Department of Legislative Services

Maryland General Assembly 2020 Session

FISCAL AND POLICY NOTE First Reader

House Bill 464

(Delegate Hettleman, et al.)

Health and Government Operations

Public Health - Overdose and Infectious Disease Prevention Services Program

This bill authorizes a "community-based organization" (CBO) to establish an Overdose and Infectious Disease Prevention Services Program. A program must, among other requirements, provide a supervised location where drug users can consume pre-obtained drugs, as well as receive other services, education, and referrals. However, a CBO must first receive approval from the Maryland Department of Health (MDH), in consultation with the local health department (LHD). MDH may not approve more than six programs and, to the extent practicable, should distribute programs evenly among urban, suburban, and rural areas of the State with each area receiving no more than two programs. Each program must operate at a single location in an area with a high incidence of drug use. **The bill takes effect July 1, 2020, and terminates June 30, 2024.**

Fiscal Summary

State Effect: The bill's requirements can likely be handled within existing budgeted resources, as discussed below. Revenues are not affected.

Local Effect: Potential significant operational and fiscal impact for some LHDs, as discussed below.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary: "Community-based organization" means a public or private organization that is representative of a community or significant segments of a community and that provides educational, health, or social services to individuals in the community. The

definition includes a hospital, clinic, substance abuse treatment center, medical office, federally qualified health center, mental health facility, LHD, and faith-based organization.

MDH, in consultation with the LHD, must make a decision regarding approval within 45 days of receiving an application and provide a written explanation of its decision to the CBO.

A program must, among other requirements, (1) provide secure sterile needle exchange; (2) answer questions about safe injection practices; (3) administer first aid, if needed, monitor for potential overdose, and administer rescue medications; (4) provide access or referrals to other health care services; (5) educate participants on the risks of contracting HIV and viral hepatitis; (6) provide overdose prevention education and access to or referrals to obtain naloxone; and (7) provide adequate security and training for staff, as specified. A program may, with permission, bill a participant's health insurance, accept specified outside financial assistance, apply for grants, coordinate with any opioid-associated substance abuse prevention and outreach program or CBO, and use a mobile facility.

A program may not be located in an area zoned for residential uses.

A program must annually collect and report a range of data about its operations, including information relating to the number of participants served, hypodermic needles and syringes distributed, overdoses experienced and reversed on-site, individuals who received overdose care, individuals referred to other services, and any other information deemed necessary by the department for assessing the impact of the program.

Program participants, staff members, and program property owners who act in accordance with the bill's provisions are not subject to arrest, prosecution, or any civil or administrative penalty (including action by a professional licensing board), nor are they subject to the seizure or forfeiture of any real or personal property used in connection with a program in accordance with State or local law. However, these individuals are not immune from criminal prosecution for any activities not authorized or approved by the program.

Current Law: Chapter 348 of 2016 authorizes an LHD or CBO, with the approval of MDH and the appropriate local health officer, to establish an opioid-associated disease prevention and outreach program. An LHD or CBO must apply to MDH and a local health officer for authorization to operate a program, and MDH and the local health officer must jointly authorize the program. An opioid-associated disease prevention and outreach program.

- secure program locations and equipment;
- allow participants to obtain and return hypodermic needles and syringes at any program location, if more than one location is available;
- have appropriate staff expertise in working with individuals who inject drugs;
- include adequate staff training;
- disseminate other means for curtailing the spread of HIV and viral hepatitis;
- link individuals to additional services, including substance-related disorder counseling, treatment, and recovery services; testing for specified diseases; reproductive health education and services; wound care; and overdose response program services;
- educate participants on the dangers of contracting HIV and viral hepatitis;
- provide overdose prevention education and access to naloxone or a referral to obtain naloxone;
- establish procedures for identifying program participants in accordance with specified confidentiality provisions;
- establish methods for identifying and authorizing staff members and volunteers who have access to hypodermic needles, syringes, and program records;
- develop a plan for data collection and program evaluation; and
- collect and report specified information to MDH at least annually.

Background: Approximately 100 supervised injection facilities (SIFs), sites where drug users can consume or inject pre-obtained illicit drugs in the presence of medical staff, have been opened in 11 countries (primarily in Europe, Canada, and Australia) as part of various strategies to reduce the harms associated with opioid use. For information on the State's growing opioid crisis, please refer to the **Appendix – Opioid Crisis**.

A 2017 publication by The Lankenau Institute for Medical Research, which compiled a review of the evidence for SIFs, found no evidence that SIFs have any effect on crime rates; however, there was evidence of a reduction in (1) overdose deaths; (2) injections done in public; (3) blood-borne disease infections; (4) discarded injection equipment; and, (5) perceived neighborhood disorder. Additionally, the study identified a potential cost savings in health services.

There are currently no SIFs in the United States. However, a Philadelphia nonprofit, Safehouse, intends to operate two injection sites. In October 2019, a federal judge in Philadelphia ruled that such a facility is not illegal. However, this ruling is not final, nor binding on other jurisdictions. Legislation to establish safe injection sites has previously been introduced in several states, including California, Colorado, Delaware, Maine, Maryland, Massachusetts, Missouri, and Vermont with no legislation being passed to date.

In an August 2018 *New York Times* op-ed, Deputy Attorney General Rod Rosenstein, reminded states considering SIFs that they are illegal and indicated that those states should expect the U.S. Department of Justice to meet the opening of any SIF with swift and aggressive action.

State Expenditures: MDH, in consultation with the LHD, must approve (or deny) applications from CBOs and provide written justification for the decision. The bill limits the number of programs that may be approved to six. The bill establishes no enforcement or ongoing requirements for MDH or LHDs. However, MDH advises that site inspections should be conducted as a matter of best practice. Although MDH advises that one full-time nursing program consultant/administrator is needed to implement the bill, the Department of Legislative Services (DLS) disagrees. Assuming that a small number of CBOs apply, and that MDH must consult with the LHD to review applications before authorizing no more than six programs, DLS advises that MDH can likely implement the bill's requirements with existing resources and staffing levels. To the extent that a significant number of CBOs apply, MDH may need additional staff to review applications and possibly conduct site visits; however, the authorization for a program terminates after four years.

Local Fiscal Effect: Expenditures increase significantly (through fiscal 2024) for any LHD that chooses to implement a program as authorized under the bill. It is unknown how much such a program will cost, and there would likely be significant variations among programs depending on the size, number of health care professionals, hours, variety of services, and population served. MDH advises, for comparison, that implementing an opioid-associated disease prevention and outreach program for an average-sized LHD costs approximately \$400,000. Thus, establishing a program under the bill likely costs at least \$400,000. However, the Maryland Association of County Health Officers (MACHO) advises that no LHD plans to set up such a facility or program at this time. DLS notes that LHDs are *not* mandated to establish a program under the bill. Any expenditures may be offset by billing insurance companies for certain services, donations, grants, or other financial assistance.

Historically, MACHO has also advised that it may also cost LHDs approximately \$1,500 to \$2,000 annually to review CBO applications and reports. A specific process may need to be established to allow for the proper consideration of program applications from LHDs, which qualify as CBOs under the bill but are also involved in the application review and approval process.

Small Business Effect: To the extent that a CBO is a small business and successfully applies to establish a program under the bill, expenditures increase significantly, as discussed under the local fiscal effect. Expenditures may be offset by billing insurance companies for certain services, donations, grants, or other financial assistance.

Additional Information

Prior Introductions: Similar legislation has been considered in recent legislative sessions. HB 139 of 2019 received a hearing in the House Health and Government Operations Committee but was withdrawn. Its cross file, SB 135, received a hearing in the Senate Finance Committee but was also withdrawn. HB 326 of 2018 received a hearing in the House Health and Government Operations Committee, but no further action was taken. Its cross file, SB 288, received a hearing in the House Health and Government Operations Committee, but no further action was taken. HB 519 of 2017 received a hearing in the House Health and Government Operations Committee, but no further action was taken. HB 1212 of 2016 received an unfavorable report from the House Health and Government Operations Committee, but no further action was taken.

Cross File: SB 990 (Senator Hettleman, et al.) - Finance.

Information Source(s): Maryland Association of County Health Officers; Maryland Department of Health; Maryland Insurance Administration; The Lankenau Institute for Medical Research; *The Washington Post*; *The New York Times*; Department of Legislative Services

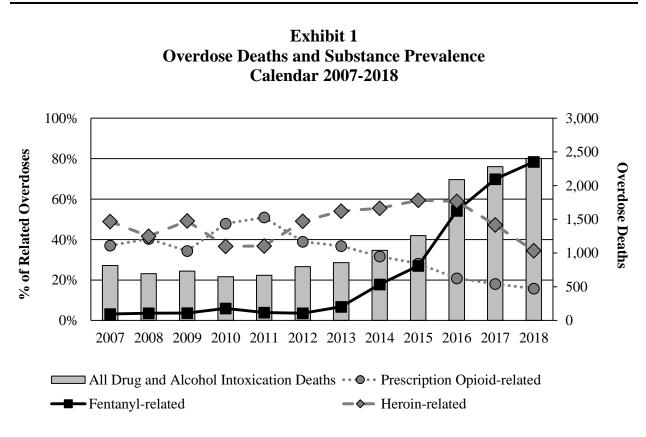
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Opioid Overdose Deaths

Maryland ranks among the top five states for the highest rates of opioid-related overdose deaths. In 2018, the State experienced the deadliest year on record for overdose deaths, due almost exclusively to the continued presence of fentanyl. **Exhibit 1** shows the total overdose deaths in the State since 2007 and the prevalence of prescription opioids, fentanyl, and heroin in contributing to overdose deaths.



Source: Maryland Department of Health

Preliminary data for 2019 suggests that 2018 may have been the peak of the opioid epidemic. Data published by the Opioid Operational Command Center indicates that the total number of overdose deaths in Maryland for the first six months of 2019 was lower than the number of deaths at the same point in 2018. **Exhibit 2** shows the total overdose deaths, overdoses involving opioids, and deaths involving heroin and fentanyl for the first six months of the last four years.

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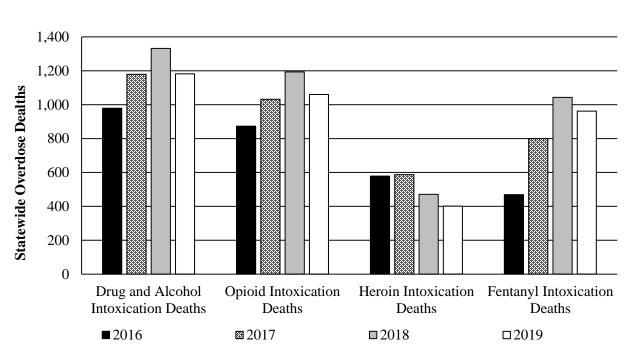


Exhibit 2 Overdose Deaths, First Six Months Calendar 2016-2019

Source: Maryland Department of Health

Although the data for the first six months of 2019 shows a decrease in fentanyl-related overdose deaths relative to 2018, fentanyl-related deaths are still well above 2017 levels. Furthermore, overdose deaths for heroin and fentanyl are not mutually exclusive, as law enforcement often finds fentanyl mixed into heroin. Nearly 30% of all overdose deaths in the State in 2018 involved both heroin and fentanyl.

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, the Heroin and Opioid Prevention Effort and Treatment Act, require the Governor's proposed budget for fiscal 2019 through 2021 to include specified 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 that provide treatment; and prohibit health insurance carriers from applying a prior authorization requirement for certain substance use disorder treatment drugs.

- Chapters 573 and 574 of 2017, the Heroin and Opioid Education and Community Action Act (Start Talking Maryland Act), expand drug education in public schools to include heroin and opioid addiction prevention; require local boards of education to establish a policy requiring each public school to store naloxone and other overdose-reversing medication to be used in an emergency; 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 149 of 2018 authorizes an emergency medical services provider or law enforcement officer to report an actual or suspected overdose to an appropriate information technology platform.
- 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 written policy for the collection and disposal of unused prescription medication and require a program employee to collect and dispose of a patient's unused medication on the death of the patient or the termination of a prescription.
- Chapter 532 of 2019 established programs for opioid use disorder screening, evaluation, and treatment (specifically medication-assisted treatment) in local correctional facilities and in the Baltimore Pretrial Complex. The programs must conduct a screening of the mental health and substance use status of each inmate as well as offer at least one formulation of each U.S. Food and Drug Administration approved full opioid agonist, partial opioid agonist, and long-acting opioid HB 464/ Page 8

antagonist used for the treatment of opioid use disorders. Phase-in of the programs begins January 1, 2020.

• Chapter 537 of 2019 established the Opioid Restitution Fund, a special fund that will retain any revenues received by the State relating to specified opioid judgments or settlements. The fund may be used only for specified opioid-related programs and services.

Legal Actions Related to the Opioid Crisis

Nationwide, lawsuits have been filed against pharmaceutical manufacturers, pharmacies, and individual providers for fueling the opioid crisis, either for aggressively marketing opioids and downplaying the known addictive qualities of the drugs, or for failing to detect and report suspicious orders. In December 2017, the U.S. Judicial Panel on Multidistrict Litigation ordered the consolidation of the nearly 200 pending opioid-related cases into multidistrict litigation in the U.S. District Court for the Northern District of Ohio. Over 2,500 jurisdictions are part of the litigation, including 32 Maryland jurisdictions (16 counties and 16 cities). In September 2019, Purdue Pharma, one of the original defendants named in the lawsuit, filed for bankruptcy. Purdue Pharma has proposed a settlement worth \$3 billion plus future revenues from OxyContin sales. Attorney General Brian E. Frosh issued a statement rejecting Purdue Pharma's proposed settlement. In May 2019, the Attorney General filed charges against Purdue Pharma, the Sackler family (owners of Purdue Pharma), Rhodes Pharmaceuticals (an entity with ties to Purdue Pharma and the Sackler family), and related entities. The State's charges allege that Purdue Pharma and the Sackler family conducted an orchestrated marketing scheme designed to mislead Maryland health care providers, patients, insurers, officials, and others about the benefits of opioids while downplaying their risks. Any payments made to the State as a result of opioid litigation will be placed in the Opioid Restitution Fund.

Funding to Address the Opioid Crisis

The fiscal 2020 budget has nearly \$710 million targeted toward addressing the opioid crisis in Maryland. Nearly \$700 million is budgeted in MDH, the vast majority of which is for substance use disorder treatment in Medicaid (\$622.5 million). Also included in MDH's fiscal 2020 budget is the second and final year of \$33 million in federal funds for the State Opioid Response Grant. The budget also contains \$3 million for the Behavioral Health Crisis Response Grant Program as mandated by the General Assembly, which will increase to \$4 million in fiscal 2021. Additional fiscal 2020 funding includes \$3 million in Department of Public Safety and Correctional Services support for medication-assisted treatment in State correctional facilities and \$725,000 between the Governor's Office of Crime Prevention, Youth, and Victim Services and the Department of State Police for various enforcement and treatment efforts.