Department of Legislative Services

Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
Enrolled

House Bill 25 (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 under certain circumstances, provided that PDMP takes specified actions. PDMP must take specified factors into account regarding a possible violation of law or breach of professional standards. PDMP must also include specified information regarding instances of possible violations of law or breaches of professional standards in its annual report.

Fiscal Summary

State Effect: General fund expenditures increase by at least $323,600 in FY 2020. Special fund expenditures may increase beginning in FY 2020, as discussed below. Future years reflect elimination of one-time costs and annualization. Revenues are not affected.

(in dollars)	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Revenues	$0	$0	$0	$0	$0
GF Expenditure	323,600	265,000	273,700	282,900	292,400
Net Effect	($323,600)	($265,000)	($273,700)	($282,900)	($292,400)

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 local 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, to the extent practicable, 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) clinical guidance regarding *methods used to identify* a possible violation of law or a possible breach of professional standards and interpretation of the prescription monitoring data *advising whether the method identifies* a possible violation of law or breach of professional standards.

If the methods used to identify a possible violation of law or breach of professional standards indicate a violation or breach and PDMP determines that outreach and education to the prescriber or dispenser is inadequate to address the breach or violation, PDMP *may* refer the possible violation of law or breach of professional standards, along with prescription monitoring data, to OCSA for further investigation, if PDMP:

- provides notice and an opportunity to TAC to make recommendations within 10 business days regarding interpretation of the data;
- provides the recommendations of TAC, if any, to OCSA; and
- notifies the prescriber or dispenser that the prescription monitoring data will be provided to OCSA for further investigation.

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.

PDMP's annual report must include specified data on the number of providers who received outreach and education from PDMP (by provider type and including the number of cases), the number of cases identified for TAC review before referral to OCSA, and the number of cases referred to OCSA for further evaluation and the outcomes.

The bill expresses the intent of the General Assembly that PDMP continue to work with TAC to further refine and enhance the quality of the algorithms and other data tools to identify possible violations of law and breaches of professional standards.

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) and must report specified information to the Governor and General Assembly on an annual basis. As of July 1, 2017, all CDS dispensers are required to register with PDMP. As of July 1, 2018, prescribers are required to (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.

Background: OCSA, in the Maryland Department of Health (MDH), enforces the Controlled Dangerous Substances 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.

Pursuant to the Maryland Program Evaluation Act, the Department of Legislative Services (DLS) completed a full sunset evaluation of PDMP in 2018. Regarding unsolicited reporting, the report noted that unsolicited reports are typically sent to prescribers about questionable patient activity. Approximately 81% of prescription drug monitoring programs nationally, including Maryland, send patient reports to prescribers. These reports help to identify patients who may be "doctor shopping," abusing or diverting CDS, or receiving unsafe amounts or combinations of prescription medications. However,

unsolicited reporting of prescriber and dispenser behaviors is less common. Some states send reports on providers to licensing boards (61%), some directly to law enforcement (47%), and others have developed peer review committees that receive reports. States have also developed unsolicited reports of providers that get reported directly back to the provider in the form of a notification, letter, or report card.

Maryland's PDMP is actively developing unsolicited reports for prescribers regarding their own prescribing behavior. Issues that have delayed implementation include limitations on the data that PDMP has access to collect and the need to establish appropriate thresholds for generating reports. For instance, PDMP data does not capture a prescriber's specialty, which is key to developing an unsolicited reporting mechanism. During the course of DLS' evaluation, PDMP indicated it would begin providing education and notices of possible violations of law or possible breaches of professional standards to prescribers and pharmacists via unsolicited reports in January 2019. Nevertheless, DLS recommended that PDMP should collect additional data, specifically provider specialty information, to aid the implementation of unsolicited reporting on prescribers and dispensers.

As of August 31, 2018, there were 32,024 prescribers and 10,768 pharmacists registered to use PDMP.

State Expenditures: General fund expenditures increase by $323,559 in fiscal 2020, which accounts for the bill's October 1, 2019 effective date. This estimate reflects the cost of hiring one grade 17 epidemiologist II position and two grade 15 administrative officer III 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 and fringe benefits; one-time information technology (IT) costs to expand storing, processing, and computing powers; one-time start-up costs; one-time training costs; and ongoing operating expenses, including additional printing and mailing costs to notify and provide education to prescribers. Additional expenditures to optimize development of notifications within Chesapeake Regional Information System for Our Patients (CRISP, which provides the IT platform for PDMP) to align with industry best practices for the notification of prescribers regarding their own prescribing practices are anticipated but are not reflected in this analysis. Any impact on OCSA can likely be absorbed with budgeted resources.

Positions	3.0
Salaries and Fringe Benefits	$193,818
Information Technology Costs	100,000
One-time Start-up Costs	14,670
One-time Training Costs	9,930
Ongoing Operating Expenses	5,141
Total FY 2020 State Expenditures	**$323,559**

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: HB 88 of 2018 passed the House and Senate as amended, but no further action was taken. Its cross file, SB 1083, passed the Senate and House as amended, but no further action was taken.

Cross File: SB 195 (Senator Kelley, *et al.*) - Finance.

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

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