HB 1549

Department of Legislative Services

Maryland General Assembly
2017 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 1549 (Chair, Health and Government Operations Committee)(By Request - Departmental - Health and Mental Hygiene)

Health and Government Operations

Public Health - Drug Overdose Prevention Programs - Revisions

This departmental bill specifies that the Department of Health and Mental Hygiene (DHMH) may deny, suspend, revoke, or refuse to renew a registration to manufacture, distribute, or dispense a controlled dangerous substance (CDS) if the applicant or registrant has surrendered federal registration or has failed to meet the requirements for registration in regulations. The bill authorizes DHMH to limit an initial registration or the renewal of a registration to the particular CDS for which grounds for denial or refusal to renew exist. The bill also authorizes local fatality review teams to review nonfatal overdoses and makes conforming changes. Additionally, the bill 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.

Fiscal Summary

State Effect: Medicaid expenditures (60% federal funds, 40% general funds) likely increase beginning in FY 2018, to the extent the bill's changes to the Overdose Response Program result in additional prescriptions for naloxone (or other opioid antagonists) covered by Medicaid. Federal fund revenues increase by a corresponding amount.

Local Effect: Minimal operational impact for local fatality review teams that review additional cases under the bill. Local health departments (LHDs) may realize improved efficiencies and may choose to redistribute funds to other resources as a result of the bill's repeal of certification requirements under the Overdose Response Program.

Small Business Effect: DHMH has determined that this bill has a meaningful impact on small business (attached). The Department of Legislative Services (DLS) concurs with this assessment.

Analysis

Bill Summary: The bill repeals references to "naloxone" under the Overdose Response Program and instead substitutes "opioid antagonist." "Opioid antagonist" means naloxone or any other medication approved by DHMH that is used to counter the effects of an opioid overdose.

DHMH 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 an opioid antagonist; and (3) access to an opioid antagonist and the necessary supplies for the administration of the opioid antagonist.

An individual who has received education and training in opioid overdose recognition and response by an authorized private or public entity may (1) receive a prescription for an opioid antagonist and the necessary supplies for its administration from any licensed health care provider with prescribing authority; (2) possess the prescribed opioid antagonist and necessary supplies for its administration; and (3) administer the opioid antagonist to an individual experiencing or believed to be experiencing an opioid overdose.

A licensed health care provider with prescribing authority may prescribe and dispense an opioid antagonist by issuing a standing order if the licensed health care provider (1) is employed by DHMH or a LHD or (2) supervises or conducts education and training on opioid overdose recognition and response in accordance with a written agreement with an authorized private or public entity. A licensed health care provider who issues a standing order may delegate the dispensing of an opioid antagonist to an employee or volunteer of an authorized private or public entity in accordance with a written agreement between the delegating licensed health care provider and the authorized private or public entity that employs the employee or volunteer. A licensed health care provider with dispensing authority may also dispense an opioid antagonist to any individual in accordance with a standing order that is issued by a licensed health care provider with prescribing authority as described above.

The bill applies existing exemptions from disciplinary action and immunity provisions to individuals who administer, prescribe, or dispense opioid antagonists in accordance with the bill.

Current Law:

Controlled Dangerous Substance Registrations

A person must be registered by DHMH in order to manufacture, distribute, or dispense a CDS in the State. DHMH may deny, suspend, revoke, or refuse to renew a registration if DHMH finds that the applicant or registrant has (1) materially falsified an application; (2) been convicted of a crime under any federal or state law relating to CDS; (3) had federal registration suspended or revoked and may no longer manufacture, distribute, or dispense a CDS; or (4) otherwise violated State law relating to CDS. DHMH may limit revocation or suspension of a registration to the particular CDS for which grounds for revocation or suspension exist.

Local Fatality Review Teams

A "local team" means the multidisciplinary and multiagency drug overdose fatality review team established for a county. The purpose of each team is to prevent drug overdose deaths by promoting cooperation and coordination among agencies that investigate drug overdose deaths, understanding the causes of such deaths, developing plans and changes within agencies, and advising DHMH on changes to prevent drug overdose deaths. To achieve this purpose, each team must review drug overdose death cases, among other activities.

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.

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.

Background:

Controlled Dangerous Substance Registrations

The bill specifies that DHMH may take action against an applicant or registrant who holds a State registration to manufacture, distribute, or dispense CDS if the applicant or registrant has surrendered federal Drug Enforcement Administration (DEA) registration. DHMH advises that surrender of DEA registration has the same effect as a suspension or revocation of DEA registration – State registration is rendered ineffective. Thus, DHMH advises that it should have the authority to take the same action under statute when DEA registration is surrendered as when it is suspended or revoked.

Additionally, specifying that DHMH may take action if an applicant or registrant has violated regulations authorizes DHMH to take action based on a licensing board's order *without* requiring DHMH to conduct a separate investigation to determine if the applicant or registrant violated *statutory* requirements. Further, specifying that DHMH may limit an

initial registration or renewal to the particular CDS for which grounds for denial or refusal to renew exist allows DHMH to ensure that registrants with CDS restrictions on their professional occupational licenses are similarly restricted on their CDS registrations.

Local Fatality Review Teams

DHMH currently provides overdose death records and technical assistance to 18 local fatality review teams in Maryland. DHMH advises that, because there is an association between a nonfatal overdose and a subsequent fatal overdose, local teams should be able to examine both types of cases. DHMH has received requests from local teams requesting a statutory change for this authorization.

Overdose Response Program

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.

DHMH advises that, since implementing the program, it has determined that the certification requirement presents a significant and unnecessary barrier to the widespread distribution of naloxone. Certification requires authorized entities to maintain records of certificate holders (including issuance of serialized certificates) and to recertify them every two years, which is a burdensome process and restricts the locations of trainings. These requirements also restrict more expansive naloxone distribution methods (*i.e.*, "street-based" outreach to high-risk individuals in unstructured venues). LHDs have also incurred costs for staff, training venues, and materials, which are covered by limited grant funds.

Further, DHMH advises that national (chain) pharmacies have expressed reservations about pharmacists having to determine whether an individual is a certificate holder before dispensing naloxone, and that these pharmacies would prefer the approach of other states where pharmacists may dispense naloxone to anyone as long as the pharmacist provides the requisite patient instruction. DHMH notes that few, if any, other states have a certification requirement and that DHMH is not aware of naloxone abuse or other issues in jurisdictions that do not require certification.

Opioid Addiction in Maryland

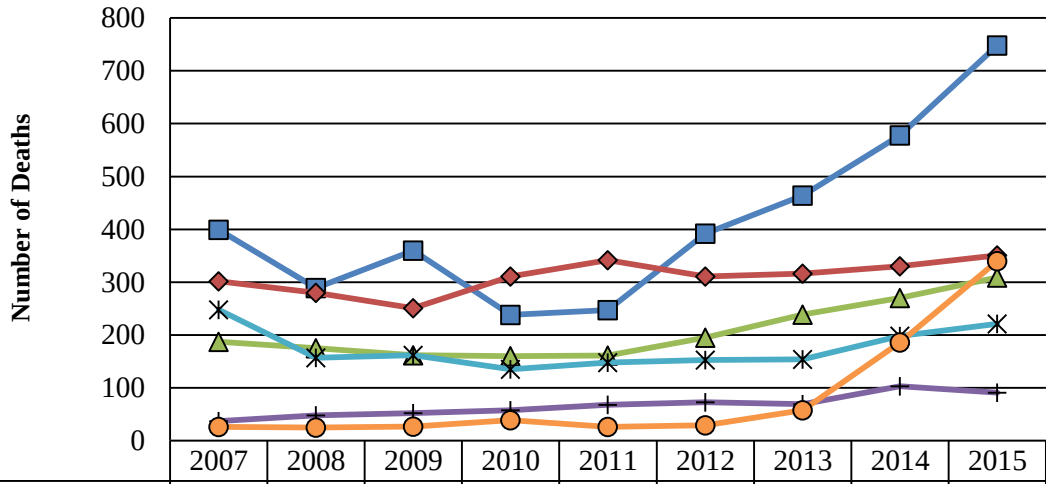
In February 2015, the Governor issued two executive orders establishing the Governor's Inter-Agency Heroin and Opioid Coordinating Council and the Heroin and Opioid Emergency Task Force to establish a coordinated statewide and multijurisdictional effort

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

State Fiscal Effect: The bill's changes relating to CDS registrations and local fatality review teams are not expected to materially affect State operations or finances.

DHMH advises that, as it does not directly train individuals or issue certificates under the Overdose Response Program, the bill's repeal of certification requirements and related changes do not materially affect DHMH operations or finances. DHMH further advises that, although the Behavioral Health Administration (BHA) provides funding to LHDs for program administration, including naloxone distribution, funding levels for LHDs are not expected to change under the bill – the bill's changes allow LHDs to redistribute funds that are otherwise used for certification to other purposes, including increased purchase of naloxone.

DLS notes that Medicaid covers naloxone prescriptions; in 2016, Medicaid enrollees filled 4,631 naloxone prescriptions. Thus, Medicaid expenditures (60% federal funds, 40% general funds) likely increase beginning in fiscal 2018, to the extent the bill results in

additional prescriptions for naloxone (or other opioid antagonists) covered by Medicaid. Federal fund revenues increase by a corresponding amount.

Local Fiscal Effect: DHMH advises that the bill's changes relating to local fatality review teams may have an operational impact on local agencies that choose to increase the number of cases reviewed. However, local fatality review teams still retain flexibility to adjust their caseloads based on capacity; thus, any operational impact is expected to be minimal.

As noted previously, BHA provides funding to LHDs for Overdose Response Program administration, including issuance of certificates and naloxone. However, funding levels are not expected to change as a result of the bill; LHDs may choose to redistribute funds toward other services or priorities, including increased purchase of naloxone. Any revised training as a result of the bill (such as training for other programs on stocking and providing naloxone) can be handled with existing staff. DHMH additionally advises that LHDs may realize improved efficiencies under the bill from no longer having to issue and renew program certificates.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Maryland Association of County Health Officers; Department of Health and Mental Hygiene; Department of Legislative Services

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fn/ljm

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ANALYSIS OF ECONOMIC IMPACT ON SMALL BUSINESSES
Department of Health and Mental Hygiene
Session 2017

BILL NUMBER: HB 1549

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PART A. ECONOMIC IMPACT RATING

This agency estimates that the proposed bill:

____ WILL HAVE MINIMAL OR NO ECONOMIC IMPACT ON MARYLAND SMALL BUSINESS

OR

__X__ WILL HAVE MEANINGFUL ECONOMIC IMPACT ON MARYLAND SMALL BUSINESSES

PART B. ECONOMIC IMPACT ANALYSIS

Health - General Article, 13-3101 through 13-3109 (currently 13-3111) (Minimum Age and ORP Certificate Requirements)

Small businesses/nonprofits that operate ORPs will be able to train individuals younger than 18 years old. In addition, BHA currently provides grant funding to private training entities, a portion of which is allocated to administrative costs such as certificate printing and management. Savings can be directed to the purchasing of naloxone and expansion of the program into new settings. Potential costs include training for programs on stocking and providing naloxone.

In addition, pharmacies will be able to issue naloxone under the Department's current standing order without having to verify an individual has an ORP certificate.