

# **Maryland Overdose Response Program**

## **Statewide Naloxone Standing Order**

### **Guidance for Pharmacy Dispensing**



#### **I. Summary**

Howard Haft, M.D. (NPI # 1639132152), Deputy Secretary for Public Health Services, Maryland Department of Health and Mental Hygiene (DHMH) 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 DHMH Overdose Response Program (ORP) and provides information for pharmacists who wish to dispense naloxone under the statewide standing order.<sup>1</sup>

#### **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.<sup>2</sup>

#### **III. Background**

**Opioid Addiction and Overdose:** Opioid addiction and overdose is a growing public health problem in Maryland and across the country. For more than a decade, rising overdose death rates have been driven primarily by the misuse of and addiction to pharmaceutical opioid analgesics, including oxycodone, hydrocodone, methadone and fentanyl. Prescription opioid addiction has occurred alongside increased use of heroin, another opioid that has become less expensive, more potent and more accessible across the country. The Centers for Disease Control and Prevention has called opioid overdose an epidemic responsible for the deaths of 91 people every day in the United States.<sup>3</sup> In Maryland, overdose deaths doubled between 2010 and 2015, driven largely by a more than tripling of heroin-related deaths and a 12-fold increase in deaths related to illicitly-manufactured fentanyl since 2012.<sup>4</sup>

**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.<sup>5</sup>

**Maryland Overdose Response Program:** Authorized by law in 2013,<sup>6</sup> the ORP was created to increase access to naloxone in Maryland. Administered by the DHMH Behavioral Health Administration, 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 are likely 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

Howard Haft, M.D., Deputy Secretary for Public Health Services, 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.<sup>7</sup> *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. 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<sup>®</sup> 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.*<sup>8</sup> Any Maryland Medicaid preferred naloxone product, including NARCAN<sup>®</sup> 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 [apply online](#)<sup>9</sup> or call the Provider Enrollment Unit at 410-767-5340 to become a DME/DMS provider.

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. The links below provide instructions for billing:

- [Pharmacy Providers](#)<sup>10</sup>
- [DME/DMS Providers \(electronic\)](#)<sup>11</sup>
- [DME/DMS Providers \(paper\)](#)<sup>12</sup>

A list of DME/DMS pharmacy providers is [available on the ORP website](#) for your reference. Members can also 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 410-767-1739.

### 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 [dhmh.naloxone@maryland.gov](mailto:dhmh.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.

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

Use Dr. Haft's NPI # 1639132152 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](http://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](#)," available on the ORP website, and send to the ORP by email at [dhmf.naloxone@maryland.gov](mailto:dhmf.naloxone@maryland.gov) or fax to 410-402-8601.
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 the ORP.

## **VIII. Optional: Reporting Naloxone Dispensing**

Naloxone is not a Controlled Dangerous Substance (CDS) and dispensing is not required to be reported to the Maryland Prescription Drug Monitoring Program (PDMP). Naloxone dispensed pursuant to a person-specific prescription or under the statewide standing order may be *voluntarily* reported to the PDMP for use by DHMH for public health program planning and evaluation purposes. Naloxone dispensing data reported to the PDMP will be accessible only by DHMH staff and will not be visible to PDMP users who are querying or requesting prescription information for clinical, investigational, or research use. Contact the ORP at [dhmf.naloxone@maryland.gov](mailto:dhmf.naloxone@maryland.gov) for more information.

## IX. 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](http://www.opioidprescribing.com/naloxone_module_1-landing)
- Patient education, videos, and additional overdose prevention education materials: [prescribetoprevent.org](http://prescribetoprevent.org).
- Maryland Overdose Response Program online naloxone training for community members: <http://www.getnaloxonenow.org/signup.aspx>.

## X. Contact the Maryland Overdose Response Program

Email: [dhmh.naloxone@maryland.gov](mailto:dhmh.naloxone@maryland.gov)

Phone: Overdose Response Program Administrator (410) 402-8634

Website: [www.naloxonemd.org](http://www.naloxonemd.org)

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<sup>1</sup> 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. Haft’s statewide standing order.

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

<sup>3</sup> For a national perspective, see the CDC’s website: <https://www.cdc.gov/drugoverdose/epidemic/index.html> Accessed May 12, 2017.

<sup>4</sup> Maryland DHMH Vital Statistics Administration: *Drug- and Alcohol-Related Intoxication Deaths in Maryland, 2015*. [https://bha.health.maryland.gov/OVERDOSE\\_PREVENTION/Documents/2015%20Annual%20Report\\_revised.pdf](https://bha.health.maryland.gov/OVERDOSE_PREVENTION/Documents/2015%20Annual%20Report_revised.pdf)

<sup>5</sup> 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.

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

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

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

<sup>9</sup> <https://encrypt.emdhealthchoice.org/emedicaid/webservices?submit=Enroll>

<sup>10</sup> <http://www.mdrxprograms.com/ooep.html#PI>

<sup>11</sup> <https://encrypt.emdhealthchoice.org/emedicaid/>

<sup>12</sup> <https://mmcp.dhmh.maryland.gov/communitysupport/pdf/Billing%20Instruction%20Pages%20DME.pdf>