Protocol for Dispensing Naloxone to Individuals at Risk of Experiencing, Witnessing, or Responding to an Opioid-Related Overdose

1. Authorization to Dispense Naloxone

This protocol is issued pursuant to K.S.A. 65-16,127 and K.A.R. 68-7-23, which allows the dispensing of emergency opioid antagonists by pharmacists pursuant to a statewide protocol established and approved by the Kansas State Board of Pharmacy. A pharmacist shall engage in naloxone dispensing pursuant to this protocol only when the pharmacist has complied with the Kansas Pharmacy Practice Act and all rules and regulations promulgated thereunder.

This authorizes the Kansas-licensed pharmacist who has signed and dated this protocol to dispense naloxone without a prescription to the following:

- 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.
- A first responder agency electing to provide an emergency opioid antagonist to its employees or volunteers.
- A school nurse.

If the eligible recipient is under 18 years of age, a parent or guardian shall provide consent.

2. Authorized Formulations, Quantities, Directions, and Supplemental Devices

A pharmacist may dispense any of the following formulations of naloxone and supplemental drug delivery devices without a prescription (only selected formulations are authorized). The pharmacist shall determine the appropriate naloxone formulation to be dispensed.

The dispensed products shall be labeled in accordance with the Kansas Pharmacy Practice Act and any implementing regulations.

<u>Prepackaged intranasal naloxone (Examples include Narcan® Nasal Spray, Kloxxado®, and naloxone nasal spray.)</u>

- Formulation: FDA-approved naloxone 4mg to 8mg in a manufactured ready-to-use nasal spray device
- Quantity for individual dispensing: Dispense one carton of up to 2 devices per carton or up to two cartons of 1 device per carton
- Quantity for first responder agency or school nurse: Dispense a quantity sufficient to meet the needs of the agency or school
- Directions: Administer one spray into one nostril for signs of opioid overdose. Call 911. May repeat ×1.

<u>Intramuscular naloxone (Examples include Narcan®, ZIMHI®, and naloxone for injection.)</u>

- Formulation: FDA-approved immediate release naloxone 0.4 mg/ml 1ml single dose vial or 5mg ready-to-use prefilled single-dose syringe
- Quantity for individual dispensing: Dispense up to 2 vials or prefilled syringes
- Quantity for first responder agency or school nurse: Dispense a quantity sufficient to meet the needs of the agency or school

- Directions: Inject the contents of one vial or syringe into outer thigh for signs of opioid overdose. Call 911. May repeat x1.
- Supplemental devices to dispense: 3ml Syringe with a 25G ×1 inch needle
    - Quantity to dispense: One syringe for each single dose vial
    - Directions: Use as directed for naloxone administration.

Intramuscular naloxone auto-injector (subject to availability)

- Formulation: FDA-approved naloxone auto-injector for administration by lay persons
- Quantity for individual dispensing: Dispense one carton of up to 2 auto-injectors per carton or up to two cartons of 1 auto-injector per carton
- Quantity for first responder agency or school nurse: Dispense a quantity sufficient to meet the needs of the agency or school
- Directions: Administer the dose from one auto-injector for signs of opioid overdose. Call 911. May repeat ×1.

Intranasal naloxone (non-FDA-approved delivery method)

- Formulation: FDA-approved naloxone 2 mg/2 ml prefilled luer lock syringe
- Quantity for individual dispensing: Dispense up to two prefilled syringes
- Quantity for first responder agency or school nurse: Dispense a quantity sufficient to meet the needs of the agency or school
- Directions: Attach atomizer to naloxone syringe then spray one-half of the contents of syringe into each nostril for signs of opioid overdose. Call 911. May repeat ×1.
- Supplemental devices to dispense: Mucosal Atomization Device (example MAD300) compatible with the prefilled syringe
    - Quantity to dispense: One device for each prefilled syringe
    - Directions: Use as directed for naloxone administration.

3. Documentation and Record-keeping Procedures for Dispensing Naloxone

Each pharmacist shall document the dispensing of naloxone by creating a prescription record for the individual or agency to whom it is dispensed. The pharmacist shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy for a period of five years from the date of dispensing.

4. Counseling, Training, and Educational Material Requirements

A pharmacist who dispenses naloxone shall instruct the individual to whom naloxone is dispensed to summon emergency medical services as soon as practicable either before or after administering naloxone. The individual should also be instructed to advise the emergency medical services personnel that naloxone has been administered.

A pharmacist shall provide in-person counseling, training, and written educational materials appropriate for the dosage form dispensed pursuant to K.A.R. 68-7-23. The person to whom an emergency opioid antagonist is dispensed pursuant to this protocol may not be permitted to waive these consultation requirements. The pharmacist shall not dispense pursuant to this protocol if the person refuses counseling. This information shall include, but is not limited to, all the following:

1. Risk factors of opioid overdose; (See Appendix A)
2. Strategies to prevent opioid overdose;
3. Signs of opioid overdose; (See Appendix B)
4. Steps in responding to an overdose;
5. Information on naloxone, to include potential side effects or adverse effects; (See Appendix C)
6. Procedures for administering naloxone;
7. Proper storage, disposal, and expiration of the naloxone product dispensed;
8. Information on where to obtain a referral for substance use disorder treatment; (See Appendix D) and
9. If dispensed to a school nurse or first responder agency, information on

    a. the requirements to keep inventory records and report any administration of the emergency opioid antagonist to the appropriate healthcare provider, and

    b. the requirement that any first responder, scientist, or technician that administers naloxone shall immediately summon emergency medical services, provide information related to the administration to the emergency medical services personnel and other involved treatment professionals (emergency room or treating physician, as appropriate), and notify the physician medical director for the first responder agency within 24 hours of administration, if applicable, and

    c. the requirement that any school nurse that administers naloxone shall notify/report such administration per the school district's policies and procedures, if applicable.

5. Documentation and Record-keeping Procedures for the Naloxone Protocol

Each pharmacist utilizing this protocol shall provide a copy of the signed and dated signature page of this protocol to the Board within five days of execution. A copy of this protocol shall be maintained for five years from the date of last dispensing at each Kansas Board of Pharmacy registered facility where the pharmacist has dispensed an emergency opioid antagonist. Each pharmacist shall notify the Board in writing within 30 days of choosing to discontinue use of this protocol.

PHARMACIST AUTHORIZATION*

Printed Name	Kansas License Number

☐ Yes ☐ No **Do you wish to be included on the K-TRACS website interactive map of pharmacies where naloxone is available?**

If yes, please provide the Pharmacy Name: _____

and Pharmacy Registration Number: **2-**_____

SIGNATURE _____ DATE SIGNED _____

PHARMACIST NOTICE OF DISCONTINUATION OF USE OF PROTOCOL*

Printed Name	Kansas License Number

SIGNATURE _____ DATE SIGNED _____

*Submit this page to the Board after signed and dated

Appendix A – Examples of Risk Factors for Opioid Overdose*

- Previous opioid intoxication or overdose.
- History of nonmedical opioid use.
- Initiation or cessation of methadone or buprenorphine for opioid use disorder treatment.
- Higher-dose (>50 mg morphine equivalent/day) or long-acting opioid prescription.
- Receiving any opioid prescription plus:
    - Rotated from one opioid to another because of possible incomplete cross-tolerance.
    - Smoking, COPD, emphysema, asthma, sleep apnea, respiratory infection, or other respiratory illness.
    - Renal dysfunction, hepatic disease, cardiac illness, or HIV/AIDS.
    - Known or suspected concurrent alcohol use.
    - Concurrent benzodiazepine or other sedative prescription.
    - Concurrent antidepressant prescription.
- Patients who may have difficulty accessing emergency medical services (distance, remoteness).

*This list is for only for sample purposes to assist the pharmacist in developing counseling materials. It is not intended to be an all-inclusive list of the risk factors for opioid overdose, nor does it represent a list of mandatory counseling points.

Appendix B – Examples of Signs of Opioid Overdose*

Signs and symptoms of opioid-related overdose in a person:

- Fentanyl patches on skin or needle in the body
- Unresponsive or unconscious individuals
- Not breathing or slow/shallow respirations
- Snoring, gurgling, or choking sounds (due to partial upper airway obstruction)
- Blue lips and/or nail beds
- Heart rate slows or stops
- Pinpoint pupils
- Pale and clammy skin
- Vomiting

Note that individuals in cardiac arrest from all causes share many symptoms with someone with a narcotic overdose (unresponsiveness, not breathing, snoring/gurgling sounds, and blue skin/nail beds). If no pulse, these individuals are in cardiac arrest and require CPR.

Environmental signs of opioid-related overdose:

- Needles
- Spoons (especially bent spoons) or other cookers
- Lighters
- Tourniquets
- Balloons or baggies
- Pill bottles
- Pills (whole or crushed)

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Appendix C – Examples of Information on Naloxone, Side Effects, and Adverse Reactions*

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. In the presence of physical dependence on opioids, naloxone will produce withdrawal symptoms. However, in the presence of opioid dependence, opioid withdrawal symptoms may appear within minutes of naloxone administration and subside in about two hours. Naloxone crosses the placenta and may precipitate fetal withdrawal symptoms when administered to a person who is pregnant.

Drug Dependence: Those who may be chronically taking opioids are more likely to experience adverse reactions from naloxone. Additionally, after administration, they may awaken disoriented. Being disoriented can sometimes lead to highly combative behavior, including physical violence, especially if naloxone is given by someone unfamiliar.

Respiratory Depression Due to Other Drugs: Naloxone is not effective against respiratory depression due to non-opioid drugs. Initiate rescue breathing or CPR as indicated and contact 911.

Pain Crisis: In patients taking an opioid medication for a painful illness such as cancer, administration of naloxone can cause a pain crisis, which is an intense increase in the experience of pain as the naloxone neutralizes the pain-relieving effect of the opioid medication. Comfort the patient as much as possible and contact 911 as the patient may need advanced medical treatment to ease the pain crisis.

Do not administer naloxone to a person with known hypersensitivity to naloxone or to any of the other ingredients contained in the package insert for naloxone.

Adverse reactions are related to reversing dependency and precipitating withdrawal and include fever, hypertension, tachycardia, seizures, agitation, restlessness, diarrhea, nausea/vomiting, myalgias, diaphoresis, abdominal cramping, nervousness, yawning, sweating, shaking, shivering, hot flashes, and sneezing.

- These symptoms may appear within minutes of naloxone administration and subside in approximately two hours.
- The severity and duration of the withdrawal syndrome is related to the dose of naloxone and the degree of opioid dependence.
- Reactions may subside within minutes of naloxone administration but may reappear within approximately 90 minutes. It is imperative that the person experiencing an opioid-related overdose receive emergency medical care following naloxone administration.
- Adverse effects beyond opioid withdrawal are rare.

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Appendix D – Examples of Locations for Information on Substance use Disorder Treatment*

The Department for Children and Families Alcohol and Drug Abuse Hotline: 1-866-645-8216

Kansas Department for Aging and Disability Services Substance Use Treatment Division.

A google search of "Kansas resources for substance use disorder treatment" will provide many resources you can use.

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