

By: Madla

S.B. No. 859

A BILL TO BE ENTITLED

AN ACT

1
2 relating to the reporting of medical errors by certain hospitals,
3 ambulatory surgical centers, and mental hospitals.

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

5 SECTION 1. The purpose of this Act is to establish programs
6 that will promote public accountability through the detection of
7 statewide trends in the occurrence of certain medical errors by
8 requiring hospitals, licensed ambulatory surgical centers, and
9 licensed mental hospitals to report these errors, by providing the
10 public with access to statewide summaries of such reports, and by
11 requiring such facilities to implement risk-reduction strategies.
12 The programs also will encourage hospitals, licensed ambulatory
13 surgical centers, and licensed mental hospitals to share best
14 practices and safety measures that have been effective in improving
15 patient safety.

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

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

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

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

1 strategies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 (i) The root cause analysis and action plan compiled by a
14 hospital in compliance with Subsections (d) and (e) and all related
15 information and materials, and the report of best practices and
16 safety measures described in Subsection (m) and all related
17 information and materials, are confidential and not subject to
18 disclosure under Chapter 552, Government Code, and are not subject
19 to discovery, subpoena, or other means of legal compulsion for
20 release to anyone. The root cause analysis and action plan and all
21 related information and materials, and the report of best practices
22 and safety measures and all related information and materials, may
23 not be admitted in evidence or otherwise disclosed in any civil,
24 criminal, or administrative proceeding. Information reported by a
25 hospital and analyses, plans, records, and reports obtained,
26 prepared, or compiled by a hospital as required by this section, and
27 all related information and materials, are subject to an absolute

1 privilege and may not be used in any form against the hospital or
2 its agents, employees, partners, assignees, or independent
3 contractors in any civil, criminal, or administrative proceeding,
4 regardless of the means by which the information, analyses, plans,
5 records, reports, or related information and materials came into
6 the possession of the person attempting to use them. A court shall
7 enforce this privilege as to all matters covered by this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 (d) and (e) and all related information and materials, and the
2 report of best practices and safety measures described in
3 Subsection (m) and all related information and materials, are
4 confidential and not subject to disclosure under Chapter 552,
5 Government Code, and are not subject to discovery, subpoena, or
6 other means of legal compulsion for release to anyone. The root
7 cause analysis and action plan and all related information and
8 materials, and the report of best practices and safety measures and
9 all related information and materials may not be admitted in
10 evidence or otherwise disclosed in any civil, criminal, or
11 administrative proceeding. Information reported by a licensed
12 ambulatory surgical center and analyses, plans, records, and
13 reports obtained, prepared, or compiled by a licensed ambulatory
14 surgical center as required by this section, and all related
15 information and materials, are subject to an absolute privilege and
16 may not be used in any form against the licensed ambulatory surgical
17 center or its agents, employees, partners, assignees, or
18 independent contractors in any civil, criminal, or administrative
19 proceeding, regardless of the means by which the information,
20 analyses, plans, records, reports, or related information and
21 materials came into the possession of the person attempting to use
22 them. A court shall enforce this privilege as to all matters
23 covered by this section.

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

1 interest in a licensed ambulatory surgical center.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 intended.

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

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

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

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

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

27 (h) All information and materials obtained or compiled by

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

9 (i) The root cause analysis and action plan compiled by a
10 licensed mental hospital in compliance with Subsections (d) and (e)
11 and all related information and materials, and the report of best
12 practices and safety measures described in Subsection (m) and all
13 related information and materials, are confidential and not subject
14 to disclosure under Chapter 552, Government Code, and are not
15 subject to discovery, subpoena, or other means of legal compulsion
16 for release to anyone. The root cause analysis and action plan and
17 all related information and materials and the report of best
18 practices and safety measures and all related information and
19 materials may not be admitted in evidence or otherwise disclosed in
20 any civil, criminal, or administrative proceeding. Information
21 reported by a licensed mental hospital and analyses, plans,
22 records, and reports obtained, prepared, or compiled by a licensed
23 mental hospital as required by this section, and all related
24 information and materials, are subject to an absolute privilege and
25 may not be used in any form against the licensed mental hospital or
26 its agents, employees, partners, assignees, or independent
27 contractors in any civil, criminal, or administrative proceeding,

1 regardless of the means by which the information, analyses, plans,
2 records, reports, or related information and materials came into
3 the possession of the person attempting to use them. A court shall
4 enforce this privilege as to all matters covered by this section.

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

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

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

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

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

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

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

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

16 (2) the extent to which the statewide summaries
17 required to be compiled by the department under Subsection (1) were
18 accessed by the public;

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

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

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

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

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

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

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

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

13 (3) licensed mental hospitals, under Section
14 577.0102, Health and Safety Code, as added by Section 4 of this Act.

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