

**PENNSYLVANIA PHARMACISTS ASSOCIATION
NALOXONE IMPLEMENTATION GUIDE**

I. Standing Order for Naloxone

A. What is a Standing Order?

1. Prescription written for the public rather than for an individual

B. How to Get Access to the Standing Order (DOH-002-2016)?

1. The standing order can be located on the Pennsylvania Department of Drug and Alcohol Programs website. The following link will also bring you to a PDF version of the Naloxone Standing Order for Overdose Prevention.

<http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/A-D/Documents/ACT%20139/Naloxone%20Standing%20Order%20DOH-General%20PublicMarch2016.pdf>

II. Filling a Prescription for Naloxone

A. How a prescription for naloxone would be processed?

1. Under Pennsylvania Act 139 of 2014 (Act 139) (amending The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780- 101 et seq.)), health care professionals otherwise authorized to prescribe naloxone are permitted to prescribe it via Standing Order to eligible persons.
2. Under the Standing Order, the following individuals are considered eligible persons and may obtain naloxone from a pharmacy:
 - a. Patients at-risk of experiencing opioid-related overdose
 - b. Family members, friends or other persons who are in a position to assist patients at-risk of experiencing opioid-related overdose
3. The Standing Order allows a pharmacist to write a hardcopy prescription under the order of Rachel L. Levine, MD. Please refer to sections V and VI for important information and proper documentation when filling a prescription for naloxone under the standing order.
4. Patients eligible to receive naloxone should be encouraged to complete an approved training program (see Section IV).

5. The following formulations of naloxone may be filled under the Standing Order:

- a. Intranasal naloxone

- i. Luer-lock syringe or mucosal atomization devices (MAD)
 - ii. Narcan[®] nasal spray
 - b. Intra-muscular naloxone, by way of Auto-Injector
 - i. Evzio[®]
- B. Filling a prescription for naloxone written by another healthcare provider?
 - 1. The naloxone standing order does not prevent a pharmacist from filling a prescription for naloxone written by another provider. If a pharmacist receives a prescription for naloxone written by another healthcare provider it is appropriate to fill that prescription under this providers' name and information.
- C. Formulations of Naloxone – Which to dispense? Quantity to be dispensed?
 - 1. Intranasal naloxone
 - a. Narcan[®] Nasal Spray
 - i. Supplied as 4-mg/0.1 mL single-dose spray
 - ii. Should dispense carton that contains 2 single-use bottles
 - b. Use of injectable solution of naloxone (1 mg/mL) with a mucosal atomization device attached to luer-lock syringe.
 - i. Each prefilled syringe contains 2-mg dose (2 mL)
 - ii. Should dispense 2 doses (with 2 separate syringes and 2 separate mucosal atomization devices)
 - a) The atomizers are generally NOT INCLUDED in the kit and may need to be purchased separately.
 - 2. Intramuscular naloxone (administered via auto-injector)
 - a. Evzio[®]
 - i. Each auto-injector contains 0.4 mg/0.4 mL
 - ii. Should dispense 2 auto-injectors + a single Trainer device (trainer device does not contain any active medication).

III. Storage of Naloxone

- A. Naloxone should be kept out of direct light and stored at room temperature (between 59°F and 77°F).¹ Storage information may differ based on different dosage forms.
 - 1. Solution, nasal spray (Narcan[®] Nasal Spray)

- a. Store at 15°C to 25°C (59°F to 77°F); excursions are permitted between 4°C and 40°C (39°F and 104°F). Do not freeze. Protect from light.²
2. Solution, auto-injector (Evzio[®])
 - a. Store at 15°C to 25°C (59°F to 77°F); excursions are permitted between 4°C and 40°C (39°F and 104°F).
 - b. Before using, check to make sure the solution in the auto-injector is not discolored. Replace Evzio[®] if the solution is discolored or contains a precipitate.³

IV. Patient Education

- A. Patients picking up prescription for themselves, a friend, family member or any other individual
 1. It is recommended that the recipient of naloxone be provided with counseling and written information on the information detailed below. While neither the standing order nor Act 139 requires that these steps be performed, in order to ensure the immunity protection that Act 139 offers, understanding an appropriate patient response to naloxone and having specific approved training for proper administration is very important.
 - a. It is recommended that the patient be educated regarding the following information, which is included in an approved training program:
 - i. Risk factors of opioid overdose
 - ii. Signs and symptoms of opioid overdose
 - iii. How to administer naloxone based on the device dispensed
 - iv. Proper storage and expiration of dispensed naloxone
 - v. Steps in responding to an overdose
 - a) Contact 911 if naloxone is used.
 - b) Remain with the patient until help arrives.
 - c) Place the patient into the safety position to reduce the risk of aspiration.
 - d) A second dose of naloxone may be needed if the patient overdosed on a high dose of a long-acting opioid medication.
 - vi. Strategies to prevent opioid overdose
 2. The Get Naloxone Now training program is a free program approved by the PA Department of Health. The website link for this program

(<http://www.getnaloxonenow.org>) as well as basic counseling information should be shared with all naloxone recipients at the point of dispensing.

3. The Pennsylvania Department of Drug and Alcohol Programs provides a concise naloxone guide for patients, friends and family members. The Friends and Family Naloxone guide can be accessed on their website or by clicking on the following link:
<http://www.ddap.pa.gov/overdose/Documents/Naloxone/Friends%20and%20Family%20Naloxone%20Guide.pdf>.
4. When naloxone is used in good faith with evidence of having taken training, the patient and administrator are immune from criminal or civil prosecution.
5. No recording or reporting aspects other than normal dispensing records are required. However, best practices include adhering to the following:
 - a. Encouraging all naloxone recipients to keep a copy of documentation stating that they completed an approved training program as this documentation will help provide legal and administrative immunity.
 - b. Encouraging all naloxone recipients to know the lot number and expiration date on the dispensed naloxone. If there is a recall of this medication, knowing this information will be critical to determine if the naloxone in their possession is affected by the recall and how they can go about obtaining replacement doses.
 - c. Following-up with those patients who received naloxone to determine if it was used, or if a new device is needed.

V. Billing and Insurance Coverage

- A. The dispensing of naloxone formulations in accordance with the Standing Order regulations allows pharmacists to bill Medicaid, State funded insurance plans, and many private insurance plans that may or may not cover the cost of naloxone. Most formulations of naloxone are covered by third party plans.
- B. Naloxone Standing Order prescriptions should be processed to **third party plans** OR processed as a **cash transaction** in the following manner:
 1. "Patient Name" OR "Person Requesting" the naloxone product should be listed on the prescription order.
 - a. Insurance companies are allowing "Person Requesting" information for the Standing order as a viable recipient requesting a naloxone product. The insurance billed should be that of the "Person Requesting" as a typical prescription processed at the pharmacy. Third Party Plans will reimburse for the dispensing of this medication as long as the information is correctly processed and documented. (Name, address, DOB, etc.)

2. Ensure proper selection of naloxone product
 3. Quantity issued
 - a. Insurance companies will typically allow for 2 doses per dispensing. The days' supply for this dispensing should be ONE day, but this quantity may vary across different insurance companies. Some insurance companies may limit the quantity of naloxone that can be filled over different lengths of time.
 4. Physician ordering will be: RACHEL LEVINE MD 050119-L
Commonwealth of Pennsylvania Physician General
- C. Currently, the atomizer lacks a National Drug Code or UPN, which are universal product identifiers typically used in insurance billing systems. Most likely, the pharmacy will have to charge the patient the cost of the atomizer if not covered by insurance.

VI. Recordkeeping

- A. Tracking lot numbers and expiration dates
1. When processing a Standing Order for a naloxone product, the prescription should have the following information recorded.
 - a. Product expiration date
 - b. Product lot number
 2. The product expiration date and product lot number should be documented on the actual hardcopy of the prescription and recorded properly in the prescription hardcopy filing system at the location from which it was issued. In addition, it is strongly recommended that the lot number and expiration date information be included or incorporated into the actual prescription direction area or produced on the prescription label. This will clearly communicate to the recipient the pertinent information about the prescription drug and minimize any integrity liabilities.
- B. Auditing by Commonwealth of Pennsylvania / Third Party Plans
1. Record retrieval is key for any form of an audit.
 2. Most computer record keeping systems should facilitate a drug dispensing print out which will list the following information:
 - a. "Patient Name" or "Person Requesting"
 - b. Prescription number
 - c. Dispensing date
 - d. Quantity dispensed

- e. Physician authorized: Rachel Levine, MD
 - f. Directions for use – can include the lot number and expiration date
 - g. Lot number
 - h. Expiration Date
3. A “patient signature” or “person requesting signature” may be also requested to show proof of purchase.

REFERENCES:

1. Pennsylvania Department of Drug and Alcohol Programs. *Friends and Family Naloxone Guide*, September 2016. Available at <http://www.ddap.pa.gov/overdose/Documents/Naloxone/Friends%20and%20Family%20Naloxone%20Guide.pdf>. Accessed January 18, 2017.
2. Narcan Nasal Spray [package insert]. Adapt Pharma, Inc. Radnor, PA: February 2016. Retrieved from: <https://www.narcan.com/pdf/NARCAN-Prescribing-Information.pdf>
3. EVZIO [package insert]. Kaleo, Inc. Richmond, VA. April 2014. Retrieved from: http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205787Orig1s000lbl.pdf

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