# LEGISLATIVE BUDGET BOARD
## Austin, Texas

## FISCAL NOTE, 78TH LEGISLATIVE REGULAR SESSION

**April 23, 2003**

**TO:** Honorable Jaime Capelo, Chair, House Committee on Public Health

**FROM:** John Keel, Director, Legislative Budget Board

**IN RE:** **HB3389** by Burnam (Relating to regulation of distressed devices.), **As Introduced**

**Estimated Two-year Net Impact to General Revenue Related Funds** for HB3389, As Introduced: a negative impact of ($1,216,866) through the biennium ending August 31, 2005.

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 |
|---|---|
| 2004 | ($610,083) |
| 2005 | ($606,783) |
| 2006 | ($606,783) |
| 2007 | ($606,783) |
| 2008 | ($606,783) |

### All Funds, Five-Year Impact:

| Fiscal Year | Probable Revenue (Loss) from *GENERAL REVENUE FUND* 1 | Probable (Cost) from *GENERAL REVENUE FUND* 1 | Change in Number of State Employees from FY 2003 |
|---|---|---|---|
| 2004 | ($96,800) | ($513,283) | 2.0 |
| 2005 | ($96,800) | ($509,983) | 2.0 |
| 2006 | ($96,800) | ($509,983) | 2.0 |
| 2007 | ($96,800) | ($509,983) | 2.0 |
| 2008 | ($96,800) | ($509,983) | 2.0 |

### Fiscal Analysis

The bill would add Chapter 442 to the Health and Safety Code to require a person who knowingly holds a distressed device to notify the Department of Health (TDH) before the sale or distribution of the device. The bill would require that upon receipt of a notice, TDH would determine if the device is unfit for use. The bill would allow the department to require an inspection of the device in order to make such a determination. The bill would prohibit any distressed device declared unfit for use by the department to be sold or distributed.

The bill would amend Chapter 432, Texas Food, Drug, Device, and Cosmetic Salvage Act, Health and Safety Code to remove all existing provisions relating to the salvaging of distressed medical devices. The provisions currently include licensure of device salvage establishments and brokers and

compliance with minimum standards established by the department. The bill would remove conforming language in Chapter 431, Texas Food, Drug and Cosmetic Act, Health and Safety Code that acknowledges certain activities performed by medical device salvagers licensed under Chapter 432, Health and Safety Code. The bill would further amend Chapter 432, Health and Safety Code to establish an exemption for the manufacture, sale, distribution or processing of a distressed device.

This bill would take effect on passage or on September 1, 2003.

## Methodology

The bill would eliminate the device salvage establishment and broker license fee revenue generated by the Texas Department of Health (TDH). According to TDH, the loss of license fee revenue would be $96,800 per year ($550 x 176 device salvage firms).

The bill would also eliminate requirements and minimum operational standards for device salvagers. TDH would have the responsibility to assess and determine compliance with provisions of Chapter 341, Health and Safety Code. It is estimated that 33 salvage firms (25 percent of 132 inspected annually) would require enforcement action to ensure that adulterated and/or misbranded medical devices are effectively removed from commerce (including adulterated and/or misbranded medical devices involved in natural or man-made disasters). According to TDH, investigating, reviewing and preparation activities by the program for 33 annual enforcement actions would require two (2) full-time positions, a cost of $124,983 per year to General Revenue.

It is assumed that an estimated 25 (75 percent of 33 salvage firms) would require TDH to rely on expert testimony in order to determine specific elements of proof necessary to assert devices are in violation of state laws. According to TDH, salvagers would not voluntarily agree to refurbish and/or destroy distressed devices. It is assumed that TDH would have to contract for professional services to have certified biomedical technicians prove in a condemnation proceeding that the particular device was adulterated and could not be refurbished. It is assumed that TDH would perform an estimated 2,500 annual evaluations of defective or noncompliant devices (an average of 100 devices per action x 25 enforcement actions). The costs associated with these contract services would be $175,000 (2,500 evaluations x $70 per hour evaluation charge) per year for direct evaluation and related travel expenses.

It is assumed that TDH would receive 3,000 notifications per year, based on annual submissions from all sources excluding salvage firms (e.g. hospitals, ambulatory surgical centers, device manufacturers and distributors, device retailers, common carriers, and consumers). In response to these notifications, TDH would have to perform evaluations to determine whether the devices are fit for use. In order to make such determinations, TDH would have to rely on contracted technical evaluations performed by certified biomedical technicians. The costs associated with these contract services would include $210,000 (3,000 evaluations x $70 per hour evaluation charge) per year for direct evaluation and related travel expenses.

## Technology

The bill would require a one-time purchase of 1 desktop computer and 1 laptop (a total cost of $3,300 in fiscal year 2004) for use by the two full-time positions.

## Local Government Impact

No fiscal implication to units of local government is anticipated.

**Source Agencies:** 501 Department of Health
**LBB Staff:** JK, EB, KF, MH, MB