SESSION OF 2012

CONFERENCE COMMITTEE REPORT BRIEF
SENATE BILL NO. 134

As Agreed to March 29, 2012

Brief*

SB 134 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. The bill would add one new substance each to Schedules IV and V of the Uniform Controlled Substances Act, and allow for the distribution of free samples of Schedule V nonnarcotic depressants by manufacturers or distributors.

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:

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

- A "pharmacist intern" would 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 instead 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

The bill also 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, it must be clearly labeled as a copy and is not valid for dispensing.

Electronic Transmission Study

The State Board of Pharmacy, in consultation with industry, would be 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 would be authorized to conduct pilot projects related to any new technology implementation when necessary and practicable, but no state moneys could 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 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) 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 would be limited to five refills within six months of the issuance of the prescription.

Prescription Monitoring Program (PMP) Act

The 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 for 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.

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

The bill would amend 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 Schedule V list. The bill also would allow 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 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 Uniform 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.

The bill would be in effect upon publication in the *Kansas Register.*

Conference Committee Action

The Conference Committee agreed to remove the contents of SB 134 (as amended by the House Committee of the Whole) and insert the contents of SB 325 (as amended by the Senate Committee) and Sub. for SB 327 (as recommended by the Senate Committee), with the following additions and revisions:

- Further amended the contents of Sub. for SB 327, concerning the electronic transmission study under the Pharmacy Act, to require the Board of Pharmacy to conduct the study in consultation with industry and to disallow the use of state moneys to conduct pilot projects related to new technology implementation; and

- Changed the effective date of the bill to upon publication in the *Kansas Register.*

The title of the bill was updated, by technical amendment, to conform to Conference Committee amendments.

Background

The original bill, **SB 134** (as amended by the House Committee of the Whole), would have amended existing law to update the title of the Advanced Registered Nurse Practitioner (ARNP) to Advance Practice Registered Nurse

(APRN), changed licensure and education requirements for the role of the APRN, and would make a definitional change regarding optometrists. The bill also would have provided a process for the reinstatement of a license for a registered professional nurse whose license had lapsed for a period of more than five years under certain circumstances.

The contents of SB 134, along with the contents of several other bills, were inserted into 2011 HB 2182 in conference committee during the 2011 Legislative Session. The resulting 2011 HB 2182 was approved by the Governor on May 25, 2011.

SB 325 was introduced at the request of the Kansas State Board of Pharmacy.

The Senate Committee on Public Health and Welfare amended the bill, as requested by Pfizer, to allow for distribution of samples of Schedule V nonnarcotic depressants by a manufacturer or distributor to certain health care professionals. The Committee also made technical amendments to the bill.

SB 327 was introduced at the request of the Kansas State Board of Pharmacy.

SB 328, which was inserted into Sub. for SB 327 by the Senate Committee on Public Health and Welfare, was introduced at the request of the Kansas Board of Pharmacy.

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 pattens 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.

Additional information about these bills is found in corresponding Supplemental Notes.

The fiscal note on the original SB 325 prepared by the Division of the Budget and provided after the Senate Committee hearing states the Board of Pharmacy indicated the bill would have no fiscal effect on its operations. The Kansas Sentencing Commission indicated the bill would affect agency expenditures, but has not yet provided an estimate. According to the Division of the Budget, once information is provided, a revised fiscal note will be submitted.

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.

Pharmacy Act, Uniform Controlled Substances Act, Prescription Monitoring Program.

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