Opioid Education

Opioid Antagonist Dispensing from Statewide Protocol

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Goals for this Session

- Be able to outline key aspects of the statute and regulations allowing pharmacists to dispense naloxone from the statewide protocol
- Be able to outline key aspects of the statewide protocol for dispensing naloxone
- Be able to identify patients who are at an increase risk for opioid overdose or opioid use disorder
- Be able to counsel patients on naloxone administration

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House Bill 2217

- An Act concerning
  - Emergency opioid antagonists
  - Relating to standards governing the use and administration thereof
  - Education requirements
  - Civil and criminal liability
- Passed and signed in Spring of 2017
- Effective July 1st, 2017 in the State of Kansas
- Created the framework for the statewide protocol, allowing pharmacists to create a prescription and dispense select opioid antagonists without a traditional prescription

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Requirements for Utilizing the Protocol

- Three easy steps:
  - 1. Review the statute and regulations—HB 2217 and KAR 68-7-23, available at:
    - https://pharmacy.ks.gov/docs/default-source/statues-regulations/hb-2217---emergency-opioid-antagonists.pdf?sfvrsn=538a601_0
    - https://pharmacy.ks.gov/docs/default-source/default-document-library/proposed-temporary-kar-68-7-23.pdf?sfvrsn=2201a601_0
  - 2. Download, review and sign the statewide protocol from the Board of Pharmacy's website:
    - https://pharmacy.ks.gov/resources-consumer-info-2/naloxone
  - 3. Send a copy of the last page of the protocol to the Kansas Board of Pharmacy
    - Fax to (785)296-8420, mail to 800 SW Jackson, Suite 1414, Topeka, KS 66612, Email to Pharmacy@ks.gov

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HB 2217–Emergency Opioid Antagonist (EOA) Bill

- Multidisciplinary effort to increase access to naloxone with the goal to decrease opioid overdose deaths
- 49th State to adopt language allowing pharmacists to dispense naloxone without a traditional prescription
- KS Board of Pharmacy to create and manage a statewide protocol for pharmacists to dispense emergency opioid antagonists to patients or concerned bystanders
- Allows other entities—school nurses, first responders, lab scientists, to obtain and administer opioid antagonists within their professional duties
- Creates "Good Samaritan" exemptions for dispensing and administration

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HB 2217 Key Changes to Pharmacy Practice

- Allows a pharmacist create a prescription under the limitations of the protocol
- Allows a pharmacist to dispense a prescription for a bystander
- Requires counseling on every fill, the patient cannot refuse
- Provide EOAs to first responder agencies, oversee their policies and procedures, training, and quality assurance measures
- Protests pharmacists from any civil liability, criminal prosecution, and regulatory discipline on their license after prescribing or dispensing emergency opioid antagonists under protocol

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KAR 68-7-23

- The regulation written to outline the protocol in law
- It also outlines requirements for first responders and school nurses to administer emergency opioid antagonists
- Allows pharmacists 5 days to submit the last page of the protocol to the Kansas Board of Pharmacy. This has to be available at all times to the Pharmacist-in-charge, the board, and boards designee.
- Notify the board within 30 days of discontinuing dispensing emergency opioid antagonists

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KAR 68-7-23 Dispensing Requirements

- The medication must be labeled in accordance with the pharmacy practice act as a prescription, with the prescriber being the pharmacist or protocol physician
- Counseling requirements:
  - Emergency services must be summoned as soon as possible-before or after administering the EOA
  - In-person counseling and written materials specific to the dosage form to educate on risk factors of overdose, strategies to prevent overdose, signs of overdose, information and procedures for administering the EOA, and information to obtain a referral for substance use disorder treatment
  - Additional education needs to be given to first responder agencies and school nurses for inventory record keeping and reporting to physician medical director

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KAR 68-7-23 First responder agencies

- Allows pharmacists to dispense EOA to and train first responders
- Training requirements:
  - Proper training on the use of EOA in accordance with the protocol
  - Summon emergency medical services as soon as possible
  - Immediately provide information related to the administration of EOA to responding EMS personnel, emergency room personnel, or any treating physician
  - Notify their physician medical director for the agency within 24 hours of administration

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

- Description
  - Naloxone is a pure opioid antagonist used to prevent or reverse the effects of opioids
  - Naloxone does not create a tolerance or dependence
  - Will produce withdrawal symptoms when administered to patients dependence on opioids. These may appear within minutes of administration and subside within 2 hours

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Protocol for Dispensing Naloxone—Indications

- 2. Indications for Use of Naloxone
  - Complete or partial reversal of opioid agonism
  - Can be dispensed without a prescription by a pharmacist under this protocol
    - Reason to believe is experiencing or at risk of experiencing an opioid-related overdose
    - A bystander (family, friend, other person able to assist) in a position to assist an individual at risk of experiencing opioid overdose
    - First responder, scientist, or school nurse

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Protocol for Dispensing Naloxone—Indications

- Previous opioid intoxication or overdose
- History of non medical opioid use
- Initiation or cessation of methadone or burp endorphins for opioid use disorder
- Higher-dose (>50 morphine mg equivalent/day) or long-acting opioid prescription
- Patients who may have difficulty accessing emergency medical services
- Voluntary request from bystander in a position to assist an individual who there is reason to believe is a risk of experiencing an opioid-related over dose
- Request from first responder agency or school nurse
- Pharmacist recommendation based on patient's prescription history

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Protocol for Dispensing Naloxone—Indications

- Patients receiving any opioid in addition to:
  - Changing from one opioid to another because of possible incomplete cross-tolerance
  - Smoking, COPD, emphysema, asthma, sleep apnea, respiratory illness
  - Renal dysfunction, hepatic disease, cardiac illness, HIV/AIDS
  - Known or suspected alcohol use
  - Concurrent benzodiazepine or other sedative prescription
  - Concurrent antidepressant prescription

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Protocol for Dispensing Naloxone—Indications

- Signs and symptoms of opioid-related overdose:
  - A history or current narcotic or opioid use, fentanyl patches on skin, needle in body
  - Unresponsive, unconscious
  - Not breathing or slow/shallow respirations
  - Snoring, gurgling, choking sounds (indicates partial airway obstruction)
  - Blue lips or nail beds
  - Slow or no pulse
  - Pinpoint pupils
  - Clammy skin

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Protocol for Dispensing Naloxone—Indications

- Environmental signs of opioid-related overdose:
  - Needles
  - Spoons, especially bent or other cookers
  - Lighters
  - Tourniquets
  - Balloons or baggies
  - Pill bottles
  - Pills (whole or crushed)

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Protocol for Dispensing Naloxone—Precautions

- Use in pregnancy—Category C
  - No adequate or well-controlled studies
  - Used as an antidote—should be administered if there is a clear indication for use
  - Does cross the placenta, and precipitate fetal withdrawal symptoms
- Drug Dependence—more likely to experience adverse reactions
- Respiratory depression d/t other drugs
  - Naloxone is not effective in treating other drug overdoses
  - Administer CPR and call 911
- Pain Crisis

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Protocol for Dispensing Naloxone—Contraindications

- One contraindication—known hypersensitivity to naloxone or any other ingredients contained in the package insert for naloxone

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Protocol for Dispensing Naloxone—Adverse Reactions

- Related to the reversing dependency and precipitating withdrawal and include fever, hypertension, tachycardia, seizures, agitation, restlessness, diarrhea, nausea/vomiting, myalgia, diaphoresis, abdominal cramping nervousness, yawning, sweating, shaking, hot flashes, and sneezing.
- Appear within minutes of naloxone administration, and last a couple of hours
- Severity and duration related to the dose of naloxone and degree of opioid dependence
- Reactions may reappear within 90 minutes, imperative to seek medical help after naloxone administration

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Protocol for Dispensing Naloxone—Assessment

- Subjective Findings
  - At risk of experiencing an opioid-related overdose or is in the position to assist a family member, friend, or any other person at risk of experiencing an opioid-related overdose
  - No reported known sensitivity or allergy to naloxone hydrochloride
- Objective Findings
  - Individual oriented to person, place, and time and able to understand and learn the essential components of overdose response and naloxone administration
  - If suspected overdose is occurring, call 911 immediately

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Protocol for Dispensing Naloxone—Follow-up

- Screen individual for contraindications/precautions, recommend further evaluation from healthcare provider if present
- If applicable, inform of treatment options available for addition/dependence
  - KS Dept for Children and Families referral hotline 1-866-645-8216
  - KS Dept for Aging and Disability Services Substance Use Treatment Division
- If dispensing to First Responder Agency or School Nurse—no follow-up required

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Protocol for Dispensing Naloxone—Documentation and Record Keeping

- Each pharmacist shall document the dispensing of naloxone in a written or electronic prescription record for the individual or agency
- Record dispensing pharmacist or protocol physician as prescriber
- Record has to be readily retrievable, securely stored for 5 years
- Each pharmacist utilizing the protocol must submit a signed copy to the Board within 5 days of execution
- Notify Board within 30 days of discontinuation

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Protocol for Dispensing Naloxone—Authorization to Dispense

- Upon meeting the requirements of patient counseling pursuant to KAR 68-7-23 and pursuant to the protocol, the pharmacist may dispense select naloxone formulations to the following individuals:
  - 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 with there is reason to believe is at risk of experiencing an opioid-related overdose
  - First responder agency or school nurse

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Protocol for Dispensing Naloxone—Authorized Formulations

- The pharmacist shall determine the appropriate naloxone product to be dispensed.
- Parent/guardian must provide consent if individual is under 18 years of age
- Approved formulations:
  - Intranasal naloxone (Narcan 4 mg)
  - Intramuscular naloxone
  - Auto-injector
  - Intranasal naloxone (MAD 2 mg)

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Protocol for Dispensing Naloxone—Narcan NS

- Naloxone 4mg/0.1mL, FDA-approved nasal spray device, 2 doses/unit
- Sig: Administer a single spray into one nostril. Call 911 immediately. May repeat once
- Directions:
  - Call 911
  - Peel back package to remove device
  - Place the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose
  - Press the plunger firmly to release the dose into one nostril
  - Repeat in other nostril after 2-3 minutes or if the victim relapses
  - Continue with rescue breathing, monitor responsiveness until EMS arrives
  - Report to first responder that naloxone was administered

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Protocol for Dispensing Naloxone—IM Naloxone

- Naloxone 4mg/mL single dose vial, 2 vials
- Sig: Inject 1 mL IM upon signs of opioid overdose. Call 911. May repeat once
- Directions:
  - Call 911
  - Uncap the naloxone vial and uncap the syringe
  - Insert the needle through the rubber membrane on the vial, turn upside down draw up 1 mL of naloxone, and withdraw needle
  - Insert the needle into the muscle of the upper arm or thighs of the victim, through clothing if needed and push on the plunger to inject the naloxone
  - Repeat the injection with a new syringe and needle if there is not response after three minutes
  - Continue with rescue breathing, monitor responsiveness until EMS arrives
  - Report to first responder that naloxone was administered

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Protocol for Dispensing Naloxone—IM Auto-Injector

- Naloxone 2mg or 0.4mg/0.4mL (depending on availability), twin-pack
- Sig: Use one auto-injector upon signs of opioid overdose. Call 911 immediately. May repeat once
- Directions:
  - Call 911
  - Pull auto-injector from case
  - Pull off red safety guard
  - Place the black end against Luther thigh, press firmly and hold for 5 seconds
  - Repeat with new auto-injector if no response after three minutes or relapse
  - Discard auto-injector in sharps container
  - Continue with rescue breathing, monitor responsiveness until EMS arrives
  - Report to first responder that naloxone was administered

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Protocol for Dispensing Naloxone—Intranasal Naloxone (non FDA-approved method)

- Naloxone 2mg/2mL profiled syringe, 2 syringes
- Sig: Spray one-half of syringe into each nostril upon signs of overdose. Call 911 immediately. May repeat once
- Two mucosal atomization divides (MAD300), Sig: Use as directed for naloxone administration
- Directions:
  - Call 911
  - Remove the two colored caps from the deliver syringe and one from the naloxone vial
  - Screw the MAD onto the top of syringe, screw the naloxone vial gently onto syringe
  - Spray half (1mL) of naloxone in one nostril and the other half (1mL) into the other nostril
  - Repeat in other nostril after 3 minutes or if the victim relapses
  - Discard syringes in sharps container
  - Continue with rescue breathing, monitor responsiveness until EMS arrives
  - Report to first responder that naloxone was administered

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Protocol for Dispensing Naloxone—Instructions and Counseling

- Pharmacists are required to provide counseling at each dispensing of naloxone with in-person training and written instructions

- ****Instruct to call 911 ASAP****

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Protocol for Dispensing Naloxone—Instructions and Counseling

- Counseling and materials must include
  - Risk factors of opioid overdose
  - Strategies to prevent overdose
  - Signs of overdose
  - Steps in responding to an overdose
  - Information on naloxone including potential adverse reactions
  - Procedures for administering naloxone
  - Proper storage, disposal, and expiration of naloxone product dispensed
  - Information on obtaining a referral for substance use disorder treatment
- If counseling is refused, naloxone cannot be dispensed

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Protocol for Dispensing Naloxone—Instructions and Counseling

- Additional counseling and instructions for first responders, scientists, technicians:
  - Requirements to keep inventory records and report any administration of EOA to the appropriate healthcare provider
  - Requirement to immediately summon EMS, provide information related to the administration to the EMS personnel and other professionals involved
  - Requirement to notify physician medical director for the agency within 24 hours of administration; school nurses to follow school district policies and procedures

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References