SESSION OF 2007

SUPPLEMENTAL NOTE ON SENATE SUBSTITUTE FOR HOUSE BILL NO. 2531

As Amended by Senate Committee of the Whole

Brief*

Senate Sub. for HB 2531 would amend the Pharmacy Act to create new requirements for wholesale drug registrants and to separate registration requirements for wholesale drug distributors from requirements for durable medical equipment distributors. The bill also would amend the Pharmacy Act in regard to pharmacists' authorization to administer vaccines to persons 18 years of age or older. Finally, the bill would authorize certain pharmacy students and interns to administer vaccines.

Wholesale distributors would be defined by the bill to include persons who engage in the wholesale distribution of prescription drugs or devices in or into Kansas. Persons engaged in the sale of durable medical equipment to consumers or patients specifically would be excluded from the definition of wholesale distributor. As under current law, it would be illegal for any person to distribute drugs at wholesale unless the person is registered with the Board of Pharmacy.

Wholesale distribution would be defined to be distribution of prescription drugs or devices by wholesale distributors to persons other than consumers or patients, including transfer of prescription drugs from one pharmacy to another if the number of units of transferred drugs during a twelve-month period is five percent or less of the total number of units dispensed by the pharmacy during the immediately preceding twelve-month period. Wholesale distribution would, among other things, not include:

———————————

*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

- Sale, purchase, or trade or the offer to sell, purchase, or trade a prescription drug or device pursuant to a prescription; for emergency medical reasons; among hospitals, chain pharmacy warehouses, pharmacies or other health care entities that are under common control; by a charitable organization to a non-profit affiliate, as permitted by law;

- Intracompany transactions, as defined by the bill, unless those transactions violate "own use" provisions;

- Return of recalled, expired, damaged or otherwise non-salable prescription drugs, by a hospital, health care entity, pharmacy, chain pharmacy warehouse, or charitable institution in accordance with rules and regulations of the Board;

- Distribution of drug samples by representatives of manufacturers and distributors; or

- Sale or transfer of expired, damaged, returned, or recalled prescription drugs from a retail pharmacy or chain pharmacy warehouse to the manufacturer, originating wholesale distributor or a third party returns processor in accordance with rules and regulations adopted by the Board.

The Board would be authorized to waive registration requirements for wholesale distributors accredited by an agency approved by the Board. The Board also would be authorized to register wholesale distributors licensed by another state if the requirements of that state are substantially equivalent to Kansas' requirements or the applicant is inspected and accredited by a third party recognized and approved by the Board. Persons licensed or approved by the federal Food and Drug Administration (FDA) to manufacture drugs or devices who also are engaged in wholesale drug distribution would only need to satisfy minimum federal licensing requirements in order to be registered in Kansas.

The bill would require that the Board of Pharmacy, or a third party recognized by the Board, to inspect wholesale drug distribution facilities prior to and periodically after registration. Post registration inspections would have to be conducted at least once every three years.

Durable medical equipment distributors also would have to register with the Board. The new provision would make it illegal for a person to sell, lease or offer for sale or lease any durable medical equipment without being registered with the Board, except if such sale is not made in the regular course of the person's business or if the sale is made by a federally tax exempt charitable organization. Durable medical equipment would be defined to be a specific set of technologically sophisticated medical devices that may be used in a residence and other similar equipment determined in rules and regulations of the Board. The registration fee set by the Board for durable medical equipment distributors would be a maximum of $300. The Board would be able to take action against persons registered to distribute durable medical equipment on the same basis as action may be taken against wholesale drug distributors under current law.

Administration of vaccines. Pharmacy students and interns working under the direct supervision and control of a pharmacist would be able to administer vaccines to persons 18 years of age or older only if they meet the same training requirements applicable to pharmacists. Currently, prior to administering vaccines, pharmacists are required to complete approved training in vaccination storage, protocols, injection technique, emergency procedures and record keeping. The bill would add a new training provision that would require pharmacists, pharmacy students, and interns to complete a cardiopulmonary resuscitation (CPR) course and maintain a current CPR certificate before they could administer a vaccine. A pharmacist supervising an administering pharmacy student or intern would have to meet the existing statutory requirements for reporting the administration of an immunization.

Background

A substitute bill was recommended by the Senate Committee on Ways and Means. The substitute bill incorporated the provisions of HB 2531 (as amended by the House Committee) with the following amendments:

- Include definitions of additional terminology associated with the distribution of drugs: "authorized distributor of record"; "drop shipment"; "manufacturer"; and "normal distribution channel" (the definitions for these terms are identical to those in 2007 HB 2392).

- Remove a registration requirement for applicants that are licensed or registered by another state to have completed an internal audit and review; and

- Include the statutory maximum for a durable medical equipment registration fee established by the bill in the statute authorizing fees for licenses, registrations, and permits.

The Senate Committee also recommended technical amendments, including the updating of statutes referenced in the bill.

The bill was introduced by the House Committee on Appropriations at the request of the Board of Pharmacy. At the House Health and Human Services Committee hearing, a representative of the Board stated that the bill was the outgrowth of the Board's task force on wholesale distributors. The bill also was supported at the House Committee hearing by a representative of the Kansas Pharmacy Coalition, which suggested amendments to the bill. Written testimony recommending amendments was provided to the Committee by a representative of the Healthcare Distribution Management Association.

The House Committee amended the bill to:

- Include a definition of “intracompany transaction”;

- Specify that chain pharmacies are under the same ownership or control, rather than being members of the same affiliated group under common ownership;

- Specify that only chain pharmacy warehouses that conduct wholesale distributions are included in the definition of “wholesale distributor”;

- Specify that distributors of durable medical equipment to consumers or patients are not included in the definition of “wholesale distributors”;

- Exclude from the definition of “wholesale distribution” the transfer of prescription drugs by one pharmacy to another pharmacy if the amount of drugs transferred in a twelve-month period exceeds 5 percent of the total number of all units dispensed by the pharmacy during the prior twelve months;

- Exclude from the definition of “wholesale distributors,” the sale or transfer of expired, damaged, returned or recalled prescription drugs from a retail pharmacy or chain pharmacy warehouse to a manufacturer, wholesale distributor or third party returns processor in accordance with Board rules and regulations;

- Establish a $300 maximum fee for registration as a durable medical equipment distributor and provide that certain charitable organizations are exempt from registration as durable medical equipment distributors;

- Require that persons who lease durable medical equipment, as well as those who sell the equipment, must register with the Board;

- Require that the Board of Pharmacy adopt rules and regulations establishing standards and requirements for

issuance and maintenance of wholesale distributor registration, including inspections of wholesale distribution facilities in Kansas;

- Require that individual or third party inspectors demonstrate to the Board that they have received training or are familiar with inspection standards; and

- Authorize the Board to register wholesale distributors licensed under another state's laws under certain circumstances.

The Senate Committee of the Whole amended the bill to incorporate provisions of HB 2097, as passed by the House, which amends provisions of the Pharmacy Act regarding administration of vaccines by pharmacists, pharmacy students, and pharmacy interns.

According to the fiscal note prepared by the Division of the Budget, HB 2531 would require the Board of Pharmacy to collect registration information from and to inspect facilities of wholesale distributors. The Board indicates that it would need 2.0 additional FTE positions to implement the bill. The Board estimates expenditures of $56,941 for the salary and benefits of the new registration position. The Board estimates expenditure of approximately $83,282 for the inspector position and associated non-personnel costs. Of that latter amount, $64,465 would be for salary and benefits, $2,350 would be for a computer and printer, $15,507 would be for the purchase of a vehicle, and $960 would be for phone service. The fiscal note also states that since the precise number of facilities' inspections the Board of Pharmacy staff would have to conduct directly is unknown, an estimate of increased travel expenditures cannot be made. Finally, the fiscal note states that the fiscal impact of the bill is in addition to amounts recommended in *The FY 2008 Governor's Budget Report*.

The Division of the Budget's fiscal note for HB 2097 states that the Kansas Board of Pharmacy indicates there would be no fiscal effect from enactment of the bill.

The substitute bill as amended by the Senate Committee of the Whole does not appear to alter the estimate fiscal impact.