SESSION OF 2012

SUPPLEMENTAL NOTE ON HOUSE SUBSTITUTE FOR SENATE BILL NO. 325

As Recommended by House Committee on Corrections and Juvenile Justice

Brief*

House Sub. for SB 325 would enact new law to require certain information about breast density be provided in mammography reports sent to patients and further require a specific notice be provided to patients with heterogeneously dense or extremely dense breast tissue. The bill also would require the Kansas State Board of Healing Arts, in conjunction with the Department of Health and Environment, to develop and make available information regarding mammography testing. The provisions of the bill would be made part and supplemental to the Kansas Healing Arts Act.

Specifically, the bill would require that information on breast density, based on the breast imaging and database system established by the American College of Radiology, be included in mammography reports sent to a patient pursuant to regulations implementing the federal Mammography Quality Standards Act promulgated by the United States Food and Drug Administration. Further, for patients with mammogram results demonstrating the presence of heterogeneously dense or extremely dense breast tissue, a notice would be included in the report expressing the known limitations of mammography in women who have dense breast tissue. The notice would state the information is provided to raise awareness and to promote discussion with the patient's physician about the test results and the possible need for additional tests the physician might recommend, depending on individual risk factors.

---

*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

Additionally, the bill would amend the 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 the Schedule V list. The bill 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.

Background

SB 325, as introduced, was requested by the Kansas State Board of Pharmacy and contained the amendments to the Controlled Substances Act. The Executive Secretary of the Board and a representative of Pfizer testified in favor of the bill before the Senate Committee on Public Health and Welfare. The Executive Secretary testified that in proposing a drug be classified as a scheduled controlled substance, the Board relies on factors set forth in Kansas statutes. The Executive Secretary further stated the Drug Enforcement Administration (DEA) issues their rulings for drugs to be classified as scheduled controlled substances using the same factors, and the DEA recently has added Carisoprodol to Schedule IV and Ezogabine to Schedule V on the federal controlled substances list. The representative of Pfizer requested an amendment to the bill to allow Schedule V nonnarcotic depressants that have an effect on the central nervous system to be distributed free of charge by a manufacturer or distributor to a practitioner, mid-level practitioner, pharmacist, or other persons. The representative stated Kansas is one of only five states prohibiting the distribution of samples of all controlled substances to prescribers, including those medications listed in Schedule V. The representative further stated that allowing the distribution of samples of the Schedule V nonnarcotic depressants would permit Kansas prescribers and patients a broader range of access to free samples of FDA-approved treatments, without jeopardizing the state's strict requirements aimed at preventing theft and diversion of prescription medicines. The

representative stated the result may be to reduce overall healthcare costs and benefit patient health by providing the ability to assess side effects and efficacy with a trial of medications before dispensing the written prescription. The representative indicated the Board unanimously agreed with the amendment requested by the Pfizer representative. No opposing or neutral testimony was presented to the Senate Committee.

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.

In the House Committee on Corrections and Juvenile Justice, the Executive Director of the Board of Pharmacy testified in support of the bill. The Committee recommended a substitute bill be passed adding the text of SB 407 to the text of SB 325.

The fiscal note prepared for SB 325, as introduced, 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.

Background on SB 407

The bill was introduced by the Senate Ways and Means Committee at the request of Senator Jean Schodorf. Testimony in favor of the bill before the Senate Committee on Public Health and Welfare was provided by Senator Jean Schodorf, Representative Sheryl Spalding, an Assistant Professor of Radiology at the University of Kansas Medical Center, and representatives of Are You Dense Advocacy, Inc.,

the Kansas Cancer Partnership, and the Kansas Medical Society. The proponents testified about the need for information to be provided regarding the limitations in the accuracy of mammograms for patients with dense breasts. The Assistant Professor testified that while the accuracy of mammography approaches 100 percent in very fatty breasts, it falls to about 50 percent in dense breasts. The Associate Professor stated dense breasts affect about 50 percent of pre-menopausal women and up to 40 percent of post-menopausal women, and the risk of breast cancer is four to six times greater in a woman with the most dense breast when compared to a fatty breast. No testimony opposing the bill was presented at the Senate Committee hearing.

Neutral testimony was presented to the Senate Committee by the Executive Director of the Kansas State Board of Healing Arts (KSBHA), who testified the Kansas Department on Health and Environment (KDHE) currently develops and distributes information on breast cancer, mammography, and mammography testing, and a link to the KDHE website could be posted on KSBHA's website at no additional cost. The Executive Director sought clarification as to whether the intent of the bill was to expand KSBHA's scope to develop a campaign to distribute public information as done by KDHE, as this could cause KSBHA to incur significant additional costs.

The Senate Committee on Public Health and Welfare amended the bill to clarify that the notice would be required for patients with heterogeneously dense or extremely dense breast tissue, that the notice clearly state the patient has dense breast tissue, and to inform the patient that additional tests might be recommended by their physician. The Committee considered specifying the types of tests which might be recommended, but did not adopt such language in the amendment presented by the proponents of the bill.

The fiscal note prepared by the Division of the Budget on SB 407, as introduced, states passage of the bill would have no fiscal effect on the KSBHA or the KDHE.