



Maryland Overdose Response Program Statewide Naloxone Standing Order Guidance for Pharmacy Dispensing Updated July 2022

Summary

Jinlene Chan, MD, MPH, (NPI # 1194847624), Deputy Secretary for Public Health Services, Maryland Department of Health (MDH), has issued an updated statewide standing order allowing all Maryland-licensed pharmacists to dispense any formulation of naloxone, including any necessary supplies for administration, to any individual. This document was created by the MDH Overdose Response Program (ORP) and provides information for pharmacists who wish to dispense naloxone under the statewide standing order.¹

Legal Protections for Pharmacists

Maryland law protects pharmacists from civil lawsuits and disciplinary action from their licensing board when dispensing naloxone and necessary paraphernalia to an individual in good faith and in accordance with the law.²

Background

Opioid Addiction and Overdose: Opioid addiction and overdose is a public health crisis in Maryland and across the country. Rising overdose death rates have been driven by the misuse of and addiction to pharmaceutical opioid analgesics, which has occurred alongside increased use of heroin and illicitly manufactured synthetic opioids, including fentanyl. The number of overdose deaths in Maryland has more than quadrupled since 2011 (from 671 in 2011 to 2,799 in 2020), with the majority of these deaths being related to opioids and increasingly involving illicitly manufactured fentanyl. In 2020, there were 2,518 overdose deaths involving opioids in Maryland; this represents 90% of all intoxication deaths in Maryland.³ Preliminary data for 2021 are similar, with 89.4% of overall unintentional alcohol and drug-related deaths attributable to opioids. The Centers for Disease Control and Prevention has called opioid overdose an epidemic responsible for the deaths of 130 people every day in the United States.⁴

Naloxone: Naloxone is a prescription opioid antagonist medication long used in emergency medicine to safely and effectively reverse potentially fatal respiratory depression caused by opioid overdose. For over 20 years, overdose education and naloxone distribution programs have successfully trained non-medical community members on opioid overdose recognition and response using naloxone. Naloxone distribution has demonstrated effectiveness at reducing the risk of opioid overdose death.⁵

¹ Many individuals may be lawfully prescribed naloxone directly by their healthcare provider. These prescriptions should be dispensed in the usual course of business and a pharmacist's professional practice. This document provides guidance specific to naloxone dispensing under Dr. Chan's statewide standing order.

² Health-General Article § 13-3107(c) and § 13-3108(b), Annotated Code of Maryland.

³ Maryland Department of Health annual and quarterly overdose death reports are available at <https://health.maryland.gov/vsa/Pages/overdose.aspx> and <https://beforeitstoolate.maryland.gov/resources-2/>.

⁴ For a national perspective, see the CDC's website: <https://www.cdc.gov/drugoverdose/epidemic/index.html> Accessed May 12, 2017.

⁵ Giglio, RE, et.al. "Effectiveness of bystander naloxone administration and overdose education programs: a meta-analysis." *Injury Epidemiology* (2015)

Maryland Overdose Response Program (ORP): Authorized by law in 2013,⁶ the ORP was created to increase access to naloxone in Maryland. Administered by the Maryland Department of Health, the ORP:

- Promotes education and awareness of opioid overdose risk and use of naloxone in overdose response;
- Provides technical assistance to healthcare providers, public health and safety authorities, community organizations, and others on implementing overdose education and naloxone distribution programs;
- Authorizes organizations to conduct overdose response training and naloxone distribution to non-medical community members who may be able to assist someone experiencing an opioid overdose;
- Purchases naloxone for community distribution;
- Provides funding to local health authorities to support community overdose response programs; and
- Collects and reports data on naloxone distribution activities throughout the state.

Statewide Standing Order

Jinlene Chan, MD, MPH, Deputy Secretary for Public Health, Maryland Department of Health, has issued an updated statewide standing order allowing all Maryland-licensed pharmacists to dispense any formulation of naloxone, including the necessary supplies for administration, to any individual.⁷ *A pharmacist does not need a person-specific paper or electronic prescription in order to lawfully dispense under the standing order.*

Pharmacist/Pharmacy Applicability: This standing order allows pharmacists to dispense at “brick and mortar” community pharmacies as well as from closed-door mail-order pharmacies. Maryland-licensed pharmacists dispensing from mail-order pharmacies must ensure compliance with the legal requirements of their home state.

Patient Applicability: The standing order allows dispensing to any individual. There are no age restrictions. An individual is not required to have previously received training or education in opioid overdose response with naloxone in order for a pharmacist to legally dispense naloxone under the standing order.

Naloxone Formulation: This standing order allows for dispensing of **two (2) doses** of naloxone hydrochloride and necessary paraphernalia for the administration of any formulation. Pharmacists may use clinical judgment in determining the specific naloxone formulation (2mg, 4mg, or 8mg), considering the lowest milligram dosage required to safely reverse an overdose, the individual’s preference, past training on overdose response, and insurance coverage. Provide basic instructions on calling 911 as soon as an overdose is witnessed, providing rescue breathing if an individual is unresponsive, and monitoring the overdose until professional help arrives. Formulation options available and instructions for use under this standing order are outlined below.

- A. Intranasal naloxone spray kits must contain a minimum of the following:
- One package of two doses of naloxone nasal spray.
 - **Directions for use:** Deliver one spray into one nostril (do not “prime” or test the spray device before spraying it into the nostril, as this will waste the medicine). Repeat with a second nasal spray device in the other nostril if there is no response after 3 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.

2:10. DOI 10.1186/s40621-015-0041-8. <http://www.injepijournal.com/content/pdf/s40621-015-0041-8.pdf> Accessed November 30, 2015.

⁶ Health-General Article, Title 13, Subtitle 31, Annotated Code of Maryland. Program regulations: COMAR 10.47.08.

⁷ The statewide standing order is authorized under Health-General Article § 13-3106(b), Annotated Code of Maryland.

B. Intramuscular naloxone kits must contain a minimum of the following:

- Two single-use 1 ml vials of naloxone hydrochloride.
- Two intramuscular needles with syringes.
- **Directions for use:** Assemble the intramuscular naloxone kit by following the step-by-step instructions below:
 - Uncap the naloxone vial and uncap the needle on the syringe.
 - Insert the needle through the rubber membrane on the naloxone vial, turn the vial upside down, draw up 1 ml of naloxone liquid, and withdraw the needle.
 - Insert the needle into the muscle of the upper arm or thigh of the victim, through the clothing if needed, and push the plunger to inject all of the naloxone.
 - Repeat the injection with a second 1 ml vial of naloxone if there is no response after 3 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.

C. Intranasal naloxone with atomizer kits must contain a minimum of the following:

- Two 2-ml Luer-Jet Luer-lock syringes prefilled with naloxone hydrochloride (2 mg/2 ml)
- Two mucosal atomization devices (MAD).
- **Directions for use:** Assemble the mucosal atomization device by following step-by-step instructions below:
 - Remove two colored caps from the delivery syringe and one from the naloxone vial.
 - Screw the naloxone vial gently into the delivery syringe.
 - Screw the mucosal atomizer device onto the tip of the syringe.
 - Spray half (1 ml) of the naloxone in one nostril and the other half (1 ml) in the other nostril.
 - Repeat if there is no response after 3 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.

Selecting a naloxone formulation

The pharmacist should familiarize themselves with the various formulations of naloxone (2mg, 4mg, and 8mg), and be prepared to discuss them with the patient. Selecting a naloxone formulation to dispense may be based on patient preference, considering the lowest milligram dosage required to reverse an overdose. While training is not required to obtain naloxone, the patient may have received overdose response training for a particular formulation and may prefer to obtain that one. Another preference may be for a nasal spray over injectable naloxone because of comfort with syringes.

When considering the various naloxone nasal sprays, there are different strengths. The Kloxxado® 8mg formulation adheres to the same pharmacokinetic mechanism as Narcan® 4mg Nasal Spray, but has not been as robustly studied in the community and published in the scientific literature to date. Currently, the scientific literature suggests that successful reversal of opioid overdose, including fentanyl-related overdoses, can be achieved with lower dose formulations of naloxone.⁸ Should patients choose the 8 mg formulation, it is important to make them aware of the increased potential for recipients to exhibit opioid withdrawal symptoms after administration.

When possible, include, or direct the individual to the appropriate place to acquire, additional materials to use when responding to an overdose, as relevant to the particular formulation and specified in the standing order.

⁸ Hill, L. G., Zagorski, C. M., & Loera, L. J. (2022). Increasingly powerful opioid antagonists are not necessary. *The International journal on drug policy*, 99, 103457.

ORP entities may provide training on the administration of one or all naloxone formulations. Ask the individual whether they have been trained to use a specific formulation, or simply which formulation they would prefer. If the individual is unsure, describe the available formulations to assess their comfort level with each. Consider demonstrating the use of any particular formulation if appropriate for the individual.

Note: The standing order does not require the pharmacist to verify the individual's knowledge, skills, or abilities prior to dispensing. When dispensing naloxone to a minor, the pharmacist should use their professional judgment to assess the minor's ability to appropriately identify and respond to an opioid overdose, including the proper administration of naloxone.

Insurance Coverage

Maryland Medical Assistance: Maryland Medicaid covers naloxone (NARCAN® nasal spray, prefilled syringe, and single-dose vials) and the atomizer used to administer the medication in combination with the 2mg/2mL single-dose Luer-Jet prefilled syringe. Only naloxone products included on the Medicaid Preferred Drug List are available for reimbursement under this standing order.⁹ Any Maryland Medicaid preferred naloxone product, including NARCAN® nasal spray and generic naloxone (0.4mg/mL single dose vials and 2mg/2mL prefilled syringe), is covered through the Pharmacy Program with a \$1 copay.

The atomizer is covered through the Durable Medical Equipment/Disposable Medical Supplies (DME/DMS) Program. Pharmacy providers must also be enrolled as a DME/DMS provider to be reimbursed for the atomizer. Pharmacies may become a DME/DMS provider by enrolling via ePREP (ePREP.health.maryland.gov). For ePREP resources, visit <https://mmcp.health.maryland.gov/Pages/ePREP.aspx>.

Providers should bill the medication through the Point-of-Sale System using the appropriate National Drug Code. The atomizer is billed using the procedure code A4210, either by paper on the CMS-1500 form, or electronically via eMedicaid. For billing instructions please visit: <https://mmcp.health.maryland.gov/Pages/Billing-Instructions.aspx>. To find a DME provider, please contact 410-767-7283.

Members can contact the Medicaid DME Unit to locate a participating pharmacy. Any further questions regarding billing of the drug can be directed to the Pharmacy Program's claims processor at 1-800-932-3918. Questions about the atomizer can be directed to the DME Program at 410-767-7283.

Commercial Insurance

Commercial insurance carriers vary in their policies related to pharmacy coverage of naloxone. Pharmacists should contact the individual's insurance carrier directly for more information.

Uninsured or Prohibitive Copays

If a patient attempts to access naloxone at a pharmacy and does not have insurance or finds the copay cost prohibitive, pharmacists may direct them to a local Overdose Response Program (ORP) for access to free naloxone and training. Pharmacists may find it helpful to provide patients with the contact information for local Overdose Response Programs. Pharmacists can contact or direct patients to mdh.naloxone@maryland.gov or visit bit.ly/MDHaccessHR for assistance locating local ORPs.

Dispensing Instructions

Obtain a faxed copy of the standing order

⁹ <https://mmcp.health.maryland.gov/pap/pages/Preferred-Drug-List.aspx>

A faxed copy meets the Maryland Medicaid Pharmacy Program's requirements for tamper resistant prescriptions, therefore allowing the pharmacy to seek reimbursement for dispensing to individuals with Medical Assistance. To request a faxed copy, send an email to mdh.naloxone@maryland.gov including the name, address, and fax number for your pharmacy.

Keep the standing order on file

A tamper proof copy of the standing order prescription will be faxed to your pharmacy and should be kept on file at the pharmacy in a manner that is accessible to pharmacists and other pharmacy staff who need to reference it. *This standing order replaces a paper prescription.*

Dispense naloxone and bill the individual's insurance as for a typical prescription

Use Dr. Chan's NPI # 1194847624 when billing the individual's insurance carrier and documenting dispensing in the pharmacy management system. Including a paper or electronic copy of the standing order in the dispensing record will suffice as documentation. *Include the copy as you would a paper prescription.* Label the naloxone in accordance with prescription labeling requirements.

Provide the individual with additional educational materials

Pharmacists are encouraged to provide counseling and instruction on recognizing the signs and symptoms of opioid overdose, the importance of calling emergency medical services, naloxone administration, administering rescue breathing, and other topics as appropriate. For instance, a plastic face shield for rescue breathing may be included with any formulation. Alcohol swabs to sterilize the injection site may be included when dispensing any formulation meant for injection. Additionally, ORPs and other organizations provide educational resources for patients, pharmacists, and other healthcare providers. Visit prescribetoprevent.org or naloxonemd.org for more information.

Optional: Reporting Naloxone Use

The ORP collects data on naloxone administrations by individuals to whom naloxone is dispensed. This information is important for documenting lives saved and demonstrating the effectiveness of the program. If an individual tells you about their use of naloxone, request that they report using *one* of the following options. Pharmacists may also choose to provide information about how to report naloxone use to patients upon initial receipt of naloxone.

Fill out the ORP Naloxone Use Report which is available as a webform at bit.ly/naloxoneusereport.

Call the Maryland Poison Center (MPC) at 1-800-222-1222. MPC works closely with the ORP to collect data on naloxone use. All personal information provided to MPC is kept confidential.

Notify the organization from which they received training (in cases where the individual received naloxone training from an authorized Overdose Response Program).

Additional Resources for Pharmacists and Community Members

- "Naloxone Access: A Practical Guideline for Pharmacists" College of Psychiatric and Neurologic Pharmacists: <http://prescribetoprevent.org/wp2015/wp-content/uploads/naloxone-access.pdf>
- Scope of Pain Module: "Overdose Education and Naloxone Rescue Kits for Prescribers and Pharmacists" Boston University: http://www.opioidprescribing.com/naloxone_module_1-landing
- Patient education, videos, and additional overdose prevention education materials: prescribetoprevent.org.

Contact the Maryland Overdose Response Program

Email: mdh.naloxone@maryland.gov Website: www.naloxonemd.org



Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

Maryland Statewide Standing Order for Opioid Overdose Reversal Drug
ISSUE DATE: July 21, 2022

Background

Naloxone is a prescription medication indicated for the reversal of respiratory depression or unresponsiveness due to opioid overdose. Under Maryland law¹, a physician employed by the Maryland Department of Health (MDH) may prescribe an opioid overdose reversal drug by issuing a standing order which authorizes dispensing to any individual who may be at risk of opioid overdose or in a position to assist someone experiencing an opioid overdose. A person-specific paper or electronic prescription is not required to dispense under this standing order, and an individual is not required to have previously received training or education on opioid overdose response to be dispensed with naloxone. An individual prescribed and dispensed naloxone under this standing order may possess naloxone and the necessary supplies for its administration and administer it to anyone they believe may be experiencing an opioid overdose. More information about opioid overdose response, naloxone and guidance to pharmacists regarding this standing order is available from the Maryland Overdose Response Program by email at mdh.naloxone@maryland.gov and online at www.naloxonemd.org.

Statewide Standing Order

This standing order is issued by **Jinlene Chan, MD, MPH (NPI # 1194847624), Deputy Secretary for Public Health, Maryland Department of Health**. It authorizes any Maryland-licensed pharmacist to dispense unlimited prescriptions and refills of naloxone, an opioid overdose reversal drug, and devices for its administration to any individual in accordance with the steps and conditions of this order, enumerated below.

1. Provide consultation with the individual regarding the naloxone dosage (2 mg, 4 mg or 8 mg) and formulation (intranasal or intramuscular) that is most appropriate. The pharmacist should use their clinical judgment and the additional information on formulation and dosage selection provided in the Guidance Document accompanying this standing order. Considerations include:
 - a. Preference for the lowest milligram dosage required to safely reverse an overdose, given that higher doses of naloxone may precipitate opioid withdrawal symptoms such as nausea, vomiting, diarrhea, restlessness, agitation, anxiety, and tremors;
 - b. The individual's preference, given past training on overdose response; and,
 - c. The individual's insurance coverage for opioid overdose reversal drugs.
2. Regardless of the formulation selected, directions for use include calling 911 as soon as an overdose is witnessed, providing rescue breathing if an individual is unresponsive, and monitoring the overdose until professional help arrives.

3. Select and dispense **two (2) doses** of naloxone hydrochloride and necessary paraphernalia for administration. Formulation options available and instructions for use under this standing order include:

a. **Intranasal naloxone spray kits**

- i. Provide one package of two doses of naloxone nasal spray.
- ii. Verbally communicate to the individual that there is an increased potential for recipients to exhibit opioid withdrawal symptoms after administration of greater than 4 mg of naloxone.
- iii. **Directions for use:**
 1. Deliver one spray into one nostril (do not "prime" or test the spray device before spraying it into the nostril, as this will waste the medicine).
 2. Repeat with a second nasal spray device in the other nostril if there is no response after 3 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.

b. **Intramuscular naloxone kits**

- i. Provide two single-use 1 ml vials of naloxone hydrochloride.
- ii. Include two intramuscular needles with syringes.
- iii. **Directions for use:** Assemble the intramuscular naloxone kit by following the step by step instructions below:
 1. Uncap the naloxone vial and uncap the needle on the syringe.
 2. Insert the needle through the rubber membrane on the naloxone vial, turn the vial upside down, draw up 1 ml of naloxone liquid, and withdraw the needle.
 3. Insert the needle into the muscle of the upper arm or thigh of the victim, through the clothing if needed, and push the plunger to inject all of the naloxone.
 4. Repeat the injection with a second 1 ml vial of naloxone if there is no response after 3 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.

c. **Intranasal naloxone with atomizer kits**

- i. Provide two 2-ml Luer-Jet Luer-lock syringes prefilled with naloxone hydrochloride (2 mg/2 ml)
- ii. Include two mucosal atomization devices (MAD).
- iii. **Directions for use:** Assemble mucosal atomization device by following step by step instructions below:
 1. Remove two colored caps from the delivery syringe and one from the naloxone vial.
 2. Screw the naloxone vial gently into the delivery syringe.
 3. Screw the mucosal atomizer device onto the tip of the syringe.
 4. Spray half (1 ml) of the naloxone in one nostril and the other half (1 ml) in the other nostril.
 5. Repeat if there is no response after 3 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.

I declare this standing order as a statewide prescription for the dispensing of naloxone.



Jinlene Chan, MD, MPH, Deputy Secretary for Public Health, Maryland Department of Health
NPI # 1194847624

Effective Date: July 1, 2022

Expiration Date: June 30, 2024

¹Health-General Article, Title 13, Subtitle 31, Code of Maryland