



New York City Pharmacist Naloxone Dispensing Protocol and Agreement

In accordance with New York State Public Health Law Section 3309, the New York City Department of Health and Mental Hygiene (DOHMH) has issued a citywide **non-patient specific prescription (“standing order”)** that allows pharmacists and supervised pharmacy interns to dispense naloxone to anyone who requests it, without a patient-specific prescription. New York City Pharmacies enrolled to dispense naloxone under standing order shall adhere to the requirements set forth in this *New York City Pharmacist Naloxone Dispensing Protocol*.

The Pharmacist Program Coordinator of Record (as defined below) is responsible for ensuring that all pharmacy staff have been educated on the standing order and dispensing protocol. Any pharmacist leaving the role of Program Coordinator is responsible for notifying DOHMH to update Agreement. Technical assistance is available by emailing pharmacynaloxone@health.nyc.gov.

Section 1: Designated Pharmacist Program Coordinator Agreement

By signing this *New York City Pharmacist Dispensing Protocol*, the designated Program Coordinator attests/agrees that all registered pharmacists and pharmacy interns at _____ (print DBA Name) have read and understand the *Naloxone Non-Patient Specific Prescription* and the *New York City Pharmacist Dispensing Protocol*, and have all received appropriate education on overdose education and naloxone distribution.

Pharmacist Program Coordinator (Print Name) Pharmacist Program Coordinator Signature NYS License Date Signed

Pharmacy Legal Name (if different from DBA) NYS Pharmacy Registration Number Pharmacy NPI

Pharmacy Street Address City ZIP code

Email Phone Number FAX

Preferred Method of Contact: Email Phone Fax Mail

How did you learn about this program? _____

If you have other New York City pharmacy locations, please provide the following location information:

_____ Pharmacy Street Address	_____ City	_____ ZIP code
_____ PNYS Pharmacy Registration Number	_____ Pharmacy NPI	

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_____ PNYS Pharmacy Registration Number	_____ Pharmacy NPI	

Email or fax this signed page to: pharmacynaloxone@health.nyc.gov or 347-396-8889 (fax).
This Agreement must be renewed every two years, or upon a change in the designated Pharmacist Program Coordinator.

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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. Any individual receiving prescription opioid analgesics (<i>Including persons receiving prescriptions under No fault/Workers' Compensation</i>) <p>Pharmacist may opt to conduct risk assessment to identify additional patients to offer naloxone.</p>								
Age requirements	<p>No age restriction. An adolescent minor may become an opioid antagonist recipient if, in the opinion of the dispenser, there are reasonably foreseeable circumstances in 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 carry out all the responsibilities of an opioid antagonist recipient. The pharmacy's records should document this maturity in its records on this responder.</p>								
Clinical Pharmacology Description	<p>Naloxone prevents or reverses the effects of opioids including respiratory depression, sedation and hypotension. 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.</p>								
Contraindications	<p>A history of known hypersensitivity to naloxone hydrochloride or any of its components. This is extremely rare.</p>								
Warnings	<p>In opioid-dependent individuals, naloxone may cause withdrawal symptoms such as: anxiety, running nose and eyes, chills, muscle discomfort, disorientation, combativeness, nausea/vomiting, diarrhea. These reactions may be dose dependent.</p>								
Route(s) of Administration:	<p>Intranasal (IN) or intramuscular (IM) formulations are available.</p>								
Product and Quantity to be Dispensed <i>Additional naloxone products approved by the FDA may be dispensed pursuant to the standing order only upon receipt of written approval by the NYC Department of Health and Mental Hygiene.</i>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td data-bbox="402 947 570 1451" rowspan="3" style="width: 20%; vertical-align: top;">Medication</td> <td data-bbox="570 947 927 1024" style="text-align: center;">Intranasal (IN)</td> <td data-bbox="927 947 1562 1024" style="text-align: center;">Intramuscular (IM)</td> </tr> <tr> <td data-bbox="570 1024 927 1062" style="text-align: center;">Single-step (Narcan®)</td> <td data-bbox="927 1024 1562 1062" style="text-align: center;">Multi-step</td> </tr> <tr> <td data-bbox="570 1062 927 1451" style="vertical-align: top;"> 1 x two-pack Narcan® 4mg/.1mL NDC 69547-353-02 Adapt Pharma </td> <td data-bbox="927 1062 1562 1451" style="vertical-align: top;"> Naloxone HCl 0.4 mg/mL 2 x 1 mL single-dose vials (SDV) Dispense 2 (two) SDV NDC 0409-1215-01 Hospira or NDC 67457-292-02 Mylan Required device: 2 (two) x intramuscular (IM) syringe, 3mL, 23 or 25 G, 1 inch </td> </tr> </table> <p>If more doses are requested than authorized above:</p> <ul style="list-style-type: none"> Remind patients that 911 should always be called in the event of an overdose Check patient's insurance for coverage of additional doses Pharmacists may dispense additional doses as requested, counseling patients about out-of-pocket cost Remind patients that naloxone can be obtained free of cost at Opioid Overdose Prevention Programs 		Medication	Intranasal (IN)	Intramuscular (IM)	Single-step (Narcan®)	Multi-step	1 x two-pack Narcan® 4mg/.1mL NDC 69547-353-02 Adapt Pharma	Naloxone HCl 0.4 mg/mL 2 x 1 mL single-dose vials (SDV) Dispense 2 (two) SDV NDC 0409-1215-01 Hospira or NDC 67457-292-02 Mylan Required device: 2 (two) x intramuscular (IM) syringe, 3mL, 23 or 25 G, 1 inch
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Refills (Recommended)	<p>There are no limits to refills. The number of refills permitted is based on the patient's insurance plan and/or ability to pay.</p>								
Prescription Label must include:	<ul style="list-style-type: none"> Name of recipient/patient Prescriber name: <i>Hillary Kunins, MD</i> The terms: Dispensed per non-patient specific prescription; Use as directed; Patient is a trained opioid overdose responder. Naloxone formulation being prescribed Date dispensed 								
Payment Options and State Naloxone Co-Payment Assistance Program (N-CAP)	<ul style="list-style-type: none"> Many insurance plans cover naloxone. Consider insurance coverage and patient preference when dispensing. Naloxone Co-Payment Assistance Program (N-CAP): Through a New York State program, co-payments for naloxone in an amount up to \$40 for each prescription dispensed can be billed to N-CAP, not to the individual getting naloxone. Pharmacies enrolled in the NYS AIDS Drug Assistance Program (ADAP) are eligible to participate in N-CAP. More information available at www.health.ny.gov/overdose If a patient cannot afford naloxone and/or copay, direct patient to a local NYC Opioid Overdose Prevention Program where naloxone can be accessed free of charge: find a site at nyc.gov/health/naloxone, Stop OD NYC mobile app, or by contacting NYC Well 24 /7: Call 1-888-NYC-WELL (1-888-692-9355) or Text "WELL" to 65173 								

PATIENT EDUCATION PROTOCOL

<p>Required Information Refer to handout: Opioid Safety and How to Use Naloxone, available in multiple languages by searching: “Pharmacy Naloxone” at nyc.gov/health</p>	<p>Per NYS law, patient education is required. Pharmacist must print and give naloxone recipient a copy of the handout Opioid Safety and How to Use Naloxone. Inclusion of this handout meets the educational requirement for naloxone dispensing under standing order. Pharmacist is encouraged to review the following with naloxone recipients:</p> <ol style="list-style-type: none"> 1. What does naloxone do? 2. How to recognize opioid overdose 3. Overdose response steps 4. Aftercare 5. Report & Refill 6. Additional information as determined appropriate by the pharmacist 7. 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/” 	
<p>What does naloxone do?</p>	<ul style="list-style-type: none"> • Naloxone is a safe medication that can reverse the effects of an opioid overdose. Opioids include heroin, fentanyl and prescription painkillers. • Only works on opioids and safe to use even if opioids are not present. • Use naloxone if you suspect overdose, even if unsure if drugs were taken. • Usually takes effect within two to five minutes and lasts for 30 to 90 minutes. 	
<p>How to recognize opioid overdose</p>	<ul style="list-style-type: none"> • Unresponsiveness; person will not wake up even when shaken. • Breathing slows or stops. • Lips and/or fingernails turn pale blue, white or gray, depending on skin tone. 	
Overdose Response Steps		
<p>Step 1: Check for responsiveness</p>	<p>Try to wake the person by vigorously rubbing your knuckles up and down the front of his or her rib cage (sternal rub).</p>	
<p>Step 2: Call 911</p>	<p>If no response to sternal rub, call 911. The 911 Good Samaritan Law provides protection to someone overdosing or anyone calling 911 to save a life, even if drugs are present, with some exceptions.</p>	
	Single-step Intranasal (Narcan®)	Multi-step Intramuscular
<p>Step 3: Administer naloxone (refer to educational insert found with medication)</p>	<ol style="list-style-type: none"> 1) Peel back the package to remove the device. 2) Put the nozzle in either nostril until your fingers touch the bottom of the person’s nose. 3) Press the plunger firmly to release the dose into the person’s nose. 4) DO NOT press the plunger until the nozzle is in the person’s nose. All the medication is dispensed once the plunger is pushed. 5) Wait 2 minutes. Repeat as necessary. 	<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 draw up entire contents of vial. 3) Inject straight – not at an angle – into the upper arm or thigh muscle (through clothing if needed). 4) Wait 2 minutes. Repeat as necessary.
<p>Step 4:</p>	<p>If you know how, do rescue breathing and/or CPR. Put person in recovery position to prevent choking.</p>	
<p>Aftercare</p>	<ul style="list-style-type: none"> • Stay with the person for as long as you can or until help arrives. • Naloxone may cause withdrawal symptoms until it wears off. • Using more drugs is unlikely to reduce withdrawal and may increase risk for another overdose. 	
<p>Report</p>	<p>If naloxone is used, complete an anonymous report using the Stop OD NYC app or by emailing naloxone@health.nyc.gov</p>	
<p>Refill</p>	<p>Replace your naloxone if:</p> <ul style="list-style-type: none"> • You use one or more doses. • You lose your kit it or it is damaged or stolen. • It expires or is near the expiration date. 	
<p>Additional information</p>	<ul style="list-style-type: none"> • Share info about naloxone, including where it will be kept and how to use, with friends and family. • Store naloxone at room temperature and out of direct light if possible. • Review overdose risk factors and risk reduction strategies. 	

A. Non-Patient Specific Prescription (standing order) and prescriber information:

- **Authorization:** New York City Department of Health and Mental Hygiene (DOHMH) will issue an authorized Non-Patient Specific Prescription (standing order) to pharmacy upon enrollment. Citywide standing order is renewed every two years.
- **Prescriber information**
 - Prescriber: Hillary Kunins, MD
 - NPI: 1619017597
 - Address: 4209 28th St, CN-14, 19th Fl., Long Island City, NY 11101-4130
 - Phone: 347-396-7128
 - License: See authorized standing order.

B. Compliance with the *Pharmacist Naloxone Dispensing Protocol*:

- **Protocol Compliance:** Upon enrollment, a Pharmacist Program Coordinator designated by the pharmacy must review and sign the *Pharmacist Naloxone Dispensing Protocol and Agreement* (page one). This *Agreement* must be renewed every two years thereafter, or upon a change in the designated Pharmacist Program Coordinator. By signing the *Protocol and Agreement*, the designated Pharmacist Program Coordinator attests/agrees that pharmacist and patient education are met in accordance with the protocol.
- **Pharmacist Education:** Pharmacist Program Coordinator is responsible for ensuring that all pharmacists and pharmacy interns under their 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.
 - Training may be obtained via live trainings, technical assistance provided through DOHMH, or by other methods.
- **Patient Education:** Pharmacist Program Coordinator is responsible for ensuring that all patients are provided with education on the essential topics outlined in the Patient Education Protocol in this document.
 - **DOHMH Patient Handout:** The handout [Opioid Safety and How to Use Naloxone](#) can be downloaded, printed and included with naloxone to meet the patient education requirement in this protocol.
 - Visit nyc.gov/health and search for “Pharmacy Naloxone” to download. Available in English, Spanish, Haitian Creole, Chinese, Russian, Korean, Bengali and Yiddish. Email pharmacynaloxone@health.nyc.gov for assistance.

C. Standard record keeping

- Records must be maintained by the pharmacy, including: the name of the recipient, the name of the dispensing pharmacist; the date dispensed, and the number of naloxone kits (1 naloxone kit=2 doses naloxone, regardless of formulation) dispensed at each interaction. Records must be able to reflect the total number of kits dispensed for each naloxone formulation/product and must be made available to the NYC or NYS Departments of Health for inspection upon request.

D. Required quarterly reporting to DOHMH

- Pharmacist Program Coordinator is responsible for ensuring that the **number of kits (2 doses=1 kit)** of each naloxone formulation/product dispensed be submitted on a quarterly basis to the NYC Health Department. Data is due:
 - **April 15th** for reporting period January 1-March 31
 - **July 15th** for reporting period April 1-June 30
 - **October 15th** for reporting period July 1-September 30
 - **January 15th** for reporting period October 1-December 31
- Data can be submitted using the electronic [Quarterly Naloxone Reporting Form for NYC Pharmacies](#).
- Email pharmacynaloxone@health.nyc.gov if you are unable to submit data using the [Quarterly Naloxone Reporting Form for NYC Pharmacies](#) (<https://nyc-prd.redcapcloud.com/survey.jsp?code=8jdu1XQYgmwA0uAt>).
- Kits dispensed under **patient-specific prescriptions** are also requested, but not required.

F. Technical Assistance

- Email pharmacynaloxone@health.nyc.gov with any questions regarding training, compliance, management, and/or maintenance of the *Naloxone Non-Patient Specific Prescription* and/or *Pharmacist Naloxone Dispensing Protocol*.

G. Additional resources available by visiting nyc.gov/health and searching “pharmacy naloxone” or by emailing pharmacynaloxone@health.nyc.gov:

- Naloxone Available Here Poster (in [English](#) and [Spanish](#))
- Patient Frequently Asked Questions – [Getting Naloxone in Pharmacies: What You Need to Know](#)
- Additional information on naloxone access available at www.nyc.gov/naloxone

Note on Emergency Response

Please note that the intent of the pharmacy naloxone standing order and dispensing protocol is to expand access to naloxone so that individuals are *prepared in advance* of an opioid-related emergency.

The standing order is not intended for emergency response.

In the event of an emergency, always call 911.