School Naloxone Administration Policy Development

Frequently Asked Questions

Opioid overdose and deaths are an epidemic nationally and in the State of Maryland. The Maryland Department of Health (MDH) and the Maryland State Department of Education (MSDE) recognizes the role of school health services (SHS) programs in responding to this epidemic. The Maryland Nurse Practice Act (Annotated Code of Maryland, Health Occupations Article, Title 8), applicable regulations (COMAR, Title 10, Subtitle 27), and State SHS policies and procedures regarding nursing practice including medication administration, guide administration of emergency medications in schools, which include the legal framework for naloxone administration. The Maryland Overdose Response Program (ORP), authorized by law in 2013, was created to increase access to naloxone, the opioid overdose reversal medication. Administered by the MDH Behavioral Health Administration, the ORP authorizes organizations to conduct overdose response trainings and naloxone distribution to non-medical community members who are likely able to assist someone experiencing an opioid overdose to help prevent fatalities when medical services are not immediately available.

In 2017, the General Assembly passed the Heroin and Opioid Education and Community Action Act of 2017 (Senate Bill 1060 and House Bill 1082), also known as the "Start Talking Maryland Act." The bills, codified as Maryland Code Education Article §7-426.5, require county boards to establish policies for obtaining and storing overdose-reversing medications, including naloxone, and for school nurses, school health services personnel, and other school staff to administer those medications if a student is reasonably believed to be experiencing an opioid overdose. This requirement went into effect July 1, 2017.

Also in 2017, the General Assembly adopted the Heroin and Opioid Prevention Effort and Treatment Act of 2017 (HOPE Act) (House Bill 1329 and Senate Bill 967). The Maryland Code, Health General Article §13-3103 states that training and education on opioid recognition or response from an authorized ORP entity is not required for a pharmacist to dispense naloxone to an individual. Section 13-3107 of the Health General Article allows individuals who are prescribed and dispensed naloxone in accordance with the law to legally possess and administer naloxone to someone believed to be experiencing an opioid overdose. Section 8-407 of the Health General Article further requires health care providers to make information on opioid use disorder available to patients. These requirements went into effect on June 1, 2017.

The following frequently asked questions (FAQ) address several key aspects related to the implementation of the new laws in the school setting.

Opioids and Naloxone

1. What are opioids?

Opioids are substances that contain opium, or its derivative. Opioids can be illegal or legally prescribed, commonly for pain relief or treatment of opioid use disorder. Illegal opioids include heroin and non-pharmaceutical fentanyl. Opioids come in a variety of forms including pill, capsule, powder, liquid, and film, that can be swallowed, smoked,

snorted, injected, inserted rectally, or placed under the tongue. Common examples of Federal Drug Administration (FDA) approved prescription opioid medications include oxycodone, hydrocodone, morphine, codeine, methadone, buprenorphine, buprenorphine/naloxone (Suboxone ®), and fentanyl.

2. What is an opioid overdose?

An opioid overdose occurs when a toxic amount of an opioid – alone or mixed with other opioid(s), drugs and/or substances – overwhelms the body's ability to handle it. In excessive amounts, opioids can suppress the urge to breathe. Respiratory depression can progress rapidly and be fatal if not treated quickly, making an opioid overdose a medical emergency.

3. What are the signs and symptoms of an opioid overdose?

The signs and symptoms of an opioid overdose include, but are not limited to: snoring or gurgling noises; pupillary constriction; blue-tinged lips/fingertips; pale/gray, clammy skin; slow, shallow, or absent breathing; slow, irregular, or absent heartbeat; a reduced level of consciousness; unconsciousness or unresponsiveness; seizure; and reduced muscle tone.

4. What is naloxone and how does it work to reverse an opioid overdose?

Naloxone is a medication that reverses the effects of opioid overdose and restores breathing and consciousness. The brain has many locations with receptors to which opioids uniquely bind. One result of opioids binding to these receptors is a depression of the respiratory system. In an opioid overdose, breathing stops because so many opioids have bound to these receptors. Naloxone is an opioid competitor that binds more strongly to these receptors in the brain and temporarily counteracts the actions of the opioids. Since naloxone does not depress the respiratory system, breathing is restored once naloxone replaces the opioids on the receptors. Naloxone is a safe medication that has been used in healthcare settings for decades with minimal side effects and no potential for abuse.

5. How is naloxone administered?

Naloxone can be administered via injectable (intramuscular, subcutaneous, or intravenous) or intranasal routes. FDA-approved naloxone products available to the public include generic injectable administered intramuscularly using a vial and syringe, generic off-label injectable administered as a nasal spray with the use of an atomizer, NARCAN® Nasal Spray, and the EVZIO® Auto-Injector.

NARCAN® and EVZIO® are the only currently available naloxone devices with labeling that includes instructions for use by non-medical professionals.

6. How might an individual respond to naloxone administration?

Naloxone will have no effect on someone who does not have opioids in his/her body. Persons allergic to naloxone may have an allergic reaction.[1] An individual who is opioid dependent or addicted may be uncomfortable and feel disoriented after the administration of naloxone. Naloxone may cause an opioid dependent person to experience withdrawal symptoms.[2] Vomiting is a possibility, so the person should be rolled on his/her side and supported in the recovery position[3] to keep from choking.

School Naloxone Policy Development

7. What are the local policy requirements to comply with HB 1082 / SB 1060, the Start Talking Maryland Act?

The Start Talking Maryland Act requires each county board to establish a policy in accordance with school health guidelines and state laws and regulations to authorize the school nurse, school health services personnel, and other school personnel to administer naloxone or other overdose-reversing medication to a student or other person located on school property who is reasonably believed to be experiencing an opioid overdose. Further, each public school is required to implement a method for notifying parents/guardians of students of the school's policy on the authorization and use of naloxone. *See* Md. Code, Educ. §7-426.5.

8. Does the law require schools to obtain and maintain naloxone?

Yes. The Start Talking Maryland Act (Educ. §7-426.5) requires all public schools to obtain, and store at the public school, naloxone or other opioid overdose reversal medication.

9. Does the law require schools to provide naloxone at school sponsored activities and events?

Yes, if the school sponsored activity or event takes place on school grounds. The law states that the local education agency (LEA) policy must require schools to obtain and store naloxone and must authorize certain persons to administer it to students and other individuals on school grounds. Although it does not contain any explicit requirements for provision of naloxone at certain times or for events after school, the requirement that it be available for students or other people located on school property means that LEAs should create a policy that covers school-sponsored events that take place on school grounds.

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[1] Symptoms of an allergic reaction may include: rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue; dizziness; fainting; fast or irregular pulse; flushing; headache; heart rhythm changes; seizures; or sudden chest pain.

[2] FDA Advisory Committee on the Most Appropriate Dose or Doses of Naloxone to Reverse the Effects of Life-threatening Opioid Overdose in the Community Settings. Retrieved from https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM522688.pdf. (Accessed 3/10/2017)

[3] National Safety Council: The Recovery Position – Adult or Child. Retrieved from http://www.nsc.org/RxDrugOverdoseDocuments/recovery-position-first-aid.pdf. (Accessed 3/15/2017)

10. Does the law require schools to provide naloxone at events that occur off campus or that are not school-sponsored?

No, if the school sponsored activity or event takes place off school grounds or an activity takes place on school grounds that is not a school-sponsored event (for example, a private group uses a school ballfield on a Saturday afternoon). Because the law only requires LEAs to develop a policy for the administration of naloxone on school grounds, a school system does not have to address events off school grounds or events the school does not sponsor or operate. Any such policy would be voluntary on the part of an LEA. Each LEA and local school health services program may, but is not required to, create policies that address the availability of naloxone for events taking place off school grounds and/or non-school-sponsored events that take place on school grounds. This guidance is specific to the administration of naloxone. This guidance does not release the LEA from the requirement to adhere to other state or federal laws, regulations or guidance related to the administration of medications during off-campus activities or programs, including school field trips.

11. What other legal authorities guide naloxone use in schools?

In addition to the requirements of the Start Talking Maryland Act, naloxone use in the school setting must comply with: 1) SHS program policies and procedures governing administration, including availability and administration of emergency medication and use of stock medications; and 2) the Maryland Nurse Practice Act including provisions for physician directed nursing protocols. It is important that the local SHS and Local Health Department (LHD) personnel be involved in the development and implementation of local policy guiding naloxone use in schools.

12. What is the definition of "other school personnel" who may administer naloxone?

The law does not define "other school personnel." The local board's policy may identify other school personnel to include non-medical school staff including, but not limited to: school administrators, teachers, school psychologists, school counselors, pupil personnel workers, school social workers, food services staff, coaches/advisors for school sponsored activities, and bus drivers. Regardless of the service delivery model, the registered nurse is always the leader of the school health services team and may determine which school personnel are to be given the responsibility for administering naloxone. For additional information on ways other school personnel may be identified and trained to assist in an opioid overdose emergency, please refer to the school system or school's emergency response plan and/or the school health services guideline on chain of survival.

13. By what authority may non-medical school staff administer naloxone in the school setting?

Health General Article, Title 13, Subtitle 31 establishes the legal authority for non-medical professionals to acquire, possess, and administer naloxone. Educ. §7-426.5 authorizes non-medical school staff to administer naloxone.

While the HOPE Act grants broad authority for naloxone administration in the community. The LEA policy determines who is authorized to administer emergency medications in the school setting, including administration of naloxone, by non-medical school staff. Local education agencies are required to develop policies that allow a broad range of persons to administer naloxone given the safety of naloxone and the critical importance of responding quickly to a suspected opioid overdose.

14. What considerations are important when developing a local education agency policy regarding the administration of naloxone by SHS program staff and other school personnel?

The local SHS program should be prepared to respond to an opioid overdose on school grounds, the LEA policy should consider the following items regarding the administration of naloxone by SHS program staff or other school personnel:

- Designating the school personnel who will be trained to administer naloxone;
- Defining the roles and responsibilities of any school personnel who respond to an opioid overdose or suspected opioid overdose;
- Legal authority to possess and administer naloxone;
- How to obtain stock naloxone stock;
- Procedures for documenting and reporting naloxone administration;
- Designating the location(s) where naloxone will be stored;
- Maintaining the privacy and confidentiality of students;
- Resources for naloxone administration training, monitoring, and oversight of the implementation of the policy;
- A plan to consider other causes of unconsciousness, or other signs of opioid overdose, when implementing a stock naloxone protocol among students with known health conditions;
- School wide awareness/educational activities on the local policies on naloxone;
- The effectiveness of the school's current emergency plan and how the use of naloxone can be incorporated into that plan;
- The types of activities and events conducted in the school building;
- Layout of the school building including any unique features;
- The availability and response times for Emergency Medical Services;
- The ability of a student (18 years of age or older) and school staff who possess naloxone to use personally obtained naloxone on school grounds during school hours or during after school activities when they reasonably believe a person is experiencing an opioid overdose; and
- Naloxone availability among first responders including School Resource Officers.

School Naloxone Policy Implementation

15. How can local education agencies obtain naloxone?

Naloxone can be obtained in the following ways:

- Local SHS programs are encouraged to partner with local health departments to obtain naloxone;
- Local SHS programs may choose to participate in pharmaceutical company programs that offer naloxone for schools and obtain naloxone in collaboration with an authorized prescriber authorized under Md. Code Ann., Health-Occupations § 12-6C-09(b)[4]; or
- A SHS program can seek authorization to become an ORP training entity and conduct overdose response training, as well as obtain and dispense naloxone.

16. May a school use naloxone products and devices that do not have labeling that includes instructions for use by non-medical professionals?

Yes. If an LEA policy includes the use of generic injectable (vial and syringe) or generic off-label injectable administered as a nasal spray with the use of an atomizer, it may be used as the stock naloxone for the purpose of compliance with the law.

17. How should naloxone be stored in the school setting?

Naloxone should be stored at room temperature and away from direct sunlight. The LEA policy should include processes to maintain naloxone and other ancillary equipment (e.g., rescue breathing barrier devices, atomizers) securely and easily accessible to those designated to administer naloxone. This may include storing naloxone in the health room, with the school's automated external defibrillator (AED), or co-located near the school's stock epinephrine auto-injector. The security of the naloxone should be checked regularly as is done with the other emergency response devices in the school (e.g., epinephrine auto-injector and AED).

Naloxone should be replaced by the expiration date. Procedures for implementing the school policy should include being proactive in anticipation of the product expiration date and replacement timeframe.

18. Who provides the training and evaluates the ability of other school personnel to administer naloxone?

The school nurse is the leader of the SHS team in the school setting. The Maryland Nurse Practice Act and the SHS Guideline on the Role of Health Services Staff in Schools describe the scope of practice of nurses and the responsibilities of school nurses. The Code of Maryland Regulations (COMAR) 10.39.04.09A (a portion of the Maryland Nurse Practice Act) states that "administration of medication is a licensed nursing function." Nurses may delegate routine medication administration to Certified

[4] Md. Code Ann., Health-Occupations § 12-6C-09(b), "[a] wholesale distributor may supply prescription drugs only to a person authorized by law to dispense or receive prescription drugs."

Medication Technicians. The school nurse has the authority to train non-medical school personnel to administer emergency medications, including but not limited to naloxone, consistent with the Maryland Nurse Practice Act and school health services guidelines. Local SHS programs operate as a collaboration between the LEA and the LHD. Collaboration with the LHD to provide the training is encouraged but does not eliminate the school nurse's role in being fully responsible for the act of medication administration in the school setting.

While the passage of the HOPE Act has removed the training and education requirements for individuals within the community to legally obtain, possess and administer naloxone, LEA policy and nursing practice standards should include training for school nurses and other SHS staff as well as non-medical school staff to effectively implement the requirements of the Start Talking Maryland Act (Educ. §7-426.5).

Monitoring and evaluation of the capability and maintenance of skills of non-medical school staff to administer naloxone may be done by the school nurse or another qualified person (e.g., from the local health department). This process should be included in the LSS policy.

An LEA may choose to collaborate with the LHD to provide training appropriate for school nurses, school health services personnel, and other personnel on the recognition of suspected opioid overdose and the administration of naloxone. An LEA may choose to enhance the implementing of the naloxone administration policy and become an ORP training entity. This may be in keeping with best practice in SHS program implementation by providing training, monitoring and oversight of naloxone administration practices in the school setting.

19. What liability protections exist for non-medical school personnel when administering naloxone in a medical emergency?

There are several provisions for immunity for individuals who respond in good faith to an individual believed to be experiencing an opioid overdose. The Start Talking Maryland Act states that except for any willful or grossly negligent act, the school nurse, other school health services personnel, or other school personnel who respond in good faith to an overdose emergency of a student may not be held personally liable for any act or omission in the course of responding to the emergency. Maryland Code, Health-General Article §13-3108 (a) states that an individual who administers naloxone to an individual who is or in good faith is believed to be experiencing an opioid overdose shall have immunity from liability under §§ 5-603 and 5-629 of the Courts and Judicial Proceedings Article.

The Maryland Code, Courts and Judicial Proceedings Article §§5-603 and 5-629 provide immunity from civil liability to anyone who responds to a medical emergency as long as they do so in good faith, do not charge the victim, and relinquish care to emergency medical personnel upon their arrival. Persons who in good faith administer personally obtained naloxone in lieu of the school stock naloxone are covered by the immunity protections in Maryland Code, Health-General Article §13-3108 (a).

School personnel may also be protected under the Maryland Code, Education Article §4-106 and Courts and Judicial Proceedings Article §5-518. Those statutes provide certain protections from personal liability to school personnel who act within the scope of their employment and without malice or gross negligence. These statutes also protect volunteers and school board members under certain circumstances.[5]

School nurses who are State employees also have the immunity from liability described in Maryland Code, Courts and Judicial Proceedings Article §5-522(b) for acts performed within the scope of their duties and without malice or gross negligence.

20. How is the administration of naloxone in schools reported?

On or before October 1 of each year, each public school will report on a form required by the Maryland State Department of Education (MSDE), each incident requiring the use of naloxone or other overdose-reversing medication at the school. The SHS program will provide a required form to be submitted by each LEA to MSDE. Individual schools should not report directly to MSDE.

In addition, the administration of naloxone may also be reported by calling the Maryland Poison Center at 1-800-222-1222.

If naloxone used was dispensed by an authorized ORP entity, naloxone administration may also be reported to the ORP entity.

Overdose Response Program (ORP)

21. What is the Overdose Response Program?

In 2013, the Maryland General Assembly created the ORP. The provisions of the ORP can be found in the Maryland Code, Health-General Article, Title 13, Subtitle 31. The corresponding regulations are in the Code of Maryland Regulations 10.47.08.01-.12.

The purpose of the ORP, a program that operates in the absence of a nursing protocol, is to authorize organizations to conduct overdose response trainings and naloxone distribution to non-medical community members who are likely able to assist someone experiencing an opioid overdose to help prevent a fatality when medical services are not immediately available. The Overdose Response Programs facilitate access to naloxone either through referral to a pharmacy or dispensing at the time of training.

The MDH oversees the ORP, authorizes private or public entities to conduct training locally, sets standards for the core training curriculum, collects public health data on entity program operations, and provides technical assistance to programs.

Training under the ORP, while still available, is no longer required for a pharmacist in Maryland to dispense naloxone to an individual pursuant to the HOPE Act.

22. How do private or public entities become authorized training entities under the ORP?

[5] This information does not constitute legal advice. Individuals should consult their school system attorney with any specific questions or concerns.

The MDH Behavioral Health Administration (BHA) authorizes local training programs under the ORP. Any public or private entity can apply to become an authorized training entity under the ORP. The ORP application form may be found at https://bha.health.maryland.gov/NALOXONE/Pages/How-to-Become-an-ORP.aspx. The application process involves a written agreement with a licensed healthcare provider, as well as dispensing protocols, if the entity intends to prescribe and dispense naloxone. BHA will work with programs to complete the application and ensure protocols are in place. Once authorized, program status is valid for two years and may be renewed.

An LEA may choose to have the local SHS program become an approved ORP training entity. Information on how to become an ORP training entity may be found in the resources section of this document.

Resources

23. Where can I find additional information?

Adapt Pharma is a pharmaceutical company with a program that offers naloxone for schools.

http://www.businesswire.com/news/home/20160125006228/en/Adapt-Pharma-Offer-U.S.-High-Schools-Free

Before it's too late is a statewide effort to bring awareness to the rapid escalation of the heroin, opioid, and fentanyl crisis in Maryland–and to mobilize all available resources for effective prevention, treatment, and recovery before it's too late. http://beforeitstoolate.maryland.gov/

Maryland Department of Health, Behavioral Health Administration:

Maryland Certified Treatment Directory provides a listing of all state certified substance abuse treatment programs in Maryland. https://bha.health.maryland.gov/Pages/Maryland-Certified-Treatment-Directory.aspx

Naloxone Saves Lives website provides information on naloxone products and administration.
https://bha.health.maryland.gov/NALOXONE/Pages/Naloxone.aspx

Overdose Prevention in Maryland website provides information related to overdose prevention.
https://bha.health.maryland.gov/OVERDOSE_PREVENTION/Pages/Index.aspx

Overdose Response Program (ORP)
https://bha.health.maryland.gov/NALOXONE/Pages/Home.aspx

Grief Recovery After a Substance Passing (GRASP) provides resources and support for individuals/families who have lost a loved one to substance abuse or addiction. http://grasphelp.org/. GRASP Chapter meeting information can be found at http://grasphelp.org/meetings/

Harm Reduction Coalition is a national harm reduction organization with resources on opioid overdose prevention and establishing take-home naloxone programs. http://harmreduction.org/issues/overdose-prevention/

Learn to Cope is a nonprofit organization that provides support for parents and family members dealing with a loved one addicted to heroin, prescription opioids and other drugs. http://www.learn2cope.org/

Naloxone and Overdose Prevention for Law Enforcement Toolkit (Rhode Island) provides a tool kit with training materials for law enforcement personnel. http://www.noperi.org/files/LEO/LEO%20toolkit.pdf

National Association of School Nurses *Naloxone use in the school setting: The role of the school nurse* (Position Statement). Silver Spring, MD. https://www.nasn.org/PolicyAdvocacy/PositionPapersandReports/NASNPositionStatementsFullView/tabid/462/ArticleId/854/Naloxone-Use-in-the-School-Setting-The-Role-of-the-School-Nurse-Adopted-June-2015. (Accessed 3/15/2017)

Opioid Overdose Prevention, Bureau of Substance Abuse Services, Massachusetts Department of Health, provides comprehensive information and educational materials on opioid overdose prevention and naloxone distribution. http://www.mass.gov/eohhs/gov/departments/dph/programs/substance-abuse/prevention/opioid-overdose-prevention.html

Partnership for Drug-Free Kids ™ provides substance abuse prevention and other resources for parents. http://drugfree.org/

Project Lazarus provides a model for community-based naloxone distribution and opioid overdose prevention. http://projectlazarus.org/

StopOverdose.org provides opioid overdose prevention education resources from Washington State. http://stopoverdose.org/

Toward the Heart is a Canadian harm reduction organization with overdose prevention and naloxone training resources, including resources for family members of opioid users. http://towardtheheart.com/naloxone/

U.S. Department of Health and Human Services (HHS) About the Epidemic webpage provides information from HHS on the opioid epidemic. https://www.hhs.gov/opioids/about-the-epidemic/

U.S. Substance Abuse and Mental Health Services Administration (SAMHSA)

Behavioral Health Treatment Services Locator webpage is a source of information for persons seeking treatment facilities in the United States or U.S. Territories for substance abuse/addiction and/or mental health problems. https://findtreatment.samhsa.gov/

Behavioral Health Treatments and Services webpage provides information on how health care professionals address common mental illnesses and substance use disorders and how SAMHSA helps people access treatments and services. https://www.samhsa.gov/treatment

http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2016/SMA16-4742

Opioid Overdose Prevention Toolkit, which includes information about administering naloxone.

Opioids webpage provides facts on the misuse and abuse of prescription opioids. https://www.samhsa.gov/atod/opioids

24. Who can I contact for additional information?

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