

Department of Legislative Services
 Maryland General Assembly
 2018 Session

FISCAL AND POLICY NOTE
 First Reader

House Bill 1207 (Delegate Beitzel, *et al.*)
 Health and Government Operations

Public Health - Ibogaine Treatment Study Program

This bill establishes an Ibogaine Treatment Study Program. By July 1, 2019, the Maryland Department of Health (MDH) must select one or more academic medical centers to participate in the program and must fund selected centers to conduct a two-year study of ibogaine treatment. The Governor must include a budget appropriation of \$250,000 in fiscal 2020 and 2021 to fund the program. Any appropriated funds that are not expended for the program at the end of fiscal 2021 revert to the general fund. By December 1, 2021, MDH must submit a report to the Governor and General Assembly with program findings and recommendations. **The bill takes effect July 1, 2018, and terminates June 30, 2022.**

Fiscal Summary

State Effect: No effect in FY 2019. General fund expenditures increase by \$250,000 in FY 2020 and 2021. Revenues are not affected. **This bill establishes a mandated appropriation in FY 2020 and 2021.**

(in dollars)	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	0	250,000	250,000	0	0
Net Effect	\$0	(\$250,000)	(\$250,000)	\$0	\$0

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

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: “Ibogaine” means the naturally occurring psychoactive substance found in the root bark of the iboga plant. “Ibogaine treatment” means the administering or dispensing of ibogaine by a health care practitioner in a health care facility to opioid-dependent individuals. “Opioid dependence” has the meaning stated in the *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, published by the American Psychiatric Association.

The purpose of the program is to evaluate the effectiveness and safety of ibogaine treatment for opioid dependence and to compare the effectiveness with conventional treatment methods and interventions, including opioid replacement therapy.

Current Law/Background: For information on the State’s opioid crisis, please refer to the **Appendix – Opioid Crisis**.

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 September 2017, the *Journal of Psychedelic Studies* published the results of a retroactive ibogaine treatment study that was conducted by the Johns Hopkins School of Medicine Behavioral Pharmacology Research Unit, the Crossroads Treatment Center in Mexico, and the Yale School of Medicine. The study surveyed 88 former patients with chronic opioid use who had previously received ibogaine treatment from the Crossroads Treatment Center between 2012 and 2015. Survey results showed that 80% of individuals experienced a drastic reduction or elimination of withdrawal symptoms; 50% reported reduced opioid cravings; and 30% reported never using opioids again following ibogaine treatment. Additionally, 70% reported a relapse following treatment, but 48% reported decreased use from pretreatment levels and 11% eventually achieved abstinence.

According to a December 2017 article in the *Psychedelic Times*, in addition to Maryland, Vermont and New York have also introduced legislation in recent years regarding the medical use or scientific research of ibogaine.

State Expenditures: The bill establishes a mandated appropriation in fiscal 2020 and 2021 for the program. Therefore, general fund expenditures for MDH increase by

\$250,000 in fiscal 2020 and 2021 to fund the program. This analysis assumes that most, if not all, appropriated funds are expended by the end of fiscal 2021; thus, any reversion of unexpended funds to the general fund at the end of fiscal 2021 is expected to be negligible.

The Department of Legislative Services notes that MDH must select academic medical centers to participate in the program by July 1, 2019 (fiscal 2020), which likely results in the receipt of applications for the program in fiscal 2019. However, the number of applications received under the bill is expected to be minimal. Thus, this analysis assumes that MDH can select one or more academic medical centers and provide the mandated funding with existing resources. MDH can also handle the bill's reporting requirement with existing resources.

Additional Comments: To the extent that the University of Maryland Medical System applies and receives funding, its revenues and expenditures increase accordingly.

Additional Information

Prior Introductions: HB 1372 of 2017, a similar bill, received a hearing in the House Health and Government Operations Committee, but no further action was taken.

Cross File: None.

Information Source(s): Maryland Department of Health; *Therapeutic Advances in Psychopharmacology*; *Human and Experimental Toxicology*; *Psychedelic Times*; *Journal of Psychedelic Studies*; Office of the Governor; President's Commission on Combating Drug Addiction and the Opioid Crisis; Department of Legislative Services

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mm/jc

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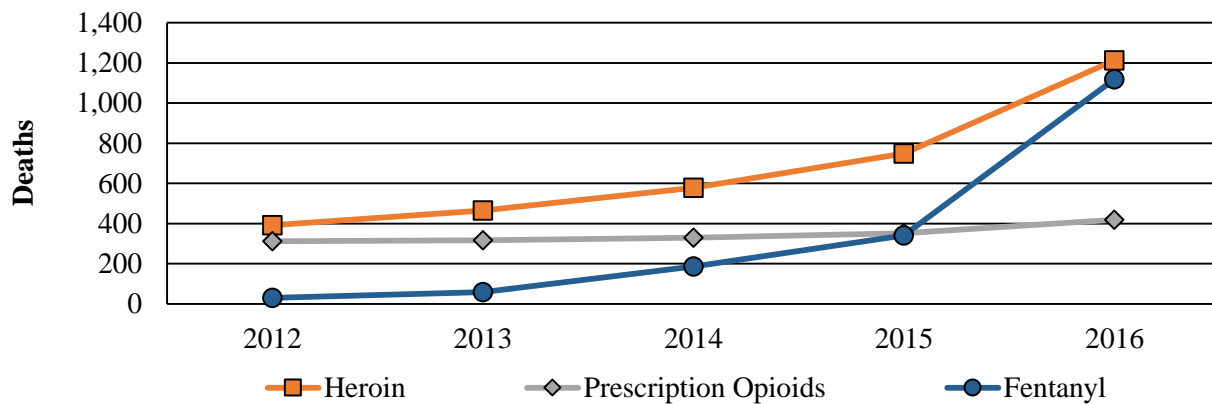
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Appendix – Opioid Crisis

Opioid Overdose Deaths

The rate of opioid-related deaths continues to rise at an alarming rate. As seen in **Exhibit 1**, between 2015 and 2016, prescription opioid-related deaths in Maryland increased by 19% (from 351 to 418), heroin-related deaths increased by 62% (from 748 to 1,212), and fentanyl-related deaths increased by 229% (from 340 to 1,119). Between January and June 2017, there were 799 deaths related to fentanyl, a 70% increase over the same time period for 2016, and 46 deaths related to carfentanil, a drug used as an elephant tranquilizer, a substance which first appeared as a cause of death in April 2017.

Exhibit 1
Total Number of Drug-related Intoxication Deaths
By Selected Substances in Maryland
2012-2016



Source: Maryland Department of Health

Federal Actions to Address the Opioid Crisis

In 2016, the Comprehensive Addiction and Recovery Act authorized over \$181 million annually, and the 21st Century Cures Act (CURES Act) authorized up to \$970 million to be distributed through the State Targeted Response to the Opioid Crisis Grants. The grants are to be used by states to increase access to treatment and reduce unmet treatment needs and opioid-related overdose deaths. In 2017, Maryland received a two-year, \$20 million grant for the prevention and treatment of opioid abuse. In March 2017, President Donald J. Trump signed an executive order establishing the President's

Commission on Combating Drug Addiction and the Opioid Crisis. The commission issued a final report in November 2017, with 56 recommendations, including a recommendation for federal block grant funding for state activities relating to opioids and substance use disorders. The full report can be found here: <https://www.whitehouse.gov/ondcp/presidents-commission>

Maryland Actions to Address the Opioid Crisis

The General Assembly passed several comprehensive acts during the 2017 session to address the State's opioid crisis, which addressed prevention, treatment, overdose response, and prescribing guidelines.

Chapters 571 and 572 of 2017, the Heroin and Opioid Prevention Effort and Treatment Act, among other things, require (1) the Behavioral Health Administration to establish crisis treatment centers that provide individuals in a substance use disorder crisis with access to clinical staff, requiring at least one center be established by June 1, 2018; (2) the Maryland Department of Health (MDH) to establish and operate a toll-free health crisis hotline; (3) certain health care facilities and systems to make available to patients the services of health care providers who are trained and authorized under federal law to prescribe opioid addiction treatment medications, including buprenorphine; (4) each hospital, by January 1, 2018, to have a protocol for discharging a patient who was treated for a drug overdose or identified as having a substance use disorder; (5) the Governor's proposed budget for fiscal 2019 through 2021 to include specified rate adjustments for community behavioral health providers; (6) the Department of Public Safety and Correctional Services and MDH to develop a plan to increase the provision of substance use disorder treatment, including medication assisted treatment, in prisons and jails; (7) the authorization of the provision of naloxone through a standing order and that MDH establish guidelines to co-prescribe naloxone to high-risk individuals; and (8) the expansion of private insurance coverage for opioid use disorders by prohibiting certain carriers from applying a pre-authorization requirement for a prescription drug when used for treatment of an opioid use disorder and that contains methadone, buprenorphine, or naltrexone.

Chapters 573 and 574 of 2017, the Heroin and Opioid Education and Community Action Act (Start Talking Maryland Act), require (1) the State Board of Education to expand an existing program in public schools to encompass drug addiction and prevention education that specifically includes instruction related to heroin and opioid addiction and prevention and information relating to the lethal effect of fentanyl; (2) each local board of education to establish a policy requiring each public school to obtain and store naloxone and other overdose-reversing medication to be used in an emergency situation; (3) each local board of education or local health department to hire a sufficient number of community action officials or develop and implement a program that provides community relations and education functions that coordinate forums and conduct public relations efforts; and

(4) specified institutions of higher education in Maryland to establish a policy that addresses heroin and opioid addiction and prevention, including awareness training for incoming students, obtaining and storing naloxone, and campus police training.

Chapter 570 of 2017 requires a health care provider, on treatment for pain and based on the provider's clinical judgment, 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 (CDS). The Act establishes that the quantity limitations do not apply to opioids prescribed to treat a substance-related disorder; pain associated with a cancer diagnosis; pain experienced while the patient is receiving end-of-life, hospice, or palliative care services; or chronic pain. A violation of the Act is grounds for disciplinary action by the appropriate health occupations board.

In January 2017, Governor Lawrence J. Hogan issued an executive order establishing an Opioid Operational Command Center (OCCC) to facilitate collaboration between State and local public health, human services, education, and public safety entities to combat the heroin and opioid crisis. OCCC will (1) develop operational strategies to continue implementing the recommendations of the Governor's Heroin and Opioid Emergency Task Force; (2) collect, analyze, and facilitate the sharing of data relevant to the epidemic from State and local sources; (3) develop a memorandum of understanding among State and local agencies that provides for the sharing and collection of health and public safety information and data relating to the heroin and opioid epidemic; (4) assist and support local agencies in the creation of opioid intervention teams; and (5) coordinate the training of and provide resources for State and local agencies addressing the threat to the public health, security, and economic well-being of the State.

In March 2017, Maryland became the first state to declare a state of emergency for the opioid crisis, activating the Governor's emergency management authority and enabling increased and more rapid coordination between the State and local jurisdictions. In conjunction with the declaration, Governor Hogan included a supplemental budget appropriation of \$10 million, part of a \$50 million, five-year commitment to address the State's heroin and opioid epidemic.

In July 2017, \$22 million was appropriated for fiscal 2018, including \$10 million in CURES Act funding, to be used for prevention, treatment, and enforcement activities. Prevention efforts include distribution of opioid intervention teams for each jurisdiction, a public awareness campaign, funding to train community teams on overdose response and linking to treatment, a pilot program to create school-based teams for early identification of the problems related to substance use disorders, and distribution of opioid information to health care facilities and providers that offer treatment. Enforcement initiatives include funding to disrupt drug trafficking organizations for the heroin coordinator program and to increase MDH's regulatory oversight of CDS. Treatment funding will be used to expand

treatment beds and implement a tracking system to identify available beds; improve access to naloxone; establish a 24-hour crisis center in Baltimore City; expand use of peer recovery support specialists; expand Screening, Brief Intervention, and Referral to Treatment to hospitals and parole, probation, and correctional facilities; increase access to medication-assisted treatment; expand law enforcement diversion programs; and improve the State's crisis hotline.