Proposed

KANSAS STATE BOARD OF PHARMACY

NOTICE OF PUBLIC HEARING ON PROPOSED REGULATION AMENDMENTS

A public hearing will be conducted at 9:00 a.m. on the 16th day of October 2014, at Via Christi Hospital - St. Joseph Campus, 3600 E. Harry, 3rd Floor, Conference Room A, Wichita, KS 67218, to consider the proposed adoption of amendments to K.A.R. 68-21-7 as permanent regulations 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 adoption of amendments to K.A.R. 68-21-7. All parties may submit written comments prior to the hearing to the Executive Secretary of the Kansas Pharmacy Board, Debra Billingsley, pharmacy@pharmacy.ks.gov, or Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, Kansas 66612. All interested parties will be given a reasonable opportunity to present their views orally on the adoption of amendments to K.A.R. 68-21-7 during the hearing. In order to give all parties an opportunity to present their views, it may be necessary to request each participant to 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 hearing should be made at least five working days in advance of the hearing by contacting Jackie Yingling at the Kansas State Board of Pharmacy at Jackie.Yingling@pharmacy.ks.gov or at (785) 296-6504. Handicapped parking is available in the parking lot directly in front of the entrance on East Harry Street.

Amendments to K.A.R. 68-21-7 are proposed for permanent adoption. A summary of the proposed amendments are as follows:

K.**A.R. 68-21-7 Drugs of Concern.** This regulation is amended to update the drugs of concern that are monitored through the Board of Pharmacy's prescription drug monitoring program ("KTRACS"). The amendment deletes carisoprodol and tramadol and adds prescription pseudoephedrine products and promethazine with codeine.

Economic Impact. The adoption of these amendments does not have any additional economic impact to the Board of Pharmacy. In addition, the Board does not anticipate that this amendment will have any impact upon other governmental agencies. The Board anticipates a nominal impact upon pharmacies that report into the state's prescription drug monitoring program database because they will need to open an additional reporting field in the software database.

Copies of the regulations and the economic impact statements may be obtained from the Kansas Pharmacy Board, 800 SW Jackson, Suite 1414, Topeka, Kansas 66612-1244, by calling (785) 296-4056, via email at pharmacy@pharmacy.ks.gov or by accessing the Board's website at http://www.pharmacy.ks.gov.

Debra Billingsley
Executive Secretary

Proposed

68-21-7. Drugs of concern. (a) Each of the following shall be classified as a drug of concern:

(1) Any product containing all three of these drugs: butalbital, acetaminophen, and caffeine;

~~(2) carisoprodol; and~~

~~(3) tramadol~~

(2) any compound, mixture, or preparation that contains any detectable quantity of ephedrine, its salts or optical isomers, or salts of optical isomers and is exempt from being reported to the statewide electronic logging system for the sale of methamphetamine precursors;

(3) any compound, mixture, or preparation that contains any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers and is exempt from being reported to the statewide electronic logging system for the sale of methamphetamine precursors; and

(4) promethazine with codeine.

(b) ~~The stakeholders of the program shall be notified by the board if a drug is to be considered by the board for classification as a drug of concern.~~

~~(c)~~ Any individual who wants to have a drug added to the program for monitoring may submit a written request to the board.

This regulation shall take effect 90 days after publication in the Kansas register.

(Authorized by K.S.A. ~~2009~~ 2013 Supp. ~~65-1682 and~~ 65-1692; implementing K.S.A. ~~2009~~ 2013 Supp. 65-1682; effective Oct. 15, 2010; amended P-_____.)

RECEIVED
JUL 21 2014
SECRETARY OF STATE

ATTORNEY GENERAL
JUL 17 2014
APPROVED BY

APPROVED
JUL 15 2014
DEPT. OF ADMINISTRATION

Proposed

KANSAS PHARMACY BOARD
ECONOMIC IMPACT STATEMENT

K.A.R. 68-21-7 Drugs of Concern

I. Summary of Proposed Amendment to Regulation, Including its Purpose.

This regulation is part of a set that established a prescription monitoring program ("KTRACS") that utilizes a database to monitor schedule II-IV drugs and drugs of concern that are dispensed in the state of Kansas. The purpose of the program is to: 1) support access to legitimate medical use of controlled substances, 2) identify and deter or prevent drug abuse and diversion, 3) facilitate and encourage the identification, intervention with and treatment of persons addicted to prescription drugs, 4) inform public health initiatives through outlining of use and abuse trends, and 5) educate individuals about Prescription Monitoring Programs and the use, abuse and diversion of and addiction to prescription drugs.

K.A.R. 68-21-7 identifies the drugs of concern that are monitored through the Prescription Monitoring Program ("KTRACS") that aren't controlled substances in schedules II-IV. Carisoprodol has been removed as a drug of concern because it is federally scheduled. Once it was federally scheduled the Board of Pharmacy asked the legislature to add it to the state schedule IV list in K.S.A. 65-4111 and this has been accomplished. Since carisoprodol is now scheduled it no longer needs to be listed as a drug of concern as it is automatically monitored in KTRACS as a schedule IV drug.

Tramadol has been removed as a drug of concern because it has been federally scheduled as a Schedule IV drug. Therefore, it will automatically be reported in the prescription drug monitoring database. The Board will ask the 2015 legislature to add

tramadol to the state schedule found at K.S.A. 65-4111. It no longer needs to be listed as a drug of concern.

Prescription pseudoephedrine products would be added to the drugs of concern list under the amendments in K.A.R. 68-21-7. Non-prescription pseudoephedrine products are currently monitored by the State's Electronic Logging System (National Precursor Log Exchange or "NPLEx"). NPLEx was implemented pursuant to the federal Combat Methamphetamine Epidemic Act of 2005 ("CMEA") and the state's Sheriff Matt Samuels Chemical Control Act. Several towns in Kansas have restricted over the counter sales of pseudoephedrine cold medications and will now accept prescription only. The KTRACS multidisciplinary advisory committee recommended that the Board of Pharmacy require prescription cold medication containing pseudoephedrine and ephedrine to be tracked through the KTRACS system as a drug of concern.

The KTRACS Advisory Committee also recommended that the Board track promethazine with codeine syrup because of an increase in the purchase and potential misuse of this medication. This is a combination medication used to treat the symptoms caused by the common cold, flu, cough, allergies and other breathing illnesses. It contains Phenergan which is an antihistamine sedative and it contains codeine which is a narcotic pain reliever and cough suppressant. The Committee advised the Board that promethazine with codeine is potentially misused as a recreational drug. It is mixed with Sprite®, or Mountain Dew® and optionally a Jolly Rancher™ hard fruit candy for sweetness. The mixture is often called by the slang names "purple drank", "sizzurp", "lean", "syrup", "drank", "barre", "purple jelly", "Texas tea", or "Tsikuni". Currently

promethazine with codeine is a Schedule V in Kansas and requires a prescription. Schedule V drugs are not monitored by KTRACS.

II. Reason or reasons the Proposed Regulations Are Required, Including Whether or Not the Regulations Are Mandated By Federal Law.

Federal law does not mandate the proposed regulations. Kansas Statutes established the development of a Prescription Monitoring Program ("KTRACS") in the state. The legislature required the Board of Pharmacy to establish and maintain a multidisciplinary advisory committee to identify patterns and activity of misuse or abuse of medications. The Advisory Committee has 14 members including medical doctors, doctors of osteopathy, pharmacists, dentists, PhD's and KBI. These regulations are authorized by K.S.A 65-1681 through K.S.A. 65-1993.

III. Anticipated Economic Impact upon the Kansas Board of Pharmacy.

The adoption of this amendment does not have an additional economic impact to the Kansas State Board of Pharmacy. The Board of Pharmacy would contact the KTRACS clearinghouse through Appriss Solutions so that they could make changes to the reporting fields. Appriss provides this service free of charge to the state.

Anticipated Financial Impact Upon Other Governmental Agencies and Upon Private Business or Individuals.

The Board does not anticipate that this amendment will have any financial impact upon other governmental agencies. Each reporting pharmacy would have to open up an additional reporting field in their database. Pharmacies generally update their drug lists as changes are made to federal and local laws and the impact is minimal. The Board of

Pharmacy has given impacted entities an additional 90 days to make changes to their software database.

IV. Less Costly or Intrusive Methods That Were Considered.

The Board is not aware of any less costly or less intrusive methods to achieve the stated purpose and thus none were considered.

IV: Environmental Regulation

These are not proposed environmental regulations or amendments to environmental regulations.