

Montana Implementation Guide for Access to Naloxone Opioid Antagonists

October 2017

Overview

The 2017 Montana Legislature passed [House Bill 333](#), the Help Save Lives from Overdose Act (Act), authorizing increased access to naloxone, an opioid antagonist used to reverse an opioid overdose. The law creates a new section in [Title 50](#) of the Montana Code Annotated (MCA) to implement increased access to naloxone and is available online at: <http://leg.mt.gov/bills/2017/billpdf/HB0333.pdf>.

The law requires the Montana Department of Public Health and Human Services (DPHHS) to issue a state-wide standing order for pharmacists to voluntarily utilize for dispensing naloxone prescriptions. Any prescription issued pursuant to the standing order must designate the eligible recipient as the patient, regardless of the eligible recipient's status as an individual, organization, agency, or other entity.

The bill also addresses immunity and Good Samaritan laws, amends [37-2-104, MCA](#) allowing medical practitioners to dispense naloxone, and amends several criminal law provisions within [Title 45, MCA](#).

This *Montana Implementation Guide for Access to Naloxone Opioid Antagonists* is intended to assist with the implementation of increased access to naloxone through pharmacies, eligible recipients, and medical practitioners. The document is organized into separate sections for: use of naloxone; pharmacists utilizing the standing order; prescription authority; eligible recipients distributing naloxone; educational information; DPHHS grant funding for purchasing naloxone; and additional information on naloxone dispensing by medical practitioners, liability, and school to naloxone.

Use of Naloxone

Naloxone is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids.

Considerations for naloxone availability include:

- An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose.
- A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.
- A person who through their normal course of duty may be required to assist an individual believed to be experiencing an opioid-related overdose.
- Patients who may have difficulty accessing emergency medical services (distance, remoteness).
- Voluntary request from a family member, friend, peace officer or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.
- Previous opioid intoxication or overdose.
- History of nonmedical opioid use.
- Initiation or cessation of methadone or buprenorphine for opioid use disorder treatment.
- High dose opioid prescription (≥ 50 mg morphine equivalent/day).
- Receiving any opioid prescription plus:
 - Smoking, COPD, emphysema, asthma, sleep apnea, respiratory infection or other respiratory illness.

- Renal dysfunction, hepatic disease, cardiac illness or HIV/AIDS.
- Known or suspected concurrent alcohol use.
- Concurrent benzodiazepine or other sedative prescription.
- Concurrent antidepressant prescription.

Pharmacists and Pharmacies Using the Naloxone Standing Order

The [Act](#) provides authorization for any naloxone prescription to designate the eligible recipient as the patient, regardless of the eligible recipient's status as an individual, organization, agency or other entity. The definition of an eligible recipient is not limited to the use of the standing order and a requirement to dispense a DPHHS educational brochure applies to all naloxone prescriptions.

Standing Order Requirements and Educational Brochure

Pharmacists utilizing the standing order authority to dispense naloxone products must:

- Maintain a copy of the standing order at the pharmacy.
- Designate the eligible recipient as the patient, regardless of the eligible recipient's status as an individual, organization, agency or other entity.
- Designate the prescriber as the State Medical Officer pursuant to the standing order.
- Process the prescription exactly as written in the standing order for the selected product strength and direction; indicate quantity to dispense; and include the patient's name (individual or other eligible recipient) and address.
- Comply with all Montana Board of Pharmacy requirements for prescription orders, labeling, recordkeeping, and counseling.
- Provide the patient with basic instruction and information, the content of which has been developed by DPHHS and made publicly available on their website at:
 - <http://dphhs.mt.gov/publichealth/emsts/prevention/opioids>.
 - The *DPHHS Opioid Overdose Recognition and Response Guide* includes information concerning recognition of the signs and symptoms of an opioid-related drug overdose, indications for the administration of an opioid antagonist, administration technique, and the need for immediate and long-term follow-up to the administration of the opioid antagonist, including calling 911.

Patients Defined as Eligible Recipients

Pursuant to the definitions in the [Act](#), eligible recipient means:

- a) a person who is at risk of experiencing an opioid-related drug overdose;
- b) a family member, friend, or other person who is in a position to assist a person who is at risk of experiencing an opioid-related drug overdose;
- c) a first responder or a first responder entity;
- d) a harm reduction organization or its representative;
- e) the Montana state crime laboratory or its representative;
- f) a person who, on behalf of or at the direction of a law enforcement agency or officer, may process, store, handle, test, transport, or possess a suspected or confirmed opioid;
- g) a probation, parole, or detention officer;
- h) a county or other local public health department or its representative; or
- i) a veterans' organization or its representative.

Prescription Authorities for Naloxone Access

Naloxone access at the pharmacy is available through the following sources for any individual patient/eligible recipient:

- Prescription from a licensed medical practitioner authorized to prescribe prescription medications.

- Collaborative practice agreement between pharmacist(s) and a prescriber(s) authorizing the pharmacist to initiate and dispense naloxone prescriptions in compliance with Montana Board of Pharmacy [requirements](#).
- *Montana Standing Order for Naloxone Opioid Antagonists* for a pharmacist to initiate and dispense naloxone prescriptions as outlined in the standing order.
 - The pharmacy must maintain a copy of the standing order if dispensing naloxone pursuant to such authority. The standing order is available online at: <http://dphhs.mt.gov/publichealth/emsts/prevention/opioids>.

Any naloxone prescription, regardless of source, must be dispensed with basic instruction and information, the content of which has been developed by DPHHS and made publicly available on their website at: <http://dphhs.mt.gov/publichealth/emsts/prevention/opioids>.

- The *DPHHS Opioid Overdose Recognition and Response Guide* includes information concerning recognition of the signs and symptoms of an opioid-related drug overdose, indications for the administration of an opioid antagonist, administration technique, and the need for immediate and long-term follow-up to the administration of the opioid antagonist, including calling 911.

Naloxone Products Allowed Per Standing Order

The standing order includes the following naloxone opioid antagonist formulations and means of administration approved for dispensing for which the pharmacist indicates the quantity to dispense:

Intranasal naloxone HCL (Narcan®)

Rx Naloxone Nasal Spray 4 mg

Administer a single spray into one nostril upon signs of opioid overdose. Call 911.

May repeat every 2-3 minutes until EMS arrives.

Quantity: _____ (minimum 2 units)

Intranasal naloxone with atomizer device (2 prescriptions):

Rx Naloxone 2 mg/2ml Prefilled Syringe

Spray one-half the content of each syringe into each nostril upon signs of opioid overdose.

Call 911. May repeat one time.

Quantity: _____ (minimum 2 syringes)

Rx Mucosal Atomization Device (MAD)

Use as directed for nasal naloxone administration. Call 911.

Quantity: _____ (minimum 2 devices)

Intramuscular naloxone HCL injection (Evzio®)

Rx Naloxone 0.4/0.4 ml Auto-Injector Twin-Pack

Administer one auto-injector upon signs of opioid overdose. Call 911.

May repeat one time.

Quantity: _____ (minimum 1 twin-pack)

Organization-based Eligible Recipients Distributing Naloxone

Eligible recipients to whom a naloxone opioid antagonist is prescribed may administer or direct another person to administer the opioid antagonist to a person who is experiencing an actual or reasonably perceived opioid-related drug overdose.

An eligible recipient may also distribute the opioid antagonist to any other person who is an eligible recipient (unlike all other prescription drugs for which such activity is prohibited). The [Act](#) imposes additional requirement on organization-based eligible recipients, including first responder entities; harm reduction organizations; the Montana state crime laboratory; law enforcement, probation and parole, detention facilities; public health entities; veterans' organizations; and authorized representatives or

employees of these groups. Any of these eligible recipients who distribute an opioid antagonist pursuant to the [Act](#), must:

- Provide the patient with basic instruction and information, the content of which has been developed by DPHHS and made publicly available on their website at: <http://dphhs.mt.gov/publichealth/emsts/prevention/opioids>.
 - The *DPHHS Opioid Overdose Recognition and Response Guide* includes information concerning recognition of the signs and symptoms of an opioid-related drug overdose, indications for the administration of an opioid antagonist, administration technique, and the need for immediate and long-term follow-up to the administration of the opioid antagonist, including calling 911.
- Develop protocol for:
 - Instructing and training the eligible recipient's employees or other authorized personnel that is consistent with the instruction and information developed by DPHHS (above), and
 - The storage, maintenance, and location of the opioid antagonist.

Educational Guidance for Administering Naloxone

- Screen individual for contraindications/precautions. If a contraindication/precaution exists, refer individual to their medical provider for further evaluation.
- Precautions:
 - Use in Pregnancy:
 - Teratogenic Effects: no adequate or well controlled studies in pregnant women.
 - Non-teratogenic Effects: pregnant women known or suspected to have opioid dependence often have associated fetal dependence. Naloxone crosses the placenta and may precipitate fetal withdrawal symptoms.
 - Nursing mothers: caution should be exercised when administering to nursing women due to transmission in human milk. Risks and benefits must be evaluated.
- Contraindications:
 - Contraindicated in patients known to be hypersensitive to it or to any of the other ingredients in naloxone hydrochloride.
- Adverse reactions:
 - Adverse reactions are related to reversing dependency and precipitating withdrawal and include fever, hypertension, tachycardia, agitation, restlessness, diarrhea, nausea/vomiting, myalgia, diaphoresis, abdominal cramping, yawning and sneezing.
 - These symptoms may appear within minutes of naloxone administration and subside in approximately 2 hours.
 - The severity and duration of the withdrawal syndrome is related to the dose of naloxone and the degree of opioid dependence.
 - Adverse effects beyond opioid withdrawal are rare.
- Instruct the individual to whom naloxone is dispensed to summon emergency services as soon as practical if naloxone is used – either before or after administering naloxone.
- Provide counseling and the educational brochure to the individual to whom naloxone is dispensed, appropriate to the dosage form of naloxone dispensed. Counseling may include but is not limited to the following:
 - Risk factors of opioid overdose;
 - Strategies to prevent opioid overdose;
 - Signs of opioid overdose;
 - Steps in responding to an overdose;
 - Information on naloxone, including possible adverse reactions;
 - Procedures for administering naloxone;

- Proper storage and expiration of naloxone product dispensed; and
- Information on where to obtain a referral for substance abuse treatment.
- If applicable, provide the individual with the following resources on treatment options available for opioid addiction/dependency:
 - Montana Addictive & Mental Disorders Divisions (AMDD) at: <http://dphhs.mt.gov/amdd>.
 - U.S. Substance Abuse and Mental Health Services Administration at: <http://findtreatment.samhsa.gov>.

DPHHS Grant Funding for Eligible Recipients Purchasing Naloxone

DPHHS has secured grant funding to help first responders, law enforcement, fire departments, school nurses, and harm reduction coalitions with the purchase of naloxone for distribution to staff who may need to administer naloxone in the normal course of duty. DPHHS has contracted with Ridgeway Pharmacy in Victor, Montana, for such purchases and requires completion of a DPHHS-approved naloxone training program(s) to use the grant funds. For additional information, see DPHHS contact information below.

An eligible recipient entity utilizing DPHHS grant funds to acquire naloxone for administration or to distribute to another eligible recipient MUST receive training through a DPHHS-approved program.

The DPHHS-approved training program must include the following:

- Understanding of the prescription overdose problem.
- Understanding of how opioids work.
- Opioid overdose response:
 - Causes and recognition of an opioid overdose.
 - Indications for administrations of naloxone.
 - Patient assessment and treatment including alerting EMS.
 - Follow-up treatment of patient after administration of naloxone.
- Administration of naloxone:
 - Understanding of how naloxone works.
 - Indications, contraindications, and possible adverse reactions to naloxone.
 - Preparation and administration of naloxone (nasal spray, auto-injector, injectable).
 - Procedures and Legal Considerations.
 - How to obtain naloxone.
 - Montana statutes related to prescription drugs and administration of naloxone.
 - Standing orders.
 - Operating procedures and protocols related to storage, maintenance, and location of naloxone.
 - Training--refresher training.

Additional Information

Medical Practitioner Dispensing Naloxone

The [Act](#) amended [37-2-104, MCA](#), allowing medical practitioners to dispense naloxone directly to patients and document the reason for which the opioid antagonist was prescribed and dispensed. The medical practitioner must comply with provisions outlined in [37-2-104, MCA](#).

The medical practitioner must also provide the patient with basic instruction and information, the content of which has been developed by DPHHS and made publicly available on their website at:

<http://dphhs.mt.gov/publichealth/emsts/prevention/opioids>.

- The *DPHHS Opioid Overdose Recognition and Response Guide* includes information concerning recognition of the signs and symptoms of an opioid-related drug overdose, indications for the

administration of an opioid antagonist, administration technique, and the need for immediate and long-term follow-up to the administration of the opioid antagonist, including calling 911.

Revisions to Liability and Good Samaritan Laws

The [Act](#) includes specific provisions regarding personal liability and Good Samaritan laws, and amended several criminal law provision in [Title 45](#), including:

- 45-5-626. Violation of order of protection.
- 45-9-102. Criminal possession of dangerous drugs.
- 45-9-107. Criminal possession of precursors to dangerous drugs.
- 45-10-103. Criminal possession of drug paraphernalia.

School Access to Naloxone

Regarding school access to naloxone, the Montana Legislature passed a separate new law in 2017, HB 323 that authorizes emergency use of opioid antagonist in a school setting. The law defines a school as a patient for purposes of dispensing naloxone prescriptions and is available online at:

<http://leg.mt.gov/bills/2017/billpdf/HB0323.pdf>. The law amended [Title 20, Chapter 5, Part 4](#), MCA and is similar to a 2013 law change that identifies a school as a patient for epinephrine prescriptions for rescue of an allergic reaction.

DPHHS Contact Information

Please contact the Chronic Disease Prevention and Health Promotion Bureau – Injury Prevention Program (1-844-684-5848) for questions about the *Montana Standing Order for Naloxone Opioid Antagonists* or visit the Department of Public Health and Human Services' EMS and Trauma Systems Section website at:

<http://dphhs.mt.gov/publichealth/emsts/prevention/opioids>.