



Non-Patient Specific Prescription for Naloxone with Pharmacy Dispensing Protocol

January 1, 2023

This non-patient specific prescription (standing order) for naloxone dispensing by pharmacists in New York State is issued contingent on compliance with the protocol and terms below. It is effective January 1, 2023, until such time that it is rescinded or revised, whichever comes first. Questions regarding the scope or applicability of this standing order should be directed to naloxonepharmacy@health.ny.gov.

NYS License Number 184365

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Section 1: Purpose

Naloxone hydrochloride (naloxone HCL; naloxone), an opioid antagonist, is an easily administered medication proven to reverse opioid overdoses effectively when used in a timely manner. For more than 15 years, non-medical persons in New York State (NYS) have successfully administered this medication on friends, family members, and complete strangers averting disability and loss of life. New York State is committed to ensuring broad, low threshold availability of naloxone, including in pharmacies where the public is accustomed to having its medication needs addressed. To that end, this standing order is issued authorizing pharmacists in New York State complying with the protocols established herein to dispense naloxone to individuals requesting this medication or who may otherwise benefit from it without a patient-specific prescription being in place. An individual prescribed and dispensed naloxone under this standing order may possess naloxone and the necessary supplies for its administration and administer it to anyone they believe may be experiencing an opioid overdose.

New York State Non-Patient Specific Prescription for Naloxone with Pharmacy Dispensing Protocol

Section 2: Authority

The Commissioner of Health has broad authority under Public Health Law Section 3309(1) pertaining to the “opioid antagonist prescribing, dispensing, distribution, possession and administration.” Non-patient specific prescribing and dispensing of naloxone is explicitly authorized in Public Health Law Section 3309(3)(b).

Section 3: Clinical Indication for Naloxone

Naloxone is indicated for the complete or partial reversal of respiratory depression induced by opioids. Untreated respiratory depression may lead to a cascade of catastrophic consequences, including cardiac arrest, brain damage and death.

Section 4: Warnings

In opioid dependent individuals, naloxone may precipitate acute opioid withdrawal whose symptoms include anxiety, running nose and eyes, chills, muscle discomfort, disorientation, combativeness, nausea, vomiting and diarrhea. These reactions may be dose dependent.

Section 5: Contraindications

Use of naloxone may be contraindicated in persons with a known history of adverse hypersensitivity to this medication or to a component of it, a rare eventuality. A history of opioid withdrawal symptoms is not a contraindication for naloxone administration.

Section 6: Authorized dispensers

This standing order applies to all pharmacists in NYS who are registered and are in good standing with the New York State Education Department’s Board of Pharmacy (Board of Pharmacy) and who are dispensing medications at a pharmacy licensed by the Board of Pharmacy in accordance with the Education Law.

Section 7: Eligible patients

Persons who request naloxone are eligible to have naloxone dispensed to them under this standing order. These persons include individuals who are at risk of experiencing an opioid overdose, as well as family members, friends and others in a position to assist an individual who is at risk of experiencing an opioid overdose.

Pharmacist-initiated dispensing of naloxone is also covered under this standing order. Pharmacists may be well-positioned to identify patients for whom having naloxone is advisable.

Adolescent patients under the age of 18 may be furnished naloxone if, in the opinion of the pharmacist, there are reasonably foreseeable circumstances in

New York State Non-Patient Specific Prescription for Naloxone with Pharmacy Dispensing Protocol

which this minor will be positioned to save a life by administering naloxone. This minor must be deemed to be sufficiently mature with respect to intellect and emotions to recognize an opioid overdose and to respond to it appropriately by calling 911 and administering naloxone. Where the requisite maturity or intellect is lacking, pharmacists, without dispensing naloxone, may still stress the importance of calling 911 in all medical emergencies.

Section 8: Naloxone formulations

The following naloxone formulations may be dispensed under this standing order:

- Nasal naloxone with each single-dose spray containing 4 mg in a 0.1mL solution, to be dispensed in units of 2 doses.
Current applicable product National Drug Codes (NDCs) include:
 - 69547-353 (Emergent Devices)
 - 0781-7176 (Sandoz)
 - 0093-2165 (Teva)
 - 45802-811 (Padagis)
- Injectable naloxone in single-use 1 mL vials with a strength of 0.4 mg/mL to be dispensed in units of 2 vials accompanied by an intramuscular syringe for each vial.
Current applicable product NDCs include:
 - 0409-1215 (Hospira)
 - 67457-292, 67457-599 and 06457-645 (Mylan)

In addition to the products specifically enumerated above, other naloxone formulations may be dispensed under this standing order so long as they have been approved by the United States Food and Drug Administration and are identical to one of the listed formulations in strength, dose volume, route of administration and pharmacologic action.

Section 9: Patient education

Patients are to be counseled and/or provided materials that address the following:

- Naloxone overview
 - Naloxone blocks the effect of opioids. Opioids include hydrocodone (Vicodin, Lorcet, Lortab, etc.), oxycodone (Percocet, Oxycontin, etc.), morphine, codeine, fentanyl, methadone, and heroin.
 - It usually takes effect within 2-5 minutes and lasts for 30-90 minutes, after which period an overdose state may return.
 - It is safe and effective when administered in a timely manner and has no effect if opioids are not present.
 - It will not reverse overdoses caused by substances other than opioids, such as stimulants (cocaine, amphetamine, methamphetamine), alcohol and benzodiazepines.

New York State Non-Patient Specific Prescription for Naloxone with Pharmacy Dispensing Protocol

- If unsure what substances were used, administer naloxone.
- Risk factors for opioid overdose
 - Use of any opioid can slow breathing and put individuals at risk for overdose.
 - Risk for overdose may be increased by changes in tolerance or mixing opioids with other drugs, alcohol or certain medications.
 - Periods of abstinence decrease tolerance and increase likelihood of an opioid overdose.
 - Using opioids alone decreases the chance someone will be able to help if an overdose occurs.
 - Fentanyl is now in many drugs, including heroin, cocaine and pressed pills. Fentanyl is a strong opioid which increases the chance of an overdose and which sometimes requires more than a single dose of naloxone after waiting 2-3 minutes after the first dose.
 - Patients who have experienced an overdose are at greater risk of having another one.
- Signs of opioid overdose
 - Person may be unresponsive and does not wake up even when shaken and shouted at. If uncertain, apply a sternal rub (rubbing vigorously and with pressure up and down the center of the chest with one's knuckles) to verify an unresponsive state
 - Breathing is very slow or not apparent.
 - There may be gurgling sounds.
 - Lips or fingernails may be blue, pale or gray.
- Steps in responding to an overdose
 - Administer naloxone
 - For nasal naloxone:
 - 1) Peel back the package to remove the device.
 - 2) Place and hold the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose.
 - 3) Press the plunger firmly to release the dose into the patient's nose.
 - 4) Repeat with a second dose if there is no response after 2-3 minutes

Note: do NOT test the device. All medication is dispensed upon pushing plunger.
 - For injectable naloxone:
 - 1) Uncap the naloxone vial and remove the syringe from its packaging.
 - 2) Insert the needle through the rubber membrane on the naloxone vial, turn the vial upside down, draw up the entire content of the vial, and withdraw the needle.

New York State Non-Patient Specific Prescription for Naloxone with Pharmacy Dispensing Protocol

- 3) Insert the needle into the muscle of the upper arm or thigh, through clothing if necessary, and push on the plunger to inject all the naloxone.
 - 4) Repeat with a second dose if there is no response after 2-3 minutes.
- Call 911
 - 1) Do this as soon as possible for any person not responding to sternal rub or otherwise suspected of experiencing an opioid overdose.
 - 2) Tell the dispatcher that you are with someone who may have overdosed and let them know the precise location.

Note: The 911/Good Samaritan law provides substantial protection against prosecution for possessing illegal drugs or for illegally providing alcohol in an emergency when aid is summoned.

- After using naloxone
 - If you can, stay with the person until emergency medical services (EMS) personnel arrive.
 - If the person wakes up:
 - Stay with them for at least 3 hours. They may stop breathing again and need more naloxone.
 - Encourage that they go with EMS personnel.
 - If the person is not breathing and responsive to stimuli after the first dose and if the responder knows either rescue breathing or CPR, use one of those techniques.
 - If the person is not breathing and remains unresponsive to stimuli 2-3 minutes after the first dose, administer another dose.
 - If you need to leave, turn the overdosed person on their side, placing one arm under the head to prevent them from choking.
- Information on how to access the NYS Office of Addiction Services and Supports (OASAS) HOPEline by calling 1-877-8-HOPENY (1-877-846-7369) or by texting to HOPENY (467369).
- Additional information as determined appropriate by the pharmacist.

Section 10: Record keeping and reporting naloxone dispensing

All naloxone dispensing must be documented consistent with applicable laws and regulations and with standard pharmacy practice.

Naloxone dispensing under this standing order must be reported to NYSDOH on a quarterly basis in a format provided by NYSDOH. The timeframes for this reporting are three-month periods starting January 1, April 1, July 1 and October

New York State Non-Patient Specific Prescription for Naloxone with Pharmacy Dispensing Protocol

1, with reports provided to the Department no later than 4 weeks after the end of each quarter. Questions regarding this reporting should be directed to naloxonepharmacy@health.ny.gov. For naloxone dispensed within New York City, reporting should also be made to the New York City Department of Health and Mental Hygiene (NYCDOHMH) in a format provided by NYCDOHMH.

Section 11: Naloxone Co-payment Assistance Program (N-CAP)

Pharmacists should make best efforts to ensure maximum use of N-CAP by 1) being enrolled for participation in this program; and 2) processing N-CAP claims for persons with prescription drug coverage as part of their health insurance.

Section 12: Public directory of pharmacies dispensing naloxone

All pharmacies must provide their address, hours of operation and telephone number in a format specified by NYSDOH for purposes of inclusion in an online, public-facing directory.