[Agency Name] Policy to Personally Furnish Naloxone Pursuant to Canton City Public Health Protocol

Name of Service Entity	
Address	
Date Protocol Delivered	
Review Frequency	Annual review by the service entity is recommended

Physician Authorization:

Physician Signature (CCPH)	License No: Ohio #35.060081
Physician Name: Jon A. Elias, M.D. Medical Director, Canton City Public Health	Date:

200-021 Overdose Education and Naloxone Distribution Program - Personally Furnishing Naloxone for Naloxone Furnishers and Responders, including Standing Orders (200-021-01-A) Personally Furnishing Naloxone Pursuant to a Protocol/Standing Orders established by the Board of Health, Canton City Public Health, on September 23, 2019.

Clinical Pharmacology of Naloxone (also called Narcan®)
Naloxone hydrochloride (naloxone) prevents or reverses the effects of opioids, including respiratory depression, sedation, and hypotension.

Naloxone is a nearly pure opioid antagonist, i.e., it does not possess the "agonistic" or morphine-like properties characteristic of other opioid antagonists. When administered in usual doses and in the absence of opioids or agonistic effects of other opioid antagonists, it exhibits almost no pharmacologic activity.

Naloxone has not been shown to produce tolerance or cause physical or psychological dependence. However, in the presence of opioid dependence, opioid withdrawal symptoms may appear within minutes of naloxone administration and subside in about 2 hours.

Naloxone may not reverse overdose in all cases, such as when high doses of opioids or particularly potent opioids (such as, fentanyl or carfentanil) have been consumed.

Indications for Personally Furnishing Naloxone
Naloxone is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids.

1. Previous opioid intoxication or overdose
2. History of nonmedical opioid use
3. Initiation or cessation of methadone or buprenorphine for opioid use disorder treatment.
4. Higher dose (≥50 mg morphine equivalent/day) opioid prescription.
5. Receiving any opioid prescription plus:
    a. Rotated from one opioid to another because of possible incomplete cross-tolerance.

b. Smoking, COPD, emphysema, asthma, sleep apnea, respiratory infection or other respiratory illness.
c. Renal dysfunction, hepatic disease, cardiac illness or HIV/AIDS.
d. Known or suspected concurrent alcohol use.
e. Concurrent benzodiazepine or other sedative prescription.
f. Concurrent antidepressant prescription.
g. Patients who may have difficulty accessing emergency medical services (distance, remoteness).

6. Voluntary request from a family member, friend or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

If staff believe that a person is currently experiencing an opioid overdose, emergency medical assistance must be summoned immediately.

Precautions, Contraindications, and Adverse Reactions

1. Precautions
   a. Use in Pregnancy:
      - Teratogenic Effects: no adequate or well controlled studies in pregnant women.
      - Non-teratogenic Effects: Pregnant women known or suspected to have opioid dependence often have associated fetal dependence. Naloxone crosses the placenta and may precipitate fetal withdrawal symptoms.

   b. Nursing mothers: caution should be exercised when administering to nursing women due to transmission in human milk. Risks and benefits must be evaluated.
2. Contraindications
   a. Contraindicated in patients known to be hypersensitive to it or to any of the other ingredients in naloxone hydrochloride.
3. Adverse reactions
   a. Adverse reactions are related to reversing dependency and precipitating withdrawal and include fever, hypertension, tachycardia, agitation, restlessness, diarrhea, nausea/vomiting, myalgia, diaphoresis, abdominal cramping, yawning and sneezing.
      - These symptoms may appear within minutes of naloxone administration and subside in approximately 2 hours.
      - The severity and duration of the withdrawal syndrome is related to the dose of naloxone and the degree of opioid dependence.
      - Adverse effects beyond opioid withdrawal are rare.

Authorization to Dispense Naloxone

Pursuant to section 4731.941 of the Ohio Revised Code (ORC), the following staff of [Agency Name] are trained and authorized to dispense naloxone without a prescription in accordance with CCPH's protocol:

- Please refer to Appendix A for updated list.

Upon completion of required overdose prevention and response training, naloxone may be dispensed to the following individuals:

- An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;
- A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose;

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This protocol authorizes the individuals listed above to dispense the following doses of intranasal formulations of naloxone:

- Two (2) naloxone 2 mg/2 mL prefilled syringes used with mucosal atomization devices
- Two (2) NARCAN® Nasal Spray 4mg/0.1 mL FDA-approved nasal spray device

Variation in dosage and/or formulation are permissible under the following circumstances:

- When high doses of opioids or particularly potent opioids (fentanyl, fentanyl analogues or carfentanil) are suspected that may require more than the standard dose of naloxone, extra doses may be distributed.

The authorized individual shall do all of the following in accordance with rule 4729-5-17 of the Ohio Administrative Code:

- Prepare, package and appropriately label the naloxone.
- Conduct the final check of the naloxone prior to personally furnishing on behalf of the prescriber.
- Keep and maintain all records in accordance with OAC 4729-9-22.
- Conduct patient counseling, including training on the use of the naloxone, as specified in this protocol.

Training of Individuals Authorized to Furnish Naloxone (Naloxone Trainers and Trained Naloxone Furnishers)

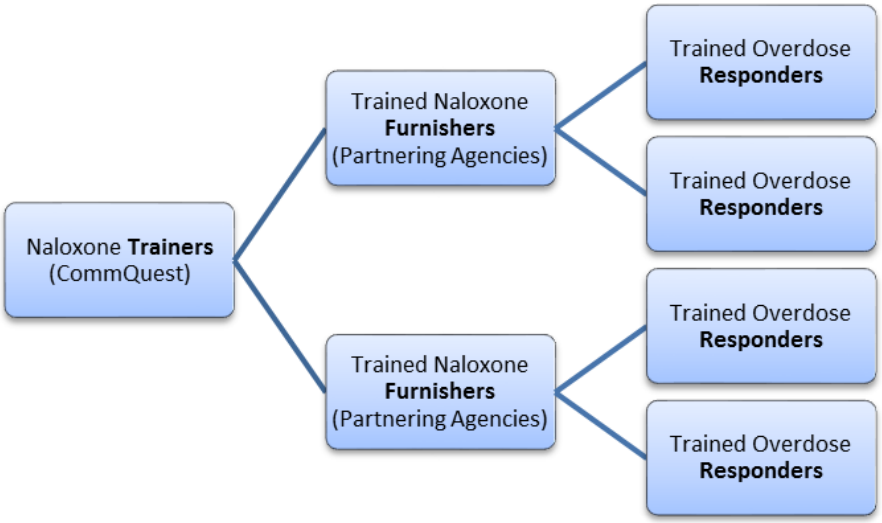

Figure 1: Flow chart of training for personally furnishing naloxone pursuant to CCPH's protocol.

Naloxone Furnishers

All OEDNP Naloxone Furnishers will attend a mandatory training conducted by CommQuest Naloxone Trainers. The training will be approximately one hour in length and will cover all elements of how to train Overdose Responders and furnish naloxone. CCPH has a partnership agreement with CommQuest Services for their Naloxone Trainers to provide 'Train-the-Trainer' instruction. Prior to furnishing naloxone, individuals authorized to furnish naloxone (Trained Naloxone Furnishers) must first complete the 'Train-the-Trainer' course. The training will be arranged by CCPH OEDNP staff with CommQuest for staff of [Agency Name]. Upon successful completion of the training, the trained staff will receive a *Certificate of Completion as a Trained Naloxone Furnisher* and will provide a copy to Canton City Public Health to be added to their protocol to personally furnish naloxone (per ORC

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4731.941). The names of trained staff will also be added to this policy under "**Authorization to Dispense Naloxone."** It is [Agency Name]'s responsibility to notify CCPH when a staff member is either no longer personally furnishing naloxone or no longer with the agency. The name of the staff member should be removed from CCPH's protocol and this policy.

Intake Documentation and Risk Assessment
An intake form will be completed for each Overdose Responder prior to or during the training session (200-021 -03-F: *Naloxone Intake Form (Version 3.0 Last update: 5/13/2019)*, including completion of the supplemental form on the back. The Trained Naloxone Furnisher will review this information and will ensure that all paperwork is completed accurately. Dispensing logs are required to be complete with each box of naloxone dispensed (200-021 -04-F: Dispensing Log).

[Agency Name] will submit paper intake forms to CCPH OEDNP staff by the **third** day of the following month. Arrangements will be made between the CCPH OEDNP staff and [Agency Name] for these forms to be returned to CCPH. Dispensing logs must be submitted to CCPH upon request.

Overdose Responders (ORs)
OENDP Naloxone Furnishers shall be responsible for training Overdose Responders (ORs) using the Project DAWN training curriculum. The training will include live demonstrations from the participants to assess their understanding and ability to respond in an overdose situation. The Project DAWN kit may contain an instructional booklet and/or DVD that will serve to reinforce these training steps. ORs will be encouraged to share these items with family and friends so that they may be better able to assist them in an overdose situation. In some situations, just the nasal naloxone kit will be provided without the instructional booklet and/or DVD. The OENDP Naloxone Furnisher is still responsible for completing a full training.

Trainings may be conducted in a variety of settings. The trainings may be in small groups or conducted one-on-one. The duration of the training shall depend on the number of responders in the class and their familiarity with drug administration and overdose.

The training curriculum shall address the following topics:

- Risk factors for opioid overdose
- Strategies to prevent opioid overdose
- Signs and symptoms of opioid overdose
- Response to opioid overdose, including calling 911 and administering rescue breathing
- Procedures for assembling and administering naloxone
- Information on naloxone, including possible adverse reactions
- Proper storage of naloxone
- Expiration date of dispensed product
- Procedure for reporting an overdose reversal
- Procedure for obtaining a replacement dose of naloxone
- Information on where to obtain a referral for substance abuse treatment

All individuals to whom naloxone is dispensed must be specifically instructed to summon emergency services as soon as practicable either before or after administering naloxone.

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Distribution of Naloxone Kits
ORs who complete the training shall be issued a naloxone kit by the Trained Naloxone Furnishers.
Each kit shall include:

Option #1	Option #2
• Two (2) doses of 4mg Narcan® nasal spray • One face shield • One pair nitrile gloves • One storage pouch	• Two (2) doses of 4 mg Narcan® nasal spray

Naloxone refills shall be made available to anyone who has previously completed Project DAWN training with another Project DAWN program. The OR and/or the naloxone furnisher shall complete the required reporting form and record the reason for the refill, i.e. loss, theft, expiration or use for an overdose reversal. Note: It is the OR's responsibility to show proof of previous training. If the OR does not have proof, then the training must be completed.

Labeling, Storage, Record-Keeping, and Administrative Requirements
Each dose of naloxone received and dispensed, including refill doses, will be recorded in a dispensing log as per OAC 4729-9-22.

Records of receipt shall include (200-021 -05-F: Receipt of Stock):
- Description of naloxone received
- Kind and quantity of naloxone received
- Name and address of the person from whom naloxone is received

Records of inventory (200-021 -05-F: Naloxone Inventory Log):
- Number/Count of naloxone added/subtracted to agency inventory
- Date that naloxone is added/subtracted to agency inventory
- Lot # of naloxone kits that are added/subtracted from agency inventory
- Expiration date of kits that are added/subtracted from agency inventory
- Signature of naloxone furnisher who is adding/subtracting from agency inventory
- Total naloxone kit balance in inventory

Records of distribution/dispensing shall include (200-021 -04-F: Dispensing Log):
- Description of the kind and quantity of naloxone dispensed
- Name and address of the person to whom, or for whose use, the naloxone was dispensed
  Each box of naloxone distributed must be labeled, pursuant to OAC 4729-5-17, with the following (200-021 -07-F: Label template):
- Name and address of the prescriber (i.e. the physician authorizing this protocol)
- Full name of the person to whom the naloxone is furnished
- Strength and formulation of naloxone
- Date that naloxone is dispensed
- Directions for use (Standing Orders: Appendix B)

Each box of naloxone will be securely stored in a locked cabinet at [Agency Name]'s choice of site and in a manner consistent with the manufacturer's guidelines, including storing at controlled room temperature,

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59°F to 77°F (15°C to 25°C). Excursions permitted between 39°F to 104°F (4°C to 40°C). Do not freeze. Protect from light (200-021-02-A: How to Store Naloxone).

As naloxone is to be stored at controlled room temperature, in the event [Agency Name] cannot maintain controlled room temperature (either hot (above 77°F) or cold (below 59°F) temperature), [Agency Name] will contact CCPH OENDP staff to make arrangements for the naloxone to be picked up at and stored at CCPH until the extreme temperature variation is restored to room temperature.

Data Tracking Procedures

Each dose of naloxone received or dispensed, including refill doses, will be recorded in a dispensing log and each box shall be appropriately labeled in accordance with CCPH standing orders. An intake form shall be completed for each OR who receives training. All forms will be securely stored, either digitally or as a hard copy, and will comply with all state and federal regulations pertaining to the proper storage of medical records.

[Agency Name] will submit paper intake forms to CCPH OENDP staff by the **third** day of the following month. Arrangements will be made between the CCPH OENDP staff and [Agency Name] for these forms to be returned to CCPH.

Safe Storage of Naloxone Supplies and Program Records

The OENDP staff shall ensure that all naloxone kits are securely stored in a locked cabinet at the program site and in a manner consistent with the manufacturer's guidelines, including storing at controlled room temperature, 59°F to 77°F (15°C to 25°C). Excursions permitted between 39°F to 104°F (4°C to 40°C). Do not freeze. Protect from light.

Quality Assurance

The OEDNP staff will supervise all naloxone furnishers when they begin training ORs and will subsequently perform quarterly quality control checks. The OENDP staff will review all documentation completed by the naloxone furnishers on a monthly basis, including intake forms, to ensure accuracy. Any clinical issues related to dispensing of naloxone and other adverse events reported by participants will be referred immediately to CCPH's medical director.

Fee Policies

ORs who complete the training and/or receive a naloxone kit have no obligation to pay any out-of-pocket costs or fees. OEDNP staff may request voluntary donations from individuals or agencies to support the Project DAWN program.

ALL APPENDICES AND FORMS/TEMPLATES AVAILABLE WITH CCPH POLICY 200-021:
WWW.CANTONHEALTH.ORG/?PG=354
CCPH OENDP Coordinator – 330.438.4646
CCPH OENDP Outreach Specialist – 330.438.4655

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Appendix A

This list will be updated as Canton City Public Health and partnering agencies train Naloxone Furnishers to enhance distribution in Stark County.

Authorization to Dispense Naloxone
Pursuant to section 4731.941 of the Ohio Revised Code (ORC), the following individuals are authorized to dispense naloxone without a prescription in accordance with this protocol:

- [Agency Name] - [Agency Address]
  Contact: [Agency Contact] - [Agency Phone]

*Add more rows as necessary

Employee	*Division/Position*	*Date Trained*

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