

Maryland Overdose Response Program

Statewide Naloxone Standing Order

Guidance for Pharmacy Dispensing



I. Summary

Jinlene Chan, MD, MPH, FAAP (NPI # 1194847624), Assistant Secretary of Health, Maryland Department of Health (MDH), has issued a statewide standing order allowing all Maryland-licensed pharmacists to dispense 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

II. 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 state law.²

III. 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 tripled since 2010, with the majority of these deaths being related to opioids and increasingly involving illicitly manufactured fentanyl. In 2017, there were 2,009 overdose deaths involving opioids in Maryland; this represents 88% of all intoxication deaths in Maryland in 2017.³ 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 nearly 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

Maryland Overdose Response Program: 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 trainings and naloxone distribution to non-medical community members who may be able to assist someone experiencing an opioid overdose;
- Provides funding to local health authorities to support community overdose response programs; and
- Collects and reports data on naloxone distribution activities throughout the state.

IV. Statewide Standing Order

Jinlene Chan, MD, MPH, FAAP, Assistant Secretary of Health, Maryland Department of Health, has issued a statewide standing order allowing all Maryland-licensed pharmacists to dispense 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 administration. A pharmacist may dispense any of the commercially available naloxone formulations listed below based on the preference of the individual or the training they received to administer a specific formulation:

1. For intranasal administration

- NARCAN® 4mg/0.1mL nasal spray. Include face shield for rescue breathing if available.
Directions for use: Administer a single spray of NARCAN® in one nostril. Repeat after 3 minutes if no or minimal response.

Or

- 2mg/2mL single-dose Luer-Jet prefilled syringe. Include one luer-lock mucosal atomization device (MAD 300) per dose dispensed. Include face shield for rescue breathing if available.
Directions for use: Spray 1 mL in each nostril. Repeat after 3 minutes if no or minimal response.

2. For intramuscular injection

- 0.4mg/mL in 1mL single-dose vials. Include one 3cc, 23g, 1” syringe per dose dispensed. Include face shield for rescue breathing and alcohol swabs if available.
Directions for use: Inject 1 mL IM in shoulder or thigh. Repeat after 3 minutes if no or minimal response.

3. For intramuscular or subcutaneous injection

- EVZIO® 2mg/0.4mL auto-injector, #1 Two-pack
Directions for use: Follow audio instructions from device. Place on thigh and inject 0.4 mL. Repeat after 3 minutes if no or minimal response.

V. 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.*⁸ 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.

VI. Dispensing Instructions

1. Obtain a faxed copy of the standing order

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.

2. Keep the standing order on file

A faxed copy of the standing order 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.

3. Select the appropriate naloxone formulation for dispensing

The specific naloxone formulation for dispensing should be selected based on the preference of the individual or in accordance with the training they received. ORP entities may provide training on 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 gauge their comfort level. Consider demonstrating use of any particular formulation if appropriate for the individual.

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. 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.

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.

4. 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.

5. 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, and other topics as appropriate. The ORP and other organizations provide educational resources for patients, pharmacists, and other healthcare providers. Visit prescribetoprevent.org or the [ORP website](#) for more information.

VII. 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:

1. Fill out the ORP "Naloxone Use Report," which you may request by sending an email to mdh.naloxone@maryland.gov, and send completed forms to the ORP at the same address.
2. 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.
3. If the individual received training from an authorized organization, notify the organization so they can report the use to MDH.

VIII. 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.
- Maryland Overdose Response Program online naloxone training for community members: <http://www.getnaloxonenow.org/signup.aspx>.

IX. Contact the Maryland Overdose Response Program

Email: mdh.naloxone@maryland.gov

Phone: (410) 767-5440

Website: www.naloxonemd.org

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://bha.health.maryland.gov/overdose_prevention/pages/data-and-reports.aspx.

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) 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.

⁸ <https://mmcp.health.maryland.gov/pap/pages/Preferred-Drug-List.aspx>