



# 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 by dispensing naloxone (Narcan®, naloxone HCl, 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 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 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 all pharmacy hours to ensure naloxone availability.

<u>Mary 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 28<sup>th</sup> 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 (***If pharmacy has more than one location, please submit a separate signed non-patient specific prescription for each 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](http://nyc.gov/health) and searching for “Pharmacy Naloxone.” Pharmacist education may also be obtained in other ways such as live trainings.

_____	_____	_____	_____
Supervising Pharmacist Name	Supervising Pharmacist Signature	NYS License Number	Date Signed

_____	_____	_____	_____
Pharmacy Name (Legal)	Pharmacy Name (Trade – if different)	Supervising Pharmacist Email	Phone number

\_\_\_\_\_ Pharmacy Address (City, State, Zip)

_____	_____
Pharmacy NPI	NYS Pharmacy Registration Number

How did you learn about this program? \_\_\_\_\_

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

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

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<b>Eligible Candidates</b>	<p>People who voluntarily request naloxone, including:</p> <ul style="list-style-type: none"> <li>• Any individual who is at risk of experiencing an opioid-related overdose</li> <li>• Any family member, friend or other person who may assist an individual at risk for an opioid-related overdose.</li> <li>• Any individual receiving prescription opioid analgesics*</li> </ul> <p>Pharmacist <b>may opt to conduct risk assessment</b> to identify additional patients to offer naloxone. The following factors increase risk and may serve as screening criteria in a pharmacy context:</p> <ol style="list-style-type: none"> <li>1. High-dose opioid prescription (<math>\geq 100</math> total morphine milligram equivalents/day) To calculate total MME per day, use the Health Department’s OpioidCalc App. Visit <a href="http://nyc.gov">nyc.gov</a> and search “OpioidCalc” or download at the App Store (iPhone) or Google Play (Android).</li> <li>2. Chronic opioid therapy (<math>\geq 3</math> months)</li> <li>3. Prescribed concurrent opioid and benzodiazepine prescriptions</li> <li>4. Opioid misuse/illicit use, including: <ul style="list-style-type: none"> <li>• Current or past history</li> <li>• In treatment for opioid use disorder (e.g., methadone, buprenorphine, naltrexone)</li> <li>• Opioid overdose history</li> </ul> </li> <li>5. Family member or friend of an individual who meets criteria <i>*Including persons receiving prescriptions under No fault/Workers’ Compensation</i></li> </ol>														
<b>Age requirements</b>	<p>No age limit. An adolescent minor may become a trained overdose responder 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 a trained overdose responder. The pharmacy’s records should document this maturity in its records on this responder. If the required maturity appears to be lacking, an effort should be made to make the minor a trained overdose responder in all ways other than furnishing that minor with naloxone, i.e. training the minor in recognizing an opioid overdose; in calling 911 and in waiting with the victim until EMS arrives.</p>														
<b>Clinical Pharmacology Description</b>	<p>Naloxone prevents or reverses the effects of opioids including respiratory depression, sedation and hypotension.</p> <ul style="list-style-type: none"> <li>• It is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids.</li> <li>• Naloxone cannot be misused or cause overdose.</li> </ul>														
<b>Contraindications</b>	<p>Known hypersensitivity to naloxone.</p>														
<b>Warnings</b>	<p>Naloxone may cause withdrawal symptoms such as: anxiety, running nose and eyes, chills, muscle discomfort, disorientation, combativeness, nausea/vomiting and/or diarrhea.</p>														
<b>Route(s) of Administration:</b>	<ul style="list-style-type: none"> <li>• Intranasal (IN) or intramuscular (IM) formulations are available.</li> <li>• <b>Some insurance plans cover naloxone. Check the patient’s coverage and dispense formulation/product based on coverage and patient preference.</b></li> <li>• <b>Unless the patient requests the injectable formulation, we recommend seeing if an intranasal formulation is covered by patient insurance.</b></li> <li>• <b>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: <a href="http://www.health.ny.gov/overdose">www.health.ny.gov/overdose</a></b></li> </ul>														
<b>Product and Quantity to be Dispensed</b>  <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>	<b>Medication</b>  <b>Required Device</b>	<table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th colspan="2">Intranasal (IN)</th> <th>Intramuscular (IM)</th> </tr> <tr> <th>Multi-step</th> <th>Single-step (Narcan®)</th> <th>Multi-step</th> </tr> </thead> <tbody> <tr> <td>Naloxone HCl 1 mg/mL 2 x 2 mL as pre-filled Luer-Lock syringe Dispense 2 (two) doses NDC 76329-3369-01 Amphastar</td> <td>1 x two-pack Narcan® 4mg/.1mL NDC 69547-353-02 Adapt Pharma</td> <td>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</td> </tr> <tr> <td>2 x Intranasal Mucosal Atomizing Devices (MAD 300) Teleflex 866-246-6990 or Safety Works, Inc. 800-723-3892</td> <td></td> <td>2 (two) x intramuscular (IM) syringe, 3mL, 23 or 25 G, 1 inch</td> </tr> </tbody> </table>	Intranasal (IN)		Intramuscular (IM)	Multi-step	Single-step (Narcan®)	Multi-step	Naloxone HCl 1 mg/mL 2 x 2 mL as pre-filled Luer-Lock syringe Dispense 2 (two) doses NDC 76329-3369-01 Amphastar	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	2 x Intranasal Mucosal Atomizing Devices (MAD 300) Teleflex 866-246-6990 or Safety Works, Inc. 800-723-3892		2 (two) x intramuscular (IM) syringe, 3mL, 23 or 25 G, 1 inch	<p>If more doses are requested than authorized above:</p> <ul style="list-style-type: none"> <li>• Remind patients that 911 should always be called in the event of an overdose</li> <li>• Check patients insurance for coverage of additional doses</li> <li>• Pharmacists may dispense additional doses as requested, counseling patients about out-of-pocket cost</li> <li>• Remind patients that naloxone can be obtained free of cost at Opioid Overdose Prevention Programs</li> </ul>
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<b>Refills</b>	<p>12 (recommended); dispense refill upon patient request. Refill not dependent on completion of reversal form.</p>														
<b>Prescription Label</b>	<p>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”</p>														

Patient Education Protocol			
<b>Required Information</b> Refer to handout: <i>Opioid Safety and How to Use Naloxone</i> , available in multiple languages by searching: "Pharmacy Naloxone" at <a href="http://nyc.gov/health">nyc.gov/health</a>	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"> <li>1. <b>Naloxone</b> overview</li> <li>2. <b>Risk factors</b> of opioid overdose</li> <li>3. <b>Signs</b> of opioid overdose</li> <li>4. <b>Overdose response</b> steps</li> <li>5. <b>Additional</b> information as determined appropriate by the pharmacist</li> <li>6. Information on how to access the NYS Office of Alcoholism and Substance Abuse Services' (OASAS) hotline: "<b>OASAS HOPEline</b> – call 1-877-8-HOPENY (1-877-846-7369), text HOPENY (467369) or visit <a href="http://www.oasas.ny.gov/accesshelp/">http://www.oasas.ny.gov/accesshelp/</a>"</li> </ol>		
<b>Naloxone Overview</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• No effect if opioids are not present. Will not reverse overdose caused by other substances (e.g., stimulants, alcohol, benzodiazepines, such as Xanax® or Valium®, or methamphetamines). If unsure what substances used, administer naloxone.</li> <li>• Usually takes effect within two to five minutes and lasts for 30 to 90 minutes</li> </ul>		
<b>Risk factors of opioid overdose</b>	Reduce risk of opioid emergency or overdose: <ul style="list-style-type: none"> <li>• Be careful if you take a break, miss doses; this can lower your tolerance.</li> <li>• Avoid mixing opioids with other medications or drugs (e.g., alcohol, benzodiazepines or cocaine.)</li> <li>• Avoid taking opioids when alone; this increases the risk of fatal overdose because nobody is around to help.</li> <li>• Be careful taking more opioids than usual. You never know how your body will react.</li> </ul>		
<b>Signs of opioid overdose</b>	<ul style="list-style-type: none"> <li>• 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).</li> <li>• Breathing slows or even stops. Lips and/or fingernails turn blue, pale or gray.</li> </ul>		
<b>Overdose Response</b>	<b>Multi-step IN</b>	<b>Single-step IN (Narcan®)</b>	<b>Multi-step IM</b>
<b>Step 1: Call 911</b>	Call 911 as soon as possible for a person suspected of an opioid overdose with respiratory depression or unresponsiveness. Follow 911 dispatcher instructions.		
<b>Step 2: Administer naloxone</b> (refer to Patient Handout: <i>Opioid Safety and How to Use Naloxone</i> )	<ol style="list-style-type: none"> <li>1) Take off yellow caps</li> <li>2) Screw on white cone (mucosal atomizer device)</li> <li>3) Take purple cap off vial of naloxone.</li> <li>4) Gently screw vial of naloxone into barrel of the syringe.</li> <li>5) Insert white cone into nostril; give a short, strong push on end of capsule to spray naloxone into nose. Spray half (1ml) of vial into each nostril. If no reaction in 3 minutes, give second dose.</li> <li>6) Repeat as necessary</li> </ol>	<ol style="list-style-type: none"> <li>1) Peel back the package to remove the device.</li> <li>2) Place and hold the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose.</li> <li>3) Press the plunger firmly to release the dose into the patient's nose.</li> </ol> <p><b>IMPORTANT NOTES:</b></p> <ul style="list-style-type: none"> <li>• Do NOT test the device. All medication is dispensed upon pushing plunger.</li> <li>• This formulation has a higher concentration of naloxone.</li> </ul>	<ol style="list-style-type: none"> <li>1) Remove cap from naloxone vial and uncover the needle.</li> <li>2) Insert the needle through rubber plug with the naloxone vial upside down. Pull back on plunger and take up entire contents.</li> <li>3) Inject whole vial into the upper arm or thigh muscle (through clothing if needed). If no reaction in three minutes, give second dose.</li> <li>4) Repeat as necessary</li> </ol>
<b>Step 3: After naloxone</b>	<ul style="list-style-type: none"> <li>• Stay with the person for as long as you can or until help arrives.</li> <li>• Make sure they do not take more opioids even if they don't feel well.</li> <li>• If there is no response, lay the person on his or her side to prevent choking.</li> </ul>		
<b>Additional information</b>	<ul style="list-style-type: none"> <li>• Share info about naloxone, including where it will be kept and how to use, with friends and family.</li> <li>• 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.</li> <li>• If a refill is requested, ask if the naloxone was used. If naloxone was used, complete an <i>Overdose Reversal Form</i> with the patient.</li> <li>• Submission of an <i>Overdose Reversal Form</i> is NOT required for a refill to be dispensed.</li> <li>• Store naloxone at room temperature and out of direct light if possible.</li> <li>• NYS' 911 Good Samaritan Law provides substantial protections when calling 911 to save a life even if drugs are present.</li> </ul>		
<b>Optional information to include if time permits:</b>	<p><b>If time permits</b>, the following can be shared with patient:</p> <ul style="list-style-type: none"> <li>• If you know how, do rescue breathing and/or CPR.</li> <li>• Instructions for administering rescue breathing:               <ol style="list-style-type: none"> <li>1) Place the person on his or her back and tilt the chin up to open airway.</li> <li>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.</li> <li>3) Give one breath every five seconds until help arrives or until the person resumes breathing.</li> </ol> </li> </ul>		

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

- **Authorization:** 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 location, a separate non-patient specific prescription needs to be signed and sent for each location. 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](http://nyc.gov/health). Signed form (pages one and two) must be submitted to [pharmacynaloxone@health.nyc.gov](mailto:pharmacynaloxone@health.nyc.gov) or 347-396-8889 (fax).
- **Prescriber information**

Prescriber: Mary T. Bassett  
NPI: 1447616065  
Address: 4209 28th St 8th FL  
Long Island City, NY 11101-4130  
Phone: 347-396-7119  
License: See authorized standing order
- **Dispenser Education:** 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](http://nyc.gov/health). This webinar is available for CE credit.
  - Training may also be obtained through other formats such as live trainings.
- **Patient Education:** 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](http://nyc.gov/health), and are available in English, Spanish, Haitian Creole, Chinese, Russian, Korean, Bengali and Yiddish.
    - 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.
- Pharmacies are also asked to submit the number of doses of each naloxone formulation/product dispensed under patient-specific prescriptions.

**C. Required reporting to NYC Health Department**

- Supervising Pharmacist is responsible for ensuring that the **number of doses** (not scripts) of each naloxone formulation/product dispensed be submitted on a quarterly basis to the NYC Health Department. Data is due: **January 31<sup>st</sup>** (reporting period October 1 – December 31), **April 30<sup>th</sup>** (January 1 – March 31), **July 31<sup>st</sup>** (April 1 – June 30) and **October 31<sup>st</sup>** (July 1 – September 30).
  - 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](http://nyc.gov/health).
  - The form can also be downloaded and submitted to [pharmacynaloxone@health.nyc.gov](mailto: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.
  - Aggregate data on doses dispensed of each product **under patient-specific prescriptions** are also requested but not required.

- When a patient requests a refill, ask if the previously purchased naloxone has been used. If a patient has used any of the naloxone (one or two doses), a reversal report must be submitted via the form specified below.
  - Submission of a reversal report is not required for a refill to be dispensed.
  - 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](http://nyc.gov/health). The form can also be downloaded and submitted to [pharmacynaloxone@health.nyc.gov](mailto: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](mailto: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*, a poster advertising naloxone availability (in English and Spanish), a list of participating pharmacies, a pharmacist checklist, and Pharmacy Naloxone FAQs are available by searching for “Pharmacy Naloxone” at [nyc.gov/health](http://nyc.gov/health).
- Additional naloxone products may be dispensed upon receipt of written approval by the NYC Health Department.

**E. Naloxone Co-Pay Assistance Program (N-CAP)**

The New York State Department of Health AIDS Institute has an important pharmacy benefit for all New Yorkers who have prescription coverage through their health insurance plans: the Naloxone Co-payment Assistance Program (N-CAP). The key elements of this program are:

- Co-payments for naloxone in an amount up to \$40 for each prescription dispensed will be billed to N-CAP, not to the individual getting naloxone.
- Pharmacies participating in the New York State AIDS Drug Assistance Program are eligible to participate in N-CAP.
- Only the following naloxone formulations are eligible for N-CAP coverage:
  - Narcan® nasal spray (4mg/0.1 mL); NDC 69547-0353-02
  - Naloxone used for intranasal administration (1 mg/1 mL in 2 mL Luer-Jet™ pre-filled glass syringes); NDC 76329-3369-01
  - Naloxone for intramuscular injection (0.4 mg/mL in 1 mL single-dose vials); NDCs 00409-1215-01, 67457-0292-02, and 00641-6132-25
- More information available at <https://www.health.ny.gov>