

# Protocol for Personally Furnishing Naloxone

<b>Original Effective Date:</b> January 24, 2019	<b>Review / Revision Date:</b> January 22, 2020	<b>Standard Operating Procedure:</b> AW 2020.01.014
---	--	--

**Subject Matter Expert:** Director of Health Promotion & Policy Integration      History:  New  Revised  Archived

**Organizational Scope:**

Administration    Community & Environmental Health    Health Promotion/Policy Integration

Health Services

**Frequency of Review:**

Annually    Biennially    5 Years    Other:

**Location:**

S-Drive: S: → Common → Policies, Plans & Procedures

Website: [www.lucascountyhealth.com/employee-login/](http://www.lucascountyhealth.com/employee-login/)

Hardcopy: TLCHD Policies & Procedures Manual in HR Office

Archived Version(s): AD 2019.01.014; AD 2019.09.014

**Requisite Signatures**

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> <br>Health Commissioner                                   | Director Nursing + Health Services<br>Date: 1-22-2020 |
| <input checked="" type="checkbox"/> <br>Director of Environmental Health & Community Services | Date: 1-22-2020                                       |
| <input checked="" type="checkbox"/> <br>Director of Health Promotion & Policy Integration     | Date: 1-22-2020                                       |
| <input checked="" type="checkbox"/> <br>Director of Nursing & Health Services                 | Health Commissioner<br>Date: 1-22-2020                |
| <input checked="" type="checkbox"/> <br>Medical Director                                      | Date: 1-22-20   |



## Protocol for Personally Furnishing Naloxone

### I. Scope

This SOP applies to all TLCHD employees and interns who provide opioid overdose response and Naloxone administration training and personally furnish individuals with Naloxone Kits.

### II. Purpose

The purpose of this SOP is to ensure that all staff and interns who provide opioid overdose response and Naloxone administration training and personally furnish individuals with Naloxone Kits will do so in a safe and consistent manner that is in compliance with Project DAWN and Ohio Revised Code (ORC) 4731.941, and Ohio Administrative Codes (OAC) 4729-5-17 and 4720-9-22.

### III. Background

Naloxone hydrochloride (naloxone) prevents or reverses the effects of opioids, including respiratory depression, sedation and hypotension.

Naloxone is an essentially 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 essentially 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 typically subside in about 2 hours.

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

### IV. Indications for Use of Naloxone

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

### V. Precautions, Contraindications, and Adverse Reactions

#### A. Precautions

1. Use in Pregnancy

- a. Teratogenic Effects: no adequate or well controlled studies in pregnant women.
- b. 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.
- c. 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.
- b. These symptoms may appear within minutes of naloxone administration and subside in approximately 2 hours.
- c. The severity and duration of the withdrawal syndrome is related to the dose of naloxone and the degree of opioid dependence.
- d. Adverse effects beyond opioid withdrawal are rare.

## VI. Authorization to Dispense Naloxone

- A.** Pursuant to ORC 4731.941, the following individuals are authorized to dispense naloxone without a prescription in accordance with this protocol:

1. TLCHD Opioid Coordinator
2. TLCHD Pharmacist
3. Northwest Ohio Syringe Services (NOSS) Staff
4. Naloxone Health Educators
5. Any properly trained Toledo-Lucas County Health Department employees or interns
6. Any properly trained UTMC Community Cares Clinic medical student
7. Any properly trained Lucas County DART (Drug Abused Response Team) member
8. Any properly trained UMADOP employee

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

1. Any individual for whom there is reason to believe may be at risk of experiencing an opioid-related overdose;
2. A family member, friend, or other person in a position to assist an individual there is reason to believe is at risk of experiencing an opioid-related overdose; or

3. A peace officer as defined in ORC 2921.51.
- C.** This protocol authorizes the individuals listed in SOP section (IV)(A) above to dispense the following doses of intranasal formulations of naloxone:
1. Two (2) naloxone 2 mg/2 mL prefilled syringes used with mucosal atomization devices
  2. Two (2) NARCAN® Nasal Spray 4mg/0.1 mL FDA-approved nasal spray device
- D.** The authorized individual shall do all of the following in accordance with OAC rule 4729-5-17:
1. Prepare, package, and appropriately label the naloxone.
  2. Conduct a final check of the naloxone (e.g., unexpired, package intact) prior to personally furnishing on behalf of the prescriber.
  3. Keep and maintain all records in accordance with SOP section (VII)(A-D).
  4. Conduct patient counseling, including training on the use of the naloxone, as specified in this protocol.

## **VII. Training Requirements**

### **A. Training Prevention Educators**

1. All authorized TLCHD employees or representatives will attend a mandatory training conducted by the project manager with oversight from the medical director.

### **B. Training of Individuals Receiving Naloxone**

1. Prior to dispensing naloxone, staff will engage each program participant in an educational session on overdose prevention and response. Training components will include the following:
  - a. Risk factors for opioid overdose
  - b. Strategies to prevent opioid overdose
  - c. Signs and symptoms of opioid overdose
  - d. Response to opioid overdose, including calling 911 and performing chest compressions
  - e. Procedures for administering naloxone
  - f. Information on naloxone, including possible adverse reactions
  - g. Proper storage of naloxone
  - h. Expiration date of the medication
  - i. Procedure for completing a naloxone intake form
  - j. Procedure for reporting an overdose reversal
  - k. Procedure for obtaining a replacement dose of naloxone
  - l. Information on where to obtain a referral for substance abuse treatment

2. Individuals need only complete the full training once if evidence of completion or authorized distribution individuals confirm previous completion.

**C. 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.**

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

**VIII. Labeling, Storage, Record-Keeping, and Administrative Requirements**

**A.** Each dose of naloxone received and dispensed, including refill doses, will be recorded in a dispensing log as per OAC 4729-9-22.

**B.** Records of receipt shall include:

1. Description of kind, lot number, and quantity of naloxone received (e.g., auto-injector, nasal spray, and dosage)
2. Name and department/program of the person from whom naloxone is received

**C.** Storage:

1. Naloxone must be stored in a location accessible to authorized Service Entity personnel in accordance with the manufacturer or distributor's labeling.
2. All doses should be checked periodically to ensure that the naloxone is not adulterated. Naloxone shall be considered adulterated when it is beyond the manufacturer or distributor's expiration date.
3. Adulterated naloxone shall be stored in a separate area apart from active drug stock to prevent its use.
4. TLCHD is licensed by the Board of Pharmacy and shall comply with all applicable state laws and rules regarding the storage of prescription drugs.

**D.** Records of distribution shall include:

1. Description of the kind and quantity of naloxone dispensed (e.g., auto-injector, nasal spray, and dosage)
2. Name and address of the person to whom, or for whose use, the naloxone was dispensed
3. All individuals furnishing naloxone must collect the *Individual Intake Form (Appendix A)* from each naloxone recipient, every time naloxone is furnished. TLCHD staff will request a participant to fill out insurance information via the provided *Insurance Form (Appendix B)* for naloxone provided by the Lucas County Mental Health and Recovery Services Board.
  - a. All forms and records must be turned into the Project Dawn Coordinator.

- E. Each box of naloxone distributed must be labeled, pursuant to OAC 4729-5-17, with the following:
1. Name and address of the prescriber (i.e. the physician authorizing this protocol)
  2. Full name of the person to whom the naloxone is furnished
  3. Strength and formulation of naloxone
  4. Date that naloxone is dispensed
  5. Directions for use

## **IX. Maintenance**

### **A. Review**

1. The Personally Furnishing Naloxone standard operating procedure is to be reviewed annually, or upon notification from ODH that there has been a revision with the Project DAWN guidelines, to ensure compliance with both agency and accreditation standards.

### **B. Revision**

1. All changes made to this SOP are to be noted on the **Record of Change**. Substantial changes will require renewed signatures from all applicable parties. This includes changes to the intent, scope, procedures, or policy statement.
2. Changes in style, format, grammar or minor error correction will not require renewed signatures but must be indicated on the Record of Change.

## Record of Change

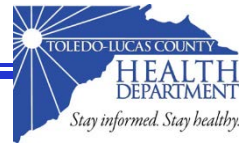
(Required for all procedures)

Date of Change	Changes Made By	Changes Made/Notes	Approved By
9/27/19	TM	Updated section III.Background; Added section IV. Indications for Use of Naloxone; added section V. Precautions, Contraindications, and Adverse Reactions; added (VI)(A)(6); added (VII)(B)(1)(i); added section (VIII)(C); updated (VIII)(D)(3) & (3)(a)	Signatories
1/22/2020	TM	Updated Authorization to Dispense Naloxone list in section (VI)(A); added "lot number" as a stated criteria for record keeping and reporting.	Signatories

## NALOXONE INTAKE FORM

<p><b>FOR OFFICE USE ONLY</b></p> <p>Form identification number: _____</p> <p>Number of kits provided: _____</p> <p style="text-align: center;">Type of kit:</p> <p><input type="radio"/> Individual    <input type="radio"/> Service entity</p>	<p>How is this naloxone funded?</p> <p><input type="radio"/> ODH general allocation</p> <p><input type="radio"/> ODH grant (IN20/IN21)</p> <p><input type="radio"/> Other _____</p>	<p style="text-align: center;">Distribution setting:</p> <p><input type="radio"/> Health Department    <input type="radio"/> Community Event</p> <p><input type="radio"/> Jail/Prison    <input type="radio"/> Emergency Department</p> <p><input type="radio"/> Mobile Unit    <input type="radio"/> Syringe Access Program</p> <p><input type="radio"/> Quick Response Team    <input type="radio"/> Treatment/Recovery</p> <p><input type="radio"/> Other _____</p>
<p><b>Today's Date:</b> ___ / ___ / ___ (MM/DD/YY)</p>		
<p><b>Age:</b> _____</p> <p><b>Do you consider yourself to be male or female?</b>    <input type="checkbox"/> Male    <input type="checkbox"/> Female</p> <p><b>What race(s) and ethnicity do you consider yourself? (check all that apply)</b></p> <p><input type="checkbox"/> White    <input type="checkbox"/> Black/African American    <input type="checkbox"/> Hispanic/Latino    <input type="checkbox"/> Asian    <input type="checkbox"/> Native Hawaiian/Pacific Islander</p> <p><input type="checkbox"/> American Indian or Alaska Native    <input type="checkbox"/> Other: _____</p>		
<p><b>In which Ohio county do you live?</b> _____    <input type="radio"/> Not available    <input type="radio"/> I do not live in Ohio</p>		
<p><b>Do you have health insurance?</b></p> <p><input type="radio"/> No    <input type="radio"/> Yes, I have Medicaid    <input type="radio"/> Yes, I have other insurance (private; Medicare; TRICARE; etc.)    <input type="radio"/> Unknown</p>		
<p><b>Intended use for naloxone (Narcan):</b>    <input type="checkbox"/> If I overdose    <input type="checkbox"/> If a friend or family member overdoses (check all that apply)    <input type="checkbox"/> If I see someone overdose    <input type="checkbox"/> For location to have on hand (service entity)</p>		
<b>Yes</b>	<b>No</b>	<b>Have you...</b>
<input type="radio"/>	<input type="radio"/>	...ever used intravenous (IV) drugs?
<input type="radio"/>	<input type="radio"/>	...ever been in a formal treatment program (other than AA, NA, or other peer support groups)?
<input type="radio"/>	<input type="radio"/>	...been released from an inpatient treatment facility within the past 30 days?
<input type="radio"/>	<input type="radio"/>	...been released from a jail or correctional facility within the past 30 days?
<input type="radio"/>	<input type="radio"/>	...ever overdosed? If yes, how many times? _____
<p><b>Is this the first naloxone (Narcan) kit you have received?</b>    <input type="radio"/> Yes    <input type="radio"/> No</p> <p><i>If no, what happened to your previous kit?</i></p> <p><input type="radio"/> My kit was used on another person who was overdosing → Did the person survive?    <input type="radio"/> Yes    <input type="radio"/> No</p> <p><input type="radio"/> My kit was used on me</p> <p><input type="radio"/> The medication in my kit expired</p> <p><input type="radio"/> Other</p> <p><b>How many times have you witnessed someone overdosing?</b> _____</p> <p><b>How many times have you administered (used) naloxone on someone overdosing?</b> _____</p>		





**Please Complete (Yes or No) Sign and Return to Event Facilitator**

LAST NAME \_\_\_\_\_ FIRST NAME \_\_\_\_\_  FEMALE  MALE

**PLEASE CHECK YES OR NO AND COMPLETE THE FORM AS INDICATED:**

**YES**, I give my informed consent\* for the pharmacy to bill my insurance for the Narcan® Nasal Spray I received at this training.

**NO**, I do not want the pharmacy to bill my insurance. **STOP** here and sign \_\_\_\_\_

DATE OF BIRTH \_\_\_\_/\_\_\_\_/\_\_\_\_

ADDRESS \_\_\_\_\_ CITY \_\_\_\_\_ ZIP \_\_\_\_\_

PHONE # \_\_\_\_\_ PREFER TO BE: CALLED OR TEXTED (CIRCLE)

Do you have Prescription Insurance Coverage?  YES  NO

If Yes, Please provide your PRESCRIPTION insurance information below.

Prescription Insurance Name	Member ID #
RX PCN #	RX Group #
RX BIN #	

I have read and completed the information on this form and my signature below gives consent for the pharmacy to bill my insurance company for the Narcan® Nasal Spray I received at this training and this is my valid information. I have read and understand the Notice of Privacy Practices. This form, when signed and filled in, contains Protected Health Information and the information is to be protected according to the Health Insurance Portability and Accountability Act (HIPAA).

**SIGN HERE** →

\_\_\_\_\_  
Signature Date

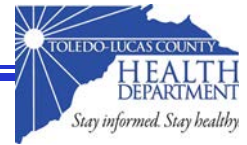
**PRINT HERE** →

\_\_\_\_\_  
Print Name

**\*My informed consent gives the pharmacy staff permission to document that I have received Narcan® Nasal Spray, and to use this information to bill my insurance company for the medication.**

**FOR OFFICE USE ONLY:**

Employee Name:	Employee Signature:
Narcan Lot #	RX Prescription Card Present? <input type="checkbox"/> Yes <input type="checkbox"/> No
Quantity Dispensed:	



## Notice of Privacy Practices

**THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.**

**Treatment** – Your health information may be used by staff members or disclosed to other health care professionals for the purpose of evaluating your health, diagnosing medical conditions, and providing treatment. For example, results of your vitals and medical history taken at the time of your transport, may be provided to the hospital upon your arrival at the emergency room.

**Payment** – Your health information may be used to seek payment from your health plan or from other sources of coverage such as an automobile insurer. For example, your health plan may request and receive information on dates of service, the services provided, and the medical condition being treated.

**Health Care Operations** – Your health information may be used as necessary to support the day-to-day activities and management of TLCHD. For example, information on the services you received may be used to support budgeting and financial reporting, and activities to evaluate and promote quality.

**Law Enforcement** – Your health information may be disclosed to public health agencies to support government audits and inspections, to facilitate law enforcement investigations, to comply with government investigations, and to comply with government mandated reporting.

---

**Uses and disclosures not listed above require your authorization.**

**Individual Rights** – You have certain rights as a patient under HIPAA regulations, these include:

- The right to request restrictions on the use and disclosure of your protected health information
- The right to receive confidential communications concerning your medical treatment
- The right to inspect and copy your protected health information\*
- The right to receive a printed copy of this notice
- The right to receive an accounting of how and to whom your protected health information had been disclosed
- The right to amend protected health information

\* You may generally inspect or copy the protected health information that we maintain. As permitted by federal regulation, we require that requests to inspect or copy protected health information be submitted in writing. You may obtain a form to request access to your records by contacting the main office at 419-213-4100. Your request will be reviewed and generally be approved unless there are legal or medical reasons to deny it.

---

**Our Duties** – We are required by law to maintain the privacy of your health information and to provide you with this notice of privacy practices. We are also required to abide by the privacy policies and practices that are outlined in this notice and inform you of any breach of unsecured information.

**Right to Revise Policy Practices** – As permitted by law, we reserve the right to amend or modify our privacy policies and practices. Upon request, we will provide you with the most recently revised notice. The revised policies and practices will be applied to all protected health information we maintain.

**Complaints** – If you would like to submit a comment or complaint about our privacy practices, or if you feel your rights have been violated, please contact our Privacy Officer:

Gwen Gregory  
635 N. Erie Street  
Toledo, Ohio 43604  
(419) 213-4174  
[gregoryg@co.lucas.oh.us](mailto:gregoryg@co.lucas.oh.us)

You can also file a complaint with the U.S. Department of Health and Human Services Office for Civil Rights by sending a letter to:  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Or by calling 1-877-696-6775, or visiting [www.hhs.gov/ocr/privacy/hipaa/complaints/](http://www.hhs.gov/ocr/privacy/hipaa/complaints/).

TLCHD will not retaliate against anyone who submits a complaint or reports a suspected violation.

*TLCHD is committed to safeguarding the privacy of your personal information. We limit the use of customer information to what is necessary to service customer accounts and conduct the business of our agency.*

*TLCHD does not disclose, share, sell, transfer, or rent your sensitive personal and financial information to nonaffiliated third parties, except and only to the extent we are required to furnish such information in response to a subpoena, court order, levy, attachment, or other legal process.*