

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 DHMH. This requirement is contingent on a determination by the Secretary of Health and Mental Hygiene that (1) the requirement will not adversely affect or delay the issuance of a CDS registration and (2) the process for obtaining a CDS registration is capable of delivering the registrations in a timely manner. The Secretary must notify the Department of Legislative Services (DLS) and specified committees of the General Assembly within five days after determining that these contingencies have been met. If such notice is not received by June 30, 2022, the requirement to register with PDMP before obtaining or renewing a CDS registration terminates.

Mandatory Use: Beginning July 1, 2018, a prescriber must (1) request at least the prior four 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 a benzodiazepine. Specified documentation by a prescriber in the patient's medical record is required.

A prescriber 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.

If a pharmacist or pharmacist delegate has a reasonable belief that a patient may be seeking a monitored prescription drug for any purpose other than the treatment of an existing medical condition, the pharmacist or pharmacist delegate must, prior to dispensing a monitored drug to the patient, request prescription monitoring data to determine if the patient has received other prescriptions that indicate misuse, abuse, or diversion of a monitored prescription drug. The pharmacist has responsibility for the proper dispensing of a prescription for a CDS, as specified under federal regulations.

The Secretary may adopt regulations to provide additional clinical, technical, or administrative exemptions to the mandatory use requirement based on new standards of practice.

These mandatory use provisions are contingent on a determination by the Secretary that (1) the technical capabilities of PDMP are sufficient to achieve a reasonable standard of access and usability by prescribers and pharmacists and (2) requiring a prescriber to request prescription monitoring data for a patient in accordance with the bill is important to protect public health and promote good patient care. The Secretary must notify DLS and specified committees of the General Assembly within five days after determining that these contingencies have been met. If such notice is not received by June 30, 2023, the mandatory use provisions terminate.

Prescriber and Pharmacist Delegates: A prescriber or pharmacist may authorize a prescriber delegate or pharmacist delegate to request prescription 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 prescription drug remains with the prescriber or pharmacist and is reasonably informed by the data obtained.

Regulations Governing PDMP: The Secretary 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. Regulations must specify that required prescription drug monitoring data be submitted by dispensers once every 24 hours. The existing requirement for regulations to specify that a prescriber or dispenser is not required or obligated to access or use prescription monitoring data under PDMP is repealed to conform with other provisions in the bill.

Technical Advisory Committee: PDMP may request that TAC review requests for information and provide certain clinical guidance. PDMP, in consultation with the PDMP advisory board, must consider policies and procedures for determining the circumstances

in which the review of requests for information and the provision of clinical guidance and interpretation by TAC is feasible and desirable. The bill also adds both a dentist and a medical professional practicing internal medicine or family practice to TAC.

Reporting Requirements: By November 1, 2016, DHMH must report to the Joint Committee on Behavioral Health and Opioid Use Disorders on the feasibility and desirability of analyzing prescription monitoring data through the use of statistical and advanced analytical techniques for specified purposes. By December 1, 2016, DHMH must report to the joint committee and specified committees of the General Assembly on the technical capacity of PDMP to analyze prescription drug monitoring data for possible violations of law and possible breaches of professional standards and the possibility of reporting them to law enforcement, licensing entities, or units of DHMH. By September 1, 2017, DHMH, in consultation with the PDMP advisory board, must report to the joint committee and specified committees of the General Assembly on the status of the implementation of providing education and notice of a possible violation of law or breach of professional standards to prescribers and dispensers and recommend whether the authority of PDMP to report possible violations of law or possible breaches of professional standards should be expanded to allow reporting to such entities.

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.

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.

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.

In addition to mandatory registration and use, the bill expands unsolicited reporting by authorizing PDMP to review prescription monitoring data for indications of a possible violation of law or possible breach of professional standards by a prescriber or dispenser. PDMP must obtain certain clinical guidance and interpretation from TAC. If indicated, PDMP must notify and provide education to the prescriber or dispenser. DHMH must submit two mandated reports on unsolicited reporting: one by December 1, 2016, and one by September 1, 2017. DHMH advises that one additional position is required to prepare

the required reports, review prescription monitoring data, obtain required guidance from TAC, and notify and educate prescribers and dispensers of any possible violations of law or possible breaches of professional standards. The bill additionally requires prescribers and pharmacists to complete training on the effective use of PDMP prior to registration with PDMP. Thus, DHMH must create an online training course.

Exhibit 1
Estimated Additional Registered Users Under the Bill

Registrant Type	Total Estimated Providers	Current Registrations[1]	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

General fund expenditures for PDMP increase by an estimated $589,743 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 three personnel (one full-time grade 19 database specialist and two full-time grade 15 administrative officers) primarily to ensure data quality, enforce the mandates, and expand unsolicited reporting. These staff can also prepare the reports required by the bill, review prescription monitoring data, obtain required guidance from TAC, and notify and educate prescribers and dispensers of any possible violations of law or possible breaches of professional standards. The estimate 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, the cost to create online instruction and training for registrants, one-time start-up costs, and ongoing operating expenses.

Positions	3
Contractual expenses	$325,489
Salaries and fringe benefits	164,860
Communications campaign	50,000
Instruction and training	30,000
One-time start-up expenses	13,089
Ongoing operating expenses	6,305
Total FY 2017 State expenditures	**$589,743**

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 if used. 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 Comments: House Bill 456/Senate Bill 382 of 2016, an Administration bill, is substantially similar to the 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 537 (Senator Klausmeier, *et al.*) - 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

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