



CHANGING
Maryland
for the Better

2017 HOPE Act: Impact on Naloxone Access & the Maryland Overdose Response Program

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Tuesday June 6, 2017



Webinar Overview

- Background on Maryland Overdose Response Program (ORP)
- 2017 HOPE Act: Changes to ORP law
- Identify areas currently under legal & policy review
- Begin soliciting feedback from ORP authorized entities and other stakeholders on changes to program regulations and policies



Background: MD Overdose Response Program

- Authorized by law in 2013: Health-General Article, Title 13, Subtitle 31, Code of Maryland
- Regulations effective March 2014
- Goal: Provide a means of authorizing non-medical individuals to:
 - Receive training on opioid recognition & response w/ naloxone
 - Acquire, possess & administer naloxone to someone experiencing suspected opioid overdose when emergency services not immediately available
- DHMH authorizes “private or public entities” to train and certify individuals
- Certified trainees may be prescribed/dispensed naloxone & administer it in emergency situation



ORP Background Ctd.

- Authorized entities (AE) must est. agreement w/ practitioner who conducts or supervises trainings
- Regulations require entities to:
 - Use DHMH-approved core curriculum
 - Retain training records
 - Report training data to DHMH
- Legal protections for naloxone prescribers/dispensers & individuals who administer naloxone
- Physicians/APNs employed by DHMH/LHDs & AE-affiliated practitioners may Rx naloxone via **standing order**
- Employee/volunteer trainers for AE, LHD RNs and pharmacists authorized to dispense under standing orders
- Providers may Rx naloxone to patients w/o AE training



2017 Heroin & Opioid Prevention Effort (HOPE) & Treatment Act

- Assessment & funding of drug court programs
- Enhance DHMH ability to deny, suspend or revoke state controlled substance prescribing/dispensing permit
- Allow Overdose Fatality Review teams to review non-fatal overdose cases
- Require est. of 24/7 behavioral health crisis treatment centers & toll-free crisis hotline
- Requires healthcare systems & facilities to make opioid use disorder medication prescribers available to patients
- DHMH est. naloxone co-Rx guidelines
- Require hospitals to est. discharge protocol for OD/SUD patients including naloxone Rx
- **Streamlining ORP statutory requirements**



Summary of ORP-Related Changes

- Fewer statutory requirements on ORP AEs will allow for streamlined operations/reduced admin burden
- Standing orders may allow pharmacists to dispense to anyone, not just ORP certificate holders
- All licensed healthcare providers w/ prescribing authority may Rx naloxone to anyone, not just ORP certificate holders or their patients
- Any type of healthcare provider w/ prescribing authority may est. agreement w/ entity & issue standing order
- Criminal and civil immunity protections expanded to include all individuals prescribed/dispensed in accordance w/ law
- Civil and disciplinary immunity protections extended to all healthcare providers w/ prescribing authority



What the HOPE Act *DOES NOT* Do

- Completely remove “training requirement”
 - All available naloxone products available by Rx only, per FDA
 - Rx status presumes use under medical direction
 - Prescriber (& dispenser) have legal obligations to provide drug recipient w/ info/education/training/counseling to ensure use in medically appropriate manner
- Make naloxone “over the counter”
 - There are no FDA-approved OTC naloxone products
 - As Rx drug, naloxone cannot be sold on retail shelf next to aspirin, etc.
 - Pharmacist must still dispense, even if person-specific paper or electronic Rx not required
 - Stating naloxone now “OTC” could give false impression of ease of access; pharmacists/pharmacies still must be educated & comfortable w/ dispensing under standing orders



Statutory Requirements Removed

- AE issuance of certificates to trainees
- Age restriction on trainees
- Licensed practitioner supervises or conducts trainings
- Supervisory agreements between practitioner & entity; new language requires agreements that cover dispensing protocols
- Specific training content
- Trainee application to AE using DHMH-approved form



IMPORTANT: Regulations Still Effective

- COMAR 10:47:08
- ORP sections of HOPE Act drafted with intent to remove many requirements currently in regulations
- Until changed, regulations remain effective where not contradicted/superseded by statute
- Legal review being conducted to identify specific regulations affected by HOPE Act
- BHA intent to expedite stakeholder feedback & regulations update
- **AEs should continue to abide by current regulations until updates take effect**



Standing Orders

- May be issued by a licensed healthcare provider w/ prescribing authority who:
 - Is employed by DHMH or LHD
 - **Has a written agreement w/ AE to establish dispensing protocols**
- Pharmacists & employee/volunteer of AE may still dispense under SO
- Effective 6/1/17 (regulations to contrary nullified):
 - Prescribers may issue SO allowing dispensing to any individual
 - Individuals not required to be trained by ORP AE for pharmacist to dispense under SO



Updated Statewide Standing Order: Dr. Haft

- Dr. Howard Haft, DHMH Dep. Sec. for Public Health Services, issued updated statewide SO for pharmacist dispensing effective 6/1/17
- Allows dispensing by any MD-licensed pharmacist to any individual who may be at risk of opioid OD or in a position to assist someone experiencing opioid OD
- ORP issued updated pharmacist guidance as well
- SO, pharmacist guidance & other docs faxed to all MD pharmacies
- Pharmacies should keep faxed copy on file for Medicaid billing purposes
- Pharmacies can obtain faxed copying by emailing dhmh.naloxone@maryland.gov



Updated Statewide Standing Order: Dr. Haft

Updated June 1, 2017

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. Under Maryland law,¹ a physician employed by the Maryland Department of Health and Mental Hygiene (DHMH) may prescribe naloxone 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 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 and online at www.naloxonemd.org.

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 individual in accordance with the conditions of this order, enumerated below.

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 individual's preference or training to administer a particular 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.

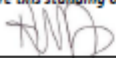
2. For intramuscular injection

- 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.

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


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

Effective Date: June 1, 2017

Expiration Date: June 1, 2019

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.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 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

[https://bha.health.maryland.gov/
NALOXONE/Pages/Statewide-
Standing-Order.aspx](https://bha.health.maryland.gov/NALOXONE/Pages/Statewide-Standing-Order.aspx)



MARYLAND
DEPARTMENT OF HEALTH
& MENTAL HYGIENE



Questions?

Contact the Maryland Overdose Response Program:

Phone: 410-402-8634

Email: dhmh.naloxone@maryland.gov

