Department of Legislative Services

Maryland General Assembly
2017 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 1129 (Senator Mathias)
Finance

Substance Use Disorder Treatment - Licensing of Outpatient Programs and Provision of Naloxone Kits

This bill prohibits the Secretary of Health and Mental Hygiene from requiring an outpatient substance use disorder treatment program to be accredited as a condition of State licensure if the program meets specified criteria. Additionally, each hospital emergency department and local health department (LHD) must provide a naloxone kit and associated training to a patient under specified circumstances. The Department of Public Safety and Correctional Services (DPSCS) must also require each State and county correctional department to provide a naloxone kit and associated training to an inmate before releasing the inmate under specified circumstances.

Fiscal Summary

State Effect: Potential significant increase in general fund expenditures for the Department of Health and Mental Hygiene (DHMH) beginning in FY 2018, to the extent additional funds are distributed to LHDs for naloxone kits. Potential significant increase in general fund expenditures for DPSCS beginning in FY 2018 to provide naloxone kits and training to qualifying inmates in State correctional facilities. Medicaid expenditures (60% federal funds, 40% general funds) also increase, potentially significantly, beginning in FY 2018, to the extent the bill's requirements for hospital emergency departments result in additional naloxone prescriptions that are covered by Medicaid. Federal matching revenues increase correspondingly.

Local Effect: Expenditures for LHDs increase, potentially significantly, beginning in FY 2018 to provide naloxone kits and training to qualifying patients. Expenditures for local correctional facilities may also increase, as discussed below. **This bill imposes a mandate on a unit of local government.**

Small Business Effect: Meaningful for those outpatient substance use treatment providers that are no longer required to obtain accreditation as a condition of State licensure.

Analysis

Bill Summary:

Outpatient Substance Use Disorder Treatment Program – Licensing

An outpatient substance use disorder treatment program may not be required to be accredited as a condition of State licensure if the program (1) does not provide residential beds; (2) does not provide methadone; (3) does not operate or manage substance use disorder halfway houses; (4) treats patients in facilities located outside of Baltimore City or Baltimore County; (5) has a capacity to treat a maximum of 100 opioid use disorder patients in a medication assisted substance abuse treatment program using buprenorphine; and (6) generates less than $2.0 million in revenue.

Provision of Naloxone Kits and Training

Each hospital emergency department must establish and implement a policy of (1) providing a naloxone kit to each patient who has been admitted for an opioid overdose and (2) training each patient who has been provided a naloxone kit in the proper method of administering the naloxone before the patient is released.

Each LHD that provides substance use disorder treatment must (1) provide a naloxone kit to each patient during the initial diagnostic evaluation after confirming a diagnosis of an opioid use disorder and (2) train each patient who has been provided a naloxone kit in the proper method of administering the naloxone.

DPSCS must require each State and county correctional department to (1) provide a naloxone kit to each inmate with a history of an opioid use disorder before releasing the inmate and (2) train each inmate who has been provided a naloxone kit in the proper method of administering the naloxone.

Current Law/Background:

Outpatient Substance Use Disorder Treatment Programs – Licensing

A behavioral health program must be licensed by the Secretary of Health and Mental Hygiene before program services may be offered in Maryland; however, the Secretary may exempt specified entities from licensure requirements, including (1) a health professional,

in either solo or group practice, who is licensed under the Health Occupations Article and who is providing mental health or substance-related disorder services according to the requirements of the appropriate professional board; (2) Alcoholics Anonymous, Narcotics Anonymous, recovery residences, peer support services, family support services, or other similar organizations, if the organization holds meetings or provides support services but does not provide any type of treatment; and (3) outpatient behavioral health treatment and rehabilitation services provided in a regulated space in a hospital, if the services are accredited by an approved accreditation organization under its behavioral health standards.

The Secretary may require a behavioral health program to be accredited by an approved accreditation organization as a condition of licensure through regulations. By becoming licensed, the program agrees to comply with all applicable standards of the accreditation organization.

Under 10.63.02.02 of the Code of Maryland Regulations, the following categories of outpatient substance use disorder programs must be accredited as a condition of licensure: (1) integrated behavioral health programs; (2) intensive outpatient treatment Level 2.1 programs; (3) outpatient treatment Level 1 programs; and (4) partial hospitalization treatment Level 2.5 programs. These programs may also offer withdrawal management services and opioid treatment services, if authorized in their license.

Overdose Response Program

Chapter 299 of 2013 established the Overdose Response Program within DHMH to authorize certain individuals (through the issuance of a certificate) to administer naloxone to an individual experiencing, or believed to be experiencing, opioid overdose to help prevent a fatality when medical services are not immediately available. Chapter 356 of 2015 expanded the program to authorize standing orders for naloxone and provided additional legal protections for prescribers and those administering naloxone.

Naloxone (also known as Narcan®) is an opioid antagonist long used in emergency medicine to rapidly reverse opioid-related sedation and respiratory depression. DHMH launched the Overdose Response Program in March 2014. As of February 8, 2017, 42,084 individuals have received training under the program. Additionally, there have been 45,498 dispensed doses of naloxone and 1,572 reported naloxone administrations.

To qualify for a certificate to administer naloxone, an individual must (1) be 18 or older; (2) have, or reasonably expect to have, the ability to assist an individual who is experiencing an opioid overdose; and (3) successfully complete an educational training program offered by a private or public entity authorized by DHMH.

An educational training program must be conducted by a licensed physician, an advanced practice nurse, a pharmacist, or an employee or volunteer of a private or public entity who is supervised in accordance with a specified written agreement. Educational training must include (1) the recognition of opioid overdose symptoms; (2) the proper administration of naloxone; (3) the importance of contacting emergency medical services; (4) the care of an individual after the administration of naloxone; and (5) any other topics required by DHMH.

If an individual completes the training program and otherwise qualifies, an authorized private or public entity must issue a serialized certificate to the individual. A replacement certificate may be issued to replace a lost, destroyed, or mutilated certificate. Each certificate is valid for two years and may be renewed if the individual completes a refresher training program or demonstrates proficiency to the entity issuing the certificate.

Under the Overdose Response Program, a licensed physician or advanced practice nurse with prescribing authority may prescribe and dispense naloxone to a certificate holder. A registered nurse may dispense naloxone to a certificate holder in a LHD if the registered nurse complies with specified requirements.

A licensed physician or advanced practice nurse with prescribing authority may prescribe and dispense naloxone to a certificate holder by issuing a standing order if the physician or nurse is employed by DHMH or a LHD or supervises or conducts an educational training program under the Overdose Response Program. These physicians and nurses may also delegate dispensing authority to a licensed registered nurse who meets specified requirements or to an employee or volunteer of a private or public entity who is authorized to conduct an educational training program under the Overdose Response Program.

Any licensed health care provider who has dispensing authority may also dispense naloxone to a certificate holder in accordance with a physician's standing order. Licensed health care providers may also prescribe naloxone to a patient who is believed to be at risk of experiencing an opioid overdose or in a position to assist an individual who is at risk of experiencing an opioid overdose. A patient who receives a naloxone prescription does not need to hold a certificate from the Overdose Response Program.

Opioid Addiction in Maryland

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

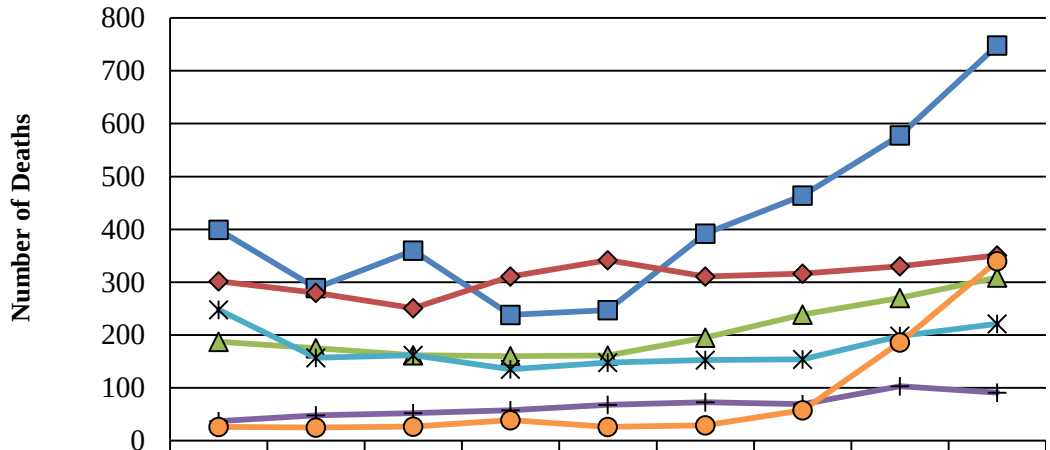
council and the effectiveness of the State Overdose Prevention Plan; local overdose prevention plans and fatality review teams; strategic planning practices to reduce prescription drug abuse; and efforts to enhance overdose response laws, regulations, and training. In January 2017, the Governor issued 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.

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.

Exhibit 1

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



	2007	2008	2009	2010	2011	2012	2013	2014	2015
Heroin	399	289	360	238	247	392	464	578	748
Prescription Opioids	302	280	251	311	342	311	316	330	351
Alcohol	187	175	162	160	161	195	239	270	309
Benzodiazepines	37	48	52	58	68	73	69	103	91
Cocaine	248	157	162	135	148	153	154	198	221
Fentanyl	26	25	27	39	26	29	58	186	340

Source: Department of Health and Mental Hygiene

Hospital Emergency Departments – Naloxone Prescriptions

According to DHMH, the number of heroin-related emergency department visits in Maryland more than quadrupled between 2010 and 2014, escalating from 346 to 1,564 over that five-year period.

In 2015, the Maryland Hospital Association (MHA) issued opioid-prescribing guidelines for Maryland emergency departments. MHA recommended that hospitals, in conjunction with emergency department personnel, develop a process to screen for substance misuse that includes services for brief intervention and referrals to treatment programs for patients at risk of developing, or who actively have, substance use disorders. MHA recommended that emergency departments not provide doses of methadone or buprenorphine for patients in a treatment program (unless the dose is verified with the program) and should not prescribe long-acting or controlled-release opioids, such as methadone. MHA further noted that, although the guidance is focused on screening patients who arrive seeking

opioid pain medication, assistance should also be provided to patients who arrive due to an opioid overdose. Prior to discharging such patients, emergency departments should discuss overdose prevention with the patient, which may include a prescription for naloxone and appropriate educational information (such as that naloxone should be administered by someone other than the person in overdose).

State Fiscal Effect:

Department of Health and Mental Hygiene

DHMH's Behavioral Health Administration (BHA) advises that it does not currently categorize outpatient substance use disorder treatment programs according to the bill's specified criteria (*e.g.,* by size and revenue); thus, it is unknown how many providers are affected by the bill's exemption from the accreditation requirement. BHA advises that it is already examining existing licensing and accreditation requirements for outpatient substance use disorder treatment programs, but that revising regulations to reflect the bill's specific changes is an extensive process necessitating significant staff resources. However, BHA did not provide a specific estimate as to the extent of this impact. The Department of Legislative Services advises that, as BHA is already reviewing issues related to the bill's requirements, this revision can likely be handled with existing staff, although staff may need to be temporarily diverted from other tasks to develop regulations in accordance with the bill's specific requirements.

The bill also requires LHDs to provide a naloxone kit to each patient during an initial diagnostic evaluation after confirming a diagnosis of an opioid use disorder and to provide associated training to the patient. BHA advises that LHDs receive funding to cover the cost of naloxone kits – funding is awarded based on need and the amount of BHA funds available. BHA advises that the cost of a naloxone kit is $75.

The Maryland Association of County Health Officers (MACHO) advises that the number of patients who receive direct substance use treatment services at each LHD varies, ranging from 100 to 1,500 patients per year depending on the size of the LHD. However, five or six LHDs no longer provide such services. MACHO also advises that the cost of a naloxone kit is $75 to $90 each. MACHO notes that one "medium-sized" LHD conducted 1,200 screenings in one year, and that 90% of these screenings (1,100) were for opioid use. *For illustrative purposes only*, under the bill, assuming all 1,100 screenings result in a confirmed diagnosis of an opioid use disorder, the LHD must provide a naloxone kit, at a cost of at least $75 for each patient, for a total cost of $82,500. Therefore, to the extent *each* LHD must provide naloxone kits and requests additional funding from BHA to cover these costs, general fund expenditures for DHMH increase, potentially significantly, beginning in fiscal 2018. Actual costs vary depending on the number of opioid disorder diagnoses through each LHD, kits that must be distributed, and BHA funds available.

The bill also requires each hospital emergency department to establish and implement a policy of providing a naloxone kit to each patient who has been admitted for an opioid overdose and to provide associated training for the patient. This analysis assumes that each hospital emergency department adopts a policy for the *prescription* of naloxone to patients who are admitted for an opioid overdose. As noted previously, MHA already recommends that hospital emergency departments prescribe naloxone in cases of opioid overdose, if appropriate for the patient. To the extent the bill results in additional prescriptions for naloxone that are covered by Medicaid, expenditures (60% federal funds, 40% general funds) increase, potentially significantly, and federal matching revenues increase correspondingly.

Department of Public Safety and Correctional Services

Under the bill, DPSCS must require each State correctional department to provide a naloxone kit to each inmate with a history of an opioid use disorder and provide associated training before releasing the inmate.

DPSCS advises that storage and recordkeeping of naloxone in correctional facilities presents a security concern and that, in order to obtain, store, and dispense naloxone, it must modify its medical provider and pharmacy contracts. Further, DPSCS advises that it likely must contract with an authorized training entity under the Overdose Response Program to provide the required training under the bill. DPSCS advises that the contracted medical provider must determine how best to implement the bill's requirements; thus, DPSCS is unable to estimate the costs of modifying the contract at this time.

DPSCS advises that it releases an average of 82 inmates per month (984 inmates per year) with a Texas Christian University Drug Screen score equal to or greater than 3, which indicates a likelihood of substance abuse. However, this information is not specific for an "opioid use disorder." DPSCS notes that the bill does not define "opioid use disorder" and that it may have to rely on self-reported information from inmates to determine qualifications under the bill. *For illustrative purposes only*, if DPSCS is required to provide a naloxone kit for all 984 inmates with a likelihood of substance abuse (according to their drug screen score), at a cost of $75 per kit, general fund expenditures for DPSCS increase by $73,800 each year for the provision of naloxone kits alone. Actual costs, and the timing of any such costs, vary depending on how many inmates are actually determined to have an opioid use disorder and when such inmates are released.

Local Expenditures:

Local Health Departments

As noted above, to the extent the bill requires LHDs to provide additional naloxone kits, expenditures for LHDs increase, potentially significantly, beginning in fiscal 2018. Some of these expenditures may be covered by funds from BHA. MACHO additionally advises that LHDs may incur costs for staff to provide the requisite training for patients; again, costs vary depending on the size of the LHD and the number of qualifying patients.

Local Correctional Facilities

Under the bill, *DPSCS* must require *local* correctional departments to provide a naloxone kit to each inmate with a history of an opioid use disorder before releasing the inmate and to provide associated training for each inmate. However, DPSCS advises that it does not have jurisdiction over such facilities, as these are local government facilities. Thus, it is unclear whether this requirement can be implemented. To the extent local correctional facilities *choose* to provide naloxone kits to qualifying inmates, expenditures for such facilities increase, potentially significantly.

Additional Comments: House Bill 1549 of 2017, introduced at the request of DHMH, makes several changes to the Overdose Response Program, including repealing the requirement that specified health care providers may only prescribe or dispense naloxone to a program certificate holder. The bill repeals existing certification requirements and instead specifies that an individual who has received education and training in opioid overdose recognition and response from an authorized private or public entity may receive a prescription for and administer an opioid antagonist.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Maryland Association of County Health Officers; Baltimore City; Montgomery and Prince George's counties; Department of Health and Mental Hygiene; Department of Public Safety and Correctional Services; Maryland Hospital Association; Department of Legislative Services

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