

## **BILL ANALYSIS**

Senate Research Center  
78R16913 YDB-D

C.S.H.B. 1614  
By: Truitt (Madla)  
Health & Human Services  
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Committee Report (Substituted)

### **DIGEST AND PURPOSE**

In 1999 the Institute of Medicine released the ground-breaking report entitled *To Err is Human: Building a Safer Healthcare System*. The report estimated that 44,000 Americans die each year from medical errors. While much data is available on hospital performance through various state agencies as well as on the Internet, reliable information about medical errors is lacking. This bill is one effort to enhance hospitals' accountability to the public, while providing valuable information to help hospitals identify and prevent errors. C.S.H.B. 1614 establishes a patient safety program at the Texas Department of Health (TDH) through which hospitals, ambulatory surgical centers, and mental hospitals will report medical errors to TDH and develop internal plans of correction to prevent future occurrences of errors.

### **RULEMAKING AUTHORITY**

Rulemaking authority is expressly granted to the Texas Department of Health in SECTION 2 (Section 241.206, Health and Safety Code), SECTION 4 (Section 243.056, Health and Safety Code), and SECTION 6 (Section 577.056, Health and Safety Code) of this bill.

### **SECTION BY SECTION ANALYSIS**

SECTION 1. Provides that the purpose of this Act is to establish programs that will promote public accountability through the detection of statewide trends in the occurrence of certain medical errors by requiring hospitals, ambulatory surgical centers, and mental hospitals to report errors, by providing the public with access to statewide summaries of such reports, and by requiring such facilities to implement risk-reduction strategies. Provides that the program also will encourage hospitals, ambulatory surgical centers, and mental hospitals to share best practices and safety measures that are effective in improving patient safety.

SECTION 2. Amends Chapter 241, Health and Safety Code, by adding Subchapter H, as follows:

#### **SUBCHAPTER H. PATIENT SAFETY PROGRAM**

Sec. 241.201. DUTIES OF DEPARTMENT. (a) Requires the Texas Department of Health (TDH) to develop a patient safety program for hospitals. Requires the program to meet certain requirements.

(b) Requires TDH to group hospitals by size for reports required by this chapter according to the number of beds in the hospital.

(c) Requires TDH to combine two or more categories described by Subsection (b) if the number of hospitals in any category falls below 40.

Sec. 241.202. ANNUAL REPORT. (a) Requires a hospital, on renewal of a license under this chapter, to submit an annual report to TDH that lists the number of occurrences at the hospital or at an outpatient facility owned or operated by the hospital of certain types of events.

(b) Prohibits TDH from requiring the annual report under Subsection (b) to include any information other than the number of occurrences, of each event listed in Subsection (a).

Sec. 241.203. ROOT CAUSE ANALYSIS AND ACTION PLAN. (a) Defines “root cause analysis.”

(b) Requires a hospital, not later than the 45th day after the date a hospital becomes aware of the occurrence of an event listed in Section 241.202, to perform certain tasks.

(c) Authorizes TDH to review a root cause analysis or action plan related to an event listed in Section 241.202 during a survey, inspection, or investigation of a hospital.

(d) Prohibits TDH from requiring a root cause analysis or action plan to be submitted to TDH.

(e) Prohibits TDH or an employee or agent of TDH in any form, format, or manner from removing, copying, reproducing, redacting, or dictating from any part of a root cause analysis or action plan.

Sec. 241.204. CONFIDENTIALITY; ABSOLUTE PRIVILEGE. (a) Provides that all information and materials, except as provided by Sections 241.205 and 241.206, obtained or compiled by a hospital under this subchapter are confidential and not subject to disclosure under Chapter 552, Government Code (Public Information), and are not subject to discovery, subpoena, or other means of legal compulsion for release to anyone subject to Section 241.203(c). Prohibits information and materials obtained or compiled by TDH under this section from being admitted in evidence or otherwise disclosed in any civil, criminal, or administrative proceeding.

(b) Provides that the confidentiality protections provided by Subsection (a) apply regardless of whether the information or materials are obtained from or compiled by a hospital or an entity that has an ownership or management interest in a hospital.

(c) Provides that the transfer of information or material under this section shall not be treated as a waiver of any privilege or protection, granted under law.

(d) Provides that information reported by a hospital under this subchapter and analyses, plans, records, and reports obtained, prepared, or compiled by a hospital as required by this subchapter, and all related information and materials, are subject to an absolute privilege and may not be used in any form against the hospital or its agents, employees, partners, assignees, or independent contractors in any civil, criminal, or administrative proceeding, regardless of the means by which the information, analysis, plan, record, report, or related information and materials came into the possession of the person attempting to use them. Requires a court to enforce this privilege as to all matters covered by this subsection.

(e) Provides that the provisions of this section regarding the confidentiality of information or materials compiled or reported by a hospital in compliance with or as authorized under this subchapter do not restrict access, to the extent authorized by law, by the patient or the patient’s legally authorized representative to records of the patient’s medical diagnosis or treatment or to other primary health records.

Sec. 241.205. ANNUAL DEPARTMENT SUMMARY. Requires TDH on an annual basis to compile and make publicly available a summary of the events that were reported by hospitals

under Section 241.202. Authorizes the summary to contain only aggregated information and may not directly or indirectly identify certain entities.

Sec. 241.206. BEST PRACTICES REPORT AND DEPARTMENT SUMMARY. (a) Requires a hospital to provide to the department at least one report of the best practices and safety measures related to a reported event.

(b) Authorizes a hospital to provide to TDH a report of other best practices and the safety measures, such as marking a surgical site and involving the patient in the marking process, that are effective in improving patient safety.

(c) Authorizes TDH by rule to prescribe the form and format of a best practices report. The department may not require a best practices report to exceed one page in length. Requires TDH to accept, in lieu of a report in the form and format prescribed by the department, a copy of a report submitted by a hospital to a patient safety organization.

(d) Requires TDH periodically to review the best practices reports, compile a summary of best practices reports determined by TDH to be effective and recommended as best practices, make the summary available to the public.

(e) Prohibits the summary from directly or indirectly identifying certain entities.

Sec. 241.207. PROHIBITION. Prohibits the hospital annual report, TDH summary, or the best practices report from distinguishing between an event that occurred at an outpatient facility owned or operated by the hospital and an event that occurred at a hospital facility.

Sec. 241.208. REPORT TO LEGISLATURE. (a) Provides that not later than December 1, 2006, the commissioner of public health must perform certain tasks.

(b) Requires the commissioner of public health to conduct the evaluation in consultation with hospitals licensed under this chapter.

(c) Requires the evaluation to address certain issues.

Sec. 241.209. GIFTS, GRANTS, AND DONATIONS. Authorizes TDH to accept and administer a gift, grant, or donation from any source to carry out the purposes of this subchapter.

Sec. 241.210. EXPIRATION. Provides that unless continued in existence, this subchapter expires September 1, 2007.

SECTION 3. Provides that Sections 243.001 through 243.016, Health and Safety Code, are designated as Subchapter A, Chapter 243, Health and Safety Code, and a heading to Subchapter A is added, as follows:

#### SUBCHAPTER A. GENERAL PROVISIONS; LICENSING AND PENALTIES

SECTION 4. Amends Chapter 243, Health and Safety Code, by adding Subchapter B, as follows:

#### SUBCHAPTER B. PATIENT SAFETY PROGRAM

Sec. 243.051. DUTIES OF DEPARTMENT. Requires TDH to develop a patient safety program for ambulatory surgical centers. Requires the program to meet certain requirements.

Sec. 243.052. ANNUAL REPORT. (a) Provides that on renewal of a license under this chapter, an ambulatory surgical center must submit to TDH an annual report that lists the number of occurrences at the center or at an outpatient facility owned or operated by the center of each of certain event, during the preceding year.

(b) Prohibits TDH from requiring the annual report to include any information other than the number of occurrences of each event listed in Subsection (a).

Sec. 243.053. ROOT CAUSE ANALYSIS AND ACTION PLAN. (a) Defines "root cause analysis."

(b) Provides that not later than the 45th day after an ambulatory surgical center becomes aware of the occurrence of an event listed in Section 243.052, the center must conduct certain tasks.

(c) Authorizes TDH to review a root cause analysis or action plan related to an event listed in Section 243.052 during a survey, inspection, or investigation of an ambulatory surgical center.

(d) Prohibits TDH from requiring a root cause analysis or action plan to be submitted to TDH.

(e) Prohibits TDH or an employee or agent of TDH from in any form, formatting, or manner removing, copying, reproducing, redacting, or dictating from any part of a root cause analysis or action plan.

Sec. 243.054. CONFIDENTIALITY; ABSOLUTE PRIVILEGE. (a) Provides that except as provided by Sections 243.055 and 243.056, all information and materials obtained or compiled by TDH under this subchapter or compiled by an ambulatory surgical center under this subchapter, including the root cause analysis, annual report of an ambulatory surgical center, action plan, best practices report, department summary, and all related information and materials, are confidential.

(b) Provides that the confidentiality protections under Subsection (a) apply without regard to whether the information or materials are obtained from or compiled by an ambulatory surgical center or an entity that has an ownership or management interest in an ambulatory surgical center.

(c) Provides that the transfer of information or materials under this subchapter is not a waiver of a privilege or protection granted under law.

(d) Provides that information reported by an ambulatory surgical center under this subchapter and analyses, plans, records, and reports obtained, prepared, or compiled by the center under this subchapter and all related information and materials are subject to an absolute privilege and may not be used in any form against the center or the center's agents, employees, partners, assignees, or independent contractors in any civil, criminal, or administrative proceeding, regardless of the means by which a person came into possession of the information, analysis, plan, record, report, or related information or material. Requires a court to enforce this privilege for all matters covered by this subsection.

(e) Provides that the provisions of this section regarding the confidentiality of information or materials compiled or reported by a hospital in compliance with or as authorized under this subchapter do not restrict access, to the extent authorized by law, by the patient or the patient's legally authorized representative to records of the

patient's medical diagnosis or treatment or to other primary health records.

Sec. 243.055. ANNUAL DEPARTMENT SUMMARY. Requires TDH to compile and make available to the public a summary of the events reported by ambulatory surgical centers as required by Section 243.052. Authorizes the summary to contain only aggregated information and prohibits it from directly or indirectly identifying certain entities.

Sec. 243.056. BEST PRACTICES REPORT AND DEPARTMENT SUMMARY. (a) Requires an ambulatory surgical center to provide to TDH at least one report of best practices and safety measures related to a reported event.

(b) Authorizes an ambulatory surgical center to provide to TDH a report of other best practices and the safety measures, such as marking a surgical site and involving the patient in the marking process, that are effective in improving patient safety.

(c) Authorizes TDH by rule to prescribe the form and format of a best practices report. Prohibits TDH from requiring a best practices report to exceed one page in length. Requires TDH to accept, in lieu of a report in the form and format prescribed by TDH, a copy of a report submitted by an ambulatory surgical center to a patient safety organization.

(d) Requires TDH periodically to review and compile a summary of best practices reports and make the summary available to the public.

(e) Prohibits the summary from directly or indirectly identifying certain factors.

Sec. 243.057. PROHIBITION. Provides that the annual report of an ambulatory surgical center, TDH summary, or the best practices report may not distinguish between an event that occurred at an outpatient facility owned or operated by the center and an event that occurred at a center facility.

Sec. 243.058. REPORT TO LEGISLATURE. (a) Requires not later than December 1, 2006, the commissioner of public health to perform certain tasks.

(b) Requires the commissioner of public health to conduct the evaluation required by this section in consultation with ambulatory surgical centers.

(c) Requires the evaluation to address certain issues.

Sec. 243.059. GIFTS, GRANTS, AND DONATIONS. Authorizes TDH to accept and administer a gift, grant, or donation from any source to carry out the purposes of this subchapter.

Sec. 243.060. EXPIRATION. Provides that unless continued in existence, this subchapter expires September 1, 2007.

SECTION 5. Provides that Sections 577.001 through 577.019, Health and Safety Code, are designated as Subchapter A, Chapter 577, Health and Safety Code, and a heading to Subchapter A is added, to read as follows:

#### SUBCHAPTER A. GENERAL PROVISIONS; LICENSING AND PENALTIES

SECTION 6. Amends Chapter 577, Health and Safety Code, by adding Subchapter B, as follows:

## SUBCHAPTER B. PATIENT SAFETY PROGRAM

Sec. 577.051 Requires TDH to develop a patient safety program for mental hospitals licensed under Section 577.001(a). Requires the program to meet certain requirements.

Sec. 577.052. ANNUAL REPORT. (a) Requires a mental hospital, on renewal of a license under this chapter, to submit an annual report to TDH that lists the number of occurrences at the hospital or at an outpatient facility owned or operated by the hospital of certain types of events.

(b) Prohibits TDH from requiring the annual report under Subsection (b) to include any information other than the number of occurrences, if any, of the events listed in Subsection (a).

Sec. 577.053. ROOT CAUSE ANALYSIS AND ACTION PLAN. (a) Defines “root cause analysis.”

(b) Requires a hospital, not later than the 45th day after the date a hospital becomes aware of the occurrence of an event listed in Section 577.052, to perform certain tasks.

(c) Authorizes TDH to review a root cause analysis or action plan related to an event listed in Section 577.052 during a survey, inspection, or investigation of a hospital.

(d) Prohibits TDH from requiring a root cause analysis or action plan to be submitted to TDH.

(e) Prohibits TDH or an employee or agent of TDH in any form, format, or manner from removing, copying, reproducing, redacting, or dictating from any part of a root cause analysis or action plan.

Sec. 577.054. CONFIDENTIALITY; ABSOLUTE PRIVILEGE. (a) Provides that all information and materials, except as provided by Sections 577.055 and 577.056, obtained or compiled by a mental hospital under this subchapter are confidential and not subject to disclosure under Chapter 552, Government Code (Public Information), and are not subject to discovery, subpoena, or other means of legal compulsion for release to anyone other than TDH or its employees or agents involved in the program. Prohibits information and materials obtained or compiled by TDH under this section from being admitted in evidence or otherwise disclosed in any civil, criminal, or administrative proceeding.

(b) Provides that the confidentiality protections provided by Subsections (a) apply regardless of whether the information or materials are obtained from or compiled by a mental hospital or an entity that has an ownership or management interest in a hospital.

(c) Provides that the transfer of information or material under this subchapter is not a waiver of any privilege or protection granted under law.

(d) Provides that information reported by a mental hospital and analyses, plans, records, and reports obtained, prepared, or compiled by a hospital as required by this subchapter, and all related information and materials, are subject to an absolute privilege and may not be used in any form against the hospital or its agents, employees, partners, assignees, or independent contractors in any civil, criminal, or administrative proceeding, regardless of the means by which the information, analyses, plans, records, reports, or related information and materials came into the possession of the person. Requires a court to enforce this privilege as to all matters covered by this subsection.

(e) Provides that the provisions of this section regarding the confidentiality of information or materials compiled or reported by a hospital in compliance with or as authorized under this subchapter do not restrict access, to the extent authorized by law, by the patient or the patient's legally authorized representative to records of the patient's medical diagnosis or treatment or to other primary health records.

Sec. 577.055. ANNUAL DEPARTMENT SUMMARY. Requires TDH on an annual basis to compile and make publicly available a summary of the events that were reported by mental hospitals under Section 577.052. Authorizes the summary to contain only aggregated information and prohibits it from directly or indirectly identifying certain factors.

Sec. 577.056. BEST PRACTICES REPORT AND DEPARTMENT SUMMARY. (a) Requires a mental hospital to provide to TDH at least one report of the best practices and safety measures related to a reported event.

(b) Authorizes a mental hospital to provide to TDH a report of other best practices and the safety measures, that are effective in improving patient safety.

(c) Authorizes TDH by rule to prescribe the form and format of a best practices report. Prohibits TDH from requiring a best practices report to exceed one page in length. Requires TDH to accept, in lieu of a report in the form and format prescribed by TDH, a copy of a report submitted by a mental hospital to a patient safety organization.

(d) Requires TDH periodically to review and compile a summary of best practices reports make the summary available to the public.

(e) Prohibits the summary from directly or indirectly identifying certain entities.

Sec. 577.057. PROHIBITION. Prohibits the hospital annual report, TDH summary, or the best practices report from distinguishing between an event that occurred at an outpatient facility owned or operated by the hospital and an event that occurred at a hospital facility.

Sec. 577.058. REPORT TO LEGISLATURE. (a) Provides that not later than December 1, 2006, the commissioner of public health must perform certain tasks.

(b) Requires the commissioner of public health to conduct the evaluation in consultation with hospitals licensed under this chapter.

(c) Requires the evaluation to address certain issues.

Sec. 577.059. GIFTS, GRANTS, AND DONATIONS. Authorizes TDH to accept and administer a gift, grant, or donation from any source to carry out the purposes of this subchapter.

Sec. 577.060. ADMINISTRATIVE PENALTY. (a) Authorizes TDH to assess an administrative penalty against a person who violates this subchapter or a rule adopted under this subchapter.

(b) Prohibits the penalty from exceeding \$1,000 for each violation. Provides that each day of a continuing violation constitutes a separate violation.

(c) Requires TDH, in determining the amount of an administrative penalty assessed under this section, to consider certain factors.

(d) Provides that all proceedings for the assessment of an administrative penalty under this subchapter are considered to be contested cases under Chapter 2001, Government Code.

Sec. 577.061. NOTICE; REQUEST FOR HEARING. (a) Requires TDH, if, after investigation of a possible violation and the facts surrounding that possible violation, TDH determines that a violation has occurred, to give written notice of the violation to the person alleged to have committed the violation. Requires the notice to include certain information.

(b) Authorizes the person notified, not later than the 20th day after the date on which the notice is received, to accept the determination of TDH made under this section, including the proposed penalty, or to make a written request for a hearing on that determination.

(c) Requires the commissioner of public health or the commissioner's designee, if the person notified of the violation accepts the determination of TDH, to issue an order approving the determination and ordering that the person pay the proposed penalty.

Sec. 577.062. HEARING; ORDER. (a) Requires TDH, if the person notified fails to respond in a timely manner to the notice under Section 577.061(b) or if the person requests a hearing, to perform certain tasks.

(b) Requires the hearings examiner to make findings of fact and conclusions of law and to promptly issue to the commissioner of public health or the commissioner's designee a proposal for decision as to the occurrence of the violation and a recommendation as to the amount of the proposed penalty if a penalty is determined to be warranted.

(c) Authorizes the commissioner of public health or the commissioner's designee by order, based on the findings of fact and conclusions of law and the recommendations of the hearings examiner, to find that a violation has occurred and to assess a penalty or to find that no violation has occurred.

Sec. 577.063. NOTICE AND PAYMENT OF ADMINISTRATIVE PENALTY; JUDICIAL REVIEW; REFUND. (a) Requires TDH to give notice of the order under Section 577.062(c) to the person notified. Requires the notice to include certain information.

(b) Requires the person to perform certain actions not later than the 30th day after the date on which the decision is final as provided by Chapter 2001, Government Code.

(c) Authorizes a person who acts under Subsection (b)(3), within the 30-day period, to perform certain tasks.

(d) Authorizes TDH, if TDH receives a copy of an affidavit under Subsection (c)(2), to file with the court, within five days after the date the copy is received, a contest to the affidavit. Requires the court to hold a hearing on the facts alleged in the affidavit as soon as practicable and to stay the enforcement of the penalty on finding that the alleged facts are true. Provides that the person who files an affidavit has the burden of proving that the person is financially unable to pay the penalty and to give a supersedeas bond.

(e) Authorizes TDH, if the person does not pay the penalty and the enforcement of the penalty is not stayed, to refer the matter to the attorney general for collection of the penalty.

(f) Provides for judicial review of the order.

(g) Authorizes the court, if the court sustains the occurrence of the violation, to uphold or reduce the amount of the penalty and order the person to pay the full or reduced amount of the penalty. Requires the court, if the court does not sustain the occurrence of the violation, to order that no penalty is owed.

(h) Requires the court, when the judgment of the court becomes final, to proceed under this subsection. Requires the court, if the person paid the amount of the penalty under Subsection (b)(2) and if that amount is reduced or is not upheld by the court, to order that TDH pay the appropriate amount plus accrued interest to the person. Provides that the rate of the interest is the rate charged on loans to depository institutions by the New York Federal Reserve Bank, and requires the interest to be paid for the period beginning on the date the penalty was paid and ending on the date the penalty is remitted. Requires the court, if the person paid the penalty and the penalty is not upheld by the court, to order the release of the escrow account or bond. Requires the court, if the person paid the penalty under Subsection (c)(1)(A) and the amount of the penalty is reduced, to order that the amount of the penalty be paid to TDH from the escrow account and that the remainder of the account be released. Requires the court, if the person gave a supersedeas bond and if the amount of the penalty is reduced, to order the release of the bond after the person pays the amount.

Sec. 577.064. EXPIRATION. Provides that unless continued in existence, this subchapter expires September 1, 2007.

SECTION 7. (a) Provides that not later than January 1, 2004, TDH, using existing resources available to it, must establish a patient safety program as required under Subchapter H, Chapter 241, Health and Safety Code, as added by this Act, under Subchapter B, Chapter 243, Health and Safety Code, as added by this Act, and under Subchapter B, Chapter 577, Health and Safety Code, as added by this Act.

(b) Provides that beginning July 1, 2004, a hospital, ambulatory surgical center, or mental hospital on renewal of a license under Chapter 241 or 243 or Section 577.001(a), Health and Safety Code, shall submit the annual report required by Section 241.202, 243.052, or 577.052, Health and Safety Code, as added by this Act.

SECTION 8. Provides that the expiration of Subchapter H, Chapter 241, Health and Safety Code, as added by this Act, Subchapter B, Chapter 243, Health and Safety Code, as added by this Act, and Subchapter B, Chapter 577, Health and Safety Code, as added by this Act, in accordance with Sections 241.210, 243.060, and 577.060, Health and Safety Code, as added by this Act, does not affect the confidentiality of and privilege applicable to information and materials or the authorized disclosure of summary reports of that information and materials under Sections 241.204, 241.205, 241.206, 241.208, 243.054, 243.055, 243.056, 243.058, 577.054, 577.055, 577.056, and 577.058, Health and Safety Code, as added by this Act, and these laws are continued in effect for this purpose.

SECTION 9. Effective date: upon passage or September 1, 2003.