

**Pharmacy Act of the State of Kansas and Uniform Controlled Substances Act—
Electronic Prescription Amendments, Free Sample Distribution of Schedule V
Nonnarcotic Depressants, and Addition of Controlled Substances;
Prescription Monitoring Program Act Amendments; SB 134**

SB 134 amends the Pharmacy Act of the State of Kansas and the Uniform Controlled Substances Act regarding electronic prescriptions and amends the Prescription Monitoring Program (PMP) Act to authorize the State Board of Pharmacy (Board) to pursue and accept grant funding and accept donations, gifts, or bequests; add two entities authorized to obtain information from the PMP; create a penalty for obtaining or attempting to obtain PMP information without authority; and authorize the PMP Advisory Committee to identify and review concerns involving controlled substances and drugs of concern, through the use of volunteer peer review committees, and to notify the appropriate entities. The bill adds one new substance each to Schedules IV and V of the Uniform Controlled Substances Act and allows for the distribution of free samples of Schedule V nonnarcotic depressants by manufacturers or distributors.

Definitions, Electronic Prescriptions

The bill adds the following key definitions, generally found in federal regulations related to electronic orders of controlled substances and electronic prescriptions for controlled substances, to the Pharmacy Act of the State of Kansas and the Uniform Controlled Substances Act:

- An "electronic prescription" is electronically prepared and authorized and transmitted from the prescriber to the pharmacy using electronic transmission;
- A "pharmacist intern" includes a pharmacy student, a pharmacy resident, or a foreign pharmacist graduate;
- A "prescriber" includes a practitioner or a mid-level practitioner; and
- A "valid prescription order" requires the prescription to be issued for a legitimate medical purpose by an individual licensed prescriber acting within such prescriber's scope of practice. Prescriptions issued without an appropriate prescriber-patient relationship, but instead issued only on an internet-based questionnaire or consultation, are not valid.

Other definitions which also are added and are based on federal regulations related to electronic orders and electronic prescriptions of controlled substances include "application service provider," "Drug Enforcement Agency," "electronic prescription application," "electronic signature," "electronically prepared prescription," "facsimile transmission," "intermediary," "pharmacy prescription application," and "readily retrievable."

The following definitions are expanded by the bill:

- "Electronic transmission" is defined and distinguished from a facsimile transmission;

- The definition of "pharmacist" is expanded in the Uniform Controlled Substances Act to mirror the definition in the Pharmacy Act of the State of Kansas; and
- "Prescription" or "prescription order" are combined as one definition to clarify no distinction is made with regard to the manner in which the prescription is communicated.

Some definitions are moved to re-alphabetize the definitions within the Acts.

Writing, Filling, Refilling, and Recording of Prescriptions Under the Pharmacy Act of the State of Kansas

The bill also moves most of the language found in KSA 2011 Supp. 65-1637 related to the writing, filling, refilling, and recording of prescriptions to a new section, thereby placing all language referring to such current practices together. New language is added to the new section to incorporate requirements pertaining to electronic prescribing of controlled substances found in federal law as follows.

Validity of Prescriptions

A valid prescription must meet the following requirements:

- Pharmacists must exercise professional judgment regarding the accuracy, validity, and authenticity of any prescription order consistent with federal and state laws and rules and regulations;
- A pharmacist is prohibited from dispensing a prescription drug if a pharmacist exercising professional judgment determines a prescription is not a valid prescription order;
- The prescriber may authorize an agent to transmit to the pharmacy a prescription order orally, by fax, or by electronic transmission with the first and last name of the transmitting agent included;
- A new written or electronic prescription must be signed manually or electronically by the prescriber and include the first and last name of the transmitting agent;
- A prescription for a controlled substance which is written or printed from an electronic prescription application must be signed by the prescriber manually prior to the delivery of the prescription to the patient or prior to the facsimile transmission to the pharmacy; and
- An electronically prepared prescription cannot be electronically transmitted if it has been printed prior to transmission and, if the prescription is printed after electronic transmission, it must be clearly labeled as a copy and is not valid for dispensing.

Electronic Transmission Study

The Board, in consultation with industry, is required to conduct a study on electronic transmission of prior authorization and step therapy protocols. The study report must be completed and submitted to the Legislature by January 15, 2013. The Board also is authorized to conduct pilot projects related to any new technology implementation when necessary and practicable, but no state moneys can be expended for this purpose.

Filling or Refilling of Prescription Orders

A refill is defined by the bill as one or more dispensings of a prescription drug or device resulting in the patient's receipt of a single fill as per the prescription and as authorized by the prescriber. In order to fill or refill a prescription, the following conditions need to be met:

- When refilling a prescription or renewing or continuing a drug therapy, an authorization may be transmitted orally, in writing, by fax, or by electronic means initiated by or directed by the prescriber;
- The prescriber's signature is not required on a fax or alternate electronic transmission when the first and last name of the prescriber's agent making the transmission is provided;
- Any refill order or renewal order which differs from an original order must be signed by the prescriber, unless transmitted by fax or electronically by the prescriber's agent and the first and last name of such agent is provided;
- Only pharmacists or pharmacist interns are authorized to receive a new order;
- A pharmacist, pharmacist intern, or a registered pharmacy technician (if authorized to do so by the supervising pharmacist) is permitted to receive a refill or renewal order;
- No more than 12 refills within 18 months of the issuance of the prescription may be authorized for a prescription drug or device which is not a controlled substance; and
- Prescriptions for Schedule III, IV, or V controlled substances are limited to five refills within six months of the issuance of the prescription.

Prescription Monitoring Program Act

The Board is authorized, for the purpose of furthering the PMP Act, to apply for and accept grants and to accept any donation, gift, or bequest. All moneys received by the Board are to be submitted for deposit in the State Treasury to the credit of the Non-federal Gifts and Grants Fund of the Board.

The bill replaces the Kansas Health Policy Authority (KHPA) with the Kansas Department of Health and Environment (KDHE) as the entity authorized to obtain PMP

information regarding authorized Medicaid program recipients, as necessitated by the passage of 2011 Executive Reorganization Order No. 38 which reorganized KHPA into the Division of Health Care Finance within KDHE.

The bill also allows access to PMP data for two new categories of persons. Prescribers and dispensers are allowed access to the data when an individual appears to be obtaining prescriptions for the misuse, abuse, or diversion of scheduled substances or drugs of concern. The Board also is able to provide information to medical examiners, coroners, or other persons authorized by law to investigate or determine causes of death.

PMP Advisory Committee Review

The PMP Advisory Committee reviews and analyzes PMP data to identify patterns and activity of concern. When individuals are suspected of obtaining prescriptions indicating misuse or abuse of controlled substances, the PMP Advisory Committee can contact the prescribers and dispensers. If the individuals are suspected of criminal activity, the PMP Advisory Committee can notify the appropriate law enforcement agency.

If the PMP information appears to indicate the occurrence of a violation on the part of a prescriber or dispenser in prescribing controlled substances or drugs of concern inconsistent with recognized standards of care for the profession, the PMP Advisory Committee determines if a report to the appropriate professional licensing, certification, or regulatory agencies or law enforcement agency is warranted.

The PMP Advisory Committee consults with appropriate regulatory agencies and professional organizations to establish criteria for standards and utilizes volunteer peer review committees to create such standards and to review individual prescriber or dispenser cases. The volunteer peer review committees have authority to request and receive information in the PMP database from the PMP Director. If referral to a regulatory or law enforcement agency is not warranted, the PMP Advisory Committee can refer prescribers or dispensers to educational or professional advising, as appropriate.

Penalty for Unauthorized Access to PMP Information

An unauthorized person who knowingly obtains or attempts to obtain prescription monitoring information is guilty of a severity level 10, nonperson felony.

Controlled Substance Additions and Distribution of Free Samples under the Uniform Controlled Substances Act

The bill amends the Uniform Controlled Substances Act to add carisoprodol to the Schedule IV controlled substances list and ezogabine N-[2-amino-4(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester to the Schedule V list. The bill also allows for the distribution of free samples of Schedule V nonnarcotic depressants by manufacturers or distributors to practitioners, mid-level practitioners, pharmacists, or other persons.

Dispensing Under the Uniform Controlled Substances Act

Controlled substances are to be dispensed with the following changes:

- Except when dispensed by a practitioner, other than a pharmacy, to the ultimate user, Schedule II controlled substances are not allowed to be dispensed unless a practitioner or mid-level practitioner provides a written or electronic prescription. In emergency situations, Schedule II substances can be dispensed upon an oral order if reduced promptly to writing or transmitted electronically and filled by the pharmacy; and
- Except when dispensed by a practitioner, other than a pharmacy, to the ultimate user, Schedule V drugs, which also are prescription drugs, are added to Schedule III and IV drugs which can be dispensed only when a paper prescription is manually signed by the prescriber, a facsimile of a manually signed paper prescription is transmitted by the prescriber or the agent, an electronic prescription is digitally signed by a prescriber with a digital certificate, or an oral prescription is made by an individual prescriber and promptly reduced to writing.

A controlled substance cannot be distributed or dispensed except by a valid prescription order as defined in this act.

Retention of Prescription Record under the Uniform Controlled Substances Act

The bill provides for electronic prescriptions to be retained electronically for five years and requires the record to be readily retrievable into a format a person can read. Paper, oral, and fax prescriptions are to be maintained as a hard copy for five years at the registered location.