

SESSION OF 2012

**SUPPLEMENTAL NOTE ON SUBSTITUTE FOR SENATE  
BILL NO. 327**

As Recommended by Senate Committee on  
Public Health and Welfare

**Brief\***

Sub. for SB 327 would amend the Pharmacy Act and the Uniform Controlled Substances Act regarding electronic prescriptions and would amend the Prescription Monitoring Program (PMP) Act to: authorize the 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.

**Definitions, Electronic Prescriptions (Sections 1 and 7)**

The bill would add 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 and the Uniform Controlled Substances Act:

- An "electronic prescription" would be electronically prepared and authorized and transmitted from the prescriber to the pharmacy using electronic transmission;

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\*Supplemental notes are prepared by the Legislative Research Department and do not express legislative intent. The supplemental note and fiscal note for this bill may be accessed on the Internet at <http://www.kslegislature.org>

- A "pharmacist intern" would be defined to include a pharmacy student, a pharmacy resident, or a foreign pharmacist graduate;
- A "prescriber" would include a practitioner or a mid-level practitioner; and
- A "valid prescription order" would require 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 rather issued only on an internet-based questionnaire or consultation, would not be valid.

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

The following definitions would be expanded by the bill:

- Electronic transmission is defined and distinguished from a facsimile transmission;
- The definition of "pharmacist" would be expanded in the Uniform Controlled Substances Act to mirror the definition in the Pharmacy Act; and
- Prescription or prescription order would be combined as one definition to clarify no distinction is made with regard to the manner in which the prescription is communicated.

Some definitions which appear to have been added are in current law, but would be moved to re-alphabetize the definitions within the Acts.

### **Writing, Filling, Refilling and Recording of Prescriptions Under the Pharmacy Act (New Section 3)**

Further, the bill would move most of the language found in KSA 2011 Supp. 65-1637 (Section 2) related to the writing, filling, refilling, and recording of prescriptions to New Section 3, thereby placing all language referring to such current practices together. New language would be added to New Section 3 to incorporate requirements pertaining to electronic prescribing of controlled substances found in federal law as follows.

#### ***Validity of Prescriptions***

A valid prescription would need to 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 would be 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, must be clearly labeled as a copy and is not valid for dispensing.

### ***Electronic Transmission Study***

The State Board of Pharmacy would be required to conduct a study on electronic transmission of prior authorization and step therapy protocols to be completed and submitted to the Legislature by January 15, 2013. The Board also would be authorized to conduct pilot projects related to any new technology implementation when necessary and practicable.

### ***Filling or Refilling of Prescription Orders***

A refill is defined 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 would 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 pharmacy 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) may 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 would be limited to five refills within six months of the issuance of the prescription.

### **Prescription Monitoring Program (PMP) Act**

The Board of Pharmacy (Board) would be 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 would be submitted for deposit in the state treasury to the credit of the Non-federal Gifts and Grants Fund of the Board.

The bill would replace 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 Executive Reorganization Order No. 38 in 2011 which reorganized KHPA into the Division of Health Care Finance within KDHE.

The bill also would allow access to PMP data to two new categories of persons. Prescribers and dispensers would be 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 would be able to provide information to medical examiners, coroners or other persons authorized by law to investigate or determine causes of death.

***PMP Monitoring Program Advisory Committee Review***

The PMP Monitoring Program Advisory Committee would review and analyze PMP data to identify patterns and activity of concern. When individuals were suspected of obtaining prescriptions indicating misuse or abuse of controlled substances, the Advisory Committee could contact the prescribers and dispensers. If the individuals were suspected of criminal activity, the Advisory Committee could 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 Advisory Committee would determine if a report to the appropriate professional licensing, certification or regulatory agencies or law enforcement agency would be warranted.

The Advisory Committee would consult with appropriate regulatory agencies and professional organizations to establish criteria for standards and would utilize volunteer peer review committees to create such standards and to review individual prescriber or dispenser cases. The

volunteer peer review committees would have authority to request and receive information in the PMP database from the PMP Director. If referral to a regulatory or law enforcement agency would not be warranted, the Advisory Committee could 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 would be guilty of a severity level 10, nonperson felony.

### **Dispensing Under the Controlled Substances Act**

Controlled substances would be dispensed with the following changes:

- Except when dispensed by a practitioner, other than a pharmacy, to the ultimate user, Schedule II controlled substances would not be allowed to be dispensed unless a practitioner or mid-level practitioner provides a written or electronic prescription. In emergency situations, Schedule II substances could 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, would be added to Schedule III and IV drugs which could only be dispensed 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 could not be distributed or dispensed except by a valid prescription order as defined in this act.

### **Retention of Prescription Record under the Controlled Substances Act**

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

### **Background**

**SB 327** was introduced at the request of the Kansas Board of Pharmacy. The Senate Committee on Public Health and Welfare heard testimony in favor of the original bill from the Director of the Kansas Prescription Monitoring Program, Kansas Board of Pharmacy, and representatives of the Kansas Medical Society (KMS) and the Kansas Association of Osteopathic Medicine. The Program Director testified the bill was intended to clean up language with regard to the dissolution of KHPA and to incorporate new funding language to help create a sustainable funding source for the PMP. According to the Program Director, the addition of two different groups who may be provided PMP information and the addition of a penalty for unauthorized access to PMP information reflect language in the Prescription Monitoring Program Model Act, a consensus document that reflects the best practices of the states that currently run PMPs and the knowledge of other states with a long standing interest in PMPs. The KMS representative testified in support of the bill and proposed an amendment allowing the PMP to initiate a report to a licensing agency or law enforcement agency upon a review process determination that such a report would be

warranted. The Kansas Association of Osteopathic Medicine representative also testified in favor of the bill and supported the proposed amendment.

Neutral testimony on SB 327 was presented by the Executive Director of the Kansas State Board of Healing Arts (KSBHA), who testified that KSBHA is prohibited from using peer review records exclusively to prove a violation of standard-of-care; so even if the PMP conducted peer review and provided the results, KSBHA would be required to conduct a thorough investigation and conduct an independent peer review, and public protection would be delayed. No testimony opposing the original bill was presented to the Senate Committee.

**SB 328** was introduced at the request of the Kansas Board of Pharmacy. The Senate Committee on Public Health and Welfare heard testimony in favor of the bill from the Executive Director of the Board of Pharmacy and representatives of the Kansas Association of Chain Drug Stores (KACDS) and Pfizer. The Executive Director of the Board of Pharmacy stated the Drug Enforcement Agency (DEA) revised its regulations to provide practitioners and mid-level practitioners with the option of writing prescriptions for controlled substances electronically. The Executive Director indicated the bill does not replace existing rules, but attempts to recodify federal law and provides pharmacies, hospitals, and prescribers with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances. The Pfizer representative supported the bill and requested an amendment to allow for electronic prior authorization. The KACDS representative spoke in support of the bill and also proposed an amendment deleting language which, according to the testimony, would place pharmacists in the position of having to police the prescribing activities of prescribers to ensure they are practicing within the confines of the laws and regulations of the Kansas State Board of Healing Arts. No opposing or neutral testimony was presented to the Senate Committee. A representative of Medco, asked by the

Committee to address the proposed prior authorization amendment, expressed concern that the changes proposed in the turn-around time would not allow sufficient time to make a determination of proper protocol.

The Senate Committee on Public Health and Welfare created Sub. for SB 327, which included the contents of SB 327 and SB 328 and incorporated changes to both bills agreed upon by the interested parties. The agreed upon changes to SB 328 included in the substitute bill were: replacing practitioner with prescriber, so as to include both practitioners and mid-level practitioners; adding a definition for a "valid prescription order;" deleting language requiring that a valid prescription order be based on a valid patient-prescriber relationship; deleting a duplicative reference to the prescriber's exercise of professional judgment; inserting language prohibiting a pharmacist from dispensing a prescription drug when the prescription is not a valid prescription order; removing the requirement for inclusion of a transmitting agent's title in electronic transmissions; requiring the Board to conduct a study on electronic transmission of prior authorizations and step therapy protocols and authorizing pilot projects related to new technology implementation; removing "certified pharmacy technician" in instances related to the acceptance of a new prescription since this is prohibited in Kansas; deleting language requiring a pharmacist to ensure a prescription order was issued for a legitimate medical purpose; deleting language prohibiting the dispensing of prescription drugs when the pharmacist knew or should have known the prescription was issued solely on the basis of an internet-based questionnaire, an internet-based consultation, or a telephonic consultation without a valid pre-existing patient practitioner relationship; removing the limitation on the number of refills allowed on substances which are not controlled; adding schedule V controlled substances which also are prescription drugs to the section describing how schedule III and IV prescription drugs may be dispensed; and prohibiting the distribution or dispensing of controlled substances without a valid prescription order. Agreed upon changes to SB 327 included in the substitute bill

authorized the previously created PMP advisory committee to: review and analyze data for purposes of identifying patterns and activity of concern and notify prescribers, dispensers, law enforcement, professional licensing, certification or regulatory agencies as the information may warrant; establish criteria for appropriate standards and use volunteer peer review committees to create the standards and review individual cases; authorize access to information from the PMP database to peer review committees; and refer prescribers to educational or professional advising resources when appropriate. Technical amendments also were made.

The fiscal note on the original SB 327 prepared by the Division of the Budget states the Board of Pharmacy indicated enactment of the bill would have no fiscal effect on its operations. The Kansas Sentencing Commission indicated enactment of the bill would have no fiscal effect on prisons or its operations, but further noted a new crime would be created for which there is no associated data that could be used to make an estimate.

The fiscal note on the original SB 328 prepared by the Division of the Budget states the Board of Pharmacy indicated enactment of the bill would have no fiscal effect.