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# SUPPLEMENTAL NOTE ON HOUSE SUBSTITUTE FOR SENATE BILL NO. 217

As Recommended by House Committee on Health and Human Services

## Brief*

House Sub. for SB 217 would amend a number of statutes in the State Pharmacy Act by establishing a licensing requirement for entities that distribute prescription drugs in Kansas. The bill also would require the State Board of Pharmacy to undertake a study of implementation of a drug pedigree system that would result in a report and recommendations to the 2007 Legislature.

### Prescription Drug Distributor Licensure

Kansas-based wholesalers who ship prescription drugs to another state would have to be licensed by that state prior to distributing wholesale drugs. Four classes of distributor licenses would be established by the bill: (1) Class A distributors would be authorized to deliver any prescription drug for human use; (2) Class B distributors would be authorized to deliver nonprescription drugs intended for human use; (3) Class C distributors would be authorized to deliver articles, devices, or medical gases that require a prescription, medical order, or that are restricted to use by a practitioner; and (4) Class D distributors would be licensed to distribute veterinary drugs or devices. The Board of Pharmacy would be authorized adopt rules and regulations establishing standards that each class of distributor or distributors' employees would have to meet to qualify for licensure. The bill would prescribe information that must be provided by applicants for licensure.

Prior to issuing a license to an applicant located in Kansas, the Board would be required to conduct a physical inspection of the applicant's facility. The Board also would be required to determine that a Class A applicant's designated representative meets the following qualifications:

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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

- Is at least 21 years of age;
- Has been employed full time for at least three years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs;
- Is employed by the applicant full time in a managerial position;
- Is actively involved in daily operation of the distributor;
- Is physically present at the applicant's facility during regular business hours;
- Serves as the designated representative of only one applicant; and
- Has not been convicted of any felony or a violation of any local, state or federal law regarding drug samples, wholesale or retail prescription drug distribution or distribution of controlled substances.

A Class A distributor license applicant would be required to file a minimum $100,000 bond or other surety to secure payment of any fines or penalties imposed by, or fees and costs incurred by the state regarding the applicant unless the applicant has a comparable bond in place in another state in which the applicant holds a valid license. The state would be able to make claims against the bond, if one is filed in Kansas, until a year after a license expires. The bond or surety would be held in the Drug Wholesaler Trust Fund that would be created by the bill. The Fund would be administered by the Executive Secretary of the State Board of Pharmacy. An applicant for a wholesale distributor license would be required to pay a maximum fee of $500 for an initial license issuance and not more than $400 for issuance of a renewal license.

The bill would amend current law to require that certain wholesaler distributors of prescription drugs, other than certain registered manufacturers, and each of their facilities be licensed annually by the State Board of Pharmacy, unless the requirement for licensure is waived by the Board. A waiver could be implemented via

rules and regulations if the Board determines that the waiver would be consistent with public health and safety.

Information submitted to the Board by license applicants could not be disclosed to anyone other than a government board or agency that needs the information for licensing or monitoring purposes.

Existing provisions of the Pharmacy Act regarding regulation of the Board's registrants and licensees would be extended to licensed distributors.

**Study of Prescription Drug Pedigrees**

The bill also would require the Board of Pharmacy to conduct a study of pedigrees for prescription drugs and possible penalties for violation of pedigree requirements. The study would have to be presented to the Legislature with a pedigree plan and recommended legislation by January 15, 2007.

## Background

SB 217 as passed by the Senate would have required tuberculosis evaluation of certain students attending college in Kansas. The substance of that bill was enacted by the 2005 Legislature.

The subject matter of House Sub. for SB 217 was introduced in 2005 HB 2397 and in 2006 HB 2820. After the House Health and Human Services Committee hearings on those bills, HB 2820 was assigned to a subcommittee. The recommendation of the Subcommittee was amended into SB 217 and this substitute bill was created.

Proponents of the concepts embodied in HB 2397 and HB 2820 at the House Committee hearings included representatives of the Healthcare Distribution Management Association and Pfizer. No opponents to the bill presented testimony to the House Committee.

The fiscal notes prepared by the Division of the Budget for 2005 HB 2397 and 2006 HB 2820 stated that the Board of Pharmacy assumed that any costs related to implementation would be passed through to distributors. A fiscal impact estimate for the House Substitute bill was not available at the time the House Committee took action on the bill.