TENNESSEE DEPARTMENT OF HEALTH
OPIOID ANTAGONIST COLLABORATIVE PHARMACY PRACTICE POLICY

Tennesseans are dying from drug overdoses at the rate of 3 or more per day. This is an extraordinary situation, and the Department of Health encourages providing life-saving opioid antagonists to appropriate recipients whenever possible. Pharmacist's accessibility to patients places them in a unique position to help address this health initiative. To legally dispense opioid antagonists in Tennessee, a pharmacist must have a prescription order or medical order from an authorized prescriber, or a collaborative pharmacy practice agreement with an authorizing prescriber (as defined in T.C.A 63-10-217). A collaborative pharmacy practice agreement is attached as authorized by T.C.A. 63-1-157.

Recent changes to Tennessee law provide additional protections for health care providers and Good Samaritans who properly use this safe and effective medication to save lives. T.C.A. § 63-1-152. Whenever a pharmacist dispenses a medication, including opioid antagonists, he or she must provide clear instructions about use. We encourage all Tennesseans involved in the prescribing, dispensing, administration, or use of an opioid antagonist to read usage instructions carefully and to view online educational material on the TDH website: https://www.tn.gov/health/health-program-areas/health-professional-boards/csmd-board/csmd-board/naloxone-training-information.html.

Those who have additional questions about dispensing an opioid antagonist should feel free to contact the Department of Health or the Board of Pharmacy. Persons should not be afraid to prescribe, dispense, administer, or use this drug. However, it is important to understand that the life-saving effects of an opioid antagonist may only be temporary; the overdose victim should have access to medical care quickly after naloxone is administered in case additional care is needed. TDH recommends calling 911 and providing information to help first responders continue the life-saving effort.

OPIOID ANTAGONIST COLLABORATIVE PHARMACY PRACTICE AGREEMENT
A PRACTICE AGREEMENT FOR OPIOID OVERDOSE RESCUE AND RESPONSE

Section 1: Purpose:

The purpose of this collaborative pharmacy practice agreement is to reduce morbidity and mortality related to opioid overdoses in Tennessee.

As one of healthcare's most accessible practitioners, the pharmacist is uniquely positioned to support public health initiatives. Pharmacists can utilize their unique access to patients as well as their knowledge and skills to help reduce morbidity and mortality associated with opioid overdose. They can do this by dispensing opioid antagonists such as naloxone (Narcan®, Evzio®, Naloxone HCl, or other generic equivalents, hereinafter referred to as "naloxone") to at-risk individuals and/or family or friends of an at risk individual, or any other person in a position to assist the person at risk of experiencing an opiate-related overdose. (T.C.A. § 63-1-152). Persons seeking naloxone through this CPPA are required to complete the proper education. This collaborative pharmacy practice agreement establishes the protocol that shall allow pharmacists to initiate a prescription for an opioid antagonist product to at risk individuals by the Chief Medical Officer for the Tennessee Department of Health. https://www.tn.gov/health/health-program-areas/health-professional-boards/csmd-board/csmd-board/naloxone-training-information.html.

Section 2: Patient Indications for Naloxone Dispensing

Opioid antagonists are indicated for the reversal of respiratory depression or unresponsiveness caused by an opioid overdose. Take-home naloxone rescue kits can be prescribed and dispensed by a pharmacist under this collaborative pharmacy practice agreement to individuals at risk of an opioid overdose or family or friends of an at risk individual, or any other person in a position to assist the person at risk of experiencing an opiate-related overdose. (T.C.A. § 63-1-152)

Pharmacists may dispense opioid antagonists to any of the following eligible candidates:

1. Individuals who may voluntarily request or be recommended opioid antagonists include:
    a. Persons who are currently using opioids or have a history of opioid use;
    b. Persons with a history of opioid intoxication, overdose, and/or recipients of emergency medical care for acute opioid poisoning;
    c. Persons prescribed a high-dose of an opioid (>50 morphine milligram equivalents daily);
    d. Persons prescribed an opioid who are known or suspected to have concurrent alcohol use;
    e. Persons prescribed an opioid prescription with concurrent prescription(s) for either benzodiazepines, SSRI's or tricyclic anti-depressants (TCAs);
    f. Prisoners recently released from correctional facilities;
    g. Persons recently released from opioid detoxification abstinence programs;
    h. Persons entering methadone maintenance treatment programs (for addiction or pain);

i. Persons prescribed an opioid with concurrent history of smoking/COPD or other respiratory illnesses or obstruction; and
j. Persons prescribed an opioid, who also have diagnoses which may put them at increased risk for opioid overdose, including but not limited to renal dysfunction, hepatic disease, cardiac disease, and/or HIV/AIDS.

2. Other at-risk individuals and/or family or friends of an at risk individual, or any other person in a position to assist the person at risk of experiencing an opiate-related overdose, who voluntarily request Naloxone;
3. Pain management clinics;
4. Primary care or ambulatory care clinics;
5. Local Health Departments;
6. School or other educational institutions;
7. A harm reduction organization;
8. Emergency medical services technicians;
9. First responders;
10. Law enforcement officers or agencies; or
11. An agent of a mental health or substance abuse treatment facility licensed under Title 33.

Section 3: Route(s) of Administration

Naloxone may be delivered intramuscularly with use of a needle, or intranasally with the use of an atomizer device or a nasal spray. Training for these administrations may be found on the Tennessee Department of Health's website at: https://www.tn.gov/health/health-program-areas/health-professional-boards/csmd-board/csmd-board/naloxone-training-information.html.

Section 4: Product and Quantity to be Dispensed

When dispensing injectable naloxone, the following options should be considered:

Injectable Kit (Option A):

1. Naloxone HCL 0.4mg/mL
   a. 1 (one) 10mL multi-dose flip top vial, or
   b. 2 (two) 1mL vials;
2. 2 (two) intramuscular syringes, 25 gauge 3cc 1" long; and
3. Patient information pamphlet with overdose prevention information and step-by-step instructions for overdose responses and naloxone administration.

Intranasal Kit (Option B):

1. One kit containing two 4 mg/0.1 mL nasal spray devices (Brand name: Narcan® Nasal Spray) or One kit containing two 8mg/0.1ml nasal spray devices (Brand name: Kloxxado™ Nasal Spray)
2. Patient information pamphlet with overdose prevention information and step by step instructions for overdose responses and naloxone administration. Comparable substitutions are accepted at the discretion of the pharmacist using reasonable care and clinical judgement

Comparable substitutions are accepted at the discretion of the pharmacist using reasonable care and clinical judgement

When dispensing intranasal naloxone, the following standard should be considered:

Intranasal Kit (Option A):

1. Two 2 mL Luer-Jet luer-lock syringes prefilled with naloxone (concentration: 1mg/1mL);
2. Two mucosal atomization devices and
3. Patient information pamphlet with overdose prevention information and step by step instructions for overdose responses and naloxone administration

Intranasal Kit (Option B):

1. One kit containing two 4 mg/0.1 mL nasal spray devices (Brand name: Narcan® Nasal Spray)
2. Patient information pamphlet with overdose prevention information and step by step instructions for overdose responses and naloxone administration

Comparable substitutions are accepted at the discretion of the dispenser using reasonable care and clinical judgement.

When dispensing a commercially packaged take-home kit, proper care should be given to makes sure the recipient is aware of the type of kit they have and where the instructions for the take home kit are located. Administration of these kits should be given as instructed.

Section 5: Recipient Education Procedures

In addition to those counseling requirements located in the rules published by the Board of Pharmacy, Pharmacists shall provide education and counseling to recipients that addresses, at a minimum, the following topics:

a. The online overdose prevention education program offered by the Department of Health;
b. Purpose for naloxone, correct way to administer Naloxone, precautions regarding medications that may interact with naloxone; and
c. High-risk overdose situations, risk reduction strategies, and appropriate response sets in addition to naloxone administration, including rescue breathing and calling 911 as overdose symptoms may return as naloxone wears off.

Section 6: Documentation and Information Policies

Pharmacists will document each recipient's participation by following these procedures:

1. Record the name of the recipient, date the drug was dispensed, the National Drug Code (NDC) for the medication dispensed, and the name and title of the person providing medication and education;
2. At the request of the department, be able to provide written notification through electronic or other transmittal process to the authorizing physician within seven (7) days

of initiating therapy with an opioid antagonist and will maintain these records for ten (10) years;

3. Contact the Chief Medical Officer or his designee in the event the pharmacist requires medical consultation for a particular patient.
4. At the request of the department, provide all documentation required herein and of education or waiver of education given to the recipient of the medication upon request and within ten business days of any such request.

Section 7: Qualifications of Pharmacist(s)

For a pharmacist to be eligible to dispense naloxone under this collaborative pharmacy practice agreement, he/she must possess an active Tennessee Pharmacist license in good standing and complete an appropriate opioid antagonist training program approved by the Tennessee Department of Health.

Section 8: Modification, Termination and Exclusion

The Chief Medical Officer reserves the right to terminate this collaborative practice agreement at any time as well as the right to override the actions of any collaborating pharmacist, which override decision shall be communicated to the pharmacist in writing within seven (7) business days. Further, the Chief Medical Officer may modify, change or add exclusions to this collaborative practice agreement with notice to the participating parties in writing. The notice provided for in this section shall be made at the location of the pharmacy as registered with the Board of Pharmacy.

This agreement is valid for a period of two years and shall be subject to review.

Should the Chief Medical Officer executing the agreement no longer be able to serve in that capacity, this agreement is immediately terminated.

Section 9: Collaborative Pharmacy Practice Agreement with Individual Pharmacist

Chief Medical Officer for the Tennessee Department of Health (Authorizing Physician):

I, Tim Jones M.D. licensed in the state of Tennessee and Chief Medical Officer of the Tennessee Department of Health, do hereby authorize licensed, properly trained pharmacists employed by ( ) to maintain supplies of naloxone rescue kits and to provide access to opioid antagonist products and education on the proper use of those products to its recipients in accordance with the laws and regulations of the State of Tennessee. This authorization shall cease and no longer be effective immediately upon my resignation, removal or retirement as the Chief Medical Officer of the State of Tennessee and the Tennessee Department of Health.

Physician Name: Tim Jones

Physician State License Number: 30704

Address: 710 James Robertson Parkway

City: Nashville State: TN Zip Code: 37243

Phone: 615-532-7760

Physician Signature: Date:

Authorized Pharmacist:

By signing this Opioid Antagonist Collaborative Pharmacy Practice Agreement for opioid antagonist therapy, I attest that I have read and understand this agreement and completed appropriate training.

Pharmacist Name: Pharmacist State License #:

Pharmacist Signature: Date:

Pharmacist Email :

This collaborative pharmacy practice agreement was issued on _____. The agreement will be effective in accordance with the rules set by the board of pharmacy. Both parties must agree upon any changes to the protocol. Should the chief medical officer that signs this agreement no longer hold the office then the department will issue notification to the authorized pharmacist, and this notice may contain a new collaborative practice agreement to minimize any gap in care to the affected patient population.

Section 10: Collaborative Pharmacy Practice Agreement with Pharmacy Practice Site

Chief Medical Officer for the Tennessee Department of Health (Authorizing Physician):

I, Tim Jones , M.D. / D.O licensed in the state of Tennessee and Chief Medical Officer of the Tennessee Department of Health, do hereby authorize licensed, properly trained pharmacists employed by ( ) to maintain supplies of naloxone rescue kits and to provide access to opioid antagonists products and education on the proper use of those products to its recipients in accordance with the laws and regulations of the State of Tennessee. This authorization shall cease and no longer be effective immediately upon my resignation, removal or retirement as the Chief Medical Officer of the State of Tennessee and the Tennessee Department of Health.

Physician Name: Tim Jones

Physician State License Number: 30704

Address: 710 James Robertson Parkway

City: Nashville State: TN Zip Code: 37243

Phone: 615-532-7760

Physician Signature: Date:

Authorized Pharmacist-In-Charge:

By signing this Naloxone collaborative pharmacy practice agreement for opioid antagonist therapy, the Pharmacist-In-Charge attests that all Licensed Pharmacists at this pharmacy practice site have read and understand this agreement and completed appropriate training.

Pharmacist Name License No: Email:
Pharmacist Name License No: Email:
Pharmacist Name License No: Email:
Pharmacist Name License No: Email:
Pharmacist Name License No: Email:

Pharmacist-In-Charge Signature: Date:

Pharmacist-In-Charge Email:

This collaborative pharmacy practice agreement was issued on _____. The agreement will be effective in accordance with the rules set by the board of pharmacy. Both parties must agree upon any changes to the protocol. Should the chief medical officer that signs this agreement no longer hold the office then the department will issue notification to the authorized pharmacist-in-charge, and this notice may contain a new collaborative practice agreement to minimize any gap in care to the affected patient population.