Department of Legislative Services

Maryland General Assembly
2023 Session

FISCAL AND POLICY NOTE
Enrolled - Revised

House Bill 571 (Delegate Kipke, *et al.*)
Health and Government Operations Finance

Opioids - Opioid Restitution Advisory Council and Fund and Overdose Response Program

This bill requires the Maryland Department of Health (MDH), subject to the limitations of the State budget, to allow specified entities to choose the formulation or dosage of an opioid overdose reversal drug approved by the U.S. Food and Drug Administration (FDA) that the entity is provided with through the Overdose Response Program (ORP). The bill also (1) authorizes the Attorney General to direct that a committee be formed within the Opioid Restitution Fund Advisory Council in accordance with the requirements of a court or administrative order or a settlement agreement and (2) requires the Attorney General to establish procedures for any such committee. Finally, the bill clarifies how specified funds received by the Opioid Restitution Fund (ORF) must be appropriated and distributed. **The bill takes effect July 1, 2023.**

Fiscal Summary

State Effect: General fund expenditures for MDH may increase minimally to provide an entity chosen formulations or dosages of FDA-approved opioid overdose reversal drugs under ORP, as discussed below. The bill's requirements related to the advisory council and ORF can be implemented with existing budgeted resources and may facilitate decision making regarding, and processing of, monies distributed to ORF. Revenues are not affected.

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: If the Attorney General directs the council to form a committee, the committee must conduct only business related to the purpose of the court or administrative order or settlement agreement; however, it may conduct business related to multiple orders or agreements if the requirements are identical. The committee may consist only of council members. Unless otherwise specified by a court or administrative order or settlement agreement, the chair of the council (or the chair's designee) must be the chair of the committee.

The bill clarifies that, as with other settlement funds under current law, funds received by ORF in accordance with any other opioid-related court or administrative judgment or settlement agreement involving the State and one or more of its political subdivisions must be appropriated as required under the court or administrative judgment or settlement agreement. Furthermore, the Secretary of Health must establish and administer a grant program for the distribution of funds to political subdivisions of the State pursuant to such judgments or agreements.

Current Law:

Overdose Response Program

ORP is administered by MDH to provide a means of authorizing certain individuals to administer an opioid overdose reversal drug to an individual experiencing or believed to be experiencing an opioid overdose to help prevent a fatality when medical services are not immediately available.

Chapter 239 of 2022 (also known as the STOP Act) allows for FDA-approved opioid overdose 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. Subject to the limitations of the State budget, 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. 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 FDA-approved opioid overdose reversal drugs; and (3) access to opioid overdose reversal drugs and the necessary supplies for the administration of the opioid overdose reversal drug. Individuals are not required to obtain the specified training and education on opioid overdose recognition and response from a private or public entity before a pharmacist may dispense an FDA-approved opioid overdose reversal drug.

Opioid Restitution Fund and Opioid Restitution Fund Advisory Council

Chapter 537 of 2019 established ORF, 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. Chapter 270 of 2022 specifies that ORF may be used for programs, services, supports, and resources for evidence-based substance use disorder (SUD) prevention, treatment, recovery, or harm reduction that have the purpose of currently authorized outcomes and activities. ORF may also be used for:

- evidence-informed SUD prevention, treatment recovery, or harm reduction pilot programs or demonstration studies that are not evidence based if the advisory council determines that emerging evidence supports funding or that there is a reasonable basis for funding with the expectation of creating an evidence-based program and approves the use of money for the pilot program or demonstration study; and
- evaluations of the effectiveness and outcomes reporting for SUD abatement infrastructure, programs, services, supports, and resources for which the fund is used.

On July 21, 2021, a $26 billion global settlement was announced by opioid manufacturer Johnson & Johnson (Janssen Settlement Agreement) and McKesson, Amerisource Bergen, and Cardinal Health (Final Distributor Agreement). 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. A copy of the Janssen Settlement can be located here. A copy of the Final Distributor Agreement can be located here. In fiscal 2022, ORF received approximately $12 million from the $573 million global settlement agreement with McKinsey & Company for its role in marketing opioids, including OxyContin. The fiscal 2024 budget as passed by the General Assembly directs $36.2 million to ORF, reflecting years one, two, and three of settlement payments from Janssen and distributors.

Chapters 84 and 85 of 2022 require that settlement funds received in accordance with the Final Distributor Agreement of July 21, 2021, as amended, and the Janssen Settlement Agreement of July 21, 2021, as amended, be appropriated as agreed upon in the State-Subdivision Agreement of January 21, 2022, as amended. The Secretary of Health must establish and administer a grant program for the distribution of funds to political subdivisions of the State pursuant to the specified State-Subdivision Agreement.

Chapter 270 established the Opioid Restitution Fund Advisory Council to report by November 1 each year on its findings and recommendations regarding the allocations of money from ORF, consistent with authorized uses of the fund and considering (1) the number of people per capita with a SUD in a jurisdiction; (2) disparities in access to care

in a jurisdiction that may preclude persons; (3) the number of overdose deaths per capita in a jurisdiction; (4) the programs, services, supports, or other resources currently available to individuals with an SUD in a jurisdiction; and (5) disparities in access to care and health outcomes in a jurisdiction. The Governor must consult at least twice annually with the advisory council to identify recommended appropriations from ORF.

State Expenditures: MDH advises that it currently purchases three types of naloxone through Cardinal Health, each in a two-dose kit: (1) Narcan nasal spray (4 mg) at $45.34; (2) Kloxxado nasal spray (8 mg) at $57.27; and (3) naloxone intramuscular injectable (0.4 mg/mL) (price not provided). Most requests that MDH receives for naloxone are for the Narcan nasal spray. However, if requests are made for higher-priced opioid overdose reversal drugs or those unavailable through Cardinal Health and MDH must honor such requests, expenditures increase to the extent that the requested drugs are more expensive. At this time, any such increase is expected to be minimal. However, to the extent it is more significant, MDH advises that it will not be able to fulfill the requests for the opioid overdose reversal drugs within budget. The Department of Legislative Services notes that the bill specifies that the requirement to allow an entity to choose the formulation or dosage with which it is provided is subject to the limitations of the State budget.

Additional Comments: FDA currently approves both nasal spray and injectable versions of opioid overdose reversal drugs sold under the names Kloxxado, Naloxone, Naloxone Hydrochloride (or Naloxone HCl), Narcan, and Zimhi.

Additional Information

Prior Introductions: Similar legislation has not been introduced within the last three years.

Designated Cross File: SB 954 (Senator Klausmeier) - Finance.

Information Source(s): Maryland Association of County Health Officers; Maryland Institute for Emergency Medical Services Systems; Maryland State Department of Education; Maryland Department of Health; Department of Housing and Community Development; Department of Human Services; Department of Juvenile Services; Department of Public Safety and Correctional Services; Department of State Police; Maryland Department of Transportation; Office of the Attorney General; Baltimore City Public Schools; Prince George's County Public Schools; U.S. Food and Drug Administration; Department of Legislative Services

Fiscal Note History: First Reader - March 1, 2023
rh/jc Third Reader - March 27, 2023
Revised - Amendment(s) - March 27, 2023
Enrolled - April 19, 2023
Revised - Amendment(s) - April 19, 2023
Revised - Budget Information - April 19, 2023

Analysis by: Amber R. Gundlach

Direct Inquiries to:
(410) 946-5510
(301) 970-5510