LEGISLATIVE BUDGET BOARD Austin, Texas

FISCAL NOTE, 79TH LEGISLATIVE REGULAR SESSION

April 18, 2005

TO: Honorable Jane Nelson, Chair, Senate Committee on Health & Human Services

FROM: John S. O'Brien, Deputy Director, Legislative Budget Board

IN RE: SB1685 by Janek (Relating to the licensing and regulation of wholesale drug distributors; providing penalties.), **As Introduced**

Estimated Two-year Net Impact to General Revenue Related Funds for SB1685, As Introduced: an impact of \$0 through the biennium ending August 31, 2007.

The bill would make no appropriation but could provide the legal basis for an appropriation of funds to implement the provisions of the bill.

General Revenue-Related Funds, Five-Year Impact:

Fiscal Year	Probable Net Positive/(Negative) Impact to General Revenue Related Funds
2006	\$0
2007	\$0
2008	\$0
2009	\$0
2010	\$0

All Funds, Five-Year Impact:

Fiscal Year	Probable (Cost) from FOOD & DRUG REGISTRATION 5024	Probable Savings from FOOD & DRUG REGISTRATION 5024	Probable Revenue (Loss) from FOOD & DRUG REGISTRATION 5024	Probable Revenue Gain from FOOD & DRUG REGISTRATION 5024
2006	(\$112,423)	\$117,888	(\$964,000)	\$112,423
2007	(\$128,103)	\$117,888	(\$964,000)	\$128,103
2008	(\$128,103)	\$117,888	(\$964,000)	\$128,103
2009	(\$128,103)	\$117,888	(\$964,000)	\$128,103
2010	(\$128,103)	\$117,888	(\$964,000)	\$128,103

Fiscal Year	Change in Number of State Employees from FY 2005
2006	1.0
2007	1.0
2008	1.0
2009	1.0
2010	1.0

Fiscal Analysis

The bill relates to the licensing and regulation of wholesale drug distributors. The bill would amend Section 431.201 of the Health and Safety Code to deregulate distributors of over-the-counter drugs and to create additional requirements for licensing as a wholesale prescription drug or device distributor. The bill requires distributors to maintain pedigrees for distributions that occur outside the normal distribution chain.

The Department of State Health Services (DSHS) would be allowed to recover reasonable costs related to the processing of licenses and conducting inspections, or the DSHS may outsource these activities to an accredited third party. DSHS is required to conduct a study on the implementation and use of electronic pedigrees.

Methodology

According to DSHS, the definitions included in the bill would remove DSHS's authority to license and inspect over-the-counter drug manufacturers and distributors. This would result in lost revenue from licensing of \$540,000 per year.

In addition, according to DSHS, certain distributors of wholesale durable medical equipment or certain prescription medical gasses would not meet the requirements of the bill and would therefore not renew their licenses. This would result in lost revenue of \$424,000 per year.

The reduction of these two licensing activities would result in a reduction of two Environmental Specialist III FTEs, for a total savings of \$117,888 per year, including salaries, benefits, travel and other operating expenses.

In order to implement the provisions of the bill, DSHS estimates that three new FTEs would be needed. Staff will be required to review wholesale drug applications, conduct criminal background checks, process bonds, and conduct credit checks of applicants. Total costs for new FTEs, including salary, benefits, rent, utilities, other operating expenses, and computer hardware total \$112,423 in the first year and \$128,103 in each subsequent year.

It is assumed that DSHS would raise fees to cover this additional cost. Estimated new fee revenue totals \$112,423 in the first year and \$128,103 in each subsequent year.

Existing DSHS staff will conduct the study of electronic pedigrees, review technology, and write new rules.

Technology

Computer hardware costs for three new FTEs would total \$903 in 2006 and \$650 in subsequent years.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 405 Department of Public Safety, 515 Board of Pharmacy, 537 Department of State Health Services

LBB Staff: JOB, CL, PP, LW