



Maryland Medicaid Pharmacy Program Pharmacy News & Views

April 2016

Maryland Department of Health and Mental Hygiene / Office of Systems, Operations and Pharmacy

Clinically Significant Drug Interactions: A Focus On Opioids And Benzodiazepines

The concurrent use of medications with similar adverse drug effects (ADEs) may lead to unintended consequences. Opioid analgesics and benzodiazepines are two commonly prescribed medication classes. While opioids analgesics are a pain reliever, benzodiazepines are used for multiple diagnoses, including anticipatory pain, seizures and anxiety. When ingested alone, both medications have central nervous system (CNS) and respiratory depressant actions. When used together, these agents tend to have a synergistic effect, leading to increased risk of ADEs and fatalities.

Opioid analgesics exert their effects through the agonism of mu-opioid receptors. In 2014, there were over 28,000 deaths attributed to opioids in the United States¹, which was a statistically significant increase of roughly 6.5% from 2013. Prescription opioids account for roughly 65% of opioid related deaths². The two drugs most commonly involved were oxycodone and hydrocodone. Risk of overdose with prescription opioids has been shown to be dose-related³, with an 8.9 fold increase in those consuming > 100 mg of morphine oral equivalents daily.

Risk of overdose is also more likely in those using medications with similar effects, such as benzodiazepines. Benzodiazepines cause respiratory and CNS depression through activation of central GABA receptors. In 2014, nearly 60% of benzodiazepine related deaths in Maryland occurred in those concomitantly using opioids⁴.

When a patient is prescribed either of these high-risk controlled substances, it is important to complete a full prescription profile review, in addition to a comprehensive medication reconciliation to assess prescription and non-prescription or recreational medication use. Accessing the Prescription Drug Monitoring Program (PDMP) is a useful tool in obtaining medication use. The PDMP collects and securely stores prescription information on drugs that contain Schedule II - V controlled substances and are dispensed to patients in or into Maryland regardless of the method of payment. Claims paid by private third party insurers, Medicaid, Medicare and even prescriptions paid for in cash are uploaded by pharmacies throughout the state within 3 business days of the dispensing, and then included in the PDMP database. Access to prescription data is made available through CRISP (Chesapeake Regional Information System for our Patients: <https://crisphealth.org/> to register for access), the state-designated health information exchange, at no-cost to physicians, nurse practitioners, pharmacists and others that provide pharmaceutical care to their patients. Patient counseling on the risk of drug interactions, as well as signs and symptoms to monitor during treatment, should be provided to each patient to reduce the risk of harm.

Additionally, naloxone is a prescription medication available for the reversal of opioid overdose as well as reversal of opiate activity (respiratory depression) with therapeutic opioid use. For more information regarding prescribing, dispensing and counseling related to naloxone, please visit the Maryland Department of Health and Mental Hygiene. <http://bha.dhmh.maryland.gov/NALOXONE/Pages/Overdose-Prevention.aspx> There currently is no publicly available antidote to reverse the respiratory depression from benzodiazepines. Therefore, in any overdose situation where opioids and/or benzodiazepines are used, emergency treatment should be sought to prevent fatal outcomes.

In This Issue

Clinically Significant Drug Interactions: A focus on Opioids and Benzodiazepines	1
Emergency Supply of Medications	2
Maryland Response Overdose Response Program: Statewide Naloxone Standing Order Guidance For Pharmacy Dispensing	2
Telephone Numbers	6

References:

- Centers for Disease Control Morbidity and Mortality Weekly Report. *MMWR Weekly* 64(50); 1378-82. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?cid=mm6450a3_w.
- American Society of Addiction Medicine. *Opioid addiction 2016 Facts & Figures*. Available at: <http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf>.
- Dunn KM, et al. *Overdose and prescribed opioids: Associations among chronic non-cancer pain patients*. *Ann Intern Med* 2010 January 19; 152(2): 85-92.
- Maryland Department of Health and Mental Hygiene. *Drug- and alcohol-related intoxication deaths in Maryland, 2014*. Available at: http://bha.dhmh.maryland.gov/OVERDOSE_PREVENTION/Pages/

Emergency Supply of Medications

Non-preferred medication denial message

When a “non-preferred medication” denial message is received on a submitted fee-for-service claim, the pharmacy should contact the prescriber to do one of the following: change the medication, or have the prescriber obtain the necessary Prior Authorization (PA). It would be beneficial for the pharmacist to advise the prescriber of alternative drug(s) that do not require a PA. The Preferred Drug List (PDL) is available online at:

<https://mmcp.dhmh.maryland.gov/pap/Pages/Preferred-Drug-List.aspx>

It is also available through the Eprocrates® system. In most cases, the prescriber can obtain a PA with a phone call to 1-800-932-3918.

When the prescriber is not available to obtain a PA, and the pharmacist in his/her professional judgment has determined that the prescription is needed on an emergency basis, the pharmacist should contact the Xerox call center at 1-800-932-3918 and request authorization to dispense a 72-hour emergency supply. Please take into account the

patient’s diagnostic and drug history, information about what medications the patient has on hand, and possible recent hospitalization, as well as any mobility, transportation or communication issues that make returning to the pharmacy difficult or expensive.

In the case of sprays, inhalers, eye or ear drops, creams, ointments, antibiotics, etc., it may be necessary to dispense the entire prescription as an emergency supply due to the way the drug is packaged or administered.

A 30-day supply is allowed for atypical antipsychotic medications while awaiting prior authorization for a non-preferred or Tier 2 drug.

For HealthChoice MCO members requiring an emergency supply of non-



mental health and non-antiretroviral drugs, the pharmacist must contact the appropriate MCO Pharmacy Benefit Manager and follow their procedures before dispensing an emergency supply.

If possible, do not let patients leave the pharmacy without medication if there is concern that the patient will be unwilling or unable to return at a later time that day after prior authorization is approved.

- | | |
|-------------------|--|
| STEP
1 | The pharmacist is to contact the prescriber who must obtain prior authorization before the remainder of the prescription can be dispensed. The pharmacist may also recommend a formulary agent that may be used in place of the non-formulary product. |
| STEP
2 | After prior authorization has been approved, the pharmacist can dispense the remainder of the prescription. |

Maryland Overdose Response Program

Statewide Naloxone Standing Order Guidance for Pharmacy Dispensing

I. Summary

Howard Haft, M.D., 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.

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 § 13-310(b), Annotated Code of Maryland

III. Background

Opioid Addiction and Overdose: Opioid addiction and overdose are growing public health problems 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.

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/mg 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.

continued on next page >>

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 dhmh.naloxone@maryland.gov



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 pre-filled 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 pre-filled 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 online⁹ 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 Providers¹⁰
- DME/DMS Providers (electronic)¹¹
- DME/DMS Providers (paper)¹²

A list of DME/DMS pharmacy providers is available online 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 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 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

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

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

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

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

¹² https://mmcp.dhmh.maryland.gov/docs/dhmh_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.

the available formulations to gauge their comfort level. Consider demonstrating the 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 his/her use of naloxone, request that the certificate holder submit a 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. inject 0.4 mL. Repeat after 3 minutes if no or minimal response.

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/Pages/Home.aspx>

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



Maryland Department of
Health and Mental Hygiene
Office of Systems,
Operations & Pharmacy



Pharmacy News & Views

Maryland Medicaid Pharmacy Program

201 West Preston Street, 4th Floor

Baltimore, Maryland 21201

1-800-492-5231 (*select option 3*)

<http://mmcp.dhmh.maryland.gov/pap>

Larry Hogan, Governor

Boyd Rutherford, Lt. Governor

Van Mitchell, Secretary, DHMH

PRESORTED
FIRST CLASS
U.S. POSTAGE
PAID
PERMIT #163
ANNAPOLIS, MD

Go Green!!!!

**Sign up to receive the MMPP
News & Views and Advisories via e-mail. Go to
<http://www.marylandmedicaidpharmacyinformation.com/>**

Advisory Keeps You in the Know

Get the latest updates regarding pharmacy issues through the Maryland Medicaid Pharmacy Program (MMPP) e-mail notification service. Called the Advisory, these communications provide the pharmacy community with the most up to date information. Advisories can be found at this link:

<https://mmcp.dhmh.maryland.gov/pap/Pages/Provider-Advisories.aspx>

Please contact the MMPP representative at 410-767-1455 if you are currently not receiving e-mail Advisories through a pharmacy organization to which you belong. You can sign up to receive Advisories and the MMPP News & Views via e-mail by going to the website:

<http://www.marylandmedicaidpharmacyinformation.com/>
and follow the links to enter your e-mail address.

TELEPHONE NUMBERS

Xerox Technical Assistance
and Preauthorizations

1-800-932-3918

24 hours a day, 7 days a week

Maryland Medicaid
Pharmacy Access Hotline

1-800-492-5231 (*select option three*)

Monday-Friday, 8:00 am to 5:00 pm

Kidney Disease Program

1-410-767-5000 or 5002

Monday-Friday, 8:00 am to 5:00 pm

Breast & Cervical Cancer
Diagnosis and Treatment

1-410-767-6787

Monday-Friday, 8:00 am to 4:30 pm

Maryland AIDS Drug
Assistance Program

1-410-767-6535

Monday-Friday, 8:30 am to 4:30 pm

Peer Review Program

1-855-283-0876

Monday-Friday, 8:00 am to 6:00 pm
with exception of State Holidays