SUBJECT: Requiring hospitals to report certain medical errors to TDH

COMMITTEE: Public Health — committee substitute recommended

VOTE: 9 ayes — Capelo, Laubenberg, Truitt, Coleman, Dawson, McReynolds, Naishtat, Taylor, Zedler

0 nays

WITNESSES: For — Eric Glenn, Humana; Matt Wall and Starr West, Texas Hospital Association; *(Registered, but did not testify:)* Yvonne Barton, Texas Medical Association; Luke Bellsnyder, Texas Association of Business; David Pearson, Texas Organization of Rural and Community Hospitals; Shari Waldie, Hospital Corp. of America

Against — Lisa McGiffert, Consumers Union; *(Registered, but did not testify:)* Collen Clark, Texas Trial Lawyers Association

On — Sharon Martin; *(Registered, but did not testify:)* Nance Stearman, Texas Department of Health

BACKGROUND: Hospitals in Texas are licensed and regulated by the Texas Department of Health's (TDH) Health Facility Licensing and Compliance Division. TDH also collects some information about hospitals through its Center for Health Statistics, including financial data, utilization rates, and program information from more than 500 acute-care and psychiatric hospitals.

In 1995, the 74th Legislature created the Texas Health Care Information Council to develop a statewide system to collect data on health-care charges, utilization, provider quality, and outcome of care. Among other projects, the council gathers data from hospitals using patient discharge billing forms and extracts a range of data, including patient diagnoses and charges for various procedures. The council released the first patient hospital discharge data in December 2000 and has released data quarterly since then. It also sells access to patient-level information (without the patient's identity) on inpatient hospital stays, which hospitals often use to compare their performance against that of peer organizations.

DIGEST:

CSHB 1614 would direct TDH to develop a patient safety program for hospitals that would serve as a clearinghouse for information about best practices and quality improvement strategies. It would require hospitals, including ambulatory surgical centers and mental hospitals, on renewing their annual licenses, to report the incidence of the following events:

- an error in medication that resulted in an unanticipated death or permanent functional impairment;
- death of an infant weighing more than 2.5 kilograms at birth that was unrelated to a congenital condition;
- suicide of a patient under 24-hour care;
- abduction of an infant;
- sexual assault of a patient;
- reaction to a blood transfusion when the wrong type of blood was administered;
- surgery on the wrong patient or wrong part of the body;
- a foreign object accidentally left in a patient; and
- death or injury from "off-label" use of a device.

In cataloging these events, hospitals would have to perform a "root-cause" analysis and develop a corrective or preventative action plan within 45 days of the occurrence. The root-cause analysis would have to identify the systemic or procedural causes of an event and what could be changed to prevent similar events in the future. A hospital would have to submit at least one report of best practices and safety measures related to a reported event and could submit other best practices. TDH could not require a best-practices report to exceed one page, and TDH would have to accept, in lieu of a report in the prescribed format, a report submitted by the hospital to a patient safety organization.

All information obtained by or compiled by TDH or a hospital about the root-cause analysis, event reporting, action plan, best practices, and other related information would be confidential and not subject to disclosure, discovery, or subpoena and could not be admitted as evidence in any civil, criminal, or administrative proceeding. The information would be subject to an absolute privilege and could not be used against a hospital or anyone related to it in any proceedings, regardless of how the information were obtained. The bill would not prohibit access to a patient's medical records to the extent allowed

by law. TDH could not require the root-cause analysis in the hospital's annual report of events, nor could a TDH employee remove, copy, reproduce, redact, or dictate any part of the analysis or action plan.

TDH could use the information to create two reports: an annual department summary and a best-practices report. The annual summary would have to contain aggregate de-identified information that would be made public. The best-practices report would be a de-identified summary of the reports submitted by hospitals, which also would be made public. These reports, along with the annual report, could not distinguish between events that occurred at a hospital facility and those that occurred at an outpatient facility owned or operated by the hospital.

By December 1, 2006, the health commissioner would have to evaluate the patient safety program and report to the Legislature. The evaluation would have to include TDH's ability to detect statewide trends from the data submitted, public interest in the summaries, the effect on patient care, and a review of national studies on the reporting of medical errors. TDH could accept or administer a gift, grant, or donation to pay for the patient safety program. The bill's provisions would expire September 1, 2007, unless extended, except for the confidentiality provisions.

The bill would take immediate effect if finally passed by a two-thirds record vote of the membership of each house. Otherwise, it would take effect September 1, 2003. The annual reporting requirements would apply to license renewals beginning July 1, 2004.

SUPPORTERS SAY:

CSHB 1614 would require the state to ensure the health and safety of its citizens by taking an active role in investigating the cause and incidence of medical errors. According to a 1999 Institute of Medicine report, as many as 98,000 Americans die each year as a result of preventable medical errors, at a cost of at least $29 billion annually in lost income, disability, and health-care costs. As health-care systems rapidly evolve, often becoming more complex, the rate of medical errors is likely to continue to rise.

While hospitals are accountable to licensing and accrediting bodies, that oversight focuses on serious lapses in safety or potential liability. Because medical errors are not intentional or negligent, no outside organization looks at

the processes and systems that may lead to most errors. Even the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), which collects similar information to what TDH would collect under CSHB 1614, accredits only about 75 percent of Texas hospitals. It would be better for the state to collect complete, statewide information.

It would be more appropriate for hospitals to collect data and share information about practices that prevent errors than to require them to implement specific strategies. The study of medical errors is at an early stage, and proscriptive best-practice models have not been developed and tested in many areas. Also, an idea for a best practice may work for a large urban hospital complex, but not for a small rural hospital. At this stage, anecdotal communication of ideas is the best approach, because hospitals can pick and choose strategies that would work for their specific situations. Also, the best-practice ideas that TDH gathers in its summary could form the basis for legislation if that seems appropriate in the future.

TDH is the best agency to house the patient safety program. The department already collects data about hospitals and has a close working relationship with hospitals through its licensing activities. Because the information could not be used to go after them, the hospitals would feel comfortable sharing that information with the licensing body.

The bill's confidentiality provisions are necessary to avoid forcing hospitals to report information that could lead to greater liability. The point of this legislation is to improve practices, not render hospitals more susceptible to lawsuits. Confidentiality would not compromise patient safety, as hospitals still would be inspected and regulated in the current manner.

Information available from the Health Care Information Council is valuable but does not address medical errors or ways to prevent them. That information is designed for hospitals, insurers, and consumers to identify service usage, costs and expenditures, quality of care, gaps in services, population needs, and fraud and abuse. Texas hospitals need a better "narrative" about what types of medical errors occur and how to prevent them.

OPPONENTS SAY:

CSHB 1614 would create a misleading perception that the state was doing something to prevent medical errors. Hospitals' peer-review processes and

risk management departments make them fully aware of the incidence of medical errors in their facilities. Professional organizations, accreditation bodies, and industry groups share plenty of anecdotal best practices as well as clinically proven strategies to reduce medical errors through publications, conferences, and onsite training sessions. The state should not waste time and resources duplicating what these entities already do.

Medical error is a symptom of a more pervasive problem in the health-care industry. Allied health professionals, such as nurses and technicians, are underpaid and overworked. Forcing someone to work daily 12-hour shifts to earn a sustaining wage leads to error. Hospitals also understaff some areas, forcing people to make snap decisions on their own. These systemic problems lead to medical error.

Instead of telling the industry what it already knows, the state should require all hospitals to implement the strategies that JCAHO publishes to identify how its member organizations meet accreditation standards and improve the safety and quality of services. This would ensure that all Texas hospitals implemented basic error-prevention strategies and would not be onerous, because three-quarters of Texas hospitals are JCAHO-accredited already.

The bill's confidentiality provisions would compromise patient safety by preventing TDH from acting on any information submitted to the agency. If a hospital disclosed an incident that clearly violated state regulations, TDH could not investigate and would have to sit idly by as the violation continued. Confidentiality should not hamper the state's regulatory authority.

OTHER OPPONENTS SAY:

The Health Care Information Council, not TDH, should conduct the patient safety program. The Legislature created the council to build an infrastructure that would benefit Texans for years to come by acting as a third party outside the regulatory relationship between hospitals and TDH. The council has worked the kinks out of collecting data from hospitals and easily could assume this new function. Many hospitals already are customers of the council and are accustomed to receiving its information.

NOTES:

The committee substitute would modify the filed version of HB 1614 by adding requirements for additional confidentiality, best-practice reporting, and authority for TDH to accept gift, grants, and donations.

SB 859 by Madla, identical to HB 1614 as filed, has been referred to the Senate Health and Human Services Committee.