

Department of Legislative Services
 Maryland General Assembly
 2017 Session

FISCAL AND POLICY NOTE
 First Reader

House Bill 1372 (Delegate Beitzel)
 Health and Government Operations

Public Health - Ibogaine Treatment Pilot Program

This bill establishes an Ibogaine Treatment Pilot Program that begins by January 1, 2019, and continues for four years (likely until January 1, 2023) to (1) provide ibogaine treatment at participating health care facilities to certain opioid dependent individuals who are not benefitting from conventional treatments for opioid dependence and (2) evaluate the effectiveness of this treatment compared to conventional treatment methods. The bill establishes a pilot program advisory board that is responsible for reviewing program proposals submitted for approval, among other things. Further, the bill specifies research, implementation, evaluation, and related reporting requirements for participating health care facilities as well as various means of funding the program. The bill establishes legal protections for participating program providers and recipients, and it requires an annual report by the Department of Health and Mental Hygiene (DHMH).

The bill terminates June 30, 2023.

Fiscal Summary

State Effect: General fund expenditures increase by at least \$35,200 in FY 2018 for one part-time contractual administrator for DHMH to staff the advisory board, collect data from participating programs, collate, and submit the compilation of reports. Future years reflect annualization. Although not reflected below, general fund expenditures may increase significantly from FY 2019 through 2023. Revenues are not affected.

(in dollars)	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	35,200	38,300	39,500	40,900	42,300
Net Effect	(\$35,200)	(\$38,300)	(\$39,500)	(\$40,900)	(\$42,300)

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

Local Effect: To the extent that a local health department runs a participating health care facility, expenditures increase, likely significantly, to fulfill the bill's requirements. These expenditures may be offset by any revenue collected from billing for services provided.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary:

Relevant Definitions

“Ibogaine” means the naturally occurring psychoactive substance found in the root bark of the iboga plant. “Opioid dependence” has the meaning stated in the *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, published by the American Psychiatric Association.

Advisory Board

DHMH staffs the seven-member board (which includes the Secretary of Health and Mental Hygiene or designee and six other members appointed by the Secretary). The purpose of the board is to review and approve proposals submitted by health care facilities that are requesting participation in the program within 30 days after receiving a proposal. The board must approve health care facilities and health care practitioners that demonstrate an ability to carry out the bill's requirements. If the board denies a request to participate, the board must state its reasons for denial and modifications that may be made to the proposal to obtain board approval.

Participating Health Care Facility

A participating health care facility must conduct research, adopt guidelines and protocols, and take measures necessary to develop and implement the program including (1) develop criteria for selecting the health care facilities and practitioners who will participate in the program; (2) establish screening and eligibility criteria and develop a recruitment strategy for participants; (3) establish assessment and treatment protocols and best clinical practices for various types of care; (4) coordinate with the federal government to obtain ibogaine for use in the program or with other best available sources if unable to obtain ibogaine from the federal government; (5) develop a broad-based program evaluation process; and (6) establish a plan for the storage and administration of ibogaine provided under the program.

Legal Protections

Providing or receiving treatment authorized under the program may not be a basis for the seizure or forfeiture of any products, materials, equipment, property, or assets. Further, a State or local criminal, civil, or administrative penalty may not be imposed on any program participant based solely on the provision or receipt of ibogaine treatment under the program. A participating health care practitioner is not subject to any disciplinary action under the Health Occupations Article solely for the act of providing treatment that is in accordance with protocols and guidelines approved by the board under the bill's provisions.

Program Fees and Funding

The bill specifies that a program provider may collect, and a program recipient may remit, fees charged for ibogaine treatment and other health care services provided to a program recipient. Further, a program provider may bill, and a program recipient's health insurance carrier may reimburse, for services performed by a program provider.

Funding for providing ibogaine treatment may come from State appropriations; fee revenue as described above; federal, State, or local grants or other assistance; and any other money made available to the program from any public or private source.

Reporting Requirements

Participating health care facilities must submit annual status reports starting on November 30, 2019. Thereafter, the report is due on November 1, with the final report due by November 1, 2022. The final report must include an analysis of the program evaluation data and specified determinations, recommendations, and conclusions on the success of the program, whether it should become permanent, and whether any changes should be made.

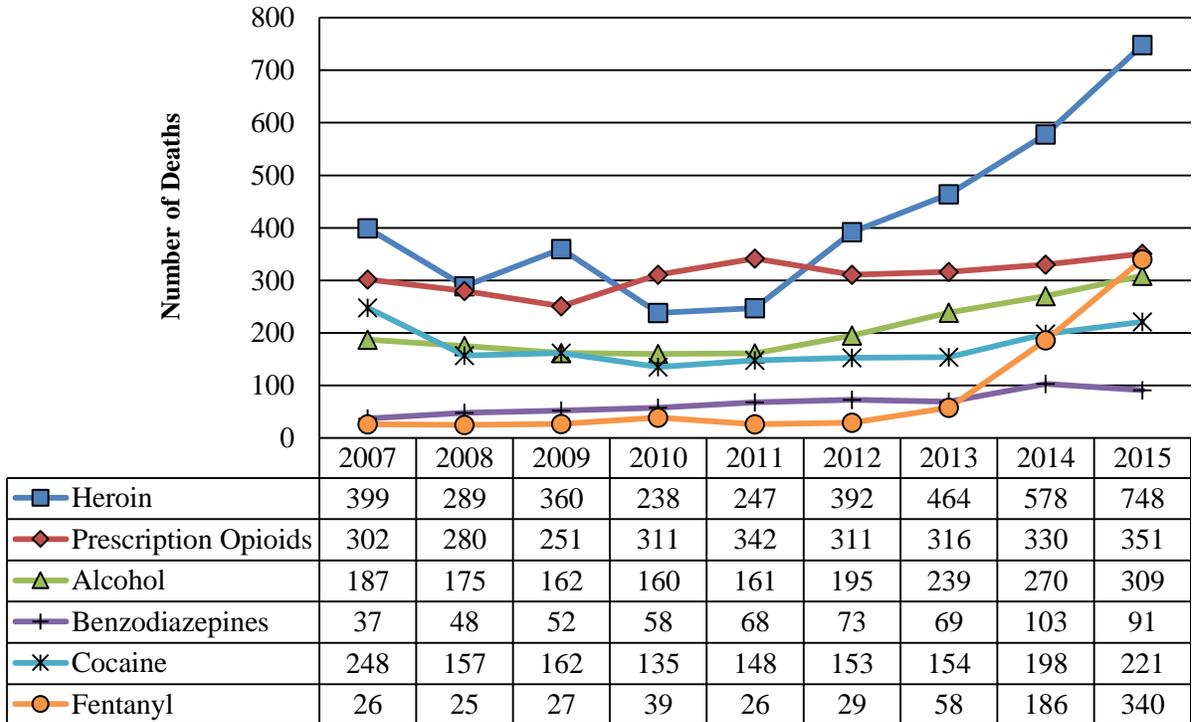
DHMH must submit an annual compilation of the required participating health care facilities' annual status reports to the Governor and General Assembly beginning December 30, 2019. Thereafter, the annual report is due on December 1.

Current Law/Background: Ibogaine is a Schedule I controlled dangerous substance under State and federal law. According to a 2016 case report in *Therapeutic Advances in Psychopharmacology*, ibogaine has been credited as a drug that can help addiction since the 1960s, although plans for a controlled trial in the United States in the early 1990s did not materialize. Although ibogaine has been found to have positive effects on addiction, a 2008 narrative review in *Human and Experimental Toxicology* reported that questions still exist regarding ibogaine treatment, including the underlying pharmacological activity that explains ibogaine's effect on addiction, the proper dosage, and the potential for abuse.

In February 2015, the Governor issued two executive orders establishing the Governor's Inter-Agency Heroin and Opioid Coordinating Council and the Heroin and Opioid Emergency Task Force to establish a coordinated statewide and multijurisdictional effort to prevent, treat, and significantly reduce heroin and opioid abuse. Additionally, Chapter 464 of 2015 established the Joint Committee on Behavioral Health and Opioid Use Disorders. The joint committee is required to monitor the activities of the coordinating council and the effectiveness of the State Overdose Prevention Plan; local overdose prevention plans and fatality review teams; strategic planning practices to reduce prescription drug abuse; and efforts to enhance overdose response laws, regulations, and training. In January 2017, the Governor issued another executive order establishing an Opioid Operational Command Center within the coordinating council to facilitate coordination and sharing of data among State and local agencies. On March 1, 2017, the Governor declared a state of emergency in response to the opioid epidemic in the State and announced a supplemental budget of \$50.0 million in new funding over a five-year period to support Maryland's prevention, recovery, and enforcement efforts.

According to DHMH's 2016 report, *Drug and Alcohol-Related Intoxication Deaths in Maryland*, drug- and alcohol-related intoxication deaths in Maryland increased for the fifth year in a row, totaling 1,259 deaths in 2015 – a 21% increase since 2014 and an all-time high. Of all intoxication deaths, 1,089 deaths (86%) were opioid-related, including deaths related to heroin, prescription opioids, and nonpharmaceutical fentanyl. Opioid-related deaths increased by 23% between 2014 and 2015 and have more than doubled since 2010. Heroin- and fentanyl-related deaths have risen particularly sharply. The number of heroin-related deaths increased by 29% between 2014 and 2015 and has more than tripled between 2010 and 2015. The number of fentanyl-related deaths increased by 83% between 2014 and 2015 and has increased nearly twelvefold since 2012. **Exhibit 1** shows trends in drug- and alcohol-related intoxication deaths in Maryland from 2007 through 2015.

Exhibit 1
Total Number of Drug- and Alcohol-related Intoxication Deaths
By Selected Substances in Maryland
2007-2015



Source: Department of Health and Mental Hygiene

Preliminary data from DHMH indicates that the number of intoxication deaths increased at an even steeper rate in 2016, with 1,468 deaths from January through September 2016 compared to 904 deaths during the same period in 2015 (a 62% increase). Additionally, for January through September 2016, the number of heroin-related deaths increased 72% and the number of fentanyl-related deaths increased nearly fourfold compared to the same period in 2015.

State Expenditures: General fund expenditures for DHMH increase by \$35,192 in fiscal 2018, which accounts for the bill’s October 1, 2017 effective date. This estimate includes costs for DHMH to staff the advisory board (with ongoing advisory board meetings), collect data from participating programs, collate, and submit the compilation of reports. Although the program must begin by January 1, 2019, this estimate assumes the staff member is necessary at the time the bill goes into effect to get the program up and running. This estimate reflects the cost of hiring one part-time contractual employee. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Contractual Position	0.5
Salary and Fringe Benefits	\$30,317
Operating Expenses	<u>4,875</u>
Total FY 2018 State Expenditures	\$35,192

Future year expenditures reflect a part-time salary with annual increases and employee turnover as well as ongoing operating expenses. This estimate does not include any health insurance costs that could be incurred for specified contractual employees under the State’s implementation of the federal Patient Protection and Affordable Care Act. This estimate assumes participation by health care facilities.

Under the bill, program providers may fund the costs of providing ibogaine treatment with appropriations provided in the State budget. This analysis assumes that such programs are funded with grants from other sources and other monies as authorized. However, to the extent State funding is provided, general funds would have to be used for this purpose. If so, general fund expenditures could increase significantly from fiscal 2019 through 2023.

Local Fiscal Effect: To the extent that a local health department chooses to implement a program, expenditures increase, likely significantly, to fulfill the bill’s reporting, data collection and analysis, and other requirements depending on the size and scope of the program implemented. To the extent that a program is successful at collecting fees for services provided, receives reimbursement from a health insurance carrier, or receives funding from another authorized source, these expenditures are offset.

Small Business Effect: To the extent that a participating health care facility is a small business, expenditures increase, likely significantly, to fulfill the bill’s reporting, data collection and analysis, and other requirements depending on the size and scope of the program implemented. To the extent that a program is successful at collecting fees for services provided, receives reimbursement from a health insurance carrier, or receives funding from another authorized source, these expenditures are offset.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene; Maryland Insurance Administration; *Therapeutic Advances in Psychopharmacology*; *Human and Experimental Toxicology*; Department of Legislative Services

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