December 27, 2019

Dear Friends and Colleagues:

Pursuant to Public Chapter 327 of 2019, the Tennessee Department of Health has conducted a review of co-prescribing of naloxone with opioids. The Commissioner's Committee on Chronic Pain Guidelines met on September 27, 2019 for its annual discussion of the chronic pain treatment guidelines. The committee recommended the inclusion of an appendix in the guidelines specifically regarding the co-prescribing of naloxone. The appendix will be incorporated into the next edition of the published guidelines in 2020.

According to data from the Centers for Disease Control and Prevention (CDC), there were more than 70,000 deaths in 2017 due to drug overdose nationwide, with 47,600 of those deaths involving an opioid. Last year, Tennessee had 1818 overdose deaths. Naloxone is a medication approved by the Food and Drug Administration (FDA) for the use in reversing the effects of an overdose involving opioids. In the appendix, the Tennessee Department of Health recommends that healthcare practitioners should incorporate into the management plan strategies to mitigate risk and lists a number of risk factors that may lead to a patient being at a heightened risk of an overdose. We believe the guidelines, including the appendix, will be a useful tool to guide practitioners in decision making when treating patients.

Thank you for your continued partnership and commitment to improve the health of Tennesseans.

Sincerely,

Lisa Piercey, MD, MBA, FAAP
Commissioner
CO-PRESCRIBING NALOXONE

I. Introduction and Epidemiology
   1. According to data from the Centers for Disease Control and Prevention, in 2017 there were 70,237 deaths due to drug overdose nationwide, with 47,600 of those deaths being the result of an overdose involving any opioid, and 17,029 of those deaths involving a prescription opioid. Tennessee had 1818 overdose deaths in 2018.
   2. Naloxone is a medication approved by the FDA for the use in reversing the effects of an overdose involving opioids, classified as a pure opioid antagonist, and works by blocking opioid receptor sites to reverse an opioid overdose, and is available in multiple dosages and routes of administration, which include intramuscular, intravenous, and intranasal formulations.

II. Risk Factors for outpatient setting only
   Patients may be at risk of an overdose for reasons related to opioid dose or pre-existing condition that could negatively interact with the opioid. These patients include those who:
   1. Are taking an opioid greater than 50 morphine milligram equivalents per day (MME/day)
   2. Are taking benzodiazepines
   3. Reportedly use or have used heroin, illicit synthetic opioids, or misuse prescription opioids or otherwise have an Opioid Use Disorder
   4. Have any other mental illness unrelated to substance use
   5. Reportedly have non-opioid substance use disorder or report excessive alcohol use
   6. Have prior history of overdose
   7. Have respiratory conditions such as COPD or sleep apnea
   8. Patients taking an opioid who have children or other dependents in the home who could have access to the medication
   9. Patients with an opioid prescription who have difficulty accessing emergency medical care
   10. A family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose

III. Co-prescribing Naloxone
   1. The Tennessee Chronic Pain Guidelines Committee recommend that clinician(s) should incorporate into the management plan strategies to mitigate risk, including offering naloxone when factors that increase the risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (greater than or equal to 50MME/day), or concurrent benzodiazepine use, are present. The best way to ensure that a patient has access to naloxone is to simultaneously prescribe naloxone to the patient at the same time a prescription for an opioid is written. While there are other introduction points for naloxone before an overdose, this can ensure that an at-risk patient has access to naloxone before a prescription opioid overdose has the opportunity to transpire (See II).
   2. The prescriber should provide a prescription for naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial
reversal of an opioid overdose event to a patient at risk as defined above in II. Exclusions for palliative and hospice care may be considered.

IV. Options for Providing/Receiving Naloxone
1. According to Tennessee Code 63-1-101, a licensed healthcare practitioner may write a prescription for naloxone for a patient, when acting in good faith and exercising reasonable care, both with an opioid prescription or any time following the prescription of an opioid.
2. Patient may receive naloxone from a dispensing licensed pharmacist educated on the proper use of naloxone who is dispensing under the supervision of a prescriber(s) by way of collaborative pharmacy practice agreement pursuant to Tennessee Code Annotated § 63-10-217. In 2016, Public Chapter 596 authorized pharmacists across the state to enter into a collaborative pharmacy practice agreement with the Chief Medical Officer for the Tennessee Department of Health which allows a trained pharmacist to initiate a prescription for naloxone for those that are at risk for an opioid overdose or may be in a position to assist someone who is at risk for experiencing an opioid overdose.
3. Patient may receive naloxone through a pharmacy that has an active standing order.
4. Drug Coalitions may also have Naloxone provided by grant.

V. Statewide Collaborative Pharmacy Practice Agreement
Tennessee Code Annotated § 63-10-217 states the requirements for a collaborative practice agreement to exist between a pharmacist and a prescriber.
1. Collaborative Pharmacy Practice Agreement (CPPA) shall be between one or more licensed pharmacists and an individual licensed prescriber or more than one licensed prescriber in an organized medical group.
2. CPPA must explain the parameters set around the patient care services provided by the pharmacists, which must also fall within the authorized prescriber’s scope of practice.
3. Patient care provided by the pharmacist must be documented and readily accessible to the authorized prescriber or must be communicated to the authorized prescriber within 3 business days.
4. A copy of the CPPA must be accessible at each practice site engaged in CPPA.
5. CPPA must be reviewed and renewed at least biennially.

Tennessee Code Annotated § 63-1-157 authorizes the chief medical officer for the department of health to implement a statewide collaborative pharmacy practice agreement specific to opioid antagonist therapy with any pharmacist licensed and practicing in the state of Tennessee.
1. Under this CPPA, a pharmacist may dispense naloxone to any individual at risk of an overdose or any individual at risk of witnessing an overdose in which they are in a position to assist the person at risk of an overdose.
2. Pharmacists must be trained in naloxone administration within the past two (2) years.

VI. Healthcare Provider Education
As stated previously, per Tennessee Code Annotated § 63-1-152, evidence of the use of reasonable care shall include the receipt of training regarding how to administer naloxone, which can be
achieved through the completion of the online overdose prevention education program offered by the Department of Health as evidenced by a certificate of completion.

1. More information on Naloxone Training for healthcare professionals, please visit https://www.tn.gov/health/health-program-areas/health-professional-boards/csmd-board/csmd-board/naloxone-training-information.html

VII. **Patient Education**

According to Board of Pharmacy rule 1140-03-.01 - Responsibilities for Pharmaceutical Care, “Upon the receipt of a medical or prescription order and following a review of the patient’s record, a pharmacist shall personally counsel the patient or caregiver “face-to-face” if the patient or caregiver is present.” A licensed, authorized pharmacist must educate and train the patient or caregiver on the proper use of naloxone upon the dispensing of the medication.

1. Training on the administration of naloxone for the general public can also be found at https://www.tn.gov/health/health-program-areas/health-professional-boards/csmd-board/csmd-board/naloxone-training-information.html