Department of Legislative Services

Maryland General Assembly 2022 Session

FISCAL AND POLICY NOTE Third Reader - Revised

Senate Bill 394 Finance (The President, et al.) (By Request - Administration)

Health and Government Operations

Statewide Targeted Overdose Prevention (STOP) Act of 2022

This Administration bill broadens existing requirements and protections relating to administration or provision of naloxone to encompass an opioid overdose reversal drug approved by the U.S. Food and Drug Administration (FDA). The bill also allows for such reversal drugs to be offered to specified individuals – free of charge – by multiple providers, programs, and entities, which are generally required to establish protocols, as specified, to do so. The Maryland Department of Health (MDH) must purchase and then provide FDA-approved opioid overdose reversal drugs, at no cost, to the entities, who may provide the reversal drugs only if MDH provides them. The bill also authorizes a cardiac rescue technician, an emergency medical technician, or a paramedic, while providing emergency medical services (EMS), to offer an FDA-approved opioid overdose reversal drug overdose or was evaluated by a crisis evaluation team. **The bill takes effect July 1, 2022.**

Fiscal Summary

State Effect: General fund expenditures increase by \$196,900 in FY 2023 for MDH to hire additional staff; future years reflect annualization. Subject to the limitations of the State budget, MDH general fund expenditures may increase by a significant additional amount beginning in FY 2023 to purchase FDA-approved opioid overdose reversal drugs (not shown below). The Department of Public Safety and Correctional Services (DPSCS) can likely implement the bill's requirements within existing budgeted resources, as discussed below. Revenues are not materially affected.

| (in dollars) | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|----------------|-------------|-------------|-------------|-------------|-------------|
| Revenues | \$0 | \$0 | \$0 | \$0 | \$0 |
| GF Expenditure | 196,900 | 232,000 | 238,600 | 244,900 | 251,500 |
| Net Effect | (\$196,900) | (\$232,000) | (\$238,600) | (\$244,900) | (\$251,500) |

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

Local Effect: Any change in local operations for specified entities to offer FDA-approved opioid overdose reversal drugs as required does not materially affect local finances.

Small Business Effect: The Administration has determined that this bill has minimal or no impact on small business (attached). The Department of Legislative Services (DLS) agrees with this assessment for the amended bill, as discussed below. (The attached assessment does not reflect amendments to the bill.)

Analysis

Bill Summary:

Definitions

A "community services program" includes a homeless services program. "Homeless services program" means a program operated by the Department of Housing and Community Development through a local administering agency or service provider for the purpose of providing shelter, food, and services to homeless family units in the State. "Intensive outpatient program" (IOP) means a treatment program that addresses substance use disorders (SUDs) or other disorders that do not require detoxification or inpatient supervision and are designated by the American Society of Addiction Medicine as a level 2.1 setting. "Opioid treatment program" (OTP) means a program approved by MDH to provide opioid maintenance therapy under MDH regulations.

Maryland Department of Health

Subject to the limitations of the State budget, MDH must purchase and provide FDA-approved opioid overdose reversal drugs, at no cost, to the providers, programs, and entities who are required to offer the drugs free of charge under the bill.

Protocols for Offering Opioid Overdose Reversal Drugs

By June 30, 2023, each OTP and each IOP must have a *protocol* to offer an FDA-approved opioid overdose reversal drug, free of charge, when an individual receives services from the OTP or IOP. However, the OTP or IOP may only provide the reversal drug if MDH provides the specified drug to the OTP or IOP.

By June 30, 2024, a community services program that provides specified services, a State correctional facility, a local correctional facility, and the Division of Parole and Probation must likewise have a *protocol* to offer FDA-approved opioid overdose reversal drugs, free

of charge, to individuals with an opioid use disorder (OUD) or who are at risk of experiencing a drug overdose when the individual receives services or is released from a facility (as appropriate). However, these entities may only provide the reversal drugs if MDH provides them with the specified drugs.

The Secretary of Health may adopt regulations to carry out these provisions.

Liability for Making an Opioid Overdose Reversal Drug Available

No cause of action may arise against any business or business owner, as specified, for any act or omission when the business or business owner acting in good faith makes an FDA-approved opioid overdose reversal drug and the necessary paraphernalia for administration available to its employees or patrons under these requirements.

Hospitals

By June 30, 2023, a hospital must require that FDA-approved opioid overdose reversal drugs are offered, free of charge, to a patient who has received treatment for a SUD, OUD, or nonfatal drug overdose event. However, this requirement is also subject to MDH providing the reversal drugs to the hospitals at no cost.

The bill repeals a requirement for hospitals to submit a specified protocol to the Maryland Hospital Association (MHA). The related requirement for MHA to submit a report to MDH and specified committees of the General Assembly, which was due in 2018, is also repealed.

Other Provisions

The bill also generally changes references from "naloxone" to "an opioid overdose reversal drug approved by FDA" throughout relevant portions of the Annotated Code of Maryland.

Current Law:

Emergency Medical Service Providers

Subject to the rules, regulations, protocols, orders, and standards of the EMS Board and subject to medical direction, while providing EMS a cardiac rescue technician, an emergency medical technician, or a paramedic may perform specified medical procedures as authorized by the EMS Board, administer specified medications or intravenous solutions, and provide emergency medical transport.

Overdose Response Program

The Overdose Response Program (ORP) is administered by MDH to provide a means of authorizing certain individuals to administer naloxone to an individual experiencing or believed to be experiencing an opioid overdose to help prevent a fatality when medical services are not immediately available. ORP also offers injectable and nasal spray naloxone at no cost for local health departments or nonprofit organizations that have an active ORP status.

MDH may authorize private or public entities to conduct education and training on opioid overdose recognition and response that includes (1) education on recognizing the signs and symptoms of an opioid overdose; (2) training on responding to an opioid overdose, including the administration of naloxone; and (3) access to naloxone and the necessary supplies for the administration of the naloxone. Each authorized private or public entity must enter into a written agreement with a licensed health care provider with prescribing authority to establish protocols for the prescribing and dispensing of naloxone to an individual.

Hospitals

Chapters 571 and 572 of 2017 require that hospitals have a protocol for discharging a patient who was treated by the hospital for a drug overdose or was identified as having a SUD, including coordination with peer recovery counselors who can conduct a screening, a brief intervention, and referral to treatment and connection of the patient with community services as well as prescribing naloxone for the patient. The protocol must be submitted to MHA.

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 ORP.

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

State Expenditures:

Maryland Department of Health

General fund expenditures increase by \$196,901 in fiscal 2023, which accounts for a 90-day start-up delay from the bill's July 1, 2022 effective date. This estimate reflects the cost of hiring one program administrator to order, invoice, and process FDA-approved opioid overdose reversal drugs; one program administrator to coordinate distribution of,

delivery of, and training to offer a reversal drug; and one epidemiologist to collect data on when, where, and how many reversal drugs are offered. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

| Positions | 3.0 |
|---|-----------|
| Salaries and Fringe Benefits | \$174,872 |
| Operating Expenses | 22,029 |
| FY 2023 MDH Administrative Expenditures | \$196,901 |

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

Subject to the limitations of the State budget, general fund expenditures may increase significantly beginning in fiscal 2023 to purchase FDA-approved opioid overdose reversal drugs for distribution to the specified programs under the bill. *For illustrative purposes only*, assuming MDH annually distributes an additional 50,000 two-dose packs of naloxone at a cost of \$75 per pack, general fund expenditures increase by an additional \$3.75 million annually.

Department of Public Safety and Correctional Services

DPSCS advises that, to provide naloxone free of charge as required under the bill, the Division of Correction (DOC) and the Patuxent Institution require 12 administrative officers and the Division of Pretrial and Detention Services needs one case manager supervisor, five case managers, and a data analyst at a total annual cost of approximately \$1.3 million. DLS disagrees and advises that DPSCS can likely implement the bill's requirements within existing budgeted resources, as discussed below.

DPSCS advises that the additional administrative officers will request FDA-approved opioid overdose reversal drugs, confirm delivery, secure the reversal drugs, ensure each employee completes online overdose education, and maintain inventory records. DPSCS also advises that its existing Office of Pretrial, Treatment, and Reentry Services will serve the functions of a "Training Director" to prepare overdose education and training modules for employees. However, the DPSCS website's data dashboard indicates that a total of 4,420 individuals in fiscal 2021 and 1,558 individuals in fiscal 2022 were scheduled to be released back into the community across all 13 DOC facilities, which equates to, on average, between 10 and 28 people per month at each facility. Upon intake at a DPSCS facility, an initial health assessment to include medical, dental, and mental health is completed for each inmate and, if appropriate, a health care treatment plan is developed. Inmates are also provided with a case management assessment and assigned to a case manager. Moreover, there are existing policies in place for reentry assessment, planning, and programming.

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DLS notes that the bill only requires DPSCS to offer an FDA-approved opioid overdose reversal drug to specified individuals (not every individual released will be offered and not every individual offered will accept an opioid overdose reversal drug) and advises that offering a reversal drug to such a small number of specified individuals upon release from DOC does not require additional staff to administer. DLS further advises that, while the bill creates an additional factor for case managers to consider upon release of an inmate, the bill does not affect the number of people who require case management services. Thus, DLS advises that DPSCS can likely implement the requirements of the bill within existing budgeted resources. To the extent that additional staff becomes necessary, general fund expenditures increase.

Small Business Effect: Small business IOPs and OTPs must develop protocols to offer FDA-approved opioid overdose reversal drugs, free of charge, to individuals under specified circumstances by June 30, 2024. However, these small businesses must only do so if MDH provides the reversal drugs to the programs at no cost.

Additional Information

Prior Introductions: None.

Designated Cross File: HB 408 (The Speaker, *et al.*) (By Request - Administration) - Health and Government Operations.

Information Source(s): Maryland Institute for Emergency Medical Services Systems; Judiciary (Administrative Office of the Courts); Maryland Department of Health; Department of Human Services; Department of Public Safety and Correctional Services; Department of Legislative Services

| Fiscal Note History: | First Reader - February 15, 2022 |
|----------------------|---|
| fnu2/jc | Third Reader - March 30, 2022 |
| | Revised - Amendment(s) - March 30, 2022 |

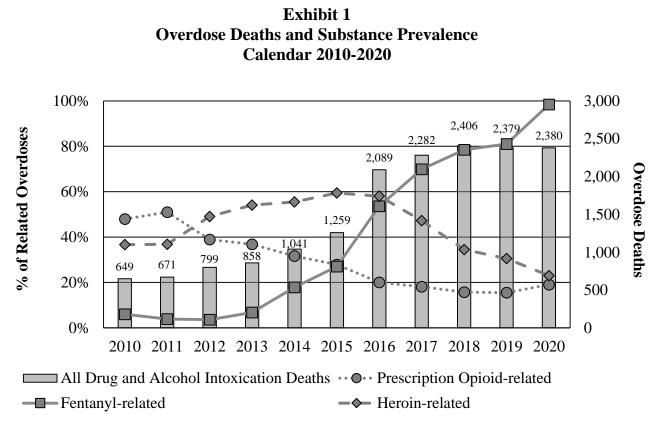
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Appendix – Opioid Crisis

Opioid Overdose Deaths

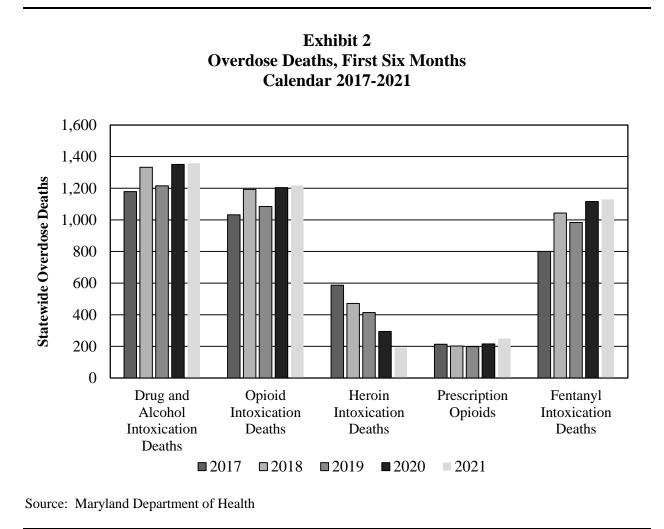
Maryland continues to be among the states hit hardest by the opioid epidemic with the fourth-highest overdose death rate in the nation, according to the most recent federal data. In 2018, the State experienced the deadliest year on record for overdose deaths, due almost exclusively to the continued presence of fentanyl. However, preliminary data from the Opioid Operational Command Center (OOCC) 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.



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. OOCC 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.



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 SB 394/ Page 8

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 OOCC activities (\$5.0 million of which will be used for grants to local behavioral health authorities).

ANALYSIS OF ECONOMIC IMPACT ON SMALL BUSINESSES

- TITLE OF BILL: Statewide Targeted Overdose Prevention (STOP) Act of 2022
- BILL NUMBER: SB 394
- PREPARED BY: Jake Whitaker

PART A. ECONOMIC IMPACT RATING

This agency estimates that the proposed bill:

 $\underline{X} \qquad \text{WILL HAVE MINIMAL OR NO ECONOMIC IMPACT ON MARYLAND SMALL} \\ \text{BUSINESS}$

OR

____ WILL HAVE MEANINGFUL ECONOMIC IMPACT ON MARYLAND SMALL BUSINESSES

PART B. ECONOMIC IMPACT ANALYSIS

N/A