



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Van Mitchell, Secretary

December 14, 2015

Dear Maryland Pharmacist,

Today, I issued a statewide standing order allowing all Maryland-licensed pharmacists to dispense naloxone without a prescription to community members who have been trained to respond to an opioid overdose under the Maryland Overdose Response Program (ORP). I am writing to ask for your support in this important public health campaign to help save the lives of Marylanders struggling with opioid addiction.

Opioid addiction and overdose has become a major public health challenge in Maryland and across the country. For more than a decade, rising overdose death rates have been driven primarily by growing addiction to prescription opioid analgesics, including oxycodone, hydrocodone, morphine and methadone. The Centers for Disease Control and Prevention has called prescription opioid overdose an “epidemic” responsible for the deaths of 44 people every day in the U.S. Many people who develop problems with prescription opioids have started using heroin as their addiction becomes more severe and pharmaceutical opioids become more costly and difficult to obtain. As a result, heroin-related overdose deaths in Maryland doubled between 2010 and 2014.

Naloxone is an important part of the State’s response to this challenge. Naloxone is an opioid antagonist medication that safely and effectively reverses an opioid overdose. It is not a “drug of abuse” and has a low risk of adverse effects. Despite common assumptions, there is no evidence that naloxone access “enables” more or riskier drug use, though there is growing evidence that it is effective in reducing overdose death risk and creating linkages to addiction treatment and recovery services. Used for decades in emergency medicine, non-medical community members can now be trained and certified to use naloxone through the ORP. This standing order allows you to dispense naloxone to anyone with a valid ORP certificate.

Please find attached a copy of the standing order and a guidance document for pharmacists with detailed information on the ORP and procedures for dispensing under the standing order. Additional information and materials can be found on the ORP website at <http://bha.dhmh.maryland.gov/NALOXONE/>.

Pharmacists play an important role in addiction and overdose prevention not only by expanding access to this life-saving medication, but also by providing valuable information on safe and appropriate use of prescription drugs, connecting patients and their families to important health services and diligent use of the Prescription Drug Monitoring Program. I thank you for your ongoing support of these efforts in Maryland.

Sincerely,

Howard Haft, MD
Deputy Secretary for Public Health Services
Department of Health and Mental Hygiene

Maryland Overdose Response Program

Statewide Naloxone Standing Order



Background

Naloxone is a prescription medication indicated for the reversal of respiratory depression or unresponsiveness due to opioid overdose. The [Maryland Overdose Response Program \(ORP\)](#) was established by the Department of Health and Mental Hygiene (DHMH) in 2013 to increase access to naloxone to reduce opioid overdose deaths throughout the state. The ORP allows non-medical community members to be trained in overdose recognition and response. DHMH authorizes organizations to provide trainings and certify individuals. Certificate holders may be prescribed and dispensed naloxone, either directly or through a standing order, and administer it to someone believed to be experiencing opioid overdose. Under state law, a physician who is employed by DHMH may issue a statewide naloxone standing order, which allows for pharmacists to dispense naloxone to ORP certificate holders in the absence of a person-specific paper or electronic prescription.¹

Statewide Standing Order

This standing order is issued by **Howard Haft, M.D. (NPI # 1639132152), Deputy Secretary for Public Health Services, DHMH**. The standing order authorizes any Maryland-licensed pharmacist to dispense naloxone to any ORP certificate holder in accordance with the conditions of this order, enumerated below.

Upon verification of an individual's ORP certificate, dispense **two (2) doses** of naloxone hydrochloride and necessary paraphernalia for administration. The specific naloxone formulation shall be selected from the list below in accordance with the certificate holder's preference or training to administer a particular formulation.

1. For intranasal administration

- 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.

Or

- NARCAN® 4 mg/0.4mL 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.

2. For intramuscular injection

- 0.4/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® 0.4mg/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.

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

A handwritten signature in black ink, appearing to read "H. Haft", written over a horizontal line.

Howard Haft, M.D., Deputy Secretary for Public Health Services, DHMH

Effective Date: December 14, 2015

Expiration Date: December 14, 2017

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

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 individuals who have been trained and certified under the Maryland Overdose Response Program (ORP). This document provides information for pharmacists who wish to dispense naloxone under the standing order.¹

II. Legal Protections for Pharmacists

A cause of action may not arise against a pharmacist when dispensing naloxone and necessary paraphernalia to an ORP certificate holder in good faith and in accordance with requirements of the ORP law.² This protects pharmacists from civil lawsuits.

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. The Centers for Disease Control and Prevention has called prescription opioid overdose an “epidemic” responsible for the deaths of 44 people every day in the U.S.³ Prescription opioid addiction has led to increased use of heroin, another opioid that has become less expensive, more potent and more accessible across the country. In Maryland, a [60% increase in overdose deaths between 2010 and 2014](#) was largely driven by a doubling of heroin-related deaths.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 (OEND) programs have successfully trained non-medical community members on opioid overdose recognition and response using naloxone. OEND programs have demonstrated effectiveness at reducing the risk of opioid overdose death.⁵

Maryland Overdose Response Program: Pursuant to legislation passed in 2013,⁶ DHMH implemented the ORP to increase access to OEND programs throughout the state. DHMH authorizes organizations to train and certify individuals who are likely able to assist someone experiencing an opioid overdose when emergency medical services are not immediately available. Authorized organizations provide training on identifying opioids and their effects, recognizing the signs of opioid overdose, contacting emergency medical services, administering naloxone and other topics. Individuals who are certified under ORP are legally authorized to be prescribed and dispensed naloxone (either directly or under a standing order) and administer it to someone believed to be experiencing an opioid overdose.

IV. Statewide Standing Order

Howard Haft, M.D., Deputy Secretary for Public Health Services, DHMH, has issued a statewide standing order⁷ allowing all Maryland-licensed pharmacists to dispense naloxone, including any necessary supplies for administration, to any ORP certificate holder. *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 all laws and regulations of their home state.

ORP Certificate Holder Applicability: The standing order allows dispensing to any individual who has been trained and certified by *any* ORP authorized training organization. DHMH has authorized many types of organizations to conduct ORP trainings, including local health departments, behavioral health and pain management providers, law enforcement agencies, fire departments and others. A complete list of authorized organizations can be found on the [ORP website](#).

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 ORP certificate holder and the training they received to administer a specific formulation:

1. For intranasal administration

- 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.

Or

- NARCAN® 4 mg/0.4mL 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.

2. For intramuscular injection

- 0.4/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® 0.4mg/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 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 generic naloxone (0.4/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](#)⁹ 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](#)¹⁰
- [DME/DMS Providers \(electronic\)](#)¹¹
- [DME/DMS Providers \(paper\)](#)¹²

A list of DME/DMS pharmacy providers is [available online](#) 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.

NARCAN®: As of December 10, 2015, NARCAN® 4 mg/0.4mL nasal spray is not commercially available or included under the MMPP formulary. DHMH will issue updated guidance if and when the status of NARCAN® changes.

Commercial Insurance

Commercial insurance carriers vary in their policies related to pharmacy coverage of naloxone. Pharmacists should contact the certificate holder'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 including the name, address and fax number for your pharmacy.¹³

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. **Verify a person's ORP certification status**

If a person is requesting naloxone under the standing order, request to see their ORP certificate. ORP authorized organizations are required to issue a serialized certificate that includes a) the name of the certificate holder, b) the name, address and telephone number of the authorized organization that issued the certificate, c) the certificate's dates of issuance and expiration, d) a serial number and e) this phrase:

"is hereby authorized to obtain a prescription for naloxone in the certificate holder's name, and possess and administer naloxone in accordance with Health-General Article, Title 13, Subtitle 31, Annotated Code of Maryland."

NOTE: If you are unsure about the certificate's validity, you may call the authorized organization listed on the back of the card to confirm they have the person's records on file.

4. **Select the appropriate naloxone formulation for dispensing**

The specific naloxone formulation for dispensing should be selected based on the preference of the certificate holder in accordance with their training. ORP authorized entities may provide training on administration of one or all naloxone formulations. Ask the certificate holder about the formulation(s) they had been trained to use, or simply which formulation they would prefer. If the certificate holder is unsure, describe the available formulations to gauge their comfort level. Consider demonstrating use of any particular formulation as a refresher for the certificate holder.

When possible, include, or direct the certificate holder 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 certificate holder's knowledge, skills or abilities prior to dispensing. Verification of certification status is the only requirement.

5. **Dispense naloxone and bill the certificate holder's insurance as for a typical prescription**

Use Dr. Haft's NPI # 1639132152 when billing the certificate holder'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.

6. **Provide the certificate holder with additional educational materials**

The ORP and other organizations provide educational materials on how to respond to an opioid overdose with naloxone. Visit the [ORP website](#) for more information.

VII. Optional: Reporting Naloxone Use

The ORP collects data on naloxone administrations by certificate holders. This information is important for documenting lives saved and demonstrating the effectiveness of the program. If a certificate holder 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,¹⁴ and send to the ORP by email at dhmf.naloxone@maryland.gov or fax at 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. Tell the authorized organization that trained and certified them. The organization can report the use to the ORP.

VIII. Additional Resources for Pharmacists and Community Members

- “Naloxone Access: A Practical Guide for Pharmacists” College of Psychiatric and Neurologic Pharmacists: <https://cpnp.org/docs/guideline/naloxone/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.
- Online naloxone training for community members: getnaloxonenow.org.

IX. Contact the Maryland Overdose Response Program

Email: dhmf.naloxone@maryland.gov

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

Website: <http://bha.dhmf.maryland.gov/NALOXONE/>

¹ Many individuals may be lawfully prescribed naloxone outside of the ORP. This guidance document is specific to naloxone dispensing under Dr. Haft’s statewide standing order. Prescriptions for naloxone should be dispensed in the usual course of business.

² Health-General Article § 13-3110(b), Annotated Code of Maryland

³ For a national perspective, see the CDC’s website: <http://www.cdc.gov/drugoverdose/index.html> Accessed November 30, 2015.

⁴ Maryland DHMH Vital Statistics Administration: *Drug- and Alcohol-Related Intoxication Deaths in Maryland, 2014*

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 Under Health-General Article § 13-3108, Annotated Code of Maryland, a standing order is a written instruction for dispensing of naloxone to ORP certificate holders. A physician who is employed by DHMH is authorized to issue a standing order. The standing order allows dispensing to ORP certificate holders only. If an individual is not an ORP certificate holder but is interested in receiving naloxone, direct them to an appropriate authorized training organization. Pharmacies interested in becoming an authorized organization should contact DHMH for more information by sending an email to dhmf.naloxone@maryland.gov.

⁸ <https://mmcp.dhmf.maryland.gov/pap/SitePages/druglist.aspx>

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

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

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

¹² https://mmcp.dhmf.maryland.gov/docs/dhmf_cms_1500_billing_instructions_092115.pdf

¹³ On December 14, 2015, DHMH faxed the standing order to all Maryland pharmacies with an active state CDS permit.

¹⁴ <http://bha.dhmf.maryland.gov/NALOXONE/Documents/BHA%20Naloxone%20Use%20Report%205-15.pdf>