

STATEWIDE NALOXONE STANDING ORDER FOR PHARMACISTS

BACKGROUND:

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 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 patient-specific prescription order. 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.

SUBJECT:

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

EFFECTIVE DATE:

August 1, 2023 (supersedes all previous versions)

EXPIRATION OF STANDING ORDER:

The statewide naloxone standing order expires August 1, 2025.

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

Wisconsin Department of Health Services (DHS)

PURPOSE:

This statewide naloxone 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. 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, including naloxone hydrochloride, intramuscular syringes, or nasal spray devices/atomizers.

AUTHORITY:

This standing order is issued pursuant to Wis. Stat. § 448.037, which permits physicians 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 dispensing naloxone rescue kits under the standing order, the pharmacy must provide the pharmacy name and address, pharmacy NPI number, and pharmacy contact information to DHS via the website below. There will also be a sample statewide standing order copy available at this address.
 - i. Go to <https://www.dhs.wisconsin.gov/opioids/professionals.htm>
 - ii. Scroll down and click on “Information for pharmacists.”
 - iii. An accordion will open and at the bottom, click on “Obtain the signed statewide standing order.”
 - iv. The link will take you to RedCap. Fill out the form and submit.
 - v. Signup requirements will appear on the screen. Before receiving a signed copy, you must agree to comply.
- 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. To be eligible to dispense under the statewide standing order, all pharmacists dispensing naloxone rescue kits via this 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. We encourage pharmacy staff to continue to educate themselves on best practices for dispensing naloxone and other related content. Training may be accessed here:
 - i. Go to <https://www.dhs.wisconsin.gov/opioids/professionals.htm>
 - ii. Scroll down and click on “Information for pharmacists.” An accordion will open.
 - iii. Scroll down to standing order training requirements and follow the instructions to access the training.
- d. All licensed pharmacists at the pharmacy must complete the required training and be 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. Pharmacists must maintain dispensing records according to Wis. Admin. Code § Phar 7.11 requirements (pharmacy records).
- g. Pharmacists **must** report to DHS quarterly all naloxone dispensed through the statewide standing order using prescriber number **1952745234**. 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 requested by DHS via an individualized link emailed to the pharmacy contact.

2. Billing/reimbursement.

- a. Some insurance plans cover naloxone; check patients’ coverage and dispense based on coverage and pharmacy benefit criteria.

- b. Medicaid coverage: Because 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.

SAMPLE VIEW ONLY

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 illnesses. ○ 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). • 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		
			<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th data-bbox="821 1690 1170 1753" style="text-align: center;">Ready to Use</th> <th data-bbox="1170 1690 1521 1753" style="text-align: center;">Assembly Required</th> </tr> </thead> <tbody> <tr> <td data-bbox="821 1753 1170 1906">Pre-packaged kits with two single-use spray devices containing naloxone hydrochloride (4 mg/0.1 ml)</td> <td data-bbox="1170 1753 1521 1906">Two 2 ml Luer-Jet Luer-lock syringes prefilled with naloxone hydrochloride (2 mg/2 ml)</td> </tr> </tbody> </table>	Ready to Use	Assembly Required
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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
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 • Patient instructions <ul style="list-style-type: none"> ○ Dispensed per standing order; and ○ Use as directed. 			
Consultation and Education				
Consultation	<ul style="list-style-type: none"> • The pharmacist shall provide a consultation in accordance with rules promulgated by the Wisconsin Pharmacy Examining 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 ever used naloxone before. Offer education on overdose recognition and naloxone administration. Emphasize the importance of establishing an overdose response plan; ensure others in their residence learn this plan in case of emergency. • Provide client with information about the naloxone delivery options and insurance coverage. 			
Patient Education	<p>Patient education regarding overdose recognition and naloxone administration is available on the Dose of Reality:</p> <ul style="list-style-type: none"> • Review common questions about opioids and address risk factors that can put someone at increased risk of overdose: Dose of Reality: Get the Facts on Opioids • Provide overview of how to recognize an overdose and proper procedure to respond to an overdose: Dose of Reality: Opioid Overdose • Discuss how to administer naloxone and when: Dose of Reality: Safer Use/Harm Reduction: Scroll down just below the map of where you can get naloxone for instructions on administering naloxone. • Discuss how to safely dispose of opioids and other unused prescription medication: Dose of Reality: Safe Disposal of Medications and Medical Supplies • Additional training is available on www.prescribeprevent.org. • Other patient education materials are available, as specified on DHS webpages. 			

Medication Administration Instructions	Intramuscular	Intranasal	
		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 1 mL 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 three (3) 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 (1 ml) of naloxone in one nostril and the other half (1 ml) in the other nostril. 5) If there is no response after three (3) minutes, repeat.
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 are 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	<ul style="list-style-type: none"> • Instruct the individual/parent/guardian to call the medical provider if questions, concerns, or problems arise. Additionally, instruct patient to communicate with prescriber regarding overdose risk or risk factors and the use of naloxone. • If individual wants information on how to talk to someone about opioids and opioid use, provide talking points resource: Dose of Reality: Start Talking About Opioids • If concerns expressed about substance use disorder, provide resources on support, recovery and treatment: Dose of Reality: Opioid Treatment and Recovery • 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 backpack or personal bag and do not store in car. • Instruct to return for a refill as needed, subject to use and expiration of naloxone. • Ask each patient if they would like to get repeat patient education around overdose prevention and opioid safety. Repeat education may not be necessary.
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Statewide Naloxone Standing Order Signature:

August 1, 2023

SIGNATURE - Dr. Jasmine Y. Zapata, DHS Chief Medical Officer

Date Signed

By dispensing naloxone rescue kits under 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 have read and understand both the naloxone standing order and the naloxone patient education materials.