By: Madla S.B. No. 859

A BILL TO BE ENTITLED

AN ACT

relating to the reporting of medical errors by certain hospitals, ambulatory surgical centers, and mental hospitals.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. 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, licensed ambulatory surgical centers, and licensed mental hospitals to report these errors, by providing the public with access to statewide summaries of such reports, and by requiring such facilities to implement risk-reduction strategies. The programs also will encourage hospitals, licensed ambulatory surgical centers, and licensed mental hospitals to share best practices and safety measures that have been effective in improving patient safety.

SECTION 2. Subchapter B, Chapter 241, Health and Safety Code, is amended by adding Section 241.030 to read as follows:

Sec. 241.030. PATIENT SAFETY PROGRAM. (a) Using existing resources, the department shall develop a patient safety program for hospitals. The program shall:

(1) be administered by the hospital licensing program within the department; and

(2) serve as a clearinghouse of information for hospitals concerning best practices and quality improvement

strategies.

(b) A hospital shall submit an annual report to the department, the due date to be based on the date of licensure or relicensure of the hospital, of the following types of events:

(1) a medication error resulting in the unanticipated death of a patient, or a major, permanent loss of a bodily function by a patient, that is not related to the natural course of the illness or underlying condition of the patient;

(2) any perinatal death unrelated to a congenital condition in an infant having a birth weight greater than 2,500 grams;

(3) the abduction from the hospital of a newborn infant patient, or the discharge from the hospital of a newborn infant patient into the custody of an individual in circumstances in which the hospital knew, or in the exercise of ordinary care should have known, that the individual did not have legal custody of the newborn infant patient;

(4) the suicide of a patient in a setting where the patient receives around-the-clock care;

(5) the sexual assault of a patient while the patient is being treated or while the patient is on the premises of the facility;

(6) a hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products having major blood group incompatibilities;

(7) the performance of surgery on the wrong patient or on the wrong body part of a patient;

(8) a foreign object's accidentally being left in a patient's body during a procedure; and

(9) the death or serious disability of a patient associated with the use or function of a device in patient care in which the device is used or functions in a manner other than that intended.

(c) The department may not require the annual report under Subsection (b) to include any information other than a listing of the number of occurrences, if any, of the events listed in that subsection.

(d) A hospital shall conduct a root cause analysis of an event listed in Subsection (b) following identification of the event.

(e) Following the performance of a root cause analysis of an event listed in Subsection (b), a hospital shall develop an action plan that identifies the strategies the hospital intends to use to reduce the risk of similar events occurring in the future.

(f) A hospital must conduct a root cause analysis and complete an action plan under Subsection (e) not later than 45 days after becoming aware of an event that must be reported under Subsection (b).

(g) The department may review a root cause analysis and action plan regarding an event that must be reported under Subsection (b) during a licensure or complaint survey but may not require that the root cause analysis or action plan be reported to the department. The department and its employees and agents are prohibited from removing, copying, reproducing, redacting, or

dictating from, all or any part of a root cause analysis or action plan. This prohibition applies to any form, format, or manner of copying, reproducing, redacting, or dictating.

(h) All information and materials obtained or compiled by the department under this section are confidential and not subject to disclosure under Chapter 552, Government Code, and are not subject to discovery, subpoena, or other means of legal compulsion for release to anyone other than the department or its employees or agents involved in the program. Information and materials obtained or compiled by the department under this section may not be admitted in evidence or otherwise disclosed in any civil, criminal, or administrative proceeding.

(i) The root cause analysis and action plan compiled by a hospital in compliance with Subsections (d) and (e) and all related information and materials, and the report of best practices and safety measures described in Subsection (m) and all related information and materials, are confidential and not subject to disclosure under Chapter 552, Government Code, and are not subject to discovery, subpoena, or other means of legal compulsion for release to anyone. The root cause analysis and action plan and all related information and materials, and the report of best practices and safety measures and all related information and materials, may not be admitted in evidence or otherwise disclosed in any civil, criminal, or administrative proceeding. Information reported by a hospital and analyses, plans, records, and reports obtained, prepared, or compiled by a hospital as required by this section, 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 attempting to use them. A court shall enforce this privilege as to all matters covered by this section.

(j) The confidentiality protections provided by Subsections (h) and (i) 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.

(k) The transfer of information or materials under this section shall not be treated as a waiver of any privilege or protection.

(l) Notwithstanding the provisions of Subsection (h), the department shall on an annual basis compile and make publicly available a summary of the events that were reported by hospitals under Subsection (b). The summary shall contain only aggregated information and may not directly or indirectly identify a specific hospital or group of hospitals, an individual, a specific reported event, or the circumstances or individuals surrounding or involved in a specific reported event.

(m) A hospital may provide to the department a report of its best practices and safety measures that have been effective in improving patient safety. The department may adopt rules regarding the form and format of the report. The department shall periodically compile a summary of such reports and make the summary

publicly available. The summary may not directly or indirectly identify a specific hospital or group of hospitals, an individual, a specific reported event, or the circumstances or individuals surrounding or involved in a specific reported event.

(n) The provisions of this section also apply to the events listed in Subsection (b) that occur in an offsite outpatient facility that is owned or operated by a hospital, and the report described in Subsection (m) shall not distinguish between those offsite outpatient facilities that are owned or operated by a hospital and those facilities that are included under the hospital's license.

(o) The commissioner of public health shall evaluate the program established under this section and submit the evaluation, together with recommendations, to the legislature not later than December 1, 2006. The evaluation shall be made in consultation with hospitals that are required to make a report under Subsection (b).

(p) The evaluation under Subsection (o) shall include the following:

(1) the degree to which the department was able to detect statewide trends in errors based on the types and numbers of errors reported;

(2) the extent to which the statewide summaries required to be compiled by the department under Subsection (l) were accessed by the public;

(3) the effectiveness of the summary of reported best practices and safety measures in assisting hospitals in improving patient care; and

(4) the impact of national studies regarding the effectiveness of state or federal systems of reporting medical errors.

(q) In this section, "root cause analysis" means a process for identifying basic or causal factors that underlie variation in performance, focusing primarily on systems and processes, progressing from special causes in clinical processes to common causes in organizational processes, and identifying potential improvements in processes or systems.

(r) This section, except for Subsections (h)-(k) and (q), expires September 1, 2007.

SECTION 3. Chapter 243, Health and Safety Code, is amended by adding Section 243.0101 to read as follows:

Sec. 243.0101. PATIENT SAFETY PROGRAM. (a) Using existing resources, the department shall develop a patient safety program for licensed ambulatory surgical centers. The program shall:

(1) be administered by the ambulatory surgical center licensing program within the department; and

(2) serve as a clearinghouse of information for licensed ambulatory surgical centers concerning best practices and quality improvement strategies.

(b) An ambulatory surgical center licensed by the department shall submit an annual report to the department, the due date to be based on the date of licensure or relicensure of the ambulatory surgical center, of the following types of events:

(1) a medication error resulting in the unanticipated death of a patient, or a major, permanent loss of a bodily function

by the patient, that is not related to the natural course of the illness or underlying condition of the patient;

(2) the suicide of a patient in an ambulatory surgical center;

(3) the sexual assault of a patient while the patient is being treated or while the patient is on the premises of the facility;

(4) a hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products having major blood group incompatibilities;

(5) the performance of surgery on the wrong patient or on the wrong body part of a patient;

(6) a foreign object's accidentally being left in a patient's body during a procedure; and

(7) the death or serious disability of a patient associated with the use of or function of a device in patient care in which the device is used or functions in a manner other than that intended.

(c) The department may not require the annual report under Subsection (b) to include any information other than a listing of the number of occurrences, if any, of the events listed in that subsection.

(d) A licensed ambulatory surgical center shall conduct a root cause analysis of an event listed in Subsection (b) following identification of the event.

(e) Following the performance of a root cause analysis of an event listed in Subsection (b), a licensed ambulatory surgical

center shall develop an action plan that identifies the strategies the licensed ambulatory surgical center intends to use to reduce the risk of similar events occurring in the future.

(f) A licensed ambulatory surgical center must conduct a root cause analysis and complete an action plan under Subsection (e) not later than 45 days after becoming aware of an event that must be reported under Subsection (b).

(g) The department may review a root cause analysis and action plan regarding an event that must be reported under Subsection (b) during a licensure or complaint survey but may not require that the action plan be reported to the department. The department and its employees and agents are prohibited from removing, copying, reproducing, redacting, or dictating from all or any part of a root cause analysis or action plan. This prohibition applies to any form, format, or manner of copying, reproducing, redacting, or dictating.

(h) All information and materials obtained or compiled by the department under this section are confidential and not subject to disclosure under Chapter 552, Government Code, and are not subject to discovery, subpoena, or other means of legal compulsion for release to anyone other than the department or its employees or agents involved in the program. Information and materials obtained or compiled by the department under this section may not be admitted in evidence or otherwise disclosed in any civil, criminal, or administrative proceeding.

(i) The root cause analysis and action plan compiled by a licensed ambulatory surgical center in compliance with Subsections

(d) and (e) and all related information and materials, and the report of best practices and safety measures described in Subsection (m) and all related information and materials, are confidential and not subject to disclosure under Chapter 552, Government Code, and are not subject to discovery, subpoena, or other means of legal compulsion for release to anyone. The root cause analysis and action plan and all related information and materials, and the report of best practices and safety measures and all related information and materials may not be admitted in evidence or otherwise disclosed in any civil, criminal, or administrative proceeding. Information reported by a licensed ambulatory surgical center and analyses, plans, records, and reports obtained, prepared, or compiled by a licensed ambulatory surgical center as required by this section, and all related information and materials, are subject to an absolute privilege and may not be used in any form against the licensed ambulatory surgical center 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 attempting to use them. A court shall enforce this privilege as to all matters covered by this section.

(j) The confidentiality protections provided by Subsections (h) and (i) apply regardless of whether the information or materials are obtained from or compiled by a licensed ambulatory surgical center or an entity that has an ownership or management

interest in a licensed ambulatory surgical center.

(k) The transfer of information or materials under this section shall not be treated as a waiver of any privilege or protection.

(l) Notwithstanding the provisions of Subsection (h), the department shall on an annual basis compile and make publicly available a summary of the events that were reported by licensed ambulatory surgical centers under Subsection (b). The summary shall contain only aggregated information and may not directly or indirectly identify a specific licensed ambulatory surgical center or group of licensed ambulatory surgical centers, an individual, a specific reported event, or the circumstances or individuals surrounding or involved in a specific reported event.

(m) A licensed ambulatory surgical center may provide to the department a report of its best practices and safety measures that have been effective in improving patient safety. The department may adopt rules regarding the form and format of the report. The department shall periodically compile a summary of the reports and make the summary publicly available. The summary may not directly or indirectly identify a specific licensed ambulatory surgical center or group of licensed ambulatory surgical centers, an individual, a specific reported event, or the circumstances or individuals surrounding or involved in a specific reported event.

(n) The commissioner of public health shall evaluate the program established under this section and report the evaluation, together with recommendations, to the legislature not later than December 1, 2006. The evaluation shall be made in consultation with

licensed ambulatory surgical centers that are required to make a report under Subsection (b).

(o) The evaluation under Subsection (n) shall include the following:

(1) the degree to which the department was able to detect statewide trends in errors based on the types and numbers of errors reported;

(2) the extent to which the statewide summaries required to be compiled by the department under Subsection (l) were accessed by the public;

(3) the effectiveness of the summary of reported best practices and safety measures in assisting licensed ambulatory surgical centers in improving patient care; and

(4) the impact of national studies regarding the effectiveness of state or federal systems of reporting medical errors.

(p) In this section, "root cause analysis" means a process for identifying basic or causal factors that underlie variation in performance, focusing primarily on systems and processes, progressing from special causes in clinical processes to common causes in organizational processes, and identifying potential improvements in processes or systems.

(q) This section, except for Subsections (h)-(k) and (p), expires September 1, 2007.

SECTION 4. Chapter 577, Health and Safety Code, is amended by adding Section 577.0102 to read as follows:

Sec. 577.0102. PATIENT SAFETY PROGRAM. (a) Using existing

resources, the department shall develop a patient safety program for mental hospitals licensed under Section 577.001(a). The program shall:

(1) be administered by the hospital licensing program within the department; and

(2) serve as a clearinghouse of information for licensed mental hospitals concerning best practices and quality improvement strategies.

(b) A licensed mental hospital shall submit an annual report to the department, the due date to be based on the date of licensure or relicensure of the licensed mental hospital, of the following types of events:

(1) a medication error resulting in the unanticipated death of a patient, or a major, permanent loss of a bodily function by the patient, that is not related to the natural course of the illness or underlying condition of the patient;

(2) the suicide of a patient in a setting where the patient receives around-the-clock care;

(3) the sexual assault of a patient while the patient is being treated or while the patient is on the premises of the facility;

(4) a hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products having major blood group incompatibilities; and

(5) the death or serious disability of a patient associated with the use or function of a device in patient care in which the device is used or functions in a manner other than that

intended.

(c) The department may not require the annual report under Subsection (b) to include any information other than a listing of the number of occurrences, if any, of the events listed in that subsection.

(d) A licensed mental hospital shall conduct a root cause analysis of an event listed in Subsection (b) following identification of the event.

(e) Following the performance of a root cause analysis of an event listed in Subsection (b), a licensed mental hospital shall develop an action plan that identifies the strategies the licensed mental hospital intends to use to reduce the risk of similar events occurring in the future.

(f) A licensed mental hospital must conduct a root cause analysis and complete an action plan under Subsection (e) not later than 45 days after becoming aware of an event that must be reported under Subsection (b).

(g) The department may review a root cause analysis and action plan regarding an event that must be reported under Subsection (b) during a licensure or complaint survey but may not require that the root cause analysis or action plan be reported to the department. The department and its employees and agents are prohibited from removing, copying, reproducing, redacting, or dictating from all or any part of a root cause analysis or action plan. This prohibition applies to any form, format, or manner of copying, reproducing, redacting, or dictating.

(h) All information and materials obtained or compiled by

the department under this section are confidential and not subject to disclosure under Chapter 552, Government Code, and are not subject to discovery, subpoena, or other means of legal compulsion for release to anyone other than the department or its employees or agents involved in the program. Information and materials obtained or compiled by the department under this section may not be admitted in evidence or otherwise disclosed in any civil, criminal, or administrative proceeding.

(i) The root cause analysis and action plan compiled by a licensed mental hospital in compliance with Subsections (d) and (e) and all related information and materials, and the report of best practices and safety measures described in Subsection (m) and all related information and materials, are confidential and not subject to disclosure under Chapter 552, Government Code, and are not subject to discovery, subpoena, or other means of legal compulsion for release to anyone. The root cause analysis and action plan and all related information and materials and the report of best practices and safety measures and all related information and materials may not be admitted in evidence or otherwise disclosed in any civil, criminal, or administrative proceeding. Information reported by a licensed mental hospital and analyses, plans, records, and reports obtained, prepared, or compiled by a licensed mental hospital as required by this section, and all related information and materials, are subject to an absolute privilege and may not be used in any form against the licensed mental 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 attempting to use them. A court shall enforce this privilege as to all matters covered by this section.

(j) The confidentiality protections provided by Subsections (h) and (i) apply regardless of whether the information or materials are obtained from or compiled by a licensed mental hospital or an entity that has an ownership or management interest in a licensed mental hospital.

(k) The transfer of information or materials under this section shall not be treated as a waiver of any privilege or protection.

(l) Notwithstanding the provisions of Subsection (h), the department shall on an annual basis compile and make publicly available a summary of the events that were reported by licensed mental hospitals under Subsection (b). The summary shall contain only aggregated information and may not directly or indirectly identify a specific licensed mental hospital or group of licensed mental hospitals, an individual, a specific reported event, or the circumstances or individuals surrounding or involved in a specific reported event.

(m) A licensed mental hospital may provide to the department a report of its best practices and safety measures that have been effective in improving patient safety. The department may adopt rules regarding the form and format of the report. The department shall periodically compile a summary of the reports and make the summary publicly available. The summary may not directly or

indirectly identify a specific licensed mental hospital or group of licensed mental hospitals, an individual, a specific reported event, or the circumstances surrounding or involved in a specific reported event.

(n) The commissioner of public health shall evaluate the program established under this section and submit the evaluation, together with recommendations, to the legislature not later than December 1, 2006. The evaluation shall be made in consultation with licensed mental hospitals that are required to make a report under Subsection (b).

(o) The evaluation under Subsection (n) shall include the following:

(1) the degree to which the department was able to detect statewide trends in errors based on the types and numbers of errors reported;

(2) the extent to which the statewide summaries required to be compiled by the department under Subsection (l) were accessed by the public;

(3) the effectiveness of the summary of reported best practices and safety measures in assisting licensed mental hospitals in improving patient care; and

(4) the impact of national studies regarding the effectiveness of state or federal systems of reporting medical errors.

(p) In this section, "root cause analysis" means a process for identifying basic or causal factors that underlie variation in performance, focusing primarily on systems and processes,

progressing from special causes in clinical processes to common causes in organizational processes, and identifying potential improvements in processes or systems.

(q) This section, except for Subsections (h)-(k) and (p), expires September 1, 2007.

SECTION 5. The 80th Legislature shall assess the effectiveness of the patient safety programs developed for:

(1) hospitals, under Section 241.030, Health and Safety Code, as added by Section 2 of this Act;

(2) licensed ambulatory surgical centers, under Section 243.0101, Health and Safety Code, as added by Section 3 of this Act; and

(3) licensed mental hospitals, under Section 577.0102, Health and Safety Code, as added by Section 4 of this Act.

SECTION 6. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2003.