Department of Legislative Services

Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 1392 (Delegate Ciliberti, *et al.*)
Rules and Executive Nominations

Public Health - Co-Prescribing, Prescribing and Dispensing Opioid Overdose Reversal Drugs

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This bill generally authorizes the prescribing, co-prescribing, or dispensing (without a prescription) of an "opioid overdose reversal drug" under specified circumstances, if the "prescribing licensed health care provider" or pharmacist has completed one hour of training on the use of an opioid overdose reversal drug. The appropriate licensing board may enforce the bill's provisions against a prescribing licensed health care provider or a pharmacist. **The bill takes effect July 1, 2019.**

Fiscal Summary

State Effect: The bill generally aligns with existing practice. To the extent administrative changes are required, the Maryland Department of Health can likely handle them with existing resources. Revenues are not affected.

Local Effect: None.

Small Business Effect: Minimal.

Analysis

Bill Summary: Under the bill, the definition of "opioid overdose reversal drug" is modified to mean naloxone or *any other* drug that *rapidly reverses the respiratory depressant effects of an opioid medication* and is approved by the U.S. Food and Drug Administration (FDA) for the treatment of a known or suspected opioid overdose.

"Prescribing licensed health care provider" means an individual who is authorized by law to prescribe a monitored prescription drug.

Any guidelines established by the Secretary of Health regarding the *prescribing* and co-prescribing of an opioid overdose reversal drug must be consistent with provisions in the bill. The Secretary of Health may post any of the established guidelines on the Maryland Department of Health's (MDH) website, including guidance on available opioid overdose reversal drug formulations, prescribing templates, and standing orders for opioid overdose reversal drugs. MDH must encourage a prescribing licensed health care provider or pharmacist to co-prescribe or dispense an opioid overdose reversal drug.

A prescribing licensed health care provider may co-prescribe or a pharmacist may dispense (without a prescription) an opioid overdose reversal drug if either one determines that a patient is at a high risk of experiencing an overdose because the individual is prescribed opioids for acute or chronic pain, being treated for an opioid use disorder, or prescribed both an opioid and a benzodiazepine. Information from the Prescription Drug Monitoring Program, the patient's medical record, and the patient's family (if appropriate and allowed by law) may be used to make a determination about the patient's risk of experiencing an overdose. An opioid overdose reversal drug may also be prescribed or dispensed (without a prescription) to a person who is at a high risk of witnessing an opioid overdose because the individual resides or spends time with another individual who is prescribed an opioid, misuses opioids, or has an opioid use disorder.

Additionally, if the prescribing licensed health care provider or pharmacist determines the patient is at risk of witnessing or experiencing an opioid overdose, the prescribing licensed health care provider or pharmacist must (1) educate the patient on the risks of an opioid overdose, including specified information; (2) offer to prescribe or dispense an opioid overdose reversal drug; (3) encourage the patient to use the opioid overdose reversal drug as directed by FDA; and (4) state that taking an opioid overdose reversal drug is not a replacement for calling 9-1-1 in the event of an overdose.

A prescribing licensed health care provider must document in the patient's medical record any prescribing, co-prescribing, or education provided under the bill.

Current Law: Under current law, "opioid overdose reversal drug" means naloxone or a similarly acting and equally safe drug that is approved by FDA for the treatment of a known or suspected opioid overdose.

Chapters 571 and 572 of 2017 (Heroin and Opioid Prevention Effort and Treatment Act of 2017, also known as the HOPE Act) required that the Secretary of Health establish guidelines for the co-prescribing of opioid overdose reversal drugs. The established guidelines must address the co-prescribing of opioid overdose reversal drugs for patients

who are at an elevated risk of overdose and are (1) receiving opioid therapy for chronic pain; (2) receiving a prescription for benzodiazepines; or (3) being treated for opioid use disorders.

Background: Pursuant to the HOPE Act, MDH published proposed regulations in the *Maryland Register* on June 22, 2018, that are substantially similar to the bill's provisions. Although MDH was authorized as of August 6, 2018, to adopt the regulations with an effective date 10 days after final publication in the *Maryland Register*, it has not done so.

On June 1, 2017, the Deputy Secretary for Public Health Services issued a statewide standing order allowing licensed pharmacists in the State to dispense naloxone to anyone who may be at risk for an opioid overdose or in a position to assist someone believed to be experiencing an opioid overdose. A person-specific paper or electronic prescription is not required for a pharmacist to dispense naloxone under the standing order. Therefore, MDH advises that the bill's provisions generally align with current practice. However, licensed health care providers and pharmacists are not currently required to have one hour of training prior to prescribing or dispensing (without a prescription) an opioid overdose reversal drug.

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

State Expenditures: Under the bill, health care providers and pharmacists must have one hour of training on the use of an opioid overdose reversal drug prior to prescribing or dispensing such a drug without a prescription. The bill does not specify how training must be completed. This analysis assumes that the appropriate health occupations boards could approve existing training or post an online training module for their respective licenses using existing budgeted resources.

Additional Comments: Health care providers and pharmacists must obtain one hour of training in order to prescribe, co-prescribe, or dispense (without a prescription) an opioid overdose reversal drug under the bill. Though likely not costly, that requirement may delay current practices under the statewide standing order.

Additional Information

Prior Introductions: None.

Cross File: SB 820 (Senator Hough, *et al.*) - Finance.

Information Source(s): Maryland Department of Health; Department of Legislative Services

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md/jc

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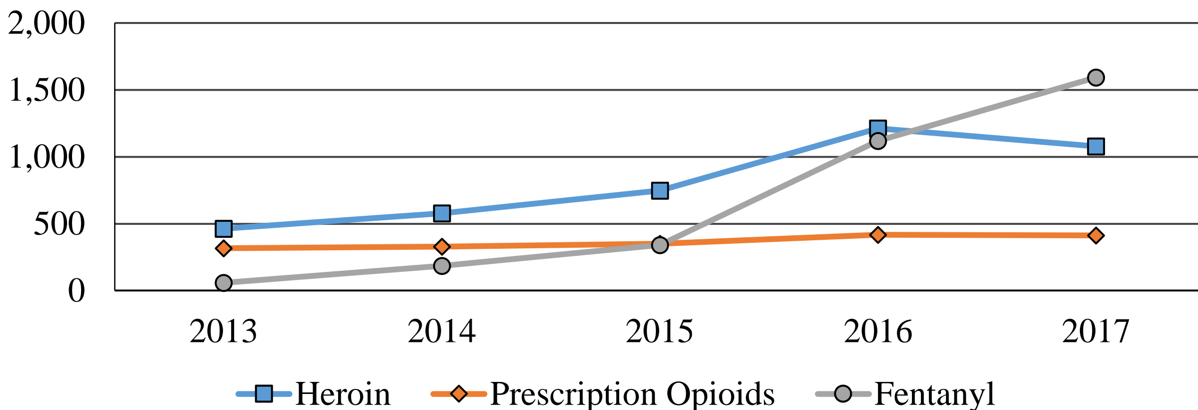
Appendix – Opioid Crisis

Opioid Overdose Deaths

While heroin and prescription opioid deaths have begun to taper off, fentanyl deaths have continued to rise at a high rate. As seen in **Exhibit 1**, between 2016 and 2017, prescription opioid-related deaths in Maryland decreased negligibly by 1% (from 418 to 413) while heroin-related deaths decreased by 11% (from 1,212 to 1,078). However, fentanyl-related deaths increased by 42% (from 1,119 to 1,594). Between January and June 2018, there were 1,038 deaths related to fentanyl, a 30% increase over the same time period for 2017.

Exhibit 1
Total Number of Drug-related Intoxication Deaths
By Selected Substances in Maryland
2013-2017



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.

In 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act was passed. The legislation expands existing programs and creates new programs to prevent substance use disorders and overdoses, including reauthorization of the Office of National Drug Control Policy, new Centers for Disease Control and Prevention grants for states and localities to improve prescription drug monitoring programs, and funding to encourage research into nonaddictive painkillers. Additionally, the legislation partially lifts the restriction that blocks states from spending federal Medicaid dollars on residential addiction treatment centers by allowing payments for residential services for up to 30 days while also allowing Medicare to cover medication-assisted treatment (MAT) in certain settings for the treatment of substance use disorder.

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; (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 to have a protocol for discharging a patient who was treated for an 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 MAT, in prisons and jails; (7) authorization of the provision of naloxone through a standing order and 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 requiring preauthorization for a prescription drug used for treatment of an opioid use disorder 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 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 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.

In January 2017, Governor Lawrence J. Hogan issued an executive order establishing an Opioid Operational Command Center (OOCC) to facilitate collaboration between State and local public health, human services, education, and public safety entities to combat the heroin and opioid crisis. OOCC 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 data sharing relevant to the heroin and opioid epidemic; (3) develop a memorandum of understanding among State and local agencies regarding sharing and collection of health and public safety information and data relating to the 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.

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 MAT; expand law enforcement diversion programs; and improve the State's crisis hotline.

In 2018, the General Assembly expanded upon the comprehensive legislation of the prior year. 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 who 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.