

STATEWIDE NALOXONE STANDING ORDER FOR PHARMACISTS

Background

In April 2014, 2013 Wisconsin Act 200 was signed into law, expanding access to life-saving opioid antagonists, defined in Wis. Stat. § 450.01(13v)(a) as a drug that binds to the opioid receptors and competes with or displaces opioid agonists at the opioid receptor site but does not activate the receptors, effectively blocking the receptor and preventing or reversing the effect of an opioid agonist. It is indicated for the reversal of overdoses of narcotic drugs, such as certain prescription medications and heroin. In December 2015, 2015 Wisconsin Act 115 was signed into law to expand on Act 200, to allow practitioners to prescribe an opioid antagonist to pharmacies under a standing order. In addition, the law allows pharmacists to deliver opioid antagonists, pursuant to a standing order, to an individual at risk for an opioid overdose or to an individual in a position to assist an individual at risk for overdose, which ensures that the people of Wisconsin have greater access to potentially life-saving opioid antagonists.

Under state law, a licensed physician, physician assistant, or advanced practice nurse certified to issue prescription orders may issue standing orders for naloxone prescriptions to be filled by pharmacists to help expand statewide naloxone access to those who need it most.

The pharmacist shall provide a consultation in accordance with rules promulgated by the board for the delivery of a prescription to the person to whom the opioid antagonist is delivered.

Statewide Standing Order

A standing order is defined in Wis. Stat. § 450.01(21p) as an order transmitted electronically or in writing by a practitioner for a drug or device for multiple patients or for one or more groups of patients. A centralized, statewide opioid antagonist standing order for pharmacists outlines predetermined conditions and criteria that, when met, enables pharmacists across Wisconsin to dispense an opioid antagonist without a prescription. A licensed physician in Wisconsin and Chief Medical Officer within the Department of Health Services (DHS) may issue standing orders for naloxone that delegate authority to pharmacists practicing and licensed in Wisconsin to dispense naloxone to those patients specified in the standing order.

Standing Order Information

The policies and procedures outlined in this standing order reflect current medical research and clinical best practice, as of September 2017. This authorization is only for pharmacists that are unable to obtain a naloxone standing order through an affiliated medical provider.

Pharmacies should go to the DHS website <http://www.dhs.wisconsin.gov/opioids/standing-order.htm> to view an unsigned version of the statewide standing order, which provides information about expectations. This site will also have a link for pharmacies to request the signed Statewide Naloxone Standing Order for Pharmacists.

In order to be eligible for a signed statewide standing order, all pharmacists dispensing naloxone rescue kits via standing order must complete at least one hour of training. The training should include, at a minimum, identification of patients at risk for opioid overdose, administration of intranasal and intramuscular naloxone, patient education and counseling, naloxone precautions and contraindications, and medication storage. For a list of trainings recommended by DHS and Pharmacy Society of Wisconsin, go to the DHS website <http://www.dhs.wisconsin.gov/opioids/standing-order.htm>.

NALOXONE STANDING ORDER FOR PHARMACISTS

SUBJECT:

Statewide Standing Order for Pharmacies for Naloxone Dispensing for Opioid Overdose Prevention

EFFECTIVE DATE:

August 2019 (supersedes all previous versions)

EXPIRATION OF STANDING ORDER:

The naloxone standing order must be renewed two years from August 1, 2019. If your pharmacy signs up at any point in time between August 2, 2019 and July 31, 2021, you will need to renew on August 1, 2021.

APPROVED FOR USE AS A POPULATION-BASED STANDING ORDER BY:

Wisconsin Department of Health Services (DHS)

PURPOSE:

This statewide standing order delegates authority to pharmacists and outlines the policies and procedures necessary for dispensing naloxone without a prescription to patients at risk of an opioid overdose or to individuals in a position to assist the patient at risk for overdose.

POLICY:

This standing order authorizes pharmacists, located and licensed in Wisconsin, to maintain supplies of naloxone kits for the purposes of dispensing to an individual at risk for an opioid overdose, or to an individual in a position to assist an individual at risk for overdose. This authorization is only for pharmacists that are unable to obtain a naloxone standing order through an affiliated medical provider. It does not prevent the use of patient-specific or third party prescriptions for naloxone written by prescribers.

This standing order covers the possession and dispensing of naloxone kits, to include naloxone hydrochloride, intramuscular syringes or nasal spray devices/atomizers, or commercial auto-injectors.

This standing order will be renewed biennially.

AUTHORITY:

This standing order is issued pursuant to Wis. Stat. § 448.037, which permits physicians and physician assistants to issue a standing order to one or more persons authorizing the dispensing of an opioid antagonist. This standing order authorizes pharmacists to dispense naloxone and devices for naloxone administration pursuant to following the procedures outlined herein. Unlimited refills are authorized.

PROCEDURES:**1. Standing order compliance requirements:**

- a. Before receiving the signed standing order, the pharmacy must provide pharmacy name and address, pharmacy NPI number, and pharmacy contact information to DHS via the following website www.dhs.wisconsin.gov/opioids/standing-order.htm
- b. A copy of the standing order signed by a DHS Chief Medical Officer, who is also a licensed physician in Wisconsin, must be maintained on file and be readily retrievable at each participating pharmacy site.
- c. Participating registered pharmacists at the site must complete at least one hour of training related to naloxone dispensing and administration recommended by the DHS and the Pharmacy Society of Wisconsin. This requirement does not apply to pharmacists who have previously completed training as part of the statewide standing order.

- d. The managing pharmacist must sign the standing order, attest that all registered pharmacists at the site have completed the required training and are familiar with naloxone rescue kits and the patient education materials.
- e. The pharmacist must educate the patient and distribute the patient education materials at the time of dispensing.
- f. As a condition of receiving a signed standing order, each pharmacy must maintain records of specified data and send summary reports to DHS every quarter to <http://www.dhs.wisconsin.gov/opioids/standing-order.htm>.

2. Record Keeping and Reporting

- a. Pharmacists must maintain dispensing records according to Wis. Admin. Code § Phar 7.07 requirements (record keeping requirements).
- b. Pharmacists **must** report to DHS quarterly all naloxone dispensed through the statewide standing order using prescriber number **1346552668**. Reporting periods and due dates are as follows:

Reporting period October 1 – December 31	Due January 31
Reporting period January 1 – March 31	Due April 30
Reporting period April 1 – June 30	Due July 31
Reporting period July 1 – September 30	Due October 31

Quarterly reports are submitted via the DHS website: <http://www.dhs.wisconsin.gov/opioids/standing-order.htm>

3. Billing/reimbursement order.

- a. Some insurance plans cover naloxone; check patients' coverage and dispense based on coverage and pharmacy benefit criteria.
- b. Medicaid coverage: Since the statewide standing order is signed by a physician who is Medicaid certified, Medicaid patients of record may be covered by their insurance.
- c. For those patients without insurance coverage, referral can be made to any other local resource for which the pharmacy is aware. See *Patient Resource Guide*.

Naloxone HCl Pharmacist Dispensing Protocol

Clinical Pharmacology Description	Naloxone is indicated for the complete or partial reversal of opioid overdose induced by natural or synthetic opioids and exhibited by respiratory depression or unresponsiveness. It may be delivered via intranasal or intramuscular routes.				
Eligible Candidates	<p>People who voluntarily request naloxone, including:</p> <ul style="list-style-type: none"> • Any individual who is at risk of experiencing an opioid-related overdose. • Any family member, friend, or other person who may assist an individual at risk for an opioid-related overdose. <p>Pharmacists and pharmacy technicians may screen and identify additional patients to offer naloxone who:</p> <ul style="list-style-type: none"> • Take prescription narcotic pain relievers for more than three months. • Take methadone or buprenorphine (Suboxone or Subutex) for treatment of opioid use disorder. • Have experienced a previous non-fatal opioid overdose. • Have a history of nonmedical opioid use. • Take a higher-dose (≥ 50 mg morphine equivalent/day) opioid prescription • Receive any opioid prescription for pain, plus: <ul style="list-style-type: none"> ○ Smoking, COPD, emphysema, asthma, sleep apnea, respiratory infection, other respiratory illness. ○ Renal dysfunction, hepatic disease, cardiac illness, HIV/AIDS. ○ Have concurrent prescription for benzodiazepines. ○ Have concurrent prescription for Selective Serotonin Reuptake Inhibitor (SSRI) or Tricyclic antidepressant. ○ Have difficulty accessing emergency medical services (distance, remoteness). <p>See Red Flag Reminder and Patient Screening Checklist.</p> <ul style="list-style-type: none"> • Have a family member or friend that meets any of the above. • Report no known contraindication, sensitivity, or allergy to naloxone hydrochloride. If contraindication exists, refer individual to medical provider for evaluation. • Are oriented to person, place, and time and able to understand and learn the essential components of overdose response and naloxone administration. 				
Order to dispense	<p>Upon satisfactory assessment that the person to receive the naloxone is a person at risk of experiencing an opioid-related overdose or an individual in a position to assist an individual at risk for overdose, and upon providing consultation to that individual regarding recognizing and responding to suspected opioid overdose, deliver one naloxone kit.</p> <p>The specific naloxone formulation shall be selected from the list below in accordance with the recipient's preference and training to administer a particular formulation.</p>				
Product and Quantity to be Dispensed	Medication	Intramuscular	Intranasal		Auto-Injector
			Ready to Use	Assembly Required	
		Two single-use 1 ml vials of naloxone hydrochloride (0.4 mg/ml)	Pre-packaged kits with two single-use spray devices containing Naloxone HCL (4 mg/0.1 ml)	Two 2ml Luer-Jet Luer-lock syringes prefilled with naloxone hydrochloride (2mg/2ml)	Naloxone hydrochloride 0.4 mg/ml pre-packaged kits containing two auto-injectors with audio instructions and one training device

Product and Quantity to be Dispensed (cont'd)	Supplies	Two intramuscular needle syringes (3 mL, 25 G, 1 inch) Gloves	None needed	Two mucosal atomization devices	N/A
Patient Handouts	<p>Pharmacist will provide education regarding overdose recognition and naloxone administration, including:</p> <ul style="list-style-type: none"> Review risk factors for opioid overdose and ways to prevent overdose: Overdose Safety and Overdose Prevention brochure (P-01571) Provide overview of how to recognize an overdose and administer naloxone: How to Respond to an Overdose and How to Administer Naloxone Handout P-01576. Inform when to initiate rescue breathing and proper procedure: How to Respond to an Overdose and How to Administer Naloxone Handout P-01576 Patient Resource Guide (P-01575) provides information on medication disposal and naloxone availability. Other patient education materials are available, as specified on DHS webpages. Previous materials have been updated, and links will automatically be updated. 				
Prescription Label	<p>Should include the following:</p> <ul style="list-style-type: none"> Name of the recipient or patient (prescribed or using) Prescriber name on the standing order Naloxone formulation and concentration Date dispensed Refills: PRN, as needed for a year Patient instructions <ul style="list-style-type: none"> Dispensed per standing order; Use as directed; and Trained opioid overdose responder 				
Consultation and Education					
Consultation	<ul style="list-style-type: none"> The pharmacist shall provide a consultation in accordance with rules promulgated by the board for the delivery of a prescription to the person to whom the opioid antagonist is delivered. Wis. Stat. 450.11(1i)(a)1 Ask if naloxone is for patient or someone else, or if ever used before. Offer naloxone to anyone/or loved one of someone who is using opioids (prescription or non-prescription). Naloxone Available Poster (P-01577) is on DHS website. To identify those at higher risk of an overdose, provide client with Patient Screening Checklist (P-01572). Consult as appropriate. Provide client with information about four different naloxone delivery options and ask what type they would like, depending on preference, availability at pharmacy, and insurance coverage. 				
Patient Education	<p>Patient education regarding overdose recognition and naloxone administration:</p> <ul style="list-style-type: none"> Review risk factors for opioid overdose and ways to prevent overdose: Opioid Safety and Overdose Prevention brochure (P-01571) Provide overview of how to recognize an overdose: Opioid Safety and Overdose Prevention brochure (P-01571) Inform when to initiate rescue breathing and proper procedure: How to Respond to an Overdose and How to Give Naloxone handout (P-01576). Discuss how to administer naloxone and when: How to Respond to an Overdose and How to Give Naloxone handout (P-01576). Additional training is available on www.prescribetoprevent.org. Other patient education materials are available, as specified on DHS webpages. Previous materials have been updated, and links will automatically be updated. 				

Medication Administration Instructions	Intramuscular	Intranasal		Auto-Injector
		Ready to Use	Assembly Needed	
	<ol style="list-style-type: none"> 1) Uncap the naloxone vial and uncap the muscle needle syringe. 2) Insert the muscle needle through the rubber membrane on the naloxone vial, turn the vial upside down, draw up 1cc of naloxone liquid into the syringe, and withdraw the needle from the vial. 3) If time allows, open alcohol wipe and rub the area where the injection will be administered. 4) Insert the needle into the muscle of the upper arm or thigh of the victim, through clothing if needed, and push on the plunger to inject the naloxone. 5) If there is no response after three (3) minutes, repeat the injection. 	<ol style="list-style-type: none"> 1) Peel back package to remove the device. 2) Place the tip of nozzle in either nostril. 3) Press plunger firmly to release the dose into patient's nose. 4) If there is no response, after two to three minutes, give an additional dose of nasal spray using a new device. 	<ol style="list-style-type: none"> 1) Pop off the 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 top of the syringe. 4) Spray half (1ml) of naloxone in one nostril and the other half (1ml) in the other nostril. 5) If there is no response after three (3) minutes, repeat. 	<ol style="list-style-type: none"> 1) Pull auto-injector from outer case and pull off the red safety guard. 2) Place the black end of the auto-injector against the outer thigh, through clothing if needed. Press firmly and hold in place for five (5) seconds. 3) If there is no response after three (3) minutes, repeat.
<p>SPECIAL NOTE: Sometimes more than one dose is needed. If there is no reaction in two to three minutes, give a second dose.</p>				
After Naloxone Administration	<ul style="list-style-type: none"> • Continue rescue breathing and monitor respiration and responsiveness of the naloxone recipient until emergency help arrives. • Once overdose victim is breathing again, put in recovery position. Naloxone can wear off after 30-90 minutes, so stay with the overdose victim until help has arrived. The victim may develop recurrent respiratory depression as the naloxone wears off and opioids are still in their system. • Make sure they do not take more opioids even if they do not feel well. 			
Contra-indications	Patients known to be hypersensitive to naloxone hydrochloride.			
Precautions	<ul style="list-style-type: none"> • Risk of recurrent respiratory depression: duration of action of opioids may exceed that of naloxone resulting in return of respiratory depression—medical attention should be sought immediately when responding to a suspected overdose. • Precipitation of opioid withdrawal: 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. <ul style="list-style-type: none"> ○ These symptoms may appear within minutes of Naloxone administration. ○ 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. • Naloxone crosses the placenta, and may precipitate withdrawal in the fetus. The fetus should be evaluated for signs of distress after naloxone is used. Naloxone should only be used in pregnant women with opioid dependence in life-threatening overdose situations. 			

Additional Patient Education

- Provide information on safe disposal of used sharps and unused/unwanted medication. For more information on safe disposal, go to the Wisconsin Department of Health Services webpage: dhs.wisconsin.gov/opioids/. Instruct the individual/parent/guardian to call the medical provider if questions, concerns, or problems arise.
- Encourage person prescribed opioids to communicate with prescriber regarding overdose risk or risk factors and the use of naloxone.
- If concerns expressed about substance use disorder, provide resources on support, recovery and treatment, including the Wisconsin Addiction Recovery Hotline (211). Also see [Patient Resource Guide \(P-01575\)](#).
- Instruct the individual/parent/guardian on how to store naloxone and a good place to keep it that is out of extreme temperatures and direct sunlight, e.g., keep in purse or backpack and do not store in car.
- Instruct to return for a refill as needed, subject to use and expiration of naloxone (18 months).
- Ask each patient if they would like to get repeat patient education around overdose prevention and opioid safety. Repeat education may not be necessary.

Naloxone Standing Order Signatures:

SIGNATURE - Dr. Jonathan Meiman, DHS Chief Medical Officer

 August 1, 2019

 Date Signed

By signing this Statewide Naloxone Standing Order for Pharmacists, the managing pharmacist attests that all registered pharmacists at this location have received one hour of training on Naloxone, and read and understand both the naloxone standing order and the naloxone patient education materials located on the DHS website.

SIGNATURE – Managing Pharmacist

 Date Signed

 Managing Pharmacist Name and License Number

 Pharmacy Name

 Store number(s)

 Pharmacy Address