Department of Legislative Services

Maryland General Assembly 2018 Session

FISCAL AND POLICY NOTE Third Reader - Revised

House Bill 88

(Delegate Barron, et al.)

Health and Government Operations

Finance

Public Health - Prescription Drug Monitoring Program - Revisions

This bill *requires*, rather than authorizes, the Prescription Drug Monitoring Program (PDMP) to review prescription monitoring data for indications of (1) possible misuse or abuse of a monitored prescription drug or (2) a possible violation of law or breach of professional standards by a prescriber or dispenser. If either is indicated, PDMP *must* notify and provide education to the prescriber or dispenser. If there is a possible violation of law or breach of professional standards, PDMP *may* provide prescription monitoring data to the Office of Controlled Substances Administration (OCSA) for further investigation. If such data is provided to OCSA, PDMP *must* notify the prescriber or dispenser. PDMP must take specified factors into account regarding a possible violation of law or breach of professional standards.

Fiscal Summary

State Effect: General fund expenditures increase by at least \$221,800 in FY 2019. Special fund expenditures may increase beginning in FY 2019 as discussed below. Future years reflect annualization. Revenues are not affected.

(in dollars)	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	221,800	271,400	279,400	289,500	300,000
SF Expenditure	-	-	-	-	-
Net Effect	(\$221,800)	(\$271,400)	(\$279,400)	(\$289,500)	(\$300,000)

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

Local Effect: The bill is not anticipated to materially affect governmental operations or finances.

Small Business Effect: None.

Analysis

Bill Summary: In determining whether its review of prescription monitoring data indicates a possible violation of law or a possible breach of professional standards, PDMP must take into account the particular specialty, circumstances, patient type, and location of the prescriber or dispenser.

Before PDMP provides notification of a possible violation of law or breach of professional standards to a prescriber or dispenser, PDMP must obtain from the Technical Advisory Committee (TAC) interpretation of the prescription monitoring data sufficient to advise on whether the method identifies a possible violation of law or breach of professional conduct (in addition to the clinical guidance required under current law). Obtaining clinical guidance and interpretation from TAC may not delay reporting of a possible violation of law or breach of professional conduct to OCSA if, in the judgment of PDMP, a delay could result in danger to public health or safety.

On receipt of prescription monitoring data and relevant records, OCSA must (1) review the data and records as part of its investigation and (2) if OCSA determines that there has been a violation of law or a breach of professional standards, take any action authorized by law, including providing the data and records to the appropriate licensing entity for possible disciplinary action.

Current Law: Before PDMP may provide notification of a possible violation of law or breach of professional standards to a prescriber or dispenser, it must first obtain from TAC (1) clinical guidance regarding indications of a possible violation of law or breach of professional standards and (2) interpretation of the prescription monitoring data that indicates a possible violation of law or breach of professional standards.

Chapter 166 of 2011 established PDMP 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 controlled dangerous substances (CDS). Since July 1, 2017, all CDS dispensers have been required to register with PDMP. 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. A prescriber is not required to request prescription monitoring data if the opioid or benzodiazepine is prescribed or dispensed to specified individuals and in other specified circumstances.

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Background: Pursuant to Chapter 147 of 2016, the Maryland Department of Health (MDH) submitted a September 2017 <u>report</u> on (1) the status of the implementation of providing education and notice of a possible violation of law or a possible breach of professional standards to prescribers and pharmacists and (2) a recommendation on whether the authority of PDMP to report possible violations of law or possible breaches of professional standards should be expanded to allow unsolicited reporting to law enforcement agencies, licensing boards, or other units of the department. The report noted that PDMP was identifying patients with multiple provider episodes ("doctor shopping") and continuing to work with partner academic researchers to develop code to "red flag" high-risk provider, dispenser, and patient behavior. MDH indicated that, rather than expanding unsolicited reporting, the department's focus was on implementing mandatory registration and use deadlines and enhancing the operational coordination and effectiveness of OCSA.

OCSA, in MDH, enforces the Controlled Dangerous Substance (CDS) Act and ensures the availability of drugs for legitimate medical and scientific purposes. OCSA also issues CDS permits to practitioners, researchers, and establishments that administer, prescribe, dispense, distribute, manufacture, conduct research, and conduct chemical analysis of CDS. In July 2017, OCSA began implementation of an enforcement expansion plan. OCSA's efforts include hiring additional inspectors, analysts, and technical specialists to allow MDH to identify CDS noncompliance, provide data analysis, and conduct case investigations that may result in action against a registrant's CDS registration. Enforcement actions may include disciplinary actions, such as educational awareness warnings, corrective action plans, CDS restrictions, revocation of registration, and referral for action by the MDH Office of the Inspector General, the Medicaid Fraud Office, the Office of the Attorney General, the federal Drug Enforcement Administration, and other relevant entities.

As of March 22, 2018, there were 34,261 prescribers and 11,709 pharmacists registered to use PDMP.

State Expenditures: General fund expenditures increase by \$221,804 in fiscal 2019, which accounts for the bill's October 1, 2018 effective date. This estimate reflects the cost of hiring two grade 17 epidemiologist III positions and two grade 15 administrative officer II positions in PDMP to conduct data preparation, analysis, and coordination with OCSA; acquire, store, and analyze additional datasets to facilitate the expanded work of TAC; and notify and provide education for prescribers and dispensers. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses. Additional expenditures for information technology upgrades to ensure secure data transfer to OCSA and from OCSA to the appropriate health occupations boards are anticipated but are not reflected in this analysis. Any additional impact on OCSA is assumed to be absorbable within existing budgeted resources.

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Positions	4
Salaries and Fringe Benefits	\$200,369
One-time Start-up Costs	19,560
Ongoing Operating Expenses	1,875
Total FY 2019 State Expenditures	\$221,804

Future year expenditures reflect full salaries with annual increases and employee turnover and ongoing operating expenses.

To the extent that OCSA determines there has been a breach of professional standards and provides prescription monitoring data to the appropriate health occupations board (specifically the State boards of Dental Examiners, Nursing, Pharmacy, Physicians, and Podiatric Medical Examiners), special fund expenditures increase by an indeterminate amount due to additional investigations of prescribers and dispensers and/or additional disciplinary actions against licensees. The impact depends on whether the boards would have investigated those providers/licensees without the OCSA referral. Also, the bill's requirement for OCSA to provide prescription monitoring data and other records to the appropriate licensing entity may facilitate investigations and related disciplinary actions that would have taken place anyway.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Maryland Department of Health; Department of Legislative Services

Fiscal Note History:	First Reader - January 26, 2018
nb/ljm	Third Reader - April 9, 2018
	Revised - Amendment(s) - April 9, 2018
	Revised - Updated Information - April 9, 2018

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