SUBJECT: Revising requirements for medical equipment salvaging and repair

COMMITTEE: Public Health — favorable, without amendment

VOTE: 8 ayes — Capelo, Laubenberg, Truitt, Dawson, McReynolds, Naishtat, Taylor, Zedler

0 nays

1 absent — Coleman

SENATE VOTE: On final passage, May 6 — 31-0, on Local and Uncontested Calendar

WITNESSES: For — Matt Wall, Texas Hospital Association

Against — None

On — Susan Tennyson, Texas Department of Health

BACKGROUND: The Texas Food, Drug, Device, and Cosmetic Salvage Act (Health and Safety Code, ch. 432) regulates the repair and reconditioning of nonfunctional ("distressed") medical equipment and devices for resale. The law precludes salvagers from offering such equipment for resale if it does not meet manufacturers' specifications.

DIGEST: SB 1392 would create an exception to the requirement that medical equipment and devices be restored to full working order before they can be offered for resale and returned to use.

The statute's pertinent regulations no longer would apply to licensed equipment salvagers selling equipment to hospitals — public, private, or state-owned — or to hospitals selling or trading equipment to other hospitals. Instead, equipment transactions between salvagers and hospitals would be subject to "appropriate disclosure." Possessors of equipment would have to disclose its condition to recipients in concise, dated written statements containing the transferring entity's name and a description of the device's condition, if known. If not, the prospect that the device might not meet

manufacturer's specifications would have to be noted. The statement also would have to include this sentence: "Prior to use, a distressed device that does not meet the manufacturer's specifications must be reconditioned."

The bill would take effect September 1, 2003.

SUPPORTERS SAY:

To reduce replacement costs, hospitals must maintain expensive medical equipment and devices for their entire useful lives. When equipment is damaged or fails, often it is more cost-effective to repair it with spare parts or to replace it with used or refurbished equipment. The Texas Department of Health (TDH) requires licensed salvagers to restore medical equipment to full functionality before offering or negotiating sales. Federal law requires disclosure that equipment no longer meets original specifications. Depending on the equipment's level of technical sophistication, advance repair can be costly and time-consuming, delaying turnaround time.

At least one hospital, in Georgetown, has an equipment technician on staff who can repair many medical devices. However, the hospital cannot accept nonfunctioning equipment because of the statutory prohibition against receiving such equipment. Removing this requirement would enable the hospital to save time and money by repairing its own equipment, which would enhance patient service. The bill would apply to all types of equipment and devices, including hospital beds.

Unused packets of surgical supplies already may be resterilized for resale. Relaxing the rule on presale repair of equipment could be a boon to hospitals in small and rural communities, many of which are struggling financially. Any reduction in their high overhead costs would help them stay open without curtailing patient services.

Allowing acquisition of nonfunctioning equipment before repair would pose no more of a risk than hospitals using worn-out or obsolete equipment beyond its useful life rather than buying new machines. Liability alone would serve as a huge disincentive against using inferior equipment that had not undergone proper reconditioning or was not in good working order. Doing so could jeopardize hospitals' insurability and the affordability of coverage. SB 1392 represents a consensus of the major stakeholders in this issue.

OPPONENTS SAY:

The medical equipment salvage industry is underregulated under current state law. TDH conducts only random inspections and does not examine all the devices that hospitals use to determine whether they meet specifications. SB 1392 would weaken already lax standards and reduce enforcement to a mere warning label. This would result in insufficient oversight of machines on which people's lives may depend.

The bill would not require disclosure to those who need it most — the patients. They might be able to learn after the fact that a reconditioned device failed after having been repaired improperly, but only after they had filed a lawsuit to recover damages from which the state should have protected them. Insurers might not be willing to assume such risks without increasing premiums or curtailing coverage.

OTHER OPPONENTS SAY:

The state should deregulate the medical equipment salvage industry completely to help health-care providers curtail costs and maintain patient service levels. Under a self-policing system, salvagers could engage in interstate trade with other salvagers, yielding further savings to the overburdened health-care system.