

Department of Legislative Services
Maryland General Assembly
2015 Session

FISCAL AND POLICY NOTE
Revised

Senate Bill 516

(Senator Klausmeier, *et al.*)

Finance

Health and Government Operations

Public Health - Overdose Response Program

This bill expands the Overdose Response Program within the Department of Health and Mental Hygiene (DHMH) by authorizing an advanced practice nurse with prescribing authority or a licensed physician to prescribe and dispense Naloxone to a certificate holder either directly or, under specified circumstances, *under a standing order*. A licensed physician or an advanced practice nurse with prescribing authority who issues a standing order may also delegate to specified persons the authority for dispensing Naloxone to certificate holders. The bill authorizes any licensed health care provider with prescribing authority to 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 at risk of experiencing an opioid overdose. The bill establishes legal and civil immunity for specified individuals.

Fiscal Summary

State Effect: None. The change is procedural in nature and does not directly affect governmental finances.

Local Effect: Local health departments may realize efficiencies.

Small Business Effect: None.

Analysis

Bill Summary: A “standing order” is defined as a written instruction for the prescribing and dispensing of Naloxone to a certificate holder in accordance with the bill’s provisions.

A licensed physician or an advanced practice nurse with prescribing authority may prescribe and dispense Naloxone to a certificate holder by issuing a standing order if he or she is employed by DHMH or a local health department or supervises or conducts an educational training program under the Overdose Response Program.

Under the bill's provisions, an applicant may take an educational program, as required for receipt of a certificate, conducted by a pharmacist. The bill also clarifies the conditions under which an employee or a volunteer of a private or public entity can conduct training. The bill establishes that a patient who receives a prescription for Naloxone from a licensed health care provider because the patient is believed to be at risk of experiencing an opioid overdose or in a position to assist another individual at risk of opioid overdose is not subject to the training requirements for certification.

A licensed physician or an advanced practice nurse with prescribing authority who issues a standing order may delegate the authority for dispensing Naloxone to a certificate holder to (1) a licensed registered nurse who is employed by a local health department and completes a DHMH-approved training program and (2) an employee or volunteer of a private or public entity who is authorized to conduct an educational training program.

Any licensed health care provider with dispensing authority is explicitly authorized to dispense Naloxone to a certificate holder in accordance with a standing order issued by a licensed physician. Additionally, pharmacists are explicitly authorized to dispense Naloxone in accordance with a therapy management contract. The bill also clarifies that a person who dispenses Naloxone in accordance with the Overdose Response Program is exempt from any laws requiring that person to maintain a permit to dispense prescription drugs.

A certificate holder administering Naloxone in accordance with statutory requirements may not be considered to be practicing registered nursing. An employee or volunteer who provides Naloxone in accordance with statutory requirements may not be considered to be practicing medicine, registered nursing, or pharmacy. An advanced practice nurse with prescribing authority who prescribes or dispenses Naloxone to a certificate holder in accordance with established protocol may not be subject to any disciplinary action under the Health Occupations Article solely for those actions.

An individual administering Naloxone to an individual who is, or in good faith is believed to be, experiencing an opioid overdose is immune from liability. Further, licensed physicians, advanced practice nurses with prescribing authority, and pharmacists are not subject to any cause of action arising from any act or omission when they prescribe or dispense Naloxone and the necessary paraphernalia in good faith and according to statutory requirements. The bill's provisions do not create a duty to obtain a certificate or to administer Naloxone.

The bill contains updates to outdated statutory language, removes all references to “nurse practitioners,” and generally replaces them with “advanced practice nurses with prescribing authority.” The bill also specifies that physicians must be licensed.

Current Law: 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. To qualify for a certificate, 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. A physician or nurse practitioner may prescribe and dispense Naloxone to a certificate holder; a physician who does so in accordance with established protocol is not subject to any disciplinary action. DHMH issued regulations implementing the program in 2014.

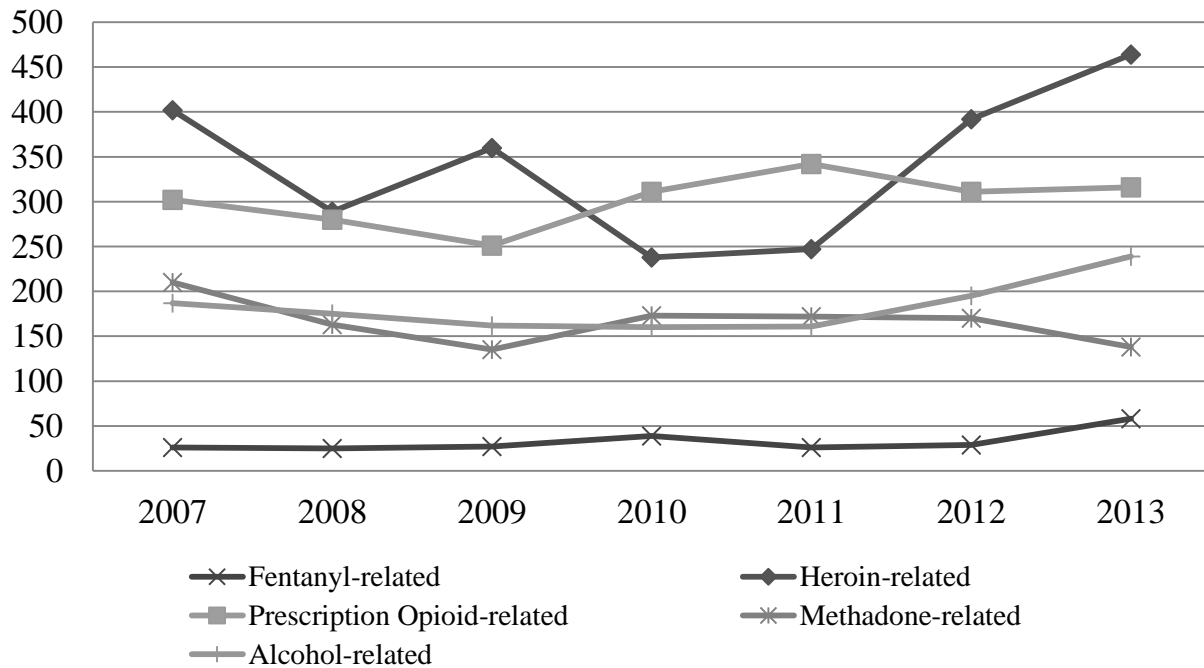
In general, specified emergency responders who provide emergency medical care without gross negligence, without a fee or other compensation at the scene of an emergency, in transit to a medical facility, or through communications with personnel providing emergency assistance are not civilly liable for any act or omission in giving any assistance or medical care. This immunity also extends to an individual who is not specified in statute so long as the individual is providing assistance during an emergency and assistance is provided in a reasonably prudent manner, without a fee or compensation, and the individual relinquishes care of the victim to a qualified professional when their service becomes available to take responsibility.

A person lawfully administering a drug or vaccine is not liable for any adverse effect that arises from the use of the drug or vaccine if the drug or vaccine is administered to immunize against a disease or is approved by the U.S. Food and Drug Administration and used properly. However, this exemption does not extend to gross negligence, a drug manufacturer from the duty to use ordinary care in preparing and handling a drug or vaccine, or a liability arising from improper or illegal administration of the drug or vaccine.

Background: DHMH’s 2013 report, titled *Drug and Alcohol-Related Intoxication Deaths in Maryland*, indicated that drug- and alcohol-related intoxication deaths in Maryland totaled 858 in 2013, a 7% increase from 2012, and an 88% increase since 2011. Increases in the number of heroin-, fentanyl-, and alcohol-related deaths contributed to the overall increase. Heroin-related deaths increased from 392 in 2012 to 464 in 2013, an 18% increase. The number of fentanyl-related deaths also doubled between 2012 and 2013, increasing from 29 to 58. There has also been a dramatic increase in heroin-related emergency visits in Maryland, and all but a small number were the result of heroin

overdoses. **Exhibit 1** shows trends in drug- and alcohol-related intoxication deaths in Maryland from 2007 through 2013.

Exhibit 1
Unintentional Intoxication Deaths in Maryland
2007-2013



Source: Department of Health and Mental Hygiene

In light of this alarming trend, there are several major statewide efforts underway to reduce heroin- and fentanyl-related overdoses. The Overdose Response Program, established in 2013, is intended to expand access to Naloxone, a life-saving medication that can safely and effectively reverse overdoses related to heroin and pharmaceutical opioids, by training and certifying individuals to administer Naloxone. Chapter 299 allows family members, friends, and associates of opioid users to legally obtain a prescription for Naloxone in their own names. There is also a statewide effort to train first responders to administer Naloxone. In 2013, all counties and Baltimore City submitted local overdose prevention plans at the request of DHMH. Chapter 650 of 2014 authorized the establishment of local fatality review teams to promote cooperation and coordination among agencies, develop plans, and recommend changes to prevent drug overdose deaths.

On June 27, 2014, Governor O'Malley issued Executive Order 01.01.2014.11, which created the Overdose Prevention Council to advise and assist agencies in a coordinated, SB 516/ Page 4

statewide effort to reduce overdoses. Maryland StateStat was tasked with calculating progress toward the goal of reducing overdose deaths by 20% by the end of 2015. DHMH also launched an aggressive public awareness campaign in June 2014 to encourage Maryland residents to fight against opioid overdoses.

The Department of State Police is augmenting enforcement against the drug trade crimes by addressing inter-jurisdictional and cross border distribution. The Prescription Drug Monitoring Program, established by Chapter 166 of 2011, and fully launched in December 2013, aims to reduce prescription drug misuse by creating a secure database of all Schedule II-V controlled dangerous substances prescribed and dispensed in Maryland.

Naloxone (also known as Narcan®) is an opioid antagonist long used in emergency medicine to rapidly reverse opioid-related sedation and respiratory depression. Naloxone is being made available to opioid users through community-based harm-reduction programs (including needle exchange and community health programs), substance use disorder treatment providers, and others that have contact with high-risk populations. These programs typically train opioid users on risk factors associated with overdose, overdose recognition, Naloxone administration, and overdose response techniques. Users are also provided with a prescription for and kit containing Naloxone (intramuscular injection or intranasal administration).

Additional Information

Prior Introductions: None.

Cross File: HB 745 (Delegate Bromwell, *et al.*) - Health and Government Operations.

Information Source(s): Department of Health and Mental Hygiene, Judiciary (Administrative Office of the Courts), Department of Legislative Services

Fiscal Note History: First Reader - February 28, 2015
mar/ljm Revised - Senate Third Reader - March 27, 2015
Revised - Enrolled Bill/Clarification - May 8, 2015

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