



Naloxone Non-Patient Specific Prescription and Pharmacist Dispensing Protocol, New York City

Section 1: Purpose

As some of health care’s most accessible practitioners, pharmacists are uniquely positioned to help reduce morbidity and mortality associated with opioid overdose. They can do this by dispensing Naloxone HCl (Narcan[®], Naloxone HCl or other generic equivalents, hereinafter “naloxone”) to at-risk patients or their friends and family members and educating them on the proper use of these products. This non-patient specific prescription (“standing order”) authorized by the New York City Department of Health and Mental Hygiene establishes the protocol that allows New York State-licensed pharmacists and supervised pharmacy interns to dispense naloxone-containing products to at-risk patients and third parties in pharmacies located in NYC.

Section 2: A Signed and Dated Medical Directive

I, Mary T. Bassett, MD, a licensed health care provider authorized to prescribe medication in the State of New York and affiliated prescriber of the NYC Department of Health and Mental Hygiene, authorize licensed pharmacists, and pharmacy interns under the supervision of licensed pharmacists, to dispense naloxone to a trained overdose responder 16 years of age and older, as defined by Section 3309 of the Public Health Law in pharmacies located in NYC in accordance with the attached protocol.

The pharmacist/pharmacy intern shall comply with this protocol and associated patient/caregiver education.

- Dispensing of naloxone must be accompanied by patient education, detailed in the protocol, which will take place on the premise of the pharmacy.
- Records must be maintained by the pharmacy, including: the name of the recipient; the name of the pharmacist; the date on which dispensing is done; and the number of doses dispensed at each interaction. Records must be able to reflect the total number of doses dispensed for each naloxone formulation/product, including the number of doses dispensed as refills, and must be made available to the NYC or NYS Departments of Health for inspection upon request.
- At least one pharmacist or intern trained on this protocol should be present during pharmacy hours to ensure naloxone availability.

<u>Mary T. Bassett, MD</u>	_____	_____	_____
Prescriber’s Name	Prescriber’s Signature	NYS License Number	Date Authorized

<u>Hillary Kunins, MD</u>	_____	_____	_____
Clinical Director’s Name	Clinical Director’s Signature	NYS License Number	Date Authorized

NYC Department of Health and Mental Hygiene, 42-09 28th Street, Long Island City, NY 11101
 Prescriber’s Address (city, state, zip)

Authorized Supervising Pharmacist – By signing this *Naloxone Non-Patient Specific Prescription*, the Supervising Pharmacist of Record attests that all registered pharmacists and interns at this location have read and understood the *Naloxone Non-Patient Specific Prescription and Pharmacist Dispensing Protocol* and have received appropriate education on overdose prevention and naloxone administration. Pharmacist education is available for CE credit through an on-line webinar: *Reducing Opioid Overdose in New York City: Naloxone Non-Patient Specific Prescription and Dispensing for Pharmacists* by visiting nyc.gov/health and searching for “Pharmacy Naloxone.” Pharmacist education may also be obtained through other formats such as live trainings.

Supervising Pharmacist Name	Supervising Pharmacist Signature	NYS License Number	Date Signed	Phone number
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Pharmacy Name	Pharmacy Address	(city, state zip)	Supervising Pharmacist E-mail
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***If this pharmacy has more than one site, please submit a separate signed non-patient specific prescription for each site**

Email or fax this signed page to: pharmacynaloxone@health.nyc.gov or 347-396-8889 (fax). The signed form will be returned to you for your records.

This non-patient specific prescription is valid for one year from the date authorized.

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Section 3: Dispensing Protocol for Naloxone to Individuals at Risk of Experiencing or Witnessing an Opioid-Overdose

Naloxone HCl Pharmacist Dispensing Protocol				
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>Pharmacist may opt to conduct risk assessment to identify additional patients to offer naloxone. The following factors increase risk and may serve as screening criteria in a pharmacy context:</p> <ul style="list-style-type: none"> • Taking prescription pain relievers (e.g., Vicodin[®], Percocet[®], oxycodone) for more than three months; • Taking methadone or buprenorphine (aka Suboxone[®]) for the treatment of opioid use disorder; • Having concurrent prescription for opioids and benzodiazepines; • Having experienced a previous non-fatal opioid overdose (if known); • Having a family member or friend of someone who meets any of the above. 			
Clinical Pharmacology Description	<p>Naloxone prevents or reverses the effects of opioids including respiratory depression, sedation and hypotension.</p> <ul style="list-style-type: none"> • It is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids. • Naloxone cannot be misused or cause overdose. 			
Contraindications	Known hypersensitivity to naloxone.			
Warnings	Naloxone may cause withdrawal symptoms such as: anxiety, running nose and eyes, chills, muscle discomfort, disorientation, combativeness, nausea/vomiting and/or diarrhea.			
Route(s) of Administration:	<ul style="list-style-type: none"> • Intranasal (IN) or intramuscular (IM) formulations are available. • Some insurance plans cover naloxone. Check the patient’s coverage and dispense formulation/product based on coverage and patient preference. If a patient cannot afford the naloxone and/or copay, offer a listing of NYC Opioid Overdose Prevention Programs, where naloxone can be accessed free of charge: www.health.ny.gov/overdose 			
Product and Quantity to be Dispensed <i>Any naloxone product approved by the FDA can also be dispensed</i>	Medication	Intranasal (IN)	Intramuscular (IM)	
	Required Device			
		<p>Naloxone HCL solution 1 mg/mL 2 x 2 mL as pre-filled Luer-Lock syringes</p> <ul style="list-style-type: none"> • Dispense 2 (two) doses • NDC #76329-3369-01 Amphastar <p>2 (two) x Intranasal Mucosal Atomizing Devices (MAD 300)</p> <ul style="list-style-type: none"> • Avail from: Teleflex (866-246-6990) or Safety Works, Inc (800-723-3892) 	<p>Naloxone HCl solution 0.4mg/mL 2 x 1mL single dose vials (SDV)</p> <ul style="list-style-type: none"> • Dispense 2 (two) SDV • NDC #00409-1215-01 Hospira <p>2 (two) x intramuscular (IM) syringe, 3mL, 25 G, 1 inch</p>	<p>Autoinjector (Evzio): 0.4 mg/mL</p> <ul style="list-style-type: none"> • 1 x two-pack • NDC #60842-030-0 Kaleo
Refills	12 (recommended)			
Prescription Label	Naloxone label must include: name of recipient/patient, prescriber name: <i>Mary T. Bassett, MD</i> , naloxone formulation and concentration, date dispensed, refills: 12 (recommended), the following terms: “Dispensed per standing order,” “Use as directed,” and “Trained opioid overdose responder”			

Section 4: Educating Patients on Overdose Prevention and Naloxone Administration

Patient Education Protocol			
Required Information Refer to handout: <i>Opioid Safety and How to Use Naloxone</i> , available by searching: "Pharmacy Naloxone" at nyc.gov/health	Per NYS law, patient education is required. Pharmacists must review a patient handout with patients, and include a written copy with the naloxone. See Patient Handout: <i>Opioid Safety and How to Use Naloxone</i> . Patient education must cover: <ol style="list-style-type: none"> 1. Naloxone overview 2. Risk factors of opioid overdose 3. Signs of opioid overdose 4. Overdose Response steps 5. Additional information as determined appropriate by the pharmacist 6. Information on how to access the NYS Office of Alcoholism and Substance Abuse Services' (OASAS) hotline: "OASAS HOPEline – call 1-877-8-HOPENY (1-877-846-7369), text HOPENY (467369) or visit http://www.oasas.ny.gov/accesshelp/" 		
Naloxone Overview	<ul style="list-style-type: none"> • Naloxone is a safe medication that blocks the effect of opioids. Opioids include hydrocodone (Vicodin[®], Lorcet[®], Lortab[®], etc.), oxycodone (Percocet[®], Oxycontin[®], etc.), morphine, codeine, fentanyl, methadone, buprenorphine (Suboxone[®]) and heroin. • No effect if opioids are not present. Will not reverse overdoses caused by other substances (e.g., stimulants, alcohol, benzodiazepines, such as Xanax[®] or Valium[®], or methamphetamines). If unsure what substances were used, administer naloxone. • Usually takes effect within two to five minutes and lasts for 30 to 90 minutes 		
Risk factors of opioid overdose	Reduce risk of opioid emergency or overdose: <ul style="list-style-type: none"> • Be careful if you take a break, miss doses; this can lower your tolerance. • Avoid mixing opioids with other medications or drugs (e.g., alcohol, benzodiazepines or cocaine.) • Avoid taking opioids when alone; this increases the risk of fatal overdose because nobody is around to help. • Be careful taking more opioids than usual. You never know how your body will react. 		
Signs of opioid overdose	<ul style="list-style-type: none"> • Person may be unresponsive and will not wake up even when shaken. Try to wake the person by vigorously rubbing your knuckles up and down the front of his or her rib cage (sternal rub). • Breathing slows or even stops. Lips and/or fingernails turn blue, pale or gray. 		
Steps in responding to an overdose	Directions for use: IN	Directions for use: IM	Directions for use: Evzio
Step 1: Call 911	Call 911 as soon as possible for a person suspected of an opioid overdose with respiratory depression or unresponsiveness. Follow 911 dispatcher instructions.		
Step 2: Administer naloxone (refer to Patient Handout: <i>Opioid Safety and How to Use Naloxone</i>)	<ol style="list-style-type: none"> 1) Take off yellow caps 2) Screw on white cone (mucosal atomizer device) 3) Take purple cap off vial of naloxone. 4) Gently screw vial of naloxone into barrel of the syringe. 5) Insert white cone into nostril; give a short, strong push on end of capsule to spray naloxone into nose. Spray one half (1ml) of vial into each nostril. If no reaction in three minutes, give second dose. 	<ol style="list-style-type: none"> 1) Remove cap from naloxone vial and uncover the needle. 2) Insert the needle through rubber plug with the naloxone vial upside down. Pull back on plunger and take up entire contents. 3) Inject whole vial into the upper arm or thigh muscle (through clothing if needed). If no reaction in three minutes, give second dose. 	The naloxone auto-injector contains a speaker that provides instructions to inject naloxone into the outer thigh, through clothing if needed. There is also a training device for practice included with each kit.
Step 3: After naloxone	<ul style="list-style-type: none"> • Stay with the person for as long as you can or until help arrives. • Make sure they do not take more opioids even if they don't feel well. • If there is no response, lay the person on his or her side to prevent choking. 		

Additional information	<ul style="list-style-type: none"> • Share info about naloxone, including where it will be kept and how to use, with friends and family. • Patients should be instructed to ask for a refill if one or more doses were used (incomplete kit), if lost or stolen or when nearing or after expiration date. • If naloxone was used, patient should inform pharmacist. Fill out the <i>Overdose Reversal Form</i> with the patient when overdose is reported or when a refill is requested. • Store naloxone at room temperature and out of direct light if possible. • NYS' 911 Good Samaritan Law provides substantial protections when calling 911 to save a life even if drugs are present.
Optional information to include if time permits:	<p>If time permits, the following can be shared with patient:</p> <ul style="list-style-type: none"> • If you know how, do rescue breathing and/or CPR. • Instructions for administering rescue breathing: <ol style="list-style-type: none"> 1) Place the person on his or her back and tilt the chin up to open airway. 2) Pinch the nose closed with one hand, make a seal between your lips and theirs, and give two even, regular-sized breaths. Blow enough air into the person's lungs to make the chest rise. 3) Give one breath every five seconds until help arrives or until the person resumes breathing.

Section 5: Documentation Policies

A. Management and maintenance of the *Naloxone Non-Patient Specific Prescription*:

- Supervising Pharmacist is responsible for downloading the *Non-Patient Specific Prescription and Pharmacist Dispensing Protocol, New York City*, signing on behalf of the pharmacy site(s) and emailing or faxing signed form (page one) to the NYC Health Department. **If the pharmacy has more than one site, a separate non-patient specific prescription needs to be signed and sent for each site.** Health Department signatures authorizing the *Non-Patient Specific Prescription* will be added and returned for your records.
 - *Non-Patient Specific Prescription and Pharmacist Dispensing Protocol, New York City* can be downloaded by searching for "Pharmacy Naloxone" at nyc.gov/health. Signed form (pages one and two) must be submitted to pharmacynaloxone@health.nyc.gov or 347-396-8889 (fax).
- Supervising Pharmacist is responsible for ensuring that all pharmacists and pharmacy interns under his/her supervision at listed pharmacy site(s) who will be dispensing naloxone have received appropriate education on overdose prevention and naloxone, as mandated by New York State Law.
 - Education is available through a pre-recorded on-line webinar: *Reducing Opioid Overdose in NYC: Naloxone Non-Patient Specific Prescription and Dispensing for Pharmacists* by searching for "Pharmacy Naloxone" at nyc.gov/health. This webinar is available for CE credit.
 - Training may also be obtained through other formats such as live trainings.
- Supervising Pharmacist is responsible for ensuring that all patients are educated on the essential elements listed on the patient handout: *Opioid Safety and How to Use Naloxone*, and that a copy of the patient handout is dispensed to each patient with naloxone.
 - Patient Handout: *Opioid Safety and How to Use Naloxone* can be downloaded by searching for "Pharmacy Naloxone" at nyc.gov/health, and are available in English, Spanish and Russian.
 - Any patient handout may be used as long as the essential overdose prevention elements are included: naloxone overview, risk factors of opioid overdose, signs of opioid overdose, steps in responding to an overdose, and additional information: replacing naloxone, storage and educating family/friends about its use. *Opioid Safety and How to Use Naloxone* may be adapted with permission from the NYC Health Department.
 - If using a different patient handout, the Supervising Pharmacist is responsible for ensuring that the NYS Office of Alcoholism and Substance Abuse Services' (OASAS) hotline information is provided to the patient: "**OASAS HOPEline – call 1-877-8-HOPENY (1-877-846-7369), text HOPENY (467369) or visit <http://www.oasas.ny.gov/accesshelp/>**"

B. Required record keeping

- For each dose of naloxone dispensed under this non-patient specific prescription, pharmacy must maintain in records, per standard practice: name of patient, name of pharmacist, and date dispensed.

C. Required reporting to NYC Health Department

- Supervising Pharmacist is responsible for ensuring that the number of doses of each naloxone formulation/product dispensed, indicating the number of refills, be submitted on a quarterly basis to the NYC Health Department. Data is due each January 31st (reporting period October 1 – December 31), April 30st (January 1 – March 31), July 31st (April 1 – June 30th) and October 31st (July 1 – September 30th).
 - Supervising Pharmacists may opt to submit the data using the electronic *Quarterly Pharmacy Naloxone Dispensing Report*, which can be accessed and completed online by searching for “Pharmacy Naloxone” at nyc.gov/health.
 - The form can also be downloaded and submitted to pharmacynaloxone@health.nyc.gov or 347-396-8889 (fax).
 - Data can also be submitted in an alternate format as long as all data points are covered.
- When a patient comes in for a refill, ask if naloxone has been used. If a patient has used the naloxone (one or two doses), a reversal report must be submitted via the form specified below. Repeat patient training is not necessary for individuals requesting a naloxone refill if they demonstrate knowledge of overdose prevention and naloxone administration.
 - Electronic *Pharmacy Overdose Reversal Reporting Form* can be completed and submitted online by searching for “Pharmacy Naloxone” at nyc.gov/health. The form can also be downloaded and submitted to pharmacynaloxone@health.nyc.gov or 347-396-8889 (fax).

D. Additional information

- Questions relating to pharmacy dispensing of naloxone under this *Naloxone Non-Patient Specific Prescription and Pharmacist Dispensing Protocol, New York City* can be emailed or faxed to: pharmacynaloxone@health.nyc.gov or 347-396.8889 (fax).
- Additional resources, such as a Pharmacist Checklist: *Dispensing Naloxone: New York City Department of Health and Mental Hygiene Standing Order*, and a poster advertising naloxone availability (in English and Spanish), are available by searching for “Pharmacy Naloxone” at nyc.gov/health.