

SESSION OF 2014

**SUPPLEMENTAL NOTE ON SENATE SUBSTITUTE FOR
HOUSE BILL NO. 2146**

As Recommended by Senate Committee on
Public Health and Welfare

Brief*

Senate Sub. for HB 2146 would make several amendments to the Kansas Pharmacy Act. Among the amendments, the bill would add the definitions of “collaborative drug therapy management,” “collaborative practice agreement,” “practice of pharmacy,” and “physician” to the Act; clarify prescription refill restrictions; and create the Collaborative Drug Therapy Management Advisory Committee. The bill also would allow the Board of Pharmacy (Board), through rules and regulations, to change the timing of expiration dates for licenses, registrations, and permits issued by the Board, and to allow for the prorating of fees for license and registration periods.

Specific changes would be made as described below.

**Pharmacy Act; Definitions, Refills and Advisory
Committee**

The “practice of pharmacy” definition would be amended to include performance of collaborative drug therapy management pursuant to a written collaborative practice agreement with one or more physicians who have an established physician-patient relationship.

*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>

The following definitions would be added to the Act:

- Collaborative practice agreement:
 - A written agreement or protocol between one or more pharmacists and one or more physicians providing for collaborative drug therapy management;
 - The contents of the collaborative practice agreement would be required to contain conditions or limitations pursuant to the collaborating physician's orders; and
 - The collaborative practice agreement would be required to be within the physician's lawful scope of practice and appropriate to the pharmacist's training and experience;

- Collaborative drug therapy management:
 - A pharmacist would be allowed to perform patient care functions for a specific patient delegated to the pharmacist by a physician through a collaborative practice agreement;
 - A physician who enters into a collaborative practice agreement would remain responsible for the care of the patient throughout the collaborative drug therapy management process; and
 - A pharmacist would not be permitted to alter a physician's orders or directions, diagnose or treat any disease, independently prescribe drugs, or independently practice medicine and surgery; and

- Physician: A person licensed to practice medicine and surgery in Kansas.

Refills

The bill would eliminate language stating no more than 12 refills are allowed within 18 months following the prescription issue date for a non-controlled substance prescription drug or device. This language is in conflict with statutory language stating all prescriptions expire one year from the date written.

Dispense as Written

The bill would clarify if a prescriber electronically signs a prescription and wants that prescription to be dispensed as written, disallowing a generic brand exchange, it must be so stated on the prescription.

Collaborative Drug Therapy Management Advisory Committee

The bill also would create the seven-member Collaborative Drug Therapy Management Advisory Committee (Committee) for the purpose of promoting consistent regulation and enhancing coordination between the Kansas Board of Pharmacy and the Kansas Board of Healing Arts with jurisdiction over licensees involved in collaborative drug therapy management. The Committee would be required to advise and make recommendations to the boards on matters relating to collaborative drug therapy management.

The Committee's membership would consist of the following:

- One member of the Board of Pharmacy, appointed by the Board of Pharmacy, who would serve as the nonvoting chairperson;

- Three licensed pharmacists appointed by the Board of Pharmacy, at least two of whom would have experience in collaborative drug therapy management; and
- Three licensed physicians, appointed by the Board of Healing Arts, at least two of whom would have experience in collaborative drug therapy management.

When making appointments to the Committee, the Board of Pharmacy would be required to consider any names submitted by the Kansas Pharmacists Association, and the Board of Healing Arts would be required to consider any names submitted by the Kansas Medical Society.

Initially, Committee members would serve staggered terms, with one pharmacist and one physician serving for one year and two pharmacists and two physicians serving for two years. Thereafter, all members would serve two-year terms. Committee expenses would be divided equally between the boards.

License, Registration, and Permit Expiration and Renewal

Under the bill, the expiration dates for licenses, registrations, and permits set in statute as dates certain would be removed and replaced with Board authority to establish expiration dates by rules and regulations. Registrations for pharmacy technicians would change to a system of biennial renewals established by rules and regulations. Pharmacist licenses would continue to be renewed biennially and all other registrations and permits issued by the Board would continue to expire annually, but the expiration dates for both groups would be determined by rules and regulations.

The 30-day grace period for renewal of a pharmacist license, a pharmacy technician registration, and registrations and permits for other entities under the authority of the Board would be removed and payment of renewal fees would be required prior to the expiration of the license or registration. Prorating of fees for pharmacist licenses or pharmacy technician registration periods less than those established by the Board by rules and regulations would be allowed.

Application blanks presently sent for the renewal of registrations and permits for pharmacies, drug manufacturers, wholesale drug distributors, sales at public auctions, samples distributors, retail distributors, institutional drug rooms, and veterinary medical teaching hospital pharmacies would be replaced with a mailed renewal notice.

The pharmacy student registration and fee requirements would be eliminated.

Maximum Fees for Duplicate Permits and Certain Renewals

Fees for duplicate registrations or permits would be limited to not more than \$1.25 for permits and \$10.00 for certificates of registration. Renewal fees for samples distribution permits would be limited to not more than \$50.00. Renewal fees for durable medical equipment registrations would be limited to not more than \$300.00.

Elimination of Single Registration for Multiple Facilities

The bill would eliminate the single registration option for a manufacturer or distributor of any drugs operating more than one facility in the state or for a parent entity with divisions, subsidiaries, or affiliate companies within the state when operations are conducted in more than one location and there is joint ownership and control among all the entities.

Pharmacy Interns

The bill would provide for the registration, discipline, training, and oversight of pharmacy interns. The new section relating to pharmacy interns would be part of the Kansas Pharmacy Act.

Fees and Expiration of Registrations

The pharmacy intern registration fee would be fixed by rules and regulations of the Board in an amount not to exceed \$25.00, and the registration would expire six years from the date of issuance.

Discipline

The Board would be allowed to limit, suspend, or revoke a registration, or deny an application for issuance or renewal of any pharmacy intern on the same grounds the Board would have authority to take action against the license of a pharmacist. The Board also would be allowed to temporarily suspend or temporarily limit the registration of any pharmacist intern with an emergency adjudicative proceeding under the Kansas Administrative Procedure Act if grounds exist for disciplinary action and continuation of pharmacist intern functions would constitute an imminent danger to public health and safety.

Change in Employer and Posting Requirements

Pharmacy interns would be required to provide the Board with the name and address of a new employer within 30 days of obtaining new employment. Each pharmacy would be required to maintain a list of the names of pharmacy interns employed by the pharmacy. Pharmacy intern registrations would be required to be displayed in the part of the business where the intern is engaged in his or her activities.

Training

The bill would authorize the Board to adopt rules and regulations necessary to ensure pharmacy interns are adequately trained as to the nature and scope of their duties.

Oversight by Supervising Pharmacist

Pharmacy interns would be required to work under the direct supervision and control of a pharmacist, who would be responsible to determine that the pharmacy intern is in compliance with applicable rules and regulations of the Board and who would be responsible for the acts and omissions of the pharmacist intern in performing the intern's duties.

Background

HB 2146, as recommended by House General Government Budget Committee, would have repealed the Cancer Drug Repository Act. These provisions mirrored provisions included in 2013 HB 2153 which were enacted as part of the 2013 conference committee report for SB 199.

In 2014, the Senate Committee on Public Health and Welfare recommended a substitute bill which deleted the contents of the bill and inserted provisions relating to the Pharmacy Act (HB 2561, as recommended by House Committee on Health and Human Services, and HB 2609, as amended by House Committee on Health and Human Services). The background for the two bills follows.

HB 2561 Background

The bill was introduced by the House Committee on Health and Human Services at the request of the Board of Pharmacy. The Board representative testified before the House Committee that establishing expiration dates for all

licenses, registrations, and permits through rules and regulations would be more efficient, provide a steady revenue stream by allowing for the collection of fees throughout the year rather than at the end of the fiscal year, and not burden the resources of the office. In support of removing statutory language permitting the issuance of a single registration to multiple locations of a distributor or manufacturer if they were owned by the same entity, the representative noted the existing language does not follow regulatory schemes in the Kansas Pharmacy Act or the Controlled Substances Act and is not practical for record keeping, for disciplinary purposes, or for following the same practices as the federal Drug Enforcement Agency (DEA). Further, the representative noted such registrations have never been issued, and the DEA requires each registrant to have a separate DEA number. There was no opponent or neutral testimony.

The House Committee recommended the bill be placed on the Consent Calendar.

The fiscal note prepared by the Division of the Budget on HB 2561 states the Board estimates passage of the bill would increase expenditures from the Pharmacy Fee Fund by approximately \$700 in FY 2015. The costs would include those related to payments to the Office of Information and Technology Services for database and file structure modifications at \$70.00 per hour. The Board also indicates costs associated with modifying the state website for online renewals and fees would be negligible. Any fiscal effect associated with the bill is not reflected in *The FY 2015 Governor's Budget Report*.

HB 2609 Background

The bill was introduced, at the request of the Kansas Board of Pharmacy, by the House Committee on Health and Human Services. At the House Committee hearing, a representative of the Kansas Board of Pharmacy and a pharmacist testified in favor of the bill. The proponents stated

the bill would codify protocols and agreements currently occurring between pharmacists and physicians, leverage the pharmacist's expertise and knowledge of drug therapy in order to supplement the physician's work, and improve drug therapy outcomes for the patient. The Kansas Independent Pharmacy Service Corporation provided written-only proponent testimony. No opponent or neutral testimony was provided.

The House Committee amended the bill by amending the definition of "practice of pharmacy"; by adding the definitions of "collaborative drug therapy management," "collaborative practice agreement," and "physician"; and by creating the Collaborative Drug Therapy Management Advisory Committee.

The fiscal note prepared by the Division of the Budget states passage of HB 2609, as introduced, would have no fiscal effect on operations of the Kansas Board of Pharmacy.