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proposed

State of Kansas
Board of Pharmacy
Notice of Hearing on Proposed Administrative Regulation

A public hearing will be conducted on Thursday, August 17, 2017 at 1:00 p.m. in the Board of Regents Board Room at 1000 SW Jackson, Suite 520, Topeka, Kansas to review and consider the adoption of a proposed permanent regulation of the Kansas State Board of Pharmacy.

This 60-day notice of the public hearing shall constitute a public comment period for the purpose of receiving written public comments on the proposed regulation. All interested parties may submit written comments prior to the public hearing to Alexandra Blasi, Executive Secretary, 800 S.W. Jackson, Suite 1414, Topeka, Kansas 66612-1244 or by e-mail to pharmacy@ks.gov. All interested parties will be given a reasonable opportunity to present their views orally regarding the adoption of the proposed regulation during the public hearing. In order to provide all parties an opportunity to present their views, it may be necessary to request that each participant limit any oral presentation to five minutes.

Any individual with a disability may request accommodation in order to participate in the public hearing and may request the regulation and economic impact statement in an accessible format. Requests for accommodation to participate in the public hearing should be made at least 10 business days in advance of the hearing by contacting Alexandra Blasi, Executive Secretary, 800 S.W. Jackson, Suite 1414, Topeka, Kansas 66612-1244 or by phone at (785) 296-4056. Handicapped parking is located across the street from the north entrance to the building. Curbs at the north entrances are accessible to individuals with disabilities.

Summaries of the proposed regulation and its economic impact follow. (Note: Statements indicating that a regulation is "not anticipated to have any economic impact" are intended to

indicate that no economic impact on the Kansas State Board of Pharmacy, other state agencies, state employees, or the general public has been identified.)

Copies of the regulation and economic impact statement may be viewed at http://pharmacy.ks.gov/statutes-regs/proposed-reg-changes.

K.A.R. 68-7-23. Dispensing and administration of emergency opioid antagonists without a prescription. In accordance with 2017 HB 2217, this regulation creates requirements for pharmacist dispensing of naloxone to patients, bystanders, first responder agencies, and school nurses without a prescription in accordance with a statewide protocol established by the Board, including labeling, counseling, wholesale sales, reporting, recordkeeping, and other duties. The regulation also sets requirements for school nurses and first responder agencies (and employees) to complete training and education necessary to receive, carry, and administer emergency opioid antagonists.

Any economic impact on the Board will be related to general licensing, document processing and storage, and program compliance and oversight. Costs to the Board might appear in the form of administrative staff time, are anticipated to be minimal, and will be absorbed by current staff and resources. Pharmacists may experience an impact related to time reviewing the protocol, acquiring necessary training, and providing notification to the Board. However, the authority to dispense without a prescription is optional for pharmacists, not mandatory. Businesses (including pharmacies, first responder agencies, or schools) may be impacted by the staff time required for necessary training/education or the costs associated with acquiring the emergency opioid antagonist and storing the drug. Costs to private individuals or other businesses would not differ from the status quo, therefore, no impact is anticipated. In all instances, the Board does not anticipate any financial impact upon other governmental agencies, and the Board is unaware of any less costly or less intrusive methods to achieve the stated purposes and thus none were considered.

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68-7-23. Dispensing and administration of emergency opioid antagonist without a prescription. (a) Any pharmacist may dispense an emergency opioid antagonist and the necessary medical supplies needed to administer an emergency opioid antagonist to a patient, bystander, first responder agency, or school nurse without a prescription, in accordance with the opioid antagonist protocol and this regulation.

(b) Each pharmacist dispensing an emergency opioid antagonist pursuant to this regulation shall submit to the board a form provided by the board, within five days of signing the opioid antagonist protocol, and shall maintain a signed and dated copy of the opioid antagonist protocol, which shall be made available to the pharmacist-in-charge, the board, and the board's designee. Each pharmacist that no longer dispenses emergency opioid antagonists pursuant to the opioid antagonist protocol shall notify the board, in writing, within 30 days of discontinuation.

(c) Each emergency opioid antagonist dispensed by a pharmacist shall be labeled in accordance with the pharmacy practice act and any implementing regulations.

(d) Each pharmacist who dispenses an emergency opioid antagonist pursuant to this regulation shall perform the following:

(1) For each patient, bystander, first responder agency, or school nurse to whom the emergency opioid antagonist is dispensed, instruct that person or entity to summon emergency medical services as soon as practicable either before or after administering the emergency opioid antagonist;

(2) for each patient or bystander to whom the emergency opioid antagonist is dispensed, provide in-person counseling, training, and written educational materials appropriate to the dosage form dispensed, including the following:

(2) for each patient or bystander to whom the emergency opioid antagonist is dispensed, provide in-person counseling, training, and written educational materials appropriate to the dosage form dispensed, including the following:

(A) Risk factors of opioid overdose;

(B) strategies to prevent opioid overdose;

(C) signs of opioid overdose;

(D) steps in responding to an overdose;

(E) information on emergency opioid antagonists;

(F) procedures for administering an emergency opioid antagonist;

(G) proper storage, disposal, and expiration date of the emergency opioid antagonist dispensed; and

(H) information on where to obtain a referral for substance use disorder treatment; and

(3) for each first responder agency or school nurse to whom the emergency opioid antagonist is dispensed, provide that person or entity with written education and training materials that meet the requirements of paragraphs (d)(1) and (2) and include the requirements to keep inventory records and report any administration of the emergency opioid antagonist to the appropriate healthcare provider pursuant to this regulation.

(e) Each pharmacist shall document the dispensing of any emergency opioid antagonist pursuant to this regulation in a written or electronic prescription record for the patient, bystander, first responder agency, or school nurse to whom the emergency opioid antagonist is dispensed. The pharmacist shall record as the prescriber either that pharmacist or the physician who has signed the opioid antagonist protocol. The prescription record shall be maintained so that the

required information is readily retrievable during the pharmacy's normal operating hours and shall be securely stored within the pharmacy for at least five years.

(f) Any of the following individuals or facilities licensed or registered with the board of pharmacy or the board of healing arts may sell emergency opioid antagonists at wholesale to a first responder agency or school nurse:

(1) A pharmacist;

(2) a physician medical director; or

(3) a pharmacy.

(g) Each first responder, scientist, and technician operating under a first responder agency administering an emergency opioid antagonist shall perform the following:

(1) Summon emergency medical services as soon as practicable either before or after administering the emergency opioid antagonist;

(2) immediately provide information related to the administration to any responding emergency medical services personnel, any emergency room personnel, or any treating physician; and

(3) notify the physician medical director for the first responder agency within 24 hours of administration.

(h) Each first responder agency that is dispensed an emergency opioid antagonist shall ensure that any first responder, scientist, or technician operating under the first responder agency is appropriately trained on the use of emergency opioid antagonists and meets the training requirements in subsection (d) and the opioid antagonist protocol. (Authorized by and implementing 2017 HB 2217, sec. 1; effective, T-_____, _____; effective P-_____.)

proposed

KANSAS STATE BOARD OF PHARMACY
ECONOMIC IMPACT STATEMENT

The Kansas State Board of Pharmacy (Board) is proposing new regulation K.A.R. 68-7-23 on a temporary and permanent basis, for the administration of 2017 HB 2217, which was approved by the Governor on April 7, 2017, and becomes effective on July 1, 2017.

I. Summary of Proposed Regulation. K.A.R. 68-7-23 is a new regulation concerning the dispensing and administration of emergency opioid antagonists (i.e., naloxone) without a prescription. The regulation creates provisions for pharmacist dispensing of emergency opioid antagonists to patients, bystanders, first responder agencies, and school nurses without a prescription in accordance with a statewide protocol established by the Board, including labeling, counseling, wholesale sales, reporting, recordkeeping, and other duties. The regulation also sets requirements for school nurses and first responder agencies (and employees) to complete training and education necessary to receive, carry, and administer emergency opioid antagonists.

II. Reason or Reasons the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. The Board is required to adopt regulations in accordance with 2017 HB 2217. There are no federal requirements implicated by this regulation.

III. Anticipated Economic Impact on the Board. Any economic impact on the Board will be related to general licensing, document processing and storage, and program compliance and oversight. Additionally, the Board anticipates creation of a webpage on our existing site dedicated to emergency opioid antagonists, training/education, and other resources. Costs to the Board might appear in the form of administrative staff time, are anticipated to be minimal, and will be absorbed by current staff and resources.

IV. Anticipated Financial Impact Upon Other Governmental Agencies and Upon Private Individuals or Businesses. The Board does not anticipate any financial impact upon other governmental agencies. Pharmacists may experience an impact in their time related to reviewing the statewide protocol, acquiring necessary training/education, and providing notification to the Board. However, most training/education is free and the authority to dispense without a prescription is optional for pharmacists, not mandatory. Businesses (including pharmacies, first responder agencies, or schools) may be impacted by the staff time required for necessary training/education or the costs associated with acquiring the emergency opioid antagonist and storing the drug. Costs to private individuals or other businesses would not differ from the status quo, therefore, no impact is anticipated.

V. Anticipated Economic Impact Upon Other Entities or Persons. There would be no negative impact on other entities or persons. There would be a positive impact on safety and welfare of Kansas citizens due to the increased available of this life-saving medication to combat opioid overdoses and deaths.

VI. Less Costly or Intrusive Methods Considered. The Board is unaware of any less costly or less intrusive methods to achieve the stated purposes and thus none were considered.

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