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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 24th day of April 2014, at the Kansas Board of Healing Arts, Board Room, 800 SW Jackson, Lower Level, Topeka, Kansas 66612, to consider the proposed adoption of amendments to K.A.R. 68-21-1 and K.A.R. 68-21-2. 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. 68-21-1 and K.A.R. 68-21-2. 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. 68-21-1 and K.A.R. 68-21-2 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 garage of the building off of 8th Street.

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Amendments to K.A.R. 68-21-1 and K.A.R. 68-21-2 are proposed for permanent adoption. A summary of the proposed amendments are as follows:

K.A.R. 68-21-1 Definitions. This regulation is amended to change the definition of "patient identification number" in the prescription monitoring system to include a person's driver's license number or another predetermined numbering mechanism, and the definition of "report" was changed to clarify language throughout the other prescription monitoring regulations.

K.A.R. 68-21-2 Electronic Reports. This regulation identifies the specifics relating to the electronic reports that must be submitted to the Prescription Monitoring Program. Amendments include requiring those that are required to report to the Program to submit Zero Reports if they go seven days without dispensing in or into the State. This regulation also changes the frequency of reporting from weekly to daily which was the original intent of the regulation. The original regulation stated that the change will take effect January 1, 2013.

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 financial impact upon other governmental agencies or upon private businesses or individuals besides the original impact of implementing such a program.

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

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(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

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68-21-1. Definitions. As used in these regulations, the following terms shall have the meanings specified in this regulation:

(a) "Authentication" means the provision of information, an electronic device, or a certificate by the board or its designee to a dispenser or prescriber that allows the dispenser or prescriber to electronically access prescription monitoring information. The authentication may include the provision of a user name, a password, or an electronic identification device or certificate.

(b) ~~"Board" means the state board of pharmacy.~~

~~(c)~~ "Dispenser identification number" means the drug enforcement administration (DEA) number if available or, if not available, the national provider identifier (NPI).

~~(d)~~ (c) "Drug enforcement administration number" means a unique registration number issued to an authorized prescriber of controlled substances by the drug enforcement administration, United States department of justice.

~~(e)~~ (d) "National provider identifier" and "NPI" mean a unique 10-digit number issued by the national provider identifier registry and used to identify each health care provider whose services are authorized by medicaid or medicare.

~~(f)~~ (e) "Patient identification number" means ~~a unique number that a dispenser uses to identify a particular person~~ that patient's unexpired temporary or permanent driver's license number or state-issued identification card number. If the patient does not have one of those numbers, the dispenser shall use the patient's insurance identification number. If the patient does not have an insurance identification number, the dispenser shall use the patient's first, middle, and last initials, followed by the patient's eight-digit birth date.

~~(g)~~ (f) "Prescriber identification number" means the DEA number if available or, if not available, the NPI.

~~(h)~~ (g) "Program" means the Kansas prescription monitoring program.

~~(i)~~ (h) "Report" means a compilation of data concerning a dispenser, patient, drug of concern, or ~~schedule II through IV drugs~~ scheduled substance as defined in K.S.A. 65-1682(g) and amendments thereto.

~~(j)~~ (i) "Stakeholder" means a person, group, or organization that could be affected by the program's actions, objectives, and policies.

~~(k)~~ (j) "Valid photographic identification" means any of the following:

(1) An unexpired permanent or temporary driver's license or instruction permit issued by any U.S. state or Canadian province;

(2) an unexpired state identification card issued by any U.S. state or Canadian province;

(3) an unexpired official passport issued by any nation;

(4) an unexpired United States armed forces identification card issued to any active duty, reserve, or retired member and the member's dependents;

(5) an unexpired merchant marine identification card issued by the United States coast guard;

(6) an unexpired state liquor control identification card issued by the liquor control authority of any U.S. state or Canadian province; or

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(7) an unexpired enrollment card issued by the governing authority of a federally recognized Indian tribe located in Kansas, if the enrollment card incorporates security features comparable to those used by the Kansas department of revenue for drivers' licenses.

(k) "Zero report" means an electronic data submission reflecting no dispensing activity for a given period.

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

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

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68-21-2. Electronic reports. (a)(1) Each dispenser shall file a report with the board for ~~schedule II through IV drugs~~ scheduled substances, as defined in K.S.A. 65-1682(g) and amendments thereto, and any drugs of concern dispensed in this state or to an address in this state. ~~On and after January 1, 2013,~~ This report shall be submitted within 24 hours of the time that the substance is dispensed, unless the board grants an extension as specified in subsection (d). ~~Before January 1, 2013, each dispenser shall submit the report within seven days of dispensing the substance.~~

(2) Each dispenser that does not dispense ~~schedule II through IV drugs~~ scheduled substances, as defined in K.S.A. 65-1682(g) and amendments thereto, or any drugs of concern in this state or to an address in this state during the reporting ~~periods~~ period specified in ~~this subsection~~ paragraph (a)(1) shall file a zero report with the board. Each zero report shall meet the following requirements:

(A) Cover not more than a seven-day period in which no such drugs were dispensed; and

(B) be filed the day following the end of the period covered by the zero report.

(b) In addition to the requirements of K.S.A. 65-1683 and amendments thereto, each dispenser shall submit the prescriber's name, the patient's telephone number, and the number of refills for the dispensed drug on the report to the board. As an alternative to reporting the dispenser identification number, any dispenser may report the pharmacy DEA number.

(c) Except as specified in K.A.R. 68-21-3, ~~the~~ each report required to be submitted pursuant to subsection (a) shall be submitted by secure file transfer protocol in the electronic format established by the American society for automation in pharmacy, dated no earlier than 2007, version 4, release 1.

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(d) An extension may be granted by the board to a dispenser for the submission of a any report required to be submitted pursuant to subsection (a) if both of the following conditions are met:

(1)(A) The dispenser suffers a mechanical or electronic failure; or

(B) the dispenser cannot meet the deadline established by subsection (a) because of circumstances beyond the dispenser's control.

(2) The dispenser files a written application for extension on a form provided by the board within 24 hours of discovery of the circumstances necessitating the extension request or on the next day the board's administrative office is open for business.

(e) An extension for the filing of a report shall be granted to a dispenser if the board is unable to receive electronic reports submitted by the dispenser.

(f) Each dispenser that is registered or licensed to dispense ~~schedule II through IV drugs~~ scheduled substances, as defined in K.S.A. 65-1682(g) and amendments thereto, or any drugs of concern in this state or to an address in this state but does not dispense any of these drugs shall notify the board in writing that the dispenser will not be reporting to the board. If the dispenser begins dispensing ~~schedule II through IV drugs~~ scheduled substances, as defined in K.S.A. 65-1682(g) and amendments thereto, or any drugs of concern in this state or to an address in this state, the dispenser shall notify the board of this fact and shall begin submitting reports to the board pursuant to this regulation.

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

(Authorized by K.S.A. ~~2009~~ 2013 Supp. 65-1683 and 65-1692; implementing K.S.A. ~~2009~~ 2013 Supp. 65-1683; effective Oct. 15, 2010; amended April 15, 2011; amended P-_____.)

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ECONOMIC IMPACT STATEMENT

Pursuant to K.S.A. 77-420(c) (4), the Kansas Pharmacy Board submits the following description of the economic impact of the proposed regulations: K.A.R. 68-21-1 and K.A.R. 68-21-2.

1. These are amended regulations that add additional criteria to the definition of a patient identification number in the prescription monitoring program. The definition expanded and clarified that what identification would be appropriate when submitting data in order for the system to identify a patient accurately. A definition for zero report was added to clarify the change that was made in K.A.R. 68-21-2.

The amendment to K.A.R. 68-21-2 amended the regulation by clarifying the requirements for transmitting zero reports electronically. The regulation also extended the effective date of the regulation to take effect 90 days after publication so that dispenser software could be adjusted accordingly.

2. The proposed regulations are not mandated by federal laws.

3. The adoption of these amendments would not have an additional economic impact to the Kansas State Board of Pharmacy.

4. The Board does not anticipate that these amendments will have any financial impact upon other governmental agencies or upon private businesses or individuals. The Board took into consideration that software vendors would need approximately 90 days to make changes to their current software.

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

6. This is not a proposed environmental regulation.