

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 80TH LEGISLATIVE REGULAR SESSION

May 18, 2007

TO: Honorable David Dewhurst, Lieutenant Governor, Senate

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

IN RE: SB943 by Janek (Relating to the licensing and regulation of wholesale distributors of prescription drugs; providing penalties.), **As Passed 2nd House**

Estimated Two-year Net Impact to General Revenue Related Funds for SB943, As Passed 2nd House: an impact of \$0 through the biennium ending August 31, 2009.

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
2008	\$0
2009	\$0
2010	\$0
2011	\$0
2012	\$0

All Funds, Five-Year Impact:

Fiscal Year	Probable Savings/(Cost) from <i>FOOD & DRUG REGISTRATION 5024</i>	Probable Revenue Gain/ (Loss) from <i>FOOD & DRUG REGISTRATION 5024</i>	Change in Number of State Employees from FY 2007
2008	(\$812,786)	\$720,370	12.0
2009	(\$818,221)	\$928,240	12.0
2010	(\$827,565)	\$928,240	12.0
2011	(\$818,221)	\$1,205,400	12.0
2012	(\$830,687)	\$1,205,400	12.0

Fiscal Analysis

The bill would amend the Health and Safety Code relating to the licensing and regulation of wholesale distributors of prescription drugs.

The bill would require the Department of State Health Services (DSHS) to conduct a physical inspection of the wholesaler's place of business, as determined by DSHS staff, before issuing a license, with the exception of manufacturers, prescription gas distributors, and third party logistics providers; change the pedigree required for each prescription drug not distributed through the normal distribution channel; implement electronic pedigrees on or after July 1, 2010 if the agency determines that track and trace technology to implement electronic pedigrees is universally available across the entire supply chain.

The bill would provide changes in the criminal penalties for persons who engage in the wholesale distribution of drugs in violation of the Health and Safety Code as amended by the bill.

The bill would take effect September 1, 2007.

Methodology

Based on information provided by DSHS, this analysis assumes that DSHS will need to conduct pre-licensing inspections for the facilities that submit an application for a prescription drug wholesale distributor license that DSHS staff feel are necessary, with the exception of manufacturers, prescription gas distributors, and third party logistics providers. DSHS currently has 2,500 licensed prescription wholesale drug distributors, which would be subject to these pre-licensing inspections. The analysis assumes that 50 percent of these firms, or 1,250 will need to be re-inspected every two years, prior to license renewal, and that there will be 676 new applicants annually; therefore, the analysis assumes that DSHS will have to complete 1,301 annual inspections. Based on information from DSHS providing that the standard work hours for an FTE of this program are 1,560 hours per year, DSHS would need an additional 7 inspectors (Environmental Specialist III) per year, 3 Environmental Specialist IVs to review all license applications for past compliance history of the firms as well as to assess the risk for counterfeiting of their firm's drug products, one Manager II to supervise the inspection staff, and one Administrative Assistant III to handle the office related duties of running this program.

Based on the analysis of DSHS, it is assumed that the provisions of the bill would necessitate additional resources at a cost of \$1,631,007 through 2009.

DSHS also estimates costs for staff of \$362,467 in fiscal year 2008 and \$483,289 in fiscal year 2009 through fiscal year 2012. Other operating expenses, computer hardware and software, rent and utilities, travel, and capitalized professional fees and services are estimated at \$347,777 in fiscal year 2008, \$198,210 in fiscal year 2009, \$207,554 in fiscal year 2010, \$198,210 in fiscal year 2011, and \$210,676 in fiscal year 2012. Estimated costs also include \$102,542 in fiscal year 2008 and \$136,722 in fiscal years 2009 through fiscal year 2012 for associated benefits.

Based on information provided by DSHS, the Board of Pharmacy, and the Department of Health and Human Services it is assumed that any additional costs related to the duties and responsibilities associated with implementing the provisions of the bill could be covered by utilizing existing resources.

Technology

The technological impact to DSHS would be \$147,922 in fiscal year 2008, \$13,922 in fiscal years 2009 through fiscal year 2011, and \$17,922 in fiscal year 2012.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 515 Board of Pharmacy, 529 Health and Human Services Commission, 537 State Health Services, Department of

LBB Staff: JOB, CL, SD, MW, AH