OPIOID SAFETY

Maryland **Pharmacists Guide** for Prescription Fulfillment, Furnishing Naloxone, & CRISP Usage

MARYLAND PDMP

Helping smart individuals to make smart decisions everyday.

Maryland
DEPARTMENT OF HEALTH

Opioid Safety

PURPOSE

The Maryland Department of Health is striving to make your practice safer and has created this comprehensive guide for the dispensing of prescribed opioids.

This guide will provide community pharmacists with easy access to:

- Best practices for dispensing prescribed opioids
- Guidance on distributing naloxone
- Instructions on how to register and use the Chesapeake Regional Information System for our Patients (CRISP)

OVERVIEW

In Maryland, prescription opioid-related fatal overdoses increased by 15.7 percent from January to June of 2021. This follows a substantial annual increase of 22.8 percent observed in 2020. [1]

Community pharmacists in Maryland are uniquely positioned to help reduce opioid misuse and opioid related overdose. This is not necessarily an easy task. Often, Maryland pharmacists are put in difficult situations of determining between patients in need and patients struggling with opioid use disorder.

Maryland pharmacists now have tools that can help them effectively address and directly impact our current epidemic of opioid misuse. As trusted, knowledgeable and valued members of our communities, pharmacists are able to provide vital information and guidance to their patients and their community neighbors.

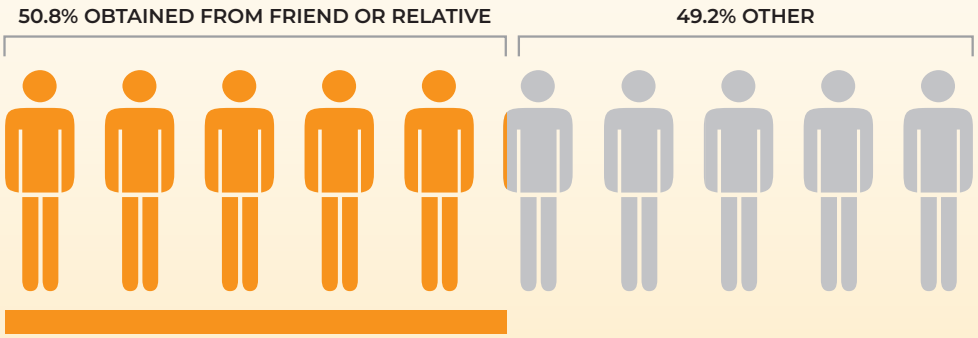
TABLE OF CONTENTS

EPIDEMIOLOGIC TRENDS IN OPIOID USE AND OVERDOSE

» 44 people die every day from overdoses involving prescription opioids.(2)

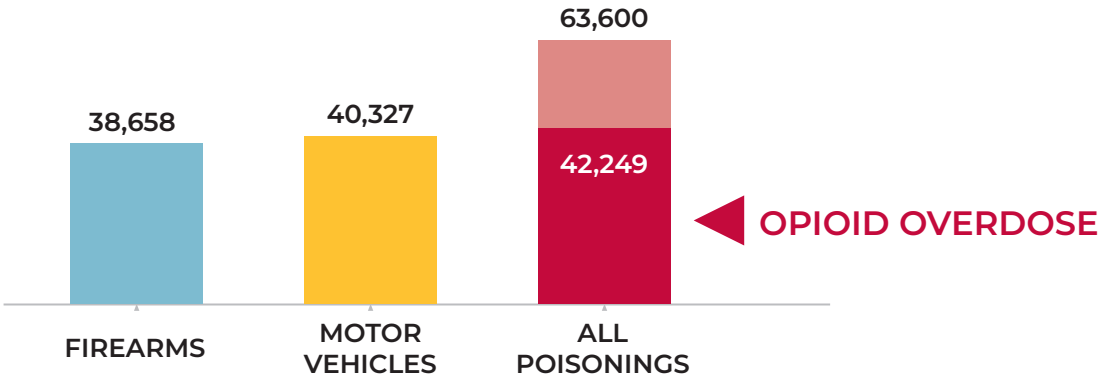
» In 2020 79.9% of drug overdose death had at least one potential opportunity for intervention.(3)

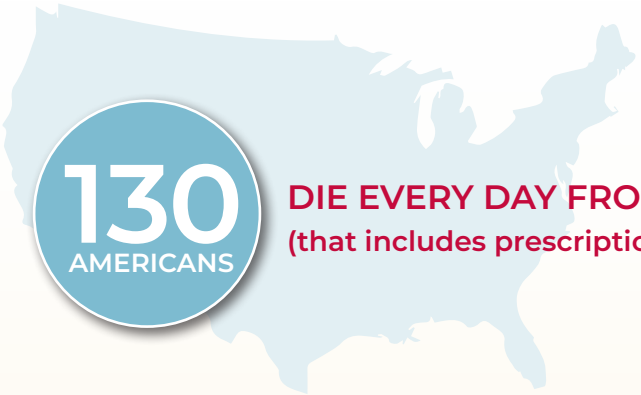
» 50.8% of people who misuse prescription opioids get them from a friend or relative.(4)



OVERDOSE DEATHS

DRUG OVERDOSE IS THE LEADING CAUSE OF INJURY-RELATED DEATH IN THE U.S.[5]



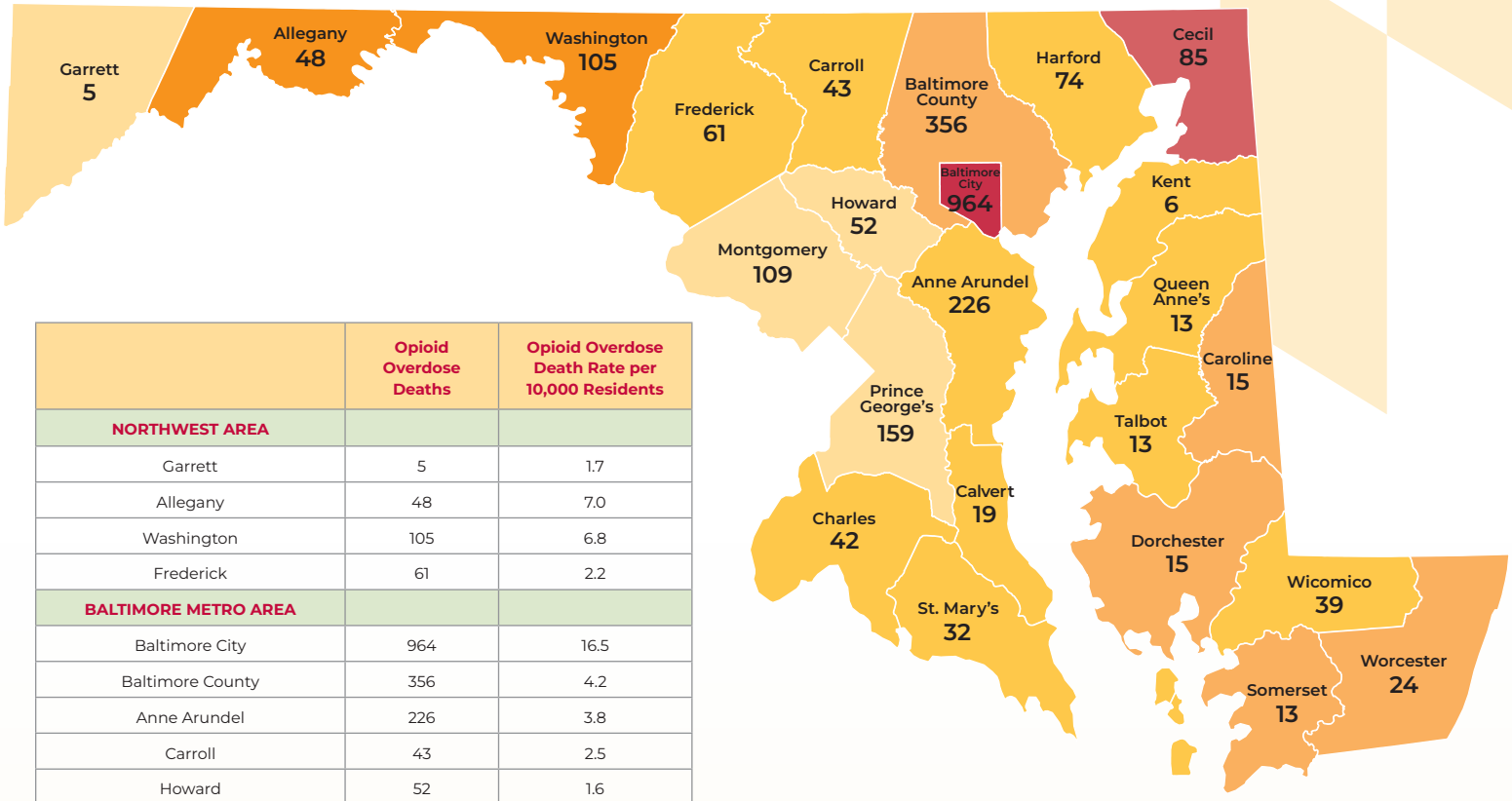


DIE EVERY DAY FROM AN OPIOID OVERDOSE
(that includes prescription opioids and heroin)[7]

Notable Maryland Statistics

- In 2021, Maryland ranked 11th in the nation with the highest number of drug related deaths. Maryland experienced 42.8 deaths per 100,000 people with the total number being 2,737 deaths.[8]
- All 24 local jurisdictions in Maryland reported opioid-related intoxication fatalities from January through June of 2021. Baltimore City (485 deaths), Baltimore County (184 deaths), and Anne Arundel County (115 deaths) experienced the highest number of fatalities, collectively accounting for 64.4 percent of all opioid-related deaths in Maryland.[9]
- Opioid-related fatal overdoses increased by the largest margin among people between the ages of 45 and 54 years old.[10]
- There were 5,473 total naloxone administrations by EMS personnel in Maryland from April through June of 2021, a 9.0 percent increase from the same time frame in 2020.[11]
- There were a total of 5,548 non-fatal, opioid-related emergency department visits in Maryland in the first six months of 2021. This represents a 42.3 percent increase from the same time frame in 2020.[12]

OPIOID OVERDOSE DEATHS IN MARYLAND 2020



	Opioid Overdose Deaths	Opioid Overdose Death Rate per 10,000 Residents
NORTHWEST AREA		
Garrett	5	1.7
Allegany	48	7.0
Washington	105	6.8
Frederick	61	2.2
BALTIMORE METRO AREA		
Baltimore City	964	16.5
Baltimore County	356	4.2
Anne Arundel	226	3.8
Carroll	43	2.5
Howard	52	1.6
Harford	74	2.8
NATIONAL CAPITAL AREA		
Montgomery	109	1.0
PG	159	1.6
SOUTHERN AREA		
Calvert	19	2.0
Charles	42	2.5
St. Mary's	32	2.8
EASTERN SHORE AREA		
Cecil	85	8.2
Kent	6	3.1
Queen Anne's	13	2.6
Caroline	15	4.5
Talbot	13	3.5
Dorchester	15	4.6
Wicomico	39	3.8
Somerset	13	5.3
Worcester	24	4.6

- This data was supplied by the Maryland Department of Health (MDH). MDH specifically disclaims responsibility for any analyses, interpretations or conclusions. *https://health.maryland.gov/vsa/Documents/Overdose/Annual_2020_Drug_Intox_Report.pdf*
- Includes deaths confirmed or suspected to be related to recent ingestion of opioids.
- Includes only deaths for which the manner of death was classified as accidental or undetermined.

The community pharmacists' role in opioid safety

IT IS CLEAR WE ARE AMID AN EPIDEMIC.

All Marylanders hope to stop the tragic death and disruption caused by opioid misuse. As a community, we must come together to prevent opioid misuse and direct those who experience opioid use disorder to effective treatment.

MAKE A POSITIVE IMPACT

- **Ensure the appropriate use of opioids.** Be well-versed in pain management and work with prescribers and patients to appropriately manage pain.

- **Read the CDC Guideline for Prescribing Opioids for Chronic Pain,** which addresses initiation, dosing and duration of treatment with opioids while assessing and mitigating potential harms of opioid use. The guideline was developed to:
  - Improve communication between providers and patients about risks and benefits of pain treatments, including opioid therapy
  - Improve safety and effectiveness of pain treatment
  - Mitigate pain
  - Improve function and quality of life for patients with pain
  - Reduce risks associated with opioid pain therapy, including opioid use disorder and overdose

  https://www.cdc.gov/opioids/healthcare-professionals/prescribing/guideline/at-a-glance.html

- **Recognize appropriate uses for opioids,** including short-term treatment of acute pain, cancer pain, or end-of-life care.

- **Limit access to opioids for illegitimate use.** For indicators of diversion or potential patient harm, refer to page 11 of this guide.

- **Assess for risk of an opioid use disorder using open-ended non-judgmental questions. Approaches like SBIRT can help identify patients at risk for opioid use disorder.**
  https://health.maryland.gov/bha/Pages/SBIRT.aspx
  https://www.samhsa.gov/sbirt
  https://www.pharmacytimes.com/view/sbirt-spells-cornerstone-of-future-pharmacy-practice

- **Become aware of treatment resources** in your community and refer patients for medication treatment for OUD with methadone, buprenorphine or naltrexone based treatments.

- **Complete Board approved training (click here)** to administer maintenance injectable medications including medications for substance use disorder as detailed in COMAR 10.34.41.

- **Provide opportunities for drug destruction and take-back events** for individuals in the community to dispose of controlled substances safely.
  https://www.deadiversion.usdoj.gov/drug_disposal/takeback/
  https://health.maryland.gov/bha/Pages/Prescription-Drop-Off-Collection-Sites.aspx

- **Educate individuals at risk for overdose about, and expand access to, life-saving naloxone.**

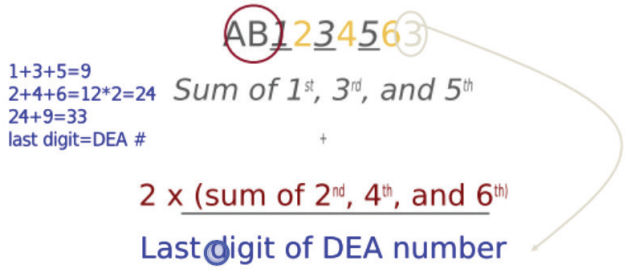
EVALUATE OPIOID PRESCRIPTIONS

Validity:

- Has prescription been forged or altered?

- Has prescriber's DEA number been verified?

https://apps.deadiversion.usdoj.gov/webforms2/spring/validationLogin?



- Is prescription within the prescriber's scope of practice?

- Has patient's identity been verified?

- Has the PDMP been checked via CRISP?

Appropriateness:

- Are opioids indicated for patient's condition?

- Is the duration of treatment appropriate for the condition?

- Is current regimen meeting treatment goals?

- Do the benefits of opioid therapy outweigh the risks?

Safety:

- Are there any medications that may interact (e.g., benzodiazepines)?

- Is patient using alcohol or illicit substances?

- Is the patient aware of the risks associated with opioids?

- Does the patient have naloxone at home in case of accidental overdoses?

LOOK FOR SIGNS OF DIVERSION OR POTENTIAL PATIENT HARM

Look for signs of possible opioid use disorder or diversion of prescription opioids to keep your patients safe. The PDMP can help identify some of these indicators.

- Forged prescriptions such as prescriptions with unusual wording or abbreviations, absence of typical abbreviations, overly meticulous writing, or an unusual signature
- For handwritten prescriptions any alterations such as prescriptions with multiple colors, ink types, or handwriting styles on one prescription
- Patients or prescriptions originating from outside the local geographic area (Be aware that telehealth may be a factor)
- Prescribers practicing outside their scope of practice (ex. podiatrist prescribing stimulants for ADHD)
- Prescriptions for high dosages or high quantities
- Patients appearing intoxicated
- Patients who pay with cash only
- Patients who ask for early refills
- Patients with multiple prescribers or multiple pharmacies
- Multiple prescriptions that may be misused in combination
- Multiple family members or patients at the same address receiving the same prescriptions

While these are common signs of diversion or potential patient harm, this is not an exhaustive list.

PHARMACY INSPECTIONS

State licensing bodies that regularly inspect pharmacies:

- **Maryland Board of Pharmacy (BOP permit)** COMAR 10.34.01-40
  - Annual inspections
  - Covers all prescription medications
  - Refers any Controlled Substance (CS) concerns to OCSA
- **Office of Controlled Substances Administration (CS license)** COMAR: 10.19.03.11A
  - Periodic inspections with no set frequency
  - Focus on controlled substances (CS)
  - Pharmacy inspectors are pharmacists

Purpose of inspections in terms of CS:

- **Evaluate compliance with state and federal regulations**
- **Provide education about CS safety and diversion**

Documents to have ready:

- **CS invoices (Schedule II and Schedules III-V)**
- **Biennial Inventory**
- **Power of attorney (if applicable)**
- **Perpetual Inventory (if applicable)**
- **A recently filled pack of Schedule II prescriptions***
- **A recently filled pack of Schedule III-V prescriptions***

What may be asked of you:

- **Perform a count of four CS medications selected by the inspector**
- **Read COMAR 10.19.03.07C(1) regarding pharmacists' corresponding responsibility when filling CS prescriptions and sign an acknowledgment of understanding**

CS Prescription Review:

- **The inspector reviews prescriptions for:**
  - Required components of the prescription and label
  - Signs of diversion or potential for patient harm
  - Mistakes when filled
  - Concerning prescribing patterns
- **Possible inspector/pharmacist discussion topics**
  - Discuss prescriptions with signs of diversion or potential patient harm
  - Discuss concerning prescribing patterns
  - Inspector can provide education on state and federal regulation and identifying signs of diversion or potential patient harm and strategies to help confirm a prescription is written for a legitimate medical purpose

** In lieu of prescriptions packs you may be asked to provide a CS dispensing report for 5 or more days that includes at minimum the patient name and address, prescription number, medication name/strength/quantity, prescribers name address and DEA number.*

IF A FRADULENT PRESCRIPTION IS SUSPECTED:

If you believe you were presented a Controlled Substances (CS) prescription from a missing or stolen prescription pad or a DEA number is fraudulently being used on prescriptions consider taking the following actions:

1. Contact the prescriber whose name is on the prescription by searching for a phone number using a Google (or equivalent search engine) search and your central prescriber database in your pharmacy computer to confirm the medical legitimacy of the prescription. DO NOT call the number on the paper prescription without first searching the number to verify it is accurate. Fraudulent prescriptions may list a number that is not associated with the prescriber.

2. Check the patient's prescription history in the PDMP to assess if the patient has received a similar prescription in the past.

3. For paper prescriptions check the Board of Pharmacy's list of recently reported stolen or missing prescription pads website. The Board offers a current list and a pre-2015 list.

If after following up with the provider, assessing the PDMP, and checking the Board of Pharmacy website you believe the prescription uses a providers DEA number fraudulently or comes from a missing or stolen prescription pad:

1. Inform the patient you are unable to fill the prescription at this time. According to Maryland regulations, you may refuse to dispense a CS if after consulting with the prescriber and based on generally accepted professional standards for the practice of pharmacy, you have reason to believe that the prescription was not issued for a legitimate medical purpose in the usual course of the prescriber's practice (COMAR 10.34.10.08).

2. Call your local police (some have narcotics divisions who may investigate).

3. Contact DEA, as they may investigate (410) 962-7580.

4. Email or call the Office of Controlled Substances Administration (OCSA) to document the complaint at *Maryland.OCSA@maryland.gov* or (667) 910-8810.

HOW TO TALK ABOUT OPIOIDS

Communicating with patients

General tips:

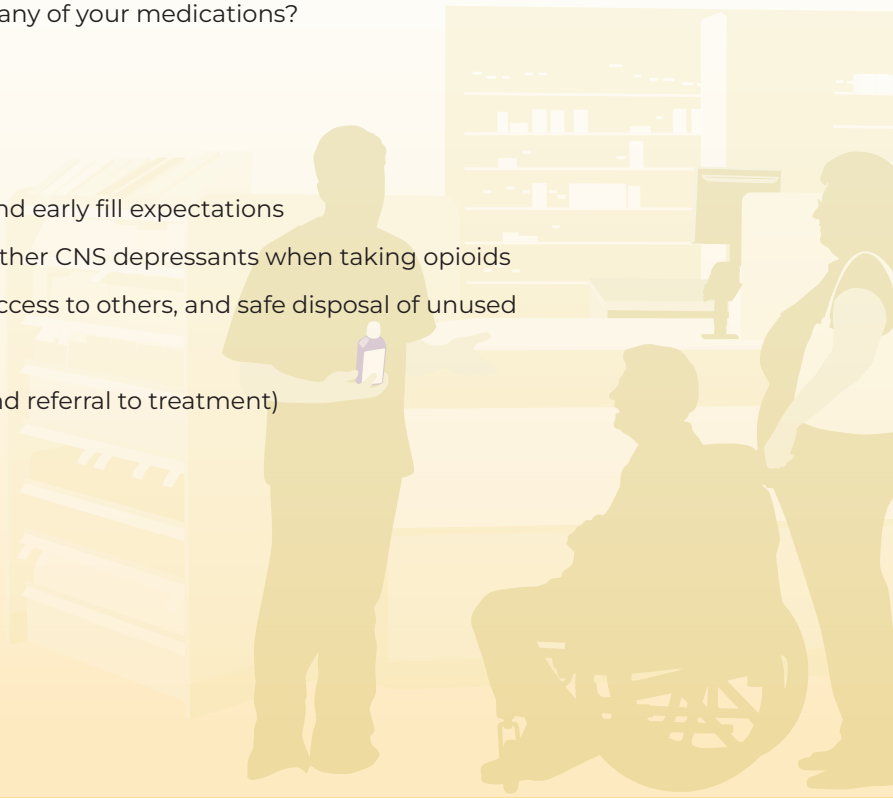
- Be empathic.
- Ask open-ended questions.
- Use active listening techniques.
- Use clear words. Avoid technical or *stigmatizing verbiage*.
- The approach should be "risky medicines" not "risky patients."
- Frame naloxone as the antidote for accidental overdose similar to how epinephrine autoinjectors are a life-saving measure to those with serious allergies.
- Direct patients to additional resources.

Questions you might ask to engage patients:

- What medications are you currently taking?
- What pain medications have you taken and how have they worked for you?
- How well is your medication working to relieve your pain?
- What other ways do you have to help manage your pain?
- Are you experiencing any side effects from your medications?
- Do you have any questions for me about any of your medications?

Provide education about:

- Pain management
- Proper use of opioids, including dosing and early fill expectations
- Avoiding alcohol, benzodiazepines, and other CNS depressants when taking opioids
- Safe and secure storage which restricts access to others, and safe disposal of unused medication
- Opioid use disorder (provide resources and referral to treatment)
- Risks and signs of opioid overdose
- Use of naloxone to reverse overdose



HOW TO TALK ABOUT OPIOIDS (CONTINUED)

Communicating with prescribers

When to call prescribers:

- Fraudulent prescription presented
- Patient appears intoxicated
- PDMP report elicits concern (e.g. multiple prescribers)
- Patient taking other CNS depressants (e.g., benzodiazepines)
- Patient presenting for early fill
- If the risks may outweigh the benefits of opioid therapy

MACS
Maryland Addiction Consultation Service

Maryland Addiction Consultation Service (MACS):

MACS Provides support to prescribers and their practices, pharmacists, and healthcare teams to address the needs of patients with substance use disorder and chronic pain management.

- Consultation for clinical questions, resources and referral information
- Education and training opportunities and events
- MACS for MOMs offers support to maternal health providers in addressing the needs of their pregnant patients with substance use disorders
- Technical assistance implementing or expanding office-based serbices for substance use disorders.

CRISP Registration and Usage

CRISP

Maryland pharmacists have a tool to protect patient safety and help prevent opioid misuse. CRISP (Chesapeake Regional Information System for our Patients) provides a portal to vital patient information that can be found at *portal.crisphealth.org*. It's all about keeping patients safer and Maryland healthier.

The following section contains:

- PMDP Fact Sheet
- Access and Registration
- Patient Advisories User Guide

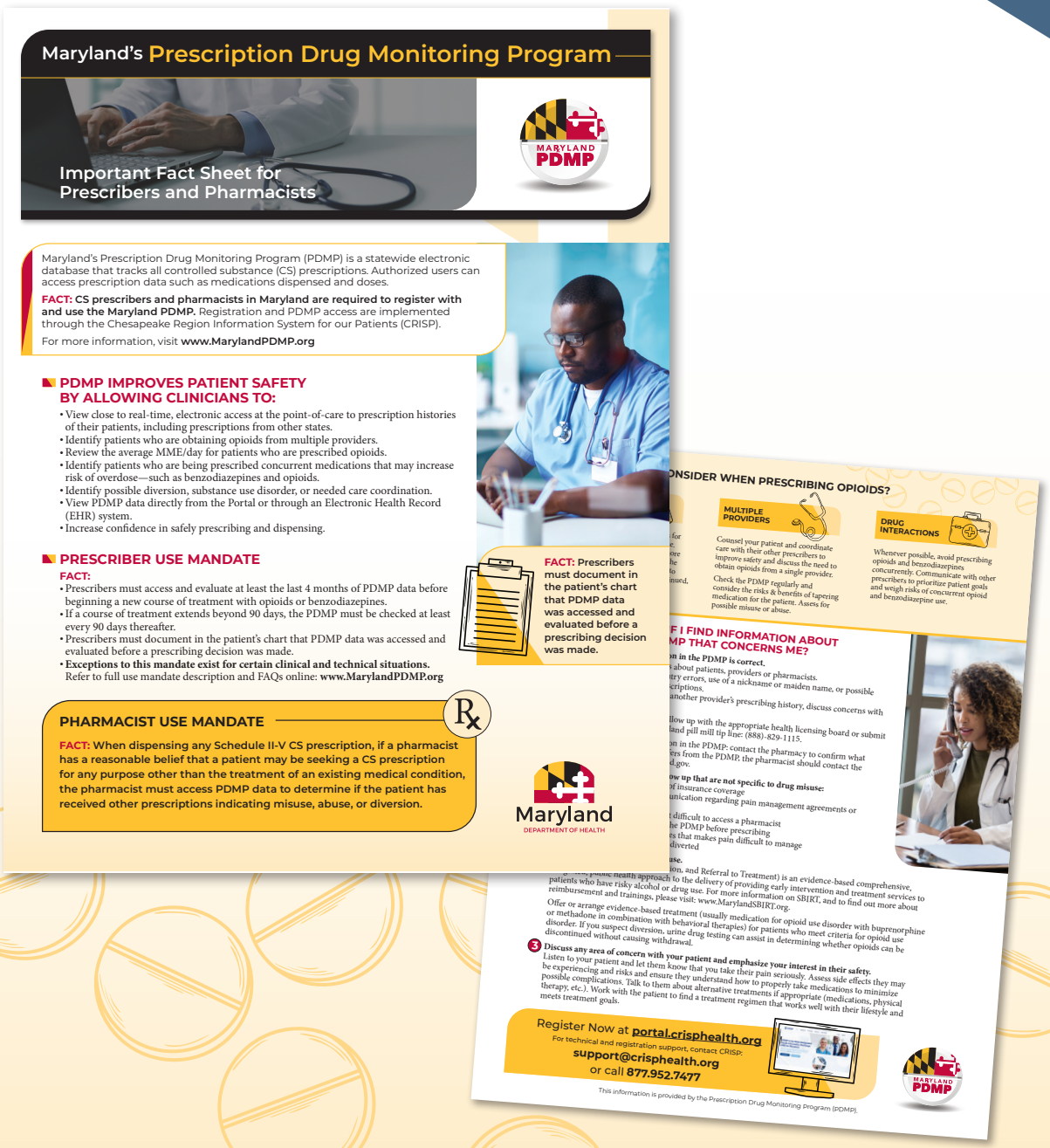
FACT

CS prescribers and pharmacists in Maryland are required to register with and use the Maryland PDMP. Registration and PDMP access are implemented through the Chesapeake Region Information System for our Patients (CRISP).

For more information, visit www.MarylandPDMP.org

CRISP RESOURCES

Important Fact Sheet for Prescribers and Pharmacists



Maryland's Prescription Drug Monitoring Program

Important Fact Sheet for Prescribers and Pharmacists

MARYLAND PDMP

Maryland's Prescription Drug Monitoring Program (PDMP) is a statewide electronic database that tracks all controlled substance (CS) prescriptions. Authorized users can access prescription data such as medications dispensed and doses.

FACT: CS prescribers and pharmacists in Maryland are required to register with and use the Maryland PDMP. Registration and PDMP access are implemented through the Chesapeake Region Information System for our Patients (CRISP).

For more information, visit **www.MarylandPDMP.org**

PDMP IMPROVES PATIENT SAFETY BY ALLOWING CLINICIANS TO:

- View close to real-time, electronic access at the point-of-care to prescription histories of their patients, including prescriptions from other states.
- Identify patients who are obtaining opioids from multiple providers.
- Review the average MME/day for patients who are prescribed opioids.
- Identify patients who are being prescribed concurrent medications that may increase risk of overdose—such as benzodiazepines and opioids.
- Identify possible diversion, substance use disorder, or needed care coordination.
- View PDMP data directly from the Portal or through an Electronic Health Record (EHR) system.
- Increase confidence in safely prescribing and dispensing.

PRESCRIBER USE MANDATE

FACT:

- Prescribers must access and evaluate at least the last 4 months of PDMP data before beginning a new course of treatment with opioids or benzodiazepines.
- If a course of treatment extends beyond 90 days, the PDMP must be checked at least every 90 days thereafter.
- Prescribers must document in the patient's chart that PDMP data was accessed and evaluated before a prescribing decision was made.
- **Exceptions to this mandate exist for certain clinical and technical situations.** Refer to full use mandate description and FAQs online: **www.MarylandPDMP.org**

FACT: Prescribers must document in the patient's chart that PDMP data was accessed and evaluated before a prescribing decision was made.

PHARMACIST USE MANDATE

FACT: When dispensing any Schedule II-V CS prescription, if a pharmacist has a reasonable belief that a patient may be seeking a CS prescription for any purpose other than the treatment of an existing medical condition, the pharmacist must access PDMP data to determine if the patient has received other prescriptions indicating misuse, abuse, or diversion.

Maryland DEPARTMENT OF HEALTH

ONSIDER WHEN PRESCRIBING OPIOIDS?

MULTIPLE PROVIDERS

DRUG INTERACTIONS

F I FIND INFORMATION ABOUT MP THAT CONCERNS ME?

Register Now at portal.crisphealth.org

For technical and registration support, contact CRISP:

support@crisphealth.org

or call 877.952.7477

This information is provided by the Prescription Drug Monitoring Program (PDMP).

CRISP RESOURCES

Pharmacist Access to Patient Clinical Information

Pharmacist Access to Patient Clinical Information

MARYLAND PDMP

IMPROVING PATIENT CARE AND SAFETY

Community pharmacists have a tool to protect patient safety and prevent opioid misuse. CRISP (Chesapeake Regional Information System for our Patients) provides a portal to vital patient information that can be found at **portal.crisphealth.org/**.

Pharmacists with clinical access can view CRISP tools and patient clinical information for purposes of treatment and care coordination. Within the PDMP query view, pharmacists will be able to see nonfatal overdose alerts.

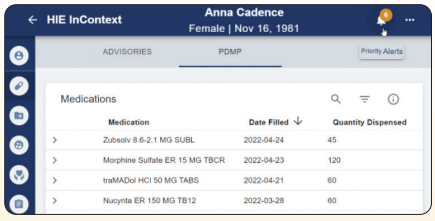
REQUIREMENTS

Pharmacists must adhere to all requirements outlined in the CRISP participation agreement and CRISP policies and procedures, including but not limited to, the below items:

- Update of Notice of Privacy Practices and patient education
- Limit access to credentialed users who have the need for access to PHI
- Signed user agreements by all credentialed users
- Audits of user access

STEPS FOR PHARMACIES TO GAIN ACCESS TO CLINICAL DATA VIA CRISP

1. An individual at the pharmacy with signing authority will work with the CRISP Outreach team to sign the CRISP Participation Agreement and review additional policies and procedures as necessary.
2. Once signed, community pharmacists associated with the organization will have access to CRISP tools and services for purposes of treatment and care coordination.



The CRISP Participation Agreement must be signed to gain access to clinical data.

INFORMATION TO REGISTER

For information about the CRISP participation agreement and how to sign, see **https://www.crisphealth.org/news/finalized-crisp-participation-agreement/.** Interested pharmacies should contact CRISP Outreach at **support@crisphealth.org.**

Maryland
DEPARTMENT OF HEALTH

This information is provided by the Prescription Drug Monitoring Program (PDMP).

CRISP RESOURCES

Patient Advisories User Guide

PDMP Patient Advisories User Guide

The Maryland PDMP launched a new feature, Patient Advisories. These are a set of key metrics based on a patient's prescription history over the last 30 or 90 days. Advisories allow providers to quickly identify when patients may be at increased risk of overdose or need additional care coordination. Advisories do not include data from prescriptions filled in other states. Advisories are available in CRISP's Portal and InContext Application (App).

WHAT DOES EACH ADVISORY MEAN? WHAT DOES AN ALERT INDICATE?

Average Daily MME: The average MME (Morphine Milligram Equivalents) of all active opioid prescriptions per day, over the last 30 days. An alert indicates the patient had at least one day with an average of 90 or more MME from all prescriptions.

Overlapping Opioids: The number of days a patient had more than one opioid prescription. An alert indicates when the "days supply" overlaps for 3 or more days within the past 90 days.

Overlapping Opioid and Benzos: The number of days a patient has one or more opioid prescription and one or more benzodiazepine prescription. An alert indicates when the "days supply" overlaps for 3 or more days within the past 90 days.

Total Prescribers/Pharmacies: The total number of prescribers and pharmacies who wrote or dispensed a controlled substances prescription to the patient within the past 90 days. An alert indicates the patient received controlled substance prescriptions from at least 5 different prescribers and visited at least 5 different pharmacies to receive prescriptions within the past 90 days.

PATIENT ADVISORIES USER GUIDE

To access the advisories in the Portal, users can initiate a search for any patient, select the "Clinical information App", select "Medication Management" and then click on the "Advisories" tab. The screenshot below displays the advisory results of a sample PDMP query. Additional information about the different advisories is available by hovering over the ⓘ next to the title of the advisory. Note that even if the search returns interstate data, interstate data is not included in the calculations for the advisories.

Maryland DEPARTMENT OF HEALTH

This information is provided by the Prescription Drug Monitoring Program (PDMP).

ent Advisories User Guide

range.

HR) to access the PDMP, Portal. Two tabs will ers will land on the tab, which will show the tab itself, or on the sories" page. For each he title, and the tooltip ue circle icon ⓘ will hat an alert indicates. ue will turn orange. verlapping Opioids has and so that value

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practices or has questions about appropriate prescribing roviders can look to the following resources:

mmendations for prescribing opioids, tapering opioids, ts about opioid safety. Please visit MarylandPDMP.org

MACS, of the Maryland Addiction Consultation Service, provides support to primary care and mental health prescribers across Maryland in the identification and treatment of substance use disorders. MACS provides a free phone consultation for clinical questions, resources, and referral information [1-855-337-MACS (6227)]. MACS also offers education and training opportunities related to substance use disorders and can assist providers in the identification of addiction and behavioral health resources that meet the needs of patients in the community. www.MarylandMACS.org

Maryland DEPARTMENT OF HEALTH

This information is provided by the Prescription Drug Monitoring Program (PDMP).

Treating opioid use disorder: Pharmacotherapy

MEDICATION FOR OPIOID USE DISORDER

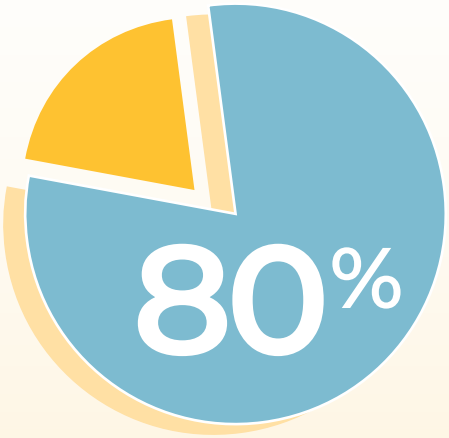
Use of medications for opioid use disorder has been shown to increase recovery rates, decrease overdose deaths, decrease criminal activity, and lower the risk of infections such as HIV and hepatitis C.

OVERVIEW

Medications for OUD including buprenorphine, methadone, and extended-release naltrexone, are often used in combination with counseling and behavioral therapies, to treat opioid use disorder.

- Barriers to medications for OUD include stigma of addiction (substance use disorder), not recognizing opioid use disorder, a lack of awareness of treatments available, lack of physician training, and limited access to treatments and treatment providers.

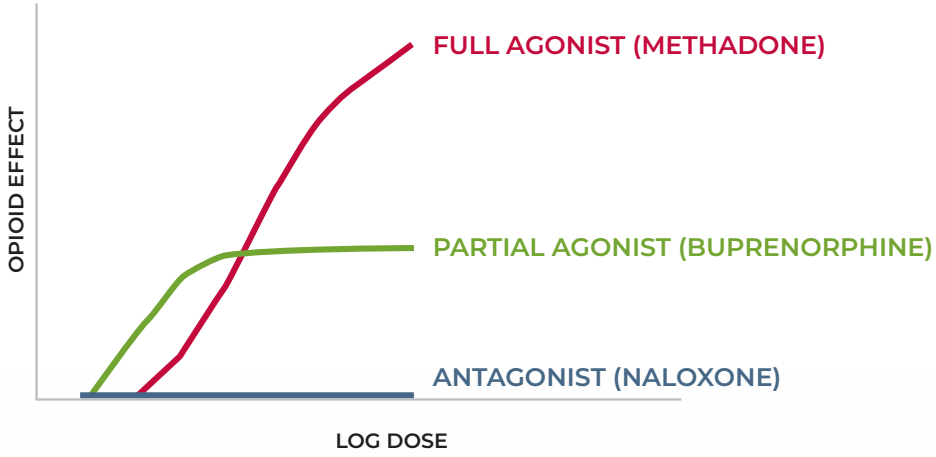
- For more information and a detailed resource on medications for OUD, please visit the Substance Abuse and Mental Health Services Administration (SAMHSA) Medication-Assisted Treatment webpage: *https://www.samhsa.gov/medication-assisted-treatment*.



Nearly 80% of those with an opioid use disorder don't receive treatment.(13)

BUPRENORPHINE

- A partial opioid agonist
- Typically lasts 36 hours
- Has very high affinity, blocking effects of heroin or other opioids



Formulations

Standard for opioid use disorder:

- Coformulated buprenorphine/naloxone sublingual (SL) tab

- Coformulated buprenorphine/naloxone SL and buccal film

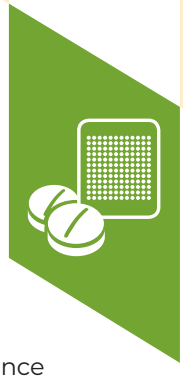
If patient does not tolerate/cannot access coformulated products:

- Monoformulated buprenorphine SL tablets

Long acting buprenorphine products:

- Monoformulated buprenorphine extended-release monthly injection

BUPRENORPHINE (CONTINUED)



For opioid use disorder:

- No prior authorization necessary for MD Medicaid (with the exception of generic buprenorphine/naloxone formulations)
- Medication is generally administered sublingually, but long-acting injectable formulations , which can be administered by trained pharmacists, are also available and may be beneficial due to increased adherence

Clinical pearls:

- "Ceiling effect" due to partial agonism; lower potential for misuse, diversion, respiratory depression, and overdose than other opioids
- Co-formulation products are not appropriate for use in opioid overdose; naloxone is added to reduce potential for diversion or injection
- Combination product generally favored
- Severe withdrawal symptoms can occur if buprenorphine started too early. There are several different strategies for initiation
- Often initially prescribed in limited quantities to ensure close follow up with increased days supply as the dose is stabilized; opportunities for pharmacist to actively assist patients in treatment for opioid use disorder

Patient counseling tips:

- **Sublingual tablets or film should be kept under tongue and buccal film should be placed on the inside of cheek until completely dissolved.** Due to low oral bioavailability, swallowing will result in reduced effect and may lead to cravings and withdrawal symptoms.
- **Tablets, sublingual film, and buccal film are not equivalent;** some patients may require a change in dose when transitioning from one product to another.
- **Avoid combining with other central nervous system (CNS) depressants,** such as alcohol or benzodiazepine, as this can increase the risk for respiratory depression and overdose toxicity. However, while the combination may increase risk, medications for OUD should not be withheld from patients taking other CNS depressants and buprenorphine may be a safer option than methadone.
- **Store in a safe and secure location** to prevent accidental ingestion by others.

METHADONE

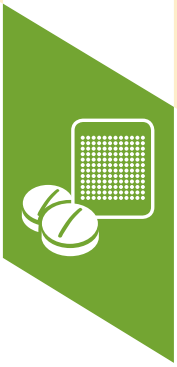
Clinical pearls:

- Full opioid agonist
- Methadone for pain prescribed then dispensed by pharmacies, but methadone for opioid use disorder only dispensed through opioid treatment programs
- Long half-life (up to 59 hours), may accumulate
- QT prolongation and increased risk for serious arrhythmias
- Potential for drug interactions
- Respiratory depression and overdose risk
- Methadone dispensed from opioid treatment programs not reported to Maryland PDMP (prescriptions dispensed at pharmacies reported)

Patient counseling tips:

- **Many medications may interact with methadone;** check with physician or pharmacist anytime you start or stop a new medicine.
- **Report excessive sedation, shallow breathing, or dizziness** to physician.
- **Avoid combining with other CNS depressants,** such as alcohol or benzodiazepine, as this can increase the risk for respiratory depression and overdose toxicity. However, while the combination may increase risk, medication-assisted treatment should not be withheld from patients taking other CNS depressants.

EXTENDED RELEASE NALTREXONE



Clinical pearls:

- Opioid antagonist; blocks euphoric effects of opioid agonists
- No addiction potential; not a controlled substance; may be prescribed by any prescriber
- More effective than oral naltrexone for opioid use disorder but may be less favored by patients compared to buprenorphine or methadone
- Withdrawal may be precipitated if agonists (full or partial) are on board; must be 7-10 days without other opioids before starting naltrexone (up to 14 days after discontinuing long-acting opioids such as buprenorphine or methadone)
- Increased risk for overdose during washout period prior to starting treatment, or during treatment if large amounts of opioids used to overcome naltrexone's opioid blockade
- Increased risk of overdose with relapse after extended release naltrexone discontinuation due to loss of tolerance
- Improved adherence with monthly dosing, which can be administered by trained pharmacists

Patient counseling tips:

- Because a patient's tolerance to opioids may be reduced, the patient's risk for overdose is increased during the waiting period to initiate naltrexone and after stopping naltrexone.

ADDITIONAL MEDICAL CARE FOR PATIENTS WITH OPIOID USE DISORDER

Due to increased risk for various complications, patients with an opioid use disorder should also be considered for:

- **Screening for infections** such as HIV, hepatitis B, hepatitis C, sexually-transmitted infections and tuberculosis (at least annually for most patients)
- **Vaccinations** such as hepatitis A, hepatitis B, tetanus- diphtheria- pertussis, influenza and pneumococcus
- **Aggressive management of cardiac risk factors,** particularly for people who also use stimulants or tobacco, including blood pressure and lipid control, as well as smoking cessation
- **Treatment of other comorbid substance use disorders,** including tobacco and alcohol use disorders
- **Treatment of comorbid psychiatric disorders**
- **Recommendation of clean injection equipment** for the prevention of infectious diseases

Providing access to naloxone

NALOXONE SAVES LIVES

Maryland has issued a statewide standing order allowing all Maryland-licensed pharmacists to dispense naloxone, including any necessary supplies for administration, to any individual.

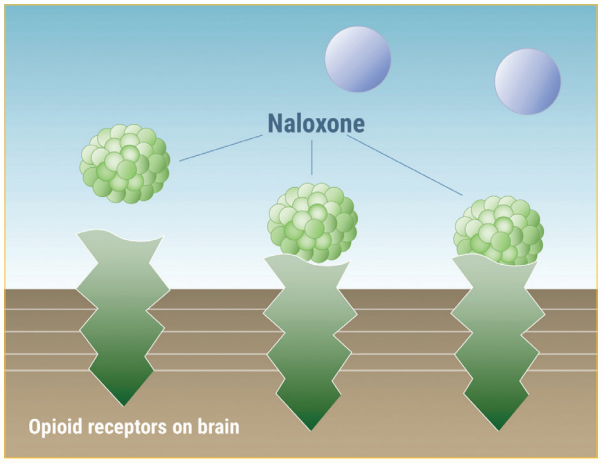
Read the order at:
health.maryland.gov/pha/NALOXONE/Pages/Statewide-Standing-Order.aspx

Providing access to naloxone

NALOXONE

Naloxone mechanism of action:

- Highly specific, high-affinity opioid antagonist used to reverse the effects of opioids
- Naloxone is not a controlled substance and doesn't get people "high"
- Lasts 30-90 minutes
- Can be administered by laypeople
- Virtually no side effects or effects in the absence of opioids
- Should still be given if overdose is due to combination of opioids and other drugs



OTC NALOXONE

In March 2023 the FDA approved the first over the counter (OTC) naloxone nasal spray.

- OTC formulations of naloxone will be available for purchase without a prescription or standing order
- Not all formulations of naloxone will be available OTC
- Prescription only formulations of naloxone will still require a prescription or use of the standing order to be dispensed
- In order for naloxone to be covered by insurance it must be dispensed via a prescription or standing order

REQUIREMENTS OF NALOXONE PROTOCOL IN MARYLAND

Naloxone prescriptions are treated like any other prescription. The Maryland Statewide Standing Order for Opioid Overdose Reversal Drug allows:

- Pharmacists to dispense naloxone without a patient-specific prescription
- Naloxone to be dispensed to any individual at risk or opioid overdose or in a position to assist someone experiencing an opioid overdose (there are no age restrictions)

Best practices when dispensing naloxone prescriptions include:

- Educate the person receiving the naloxone product regarding:
  - Overdose prevention, recognition, and response
  - Safe administration of naloxone (dosing, effectiveness, storage conditions, shelf-life)
  - Potential side effects
  - Importance of seeking emergency medical care
- Provide the naloxone fact sheet when furnishing naloxone. *[https://howtoadministernaloxone.maryland.gov/en/files/naloxone-brochure.pdf]* This can be found in various languages on the Board of Pharmacy website: *tinyurl.com/l45d5c3*.

Standing order:

https://drive.google.com/file/d/1qRRh8f0_sfMA9umccUgQ33ppmK3cQRHY/view

Guidance to naloxone from MD standing order:

https://health.maryland.gov/pha/NALOXONE/Pages/Home.aspx

Resource from MD standing order:

https://www.getnaloxonenow.org/#home

MD naloxone co-prescribing fact sheet:

https://health.maryland.gov/pdmp/Documents/Clinical%20Docs/Naloxone%20Co-Prescribing%20Fact%20Sheet.pdf

Providing access to naloxone

IDENTIFYING PATIENTS FOR NALOXONE

- Patients who have previously experienced opioid overdose
- Patients with recent period of opioid abstinence and reinitiation of opioid
- Patients on long-term opioid therapy, on high dose opioids (≥ 50 morphine milligram equivalents/day), or those with recent changes in dosage
- Patients with a history of opioid or other substance use disorder (including, but not limited to, alcohol, marijuana, cocaine, methamphetamines)
- Patients on long-acting opioids (e.g., methadone, fentanyl patch) or on regimens of multiple opioids
- Patients on concurrent benzodiazepine or other CNS depressant
- Patients requesting access to naloxone
- Family members or friends of any patient meeting above criteria or anyone at risk of witnessing an overdose

EDUCATE PATIENTS AND CAREGIVERS ABOUT PREVENTING OVERDOSE

How to counsel patients and caregivers

- Only take medicine prescribed to you.
- Don't take more than prescribed; call your doctor if pain not controlled.
- Don't mix with alcohol or sleeping pills.
- Don't take opioids while alone when initiating therapy or changing dose; don't use opioids from an unknown source.
- Abstinence lowers tolerance; do not restart opioid therapy at the previous dosage.
- Store in a secure place.
- Dispose of unused medications.
- Teach your family and friends how to respond to an overdose and how to use naloxone.
- If you are having difficulty taking opioids safely, I can refer you to help.

Providing access to naloxone

HOW TO FURNISH, ORDER, AND BILL FOR NALOXONE

- **Collect resources to have on hand:**
  - Naloxone products commercially available
    - Nasal spray
    - Single dose vials and syringes
    - Devices for lay use (branded nasal spray and auto-injector) offer ease of use and are marketed with patient education materials. If pricing and access are issues, provide generic products with educational materials referenced below.

  - Patient education materials:
    https://howtoadministernaloxone.maryland.gov/en/index.html
    https://health.maryland.gov/pha/NALOXONE/Pages/Home.aspx

  - Training devices for demonstration purposes (break open from stock or request placebo trainers from manufacturers)

- **Develop onsite procedures for naloxone requests** and proactive criteria for patient selection. Train pharmacy employees to ensure procedure is executed consistently.

- Naloxone is covered by Maryland Medicaid and Medicare
  See: *https://drive.google.com/file/d/1qRRh8f0_sfMA9umccUgQ33ppmK3cQRHY/view*

- Atomizer component is covered through Durable Medical Equipment/Disposable Medical Supplies

- Formulations on the Prefered drug list are reimbursable under the standing order
  https://health.maryland.gov/mmcp/pap/Documents/PDL%207.1.2022_10.15.2022%20with%20high%20cost.pdf

If a patient does not have insurance they can be directed to local Overdose Response Program (ORP) for free naloxone and training *https://health.maryland.gov/pha/NALOXONE/Pages/Home.aspx*

To dispense:

- Obtain a faxed copy of the standing order *(email mdh.naloxone@maryland.gov)*
- Keep on file in the same manner that paper prescriptions are kept
- Dr. Herrera Scott's NPI # (1285684274) should be used when billing insurance
- Use clinical judgment when selecting formulation and dosage selection
- Pharmacists determine the number of refills on the prescription

Providing access to naloxone

HOW TO RESPOND TO AN OVERDOSE

1 Recognize the signs of an overdose

- Slow or shallow breathing; gasping for air while sleeping; pale, clammy, or bluish skin or fingernails; slowed heartbeat; low blood pressure; won't wake up or respond (rub knuckles on sternum).

2 Call 911 and give naloxone

- Administer dose per instructions in patient education guides provided with naloxone products, or view educational videos online: *prescribetoprevent.org/patient-education/videos*.
- Assess response; give repeat dose if no or minimal response in 1-3 minutes.
- Lay the person on his or her side to prevent choking.
- Quick response improves survival.
- Say "Someone is unresponsive and not breathing." Give clear address and location.

3 Follow 911 dispatcher instructions

- Clear airway, give rescue breaths if not breathing and/or chest compressions.
- With victim laying flat on back, put one hand on chin, tilt head back, pinch nose closed, make seal over mouth, and breathe 1 breath every 5 seconds. Chest should rise, not stomach.

4 Stay until help arrives—naloxone effects last 30-90 minutes

- Patient can go back into overdose if long-acting opioids were taken (e.g., fentanyl patch, methadone, extended-release formulations of morphine or oxycodone).
- Following up naloxone administration with medical care is important.

NALOXONE FORMULATIONS

These devices are designed for lay use. Manufacturers provide written patient education.

Intranasal

- Naloxone 4mg two pack (Brand: Narcan)
- Naloxone 3mg two pack (Brand: RiVive)
- Naloxone 8mg two pack (Brand: Kloxxado)
- Dispense #1
- SIG: Use as needed for suspected opioid overdose. Spray into one nostril upon signs of opioid overdose. Repeat into other nostril with a new spray after 1-3 minutes if no or minimal response.
- Call 911.
- Repeat in each nostril after 2-3 minutes if no response until help arrives.

Intranasal naloxone with atomizer kits

i. Provide two 2-ml Luer-Jet Luer-lock syringes prefilled with naloxone hydrochloride (2 mg/2 ml)

ii. Include two mucosal atomization devices (MAD).

iii. Directions for use: Assemble mucosal atomization device by following step by step instructions below:

1. Remove two colored caps from the delivery syringe and one from the naloxone vial.
2. Screw the naloxone vial gently into the delivery syringe.
3. Screw the mucosal atomizer device onto the tip of the syringe.
4. Spray half (1 ml) of the naloxone in one nostril and the other half (1 ml) in the other nostril.
5. Repeat If there is no response after 3 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.

- Inform patients to alert others about naloxone, how to use it and where it's kept, as it is generally not self-administered.
- Shelf life is 12-24 months; store at room temperature.
- Side effects include risk for withdrawal, anxiety, sweating, nausea/vomiting, or shaking.

NALOXONE FORMULATIONS (CONTINUED)

If the devices on the previous page are not available, dispense the injectable formulation and provide thorough education on assembly and use.

Injectable

- Naloxone 2mg/ml prefilled syringe 1ml single dose vial
- Naloxone 5mg/0.5ml prefilled syringe (Brand: Zimhi)
  - Dispense #2
  - SIG: Use as needed for suspected opioid overdose. Inject 1 ml IM in shoulder or thigh upon signs of opioid overdose. Repeat after 2-3 minutes if no or minimal response. Call 911.
- 3ml syringe with 25g 1" needle
  - Dispense #2
  - Use as directed for naloxone administration.

Clinical pearls

- Can use 3ml syringe with 23-35 gauge 1-1.5 inch needles
- All components available at community pharmacies
- Third party reimbursement possible
- Some patients may not be comfortable with needles

FORMULATIONS NOT APPROPRIATE FOR PHARMACIST FURNISHING

DO NOT furnish these for take-home reversal of an opioid overdose:

- **Naloxone Carpuject Luer Lock Glass Syringe (requires injector, difficult to assemble, not appropriate for layperson use)**
- **Min-I-Jet Fixed Needle Syringe (not appropriate for layperson use)**

Frequently Asked Questions about Naloxone in Maryland

Do patients need a prescription?

No. Anyone can get naloxone from a pharmacy without an individual prescription under the statewide standing order. Anyone can get naloxone from a pharmacy without proof of certification or training.

Is naloxone free at a pharmacy?

No, naloxone is not free at a pharmacy, but it is covered by many insurance plans (copays vary) and Maryland Medicaid. Patients can also get free Naloxone through Maryland Overdose Response Programs (ORP).

Where can patients find an Overdose Response Program for free Naloxone?

Patients can reach out to an ORP for free naloxone.

To find locations, please view the ORP map.

https://www.google.com/maps/d/embed?mid=1Oc8m4uYRvpJmIKdtG-73GUFLcTQuPmpa&ehbc=2E312F

Can patients order Naloxone by mail?

Residents in certain Maryland counties may be eligible to receive free naloxone delivered to their home. To see a list of Overdose Response Programs click here and ask if they deliver by mail.

https://docs.google.com/document/d/1AL4WsGJNsBElDHCifZZFyEPnOxg59_izGuctQw7goQ/edit

How can patients learn how to use Naloxone?

Click here for instructions and a downloadable brochure.

https://howtoadministernaloxone.maryland.gov/en/index.html

Additional Resources

Centers for Disease Control and Prevention (CDC) Clinical Tools:
https://www.cdc.gov/drugoverdose/index.html

- *Guideline for Prescribing Opioids for Chronic Pain*
- *Pharmacists: On the Front Lines*
- *Tapering Opioids for Chronic Pain*
- *Nonopioid Treatments for Chronic Pain*
- *Assessing Benefits and Harms of Opioid Therapy*
- *Calculating Total Daily Dose of Opioids for Safer Dosage*
- *Prescription Drug Monitoring Programs*
- *Free Opioid Guide App* (calculate total daily opioid dose, clinical guidance, motivational interviewing communication skills):
  https://www.cdc.gov/opioids/healthcare-professionals/prescribing/app.html
- *Prescription Opioids: What You Need to Know:* One-page patient education fact sheet for patients taking prescription opioids
  https://www.cdc.gov/opioids/patients/materials.html

Substance Abuse and Mental Health Services Administration (SAMHSA):
https://www.samhsa.gov/medications-substance-use-disorders

- Regulations, training resources, and treatment guidelines for medications used in opioid use disorder such as buprenorphine, methadone, and naltrexone
- Opioid treatment program directory (services locator)
  https://dpt2.samhsa.gov/treatment/directory.aspx

American Association of Psychiatric Pharmacies

- *Opioid Use Disorders: Interventions for Community Pharmacists:* Guideline to educate community pharmacists on interventions to provide safe access to opioids while protecting communities from consequences of misuse: *https://aapp.org/guideline/oud*
- *Naloxone Access: A Practical Guide for Pharmacists:* Guideline to educate community pharmacists on increasing access to naloxone: *https://aapp.org/guideline/naloxone*

Other Resources

- Resources related to legal and advocacy issues
  Maryland Department of Health: health.maryland.gov

Prescribe to Prevent: *prescribetoprevent.org*

- Information on prescribing and dispensing naloxone
- Resources targeted to prescribers and pharmacists
- Excellent resources for patient education including posters and videos
- CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States, 2022
  https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm
- Tools you can use to fight the opioid epidemic:
  https://www.mbp.state.md.us/resource_information/res_con/resource_consumer_od_board_guidance.aspx

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(3) *https://www.cdc.gov/drugoverdose/fatal/dashboard/index.html*

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About this publication

This publication was adapted for use by the Maryland Department of Health with permission from the San Francisco Department of Public Health (SFDPH), California Department of Public Health (CDPH), and Keck Graduate Institute (KGI).

The recommendations contained in this brochure are general and informational only; specific clinical decisions should be made by providers on an individual case basis.

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