

Department of Legislative Services
 Maryland General Assembly
 2022 Session

FISCAL AND POLICY NOTE
Third Reader

Senate Bill 200

(Chair, Finance Committee)(By Request - Departmental - Health)

Finance

Health and Government Operations

Public Health - Prescription Drug Monitoring Program - Naloxone Medication Data

This departmental bill (1) requires the Prescription Drug Monitoring Program (PDMP) to monitor the dispensing of “naloxone medication”; (2) establishes standards surrounding the disclosure of “naloxone medication data”; and (3) generally applies the PDMP statute to naloxone medication data.

Fiscal Summary

State Effect: Federal fund expenditures for the Maryland Department of Health (MDH) increase by \$48,200 in FY 2023, and \$144,500 in FY 2024, to enhance the current PDMP data collection system, as discussed below. Additional requirements under the bill can be absorbed within existing budgeted resources. Revenues are not affected, as discussed below.

(in dollars)	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Revenues	\$0	\$0	\$0	\$0	\$0
FF Expenditure	48,200	144,500	0	0	0
Net Effect	(\$48,200)	(\$144,500)	\$0	\$0	\$0

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

Local Effect: None.

Small Business Effect: MDH has determined that this bill has minimal or no impact on small business (attached). The Department of Legislative Services concurs with this assessment.

Analysis

Bill Summary: “Naloxone medication” means an opioid antagonist approved by the federal Food and Drug Administration for the reversal of an opioid overdose. Naloxone medication is specifically excluded from the definition of “monitored prescription drug.” Naloxone medication data means the information submitted to PDMP for naloxone medication.

Use of Naloxone Medication Data

Naloxone medication data is confidential and privileged and not subject to discovery, subpoena, or other means of legal compulsion in civil litigation. Naloxone medication data is not a public record and may not be disclosed to any person except as specifically authorized under the bill. PDMP must disclose naloxone medication data in accordance with regulations adopted by the Secretary of Health for public health surveillance, research, analysis, public reporting, and education after redaction of all information that could identify a patient, prescriber, dispenser, or any other individual. Before disclosing naloxone medication data, the Secretary may require submission of an abstract explaining the scope and purpose for which disclosure is requested.

Current Law: 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). All CDS dispensers are required to register with PDMP. All 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. Prescribers include the following practitioners with CDS prescriptive authority: physicians, physician assistants, dentists, podiatrists, nurse practitioners, and advanced practice nurse midwives.

Background: Patients can receive a prescription for naloxone from their prescriber or obtain naloxone directly from a pharmacist under the Maryland standing order if they, or someone they know, is at risk of experiencing an opioid-related overdose. Maryland residents may also obtain naloxone from their local Overdose Response Program (ORP). MDH already tracks naloxone distributed by ORPs and dispensed by Maryland pharmacies that is paid for by Medicaid. However, there is not a central repository of information on

naloxone dispensed from Maryland pharmacies paid for by private health insurers or directly by a consumer, creating a public health surveillance gap.

According to the Training and Technical Assistance Center for Prescription Drug Monitoring Programs, 27 states currently collect data on naloxone dispenses or administrations in their respective PDMP, and 17 states redisclose dispenses for public health surveillance purposes and do not make data available to clinical users of the PDMP.

For information on the State’s growing opioid crisis, please refer to the **Appendix – Opioid Crisis**.

State Revenues: MDH advises that it has identified a federal grant (already received by the department) that can be used to enhance the PDMP data collection system. As these MDH federal fund revenues have already been realized in a prior fiscal year and are not a result of the bill, revenues are not affected.

State Expenditures: MDH advises that it will cost approximately \$192,699 (incurred over two fiscal years) to enhance the PDMP data system to allow for the collection of naloxone data under the bill. MDH further advises that federal grant funds will be used to cover these costs. Thus, federal fund expenditures increase by approximately \$48,175 in fiscal 2023 and \$144,524 in fiscal 2024.

Other responsibilities associated with educating pharmacists about the new reporting requirements and producing reports for public health surveillance efforts can be absorbed with existing staff resources.

Additional Information

Prior Introductions: None.

Designated Cross File: None.

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

Fiscal Note History: First Reader - January 23, 2022
fnu2/jc Third Reader - February 17, 2022

Analysis by: Amber R. Gundlach

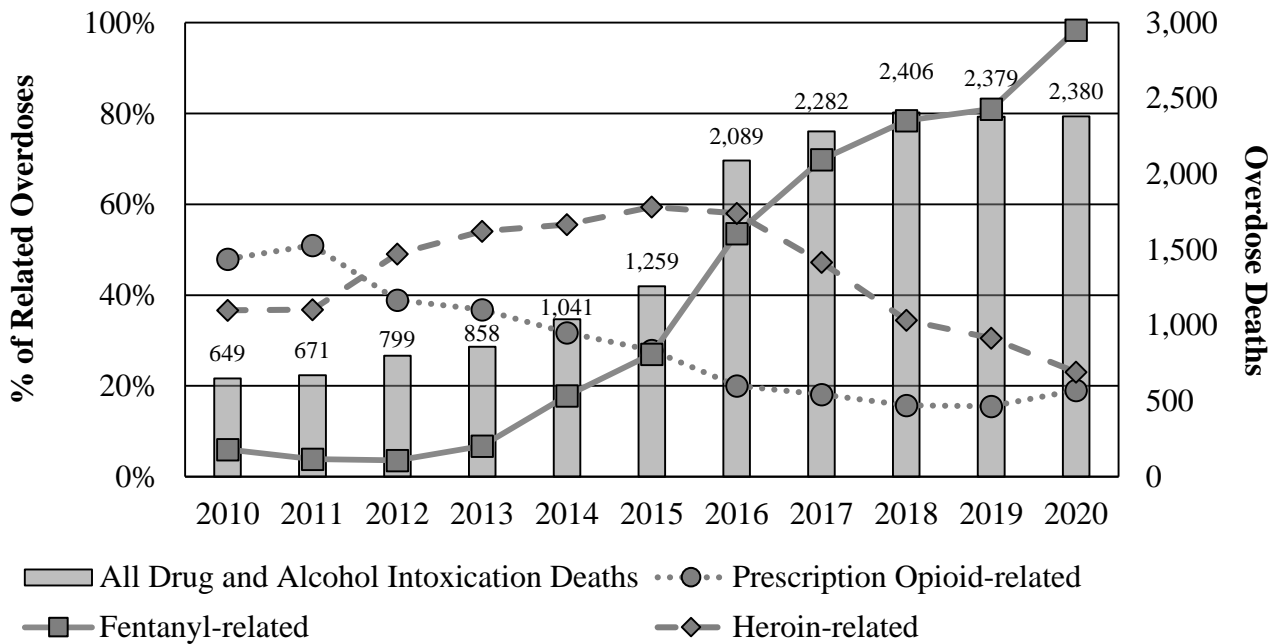
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Appendix – Opioid Crisis

Opioid Overdose Deaths

Maryland continues to be among the states hit hardest by the opioid epidemic with the fourth-highest overdose death rate in the nation, according to the most recent federal data. In 2018, the State experienced the deadliest year on record for overdose deaths, due almost exclusively to the continued presence of fentanyl. However, preliminary data from the Opioid Operational Command Center (OCCC) indicates that the first six months of 2021 have surpassed the first six months of all prior years on record. **Exhibit 1** shows the total overdose deaths in the State from 2010 through 2020 and the prevalence of prescription opioids, fentanyl, and heroin in contributing to overdose deaths.

Exhibit 1
Overdose Deaths and Substance Prevalence
Calendar 2010-2020

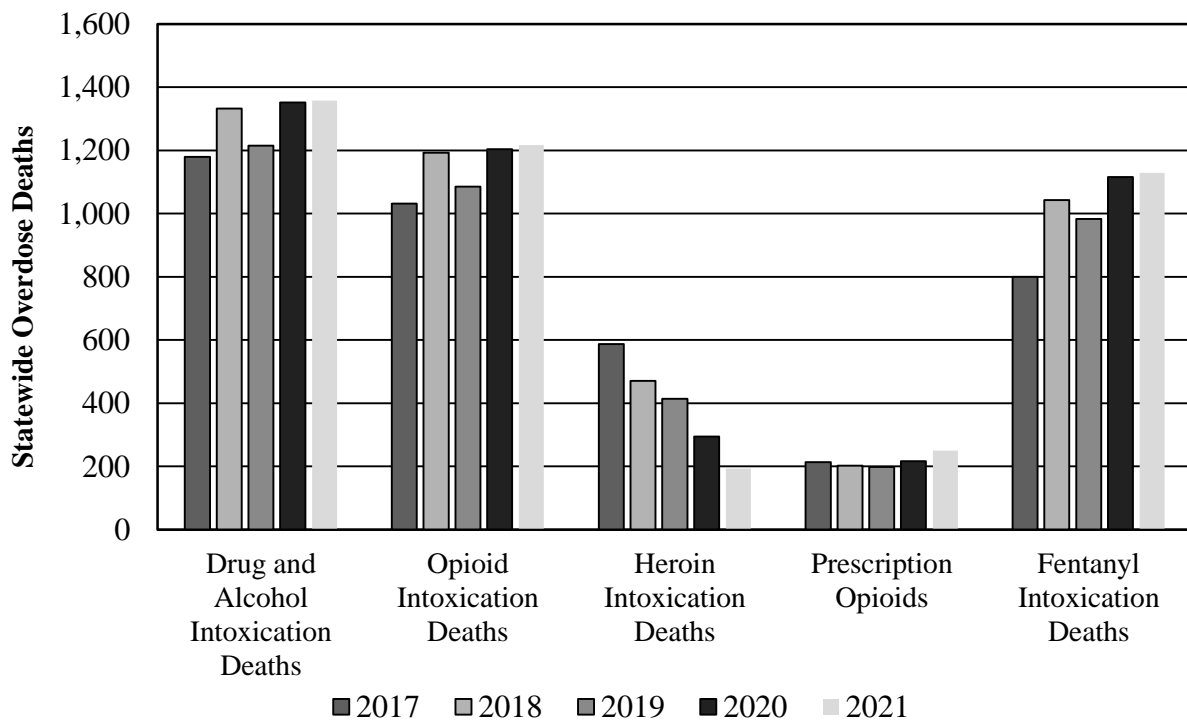


Source: Maryland Department of Health

The COVID-19 Pandemic and the Opioid Epidemic

Preliminary data for 2020 and 2021 suggests that the COVID-19 pandemic has contributed to increases in intoxication fatalities related to nearly all major drug categories in Maryland with the exception of heroin-related deaths, which continued to decline. OCCC data indicates that the total number of overdose deaths in Maryland for the first six months of 2021 outpaced the number of deaths during the first six months of 2018, the State’s previous high watermark for fatalities. **Exhibit 2** shows total overdose deaths from all substances and overdose deaths involving opioids, heroin, prescription opioids, and fentanyl for the first six months of calendar 2017 through 2021.

Exhibit 2
Overdose Deaths, First Six Months
Calendar 2017-2021



Source: Maryland Department of Health

Conversely, the State saw significantly fewer hospital emergency department (ED) visits during the first six months of 2020, with a 23.3% decline in visits for nonfatal opioid overdoses compared to the first half of 2019. Historically, the number of ED visits has a positive correlation with the number of opioid intoxication deaths. The inverse correlation

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shown between opioid overdose deaths and ED visits may be the result of concerns about visiting the ED due to COVID-19. However, the number of ED visits for 2021 was up by 23.4% over 2020, an increase of 5.6% over 2019.

Maryland Actions to Address the Opioid Crisis

Legislative Response: The General Assembly has passed numerous acts to address the State's opioid crisis, including prevention, treatment, overdose response, and prescribing guidelines.

- Chapters 571 and 572 of 2017 require the fiscal 2019 through 2021 proposed budgets to include rate adjustments for community behavioral health providers; require development of a plan to increase provision of treatment; expand access to naloxone; require the Maryland Department of Health (MDH) to distribute evidence-based information about opioid use disorders to health care facilities and providers; and prohibit health insurance carriers from applying a prior authorization requirement for certain substance use disorder (SUD) treatment drugs.
- Chapters 573 and 574 of 2017 expand drug education in public schools to include heroin and opioid addiction prevention; require local boards of education to require each public school to store naloxone and other overdose-reversing medication; and require institutions of higher education that receive State funding to establish a policy that addresses heroin and opioid addiction and prevention.
- Chapter 570 of 2017 requires a health care provider to prescribe the lowest effective dose of an opioid and a quantity that is no greater than that needed for the expected duration of pain severe enough to require an opioid that is a controlled dangerous substance, with specified exceptions.
- Chapter 211 of 2018 requires MDH to identify a method for establishing a tip line for a person to report a licensed prescriber whom the person suspects is overprescribing certain medications.
- Chapters 215 and 216 of 2018 require a health care provider to advise a patient of the benefits and risks associated with a prescribed opioid or co-prescribed benzodiazepine.
- Chapters 439 and 440 of 2018 require a general hospice care program to establish a policy for the collection and disposal of unused prescription medication.

- Chapter 532 of 2019 establishes programs for opioid use disorder screening, evaluation, and treatment (specifically medication-assisted treatment) in local correctional facilities and in the Baltimore Pretrial Complex.
- Chapter 537 of 2019 establishes the Opioid Restitution Fund, a special fund to retain any revenues received by the State relating to specified opioid judgments or settlements, which may be used only for opioid-related programs and services.
- Chapters 172 and 173 of 2020 authorize MDH to include comprehensive crisis response centers, crisis stabilization centers, crisis treatment centers, and outpatient mental health clinics in the list of emergency facilities published annually related to emergency mental health evaluations and require MDH to give the list to each local behavioral health authority.
- Chapter 547 of 2020 establishes a Crisis Intervention Team Center of Excellence in the Governor's Office of Crime Prevention, Youth, and Victim Services.
- Chapters 211 and 212 of 2020 require health insurance carriers to report on compliance with the federal Mental Health Parity and Addiction Equity Act.

Opioid Response During the COVID-19 Pandemic: In June 2020, OOCC, in consultation with MDH and other State agencies, developed and released Maryland's COVID-19 Inter-Agency Overdose Action Plan to lay out a comprehensive strategy for coordinating response efforts.

Legal Actions Related to the Opioid Crisis: In October 2020, the U.S. Department of Justice announced a global resolution of its criminal and civil investigations of opioid manufacturer Purdue Pharma with an agreement that Purdue (1) plead guilty to a three-count felony related to conspiracy charges; (2) pay a criminal fine of \$3.5 billion; (3) pay an additional \$2.0 billion in criminal forfeitures; (4) pay a civil settlement of \$2.8 billion to resolve civil liability under the False Claims Act; and (5) emerge from bankruptcy as a public benefit company. However, the resolution was subject to approval by the bankruptcy court for the Southern District of New York, which rejected the bankruptcy settlement in December 2021.

In July 2021, a \$26 billion global settlement was announced by opioid manufacturer Johnson & Johnson and three of its distributors (McKesson, Amerisource Bergen, and Cardinal Health). On September 8, 2021, Maryland Attorney General Brian E. Frosh announced Maryland's participation in the global settlement. Maryland is expected to receive approximately \$500 million as part of the settlement.

Funding to Address the Opioid Crisis: The fiscal 2022 budget has more than \$978.0 million targeted toward mental health and substance abuse in Maryland, including \$296.0 million for SUD services, \$231.8 million for mental health and SUD treatment for the uninsured, and more than \$10.0 million to fund OCCC activities (\$5.0 million of which will be used for grants to local behavioral health authorities).

ANALYSIS OF ECONOMIC IMPACT ON SMALL BUSINESSES

BILL TITLE: Public Health – Prescription Drug Monitoring Program – Naloxone Medication Data

PREPARED BY: SB 200

(Program)(Unit): Office of the Prescription Drug Monitoring Program

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

The direct economic impact of collecting naloxone dispenses in the PDMP has not been measured, but opioid use disorder and overdoses have a substantial impact on the economy. Florence et al. found that the cost for opioid use disorder and fatal opioid overdose in 2017 were estimated to be \$1.02 trillion. The majority of the economic burden is due to reduced quality of life from opioid use disorder and the value of life lost due to fatal opioid overdose.¹ Expanding access to naloxone will reduce fatal opioid related overdoses by providing public health officials with a more comprehensive view of naloxone uptake that can be used to inform targeted naloxone distribution.² Targeted naloxone distribution is listed as an evidence-based strategy by the Center for Disease Control and Prevention.³ Targeted naloxone distribution can be facilitated by expanding public health surveillance to ensure resources are disseminated in the most high need communities.

¹ Florence, C., Luo, F., & Rice, K. (2021). The economic burden of opioid use disorder and fatal opioid overdose in the United States, 2017. *Drug and alcohol dependence*, 218, 108350.

² Abouk, R., Pacula, R. L., & Powell, D. (2019). Association between state laws facilitating pharmacy distribution of naloxone and risk of fatal overdose. *JAMA internal medicine*, 179(6), 805-811.

³ Centers for Disease Control and Prevention. Evidence-Based Strategies for Preventing Opioid Overdose: What's Working in the United States. National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2018. Accessed July 18, 2021 from <http://www.cdc.gov/drugoverdose/pdf/pubs/2018-evidence-based-strategies.pdf>.