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 8th day of January 2015, at the Board of Pharmacy Meeting, Rasmussen College, 620 SW Governor View, Room 116, Topeka, Kansas, 66606 to consider the proposed adoption of amendments to K.A.R. 68-2-22 and K.A.R. 68-20-10a 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. 68-2-22 and K.A.R. 68-20-10a. 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. 68-2-22 and K.A.R. 68-20-10a 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 next to the front door of the building and is marked accordingly.

Proposed

Amendments to K.A.R. 68-2-22 and K.A.R. 68-20-10a are proposed for permanent adoption. A summary of the proposed amendments are as follows:

K.**A.R. 68-2-22. Electronic transmission of a prescription.** This regulation is amended to permit schedule II substances to be communicated electronically by a prescriber to the pharmacy.

K.A.R 68-20-10a. Electronic transmission of a controlled substance prescription. This regulation is amended to permit schedule II substances to be communicated electronically by a prescriber to the pharmacy.

Economic Impact. The adoption of these two 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 financial impact upon other governmental agencies. Electronic prescribing is permitted in 49 states and was put in place to reduce fraud and abuse, secure electronic records and improve safety and patient care. The regulatory change will limit the burden and cost required of a prescriber to write a hard-copy prescription for each patient.

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, 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

68-2-22. Electronic transmission of a prescription. (a) Each prescription drug order transmitted electronically shall be issued for a legitimate medical purpose by a prescriber acting within the course of legitimate professional practice.

(b) Each prescription drug order communicated by way of electronic transmission shall meet these requirements:

(1) Be transmitted to a pharmacist in a licensed pharmacy of the patient's choice, exactly as transmitted by the prescriber;

(2) identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the transmission, as well as any other information required by federal and state laws and regulations;

(3) be transmitted by an authorized prescriber or the prescriber's designated agent; and

(4) be deemed the original prescription drug order, if the order meets the requirements of this regulation.

(c) Any prescriber may authorize an agent to communicate a prescription drug order orally or electronically to a pharmacist in a licensed pharmacy if the identity of the transmitting agent is included in the order.

(d) Each pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order communicated by way of electronic transmission, consistent with existing federal and state laws and regulations.

(e) All electronic equipment for receipt of prescription drug orders communicated by way of electronic transmission shall be maintained so as to ensure against unauthorized access.

(f) Persons other than those bound by a confidentiality agreement shall not have access

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to pharmacy records containing confidential information or personally identifiable information concerning the pharmacy's patients.

(g) If communicated by electronic transmission, the prescription drug order shall be maintained in hard copy or as an electronic document for the time required by existing federal or state laws and regulations, whichever is longer.

(h) Any prescription drug order, including that for any controlled substance listed in schedules II, III, IV, and V ~~and, in certain situations, that for any controlled substance listed in schedule II~~, may be communicated by way of electronic transmission, if all requirements of K.A.R. 68-20-10a are met.

(i) After the pharmacist views the prescription drug order, this order shall be immediately reduced to a hard copy or an electronic document and shall contain all information required by federal and state laws and regulations.

(j) Each electronic prescription drug order created and transmitted in conformance with 21 ~~CFR~~ C.F.R. part 1311 shall be considered an original, written, signed prescription drug order ~~even if the order is transmitted electronically~~. (Authorized by K.S.A. 65-1630 and K.S.A. 2014 Supp. 65-1642; implementing K.S.A. ~~2009~~ 2014 Supp. 65-1637b and K.S.A. 2014 Supp. 65-1642; effective Feb. 5, 1999; amended Dec. 27, 1999; amended June 2, 2006; amended Oct. 23, 2009; amended May 20, 2011; amended P-_____.)

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Proposed

68-20-10a. Electronic transmission of a controlled substance prescription. (a) Each prescription drug order transmitted electronically shall be issued for a legitimate medical purpose by a prescriber acting within the course of legitimate professional practice.

(b) Each prescription drug order communicated by way of electronic transmission shall fulfill all the requirements of K.A.R. 68-2-22.

(c) ~~If communicated by electronic transmission, the prescription drug order shall be maintained in hard copy for the time required by existing federal and state laws and regulations.~~

(~~d~~) A prescription drug order, including that for any controlled substance listed in schedules II, III, IV, and V ~~and, in certain situations, that for any controlled substance listed in schedule II~~, may be communicated by electronic transmission in accordance with 21 C.F.R. part 1311.

~~(e) The electronic transmission of a prescription drug order for any schedule II controlled substance shall meet these requirements:~~

~~(1) A prescription drug order for any schedule II controlled substance may be communicated by the prescriber or that prescriber's designated agent by way of electronic transmission if the original, written, signed prescription drug order is presented to the pharmacist for review before the actual dispensing of the controlled substance, except as noted in this subsection.~~

~~(2) A prescription drug order for any schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be communicated by the prescriber or that prescriber's designated agent to the pharmacy by way of electronic transmission. The hard copy of this electronic transmission shall serve as the original, written prescription drug order for purposes of this~~

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~~subsection, and the hard copy shall be maintained as such.~~

~~(3) A prescription drug order for any schedule II controlled substance for a resident of a nursing facility, a nursing facility for mental health, or an assisted living facility may be communicated by the prescriber or that prescriber's designated agent by way of electronic transmission. The hard copy of this electronic transmission shall serve as the original, written prescription drug order for purposes of this subsection, and the hard copy shall be maintained as such.~~

~~(4) A prescription drug order for any schedule II controlled substance for a patient released by a registered institution to a home hospice setting that continues to provide daily skilled nursing care to the home hospice setting may be transmitted by the prescriber or that prescriber's designated agent by way of electronic transmission to the dispensing pharmacy. The hard copy of this electronic transmission shall serve as the original, written prescription drug order for purposes of this subsection, and the hard copy shall be maintained as such.~~

~~(5) In the case of an emergency situation, a prescription drug order for any schedule II controlled substance may be communicated by the prescriber by way of electronic transmission if the following requirements are met:~~

~~(A) The quantity prescribed and dispensed shall be limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period shall be pursuant to a written prescription drug order signed by the prescriber.~~

~~(B) After the pharmacist views the prescription drug order, this order shall be immediately reduced to a hard copy and shall contain all information required by federal and~~

~~state laws and regulations.~~

~~(C) The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order communicated by way of electronic transmission, consistent with existing federal and state laws and regulations.~~

~~(D)(i) Within seven days after authorizing an emergency prescription drug order, the prescriber shall cause a written prescription drug order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to all other federal and state laws and regulations, the prescription drug order shall have written on its face "authorization for emergency dispensing" and the date of the transmitted prescription drug order.~~

~~(ii) The written prescription drug order shall be delivered to the pharmacist in person within seven days of authorization, or if delivered by mail, the order shall be postmarked within the seven-day period.~~

~~(iii) Upon receipt, the dispensing pharmacist shall attach this written prescription drug order to the hard copy of the electronically transmitted prescription drug order. The pharmacist shall notify the nearest office of the U.S. drug enforcement administration (DEA) if the prescriber fails to deliver a written prescription drug order.~~

~~(f)~~ (d) Each electronic prescription drug order created and transmitted in conformance with 21 ~~CFR~~ C.F.R. part 1311 shall be considered an original, written, signed prescription drug order ~~even if the order is transmitted electronically~~. (Authorized by ~~and implementing~~ K.S.A. 65-1630, K.S.A. ~~2009~~ 2014 Supp. 65-1642, and K.S.A. ~~2009~~ 2014 Supp. 65-4102, ~~and~~ ; implementing K.S.A. 2014 Supp. 65-1642, 65-4102, and 65-4123; effective Feb. 5, 1999;

amended Dec. 27, 1999; amended April 23, 2010; amended May 20, 2011; amended P-

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Proposed

KANSAS PHARMACY BOARD
ECONOMIC IMPACT STATEMENT

K.A.R. 68-2-22 and K.A.R. 68-20-10a

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

These regulations control how a Schedule II controlled substance prescription may be communicated from a prescriber to a pharmacy when sent electronically.

Previously, the Drug Enforcement Administration (DEA) did not allow prescriptions for controlled substances to be sent electronically. Safeguards have now been put in place so that sending an electronic prescription reduces fraud and abuse, secures electronic records, and improves safety and patient care.

K.A.R. 68-2-22 applies to all prescriptions including controlled substances. The regulations currently permit a Schedule III through V to be communicated electronically and the amendment adds Schedule II controlled substances.

K.A.R. 68-20-10a is a similar regulation but it was applicable only to controlled substances communicated electronically. E prescribing gives a prescriber the ability to electronically send an accurate, error-free and understandable prescription directly to the pharmacy from the point-of-care. The amendment added Schedule II controlled substances rather than just III through V controlled substances.

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

III.

The amendment is proposed so that prescribers may electronically prescribe a Schedule II prescriptions. They are currently able to electronically prescribe a Schedule II through V prescription. E prescribing is not federally mandated but the Medicare Modernization Act (MMA) of 2003 gave momentum to the movement and the Centers

for Medicare and Medicaid Services (CMS) began adopting standards to facilitate E-prescribing. It is a key action item in the government's plan to expedite the adoption of electronic medical records and to build a national electronic health information infrastructure in the United States. It is anticipated that eventually all prescriptions will be sent electronically.

IV. 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.

V. 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. It is expected to show a reduction in fraudulent prescriptions so this may help governmental agencies tracking fraud. Electronic prescriptions are not required but they may be less costly and require less time for the prescriber and pharmacy.

VI. 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.