

By: Leibowitz

H.B. No. 3099

A BILL TO BE ENTITLED

AN ACT

relating to the reporting of preventable adverse events and the establishment of a patient safety program in hospitals and ambulatory surgical centers; providing an administrative penalty.

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

SECTION 1. Chapter 241, Health and Safety Code, is amended by adding Subchapter H to read as follows:

SUBCHAPTER H. PATIENT SAFETY PROGRAM

Sec. 241.201. DEFINITION. In this subchapter, "serious disability" means:

(1) a physical or mental impairment that substantially limits one or more major life activities of an individual such as seeing, hearing, speaking, walking, or breathing, or a loss of a bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from a hospital;
or

(2) loss of a body part.

Sec. 241.202. DUTIES OF DEPARTMENT. (a) The department shall develop a patient safety program for hospitals. The program must:

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

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

1 strategies.

2 (b) The department shall group hospitals by size for the
3 reports required by this chapter as follows:

4 (1) fewer than 50 beds;

5 (2) 50 to 99 beds;

6 (3) 100 to 199 beds;

7 (4) 200 to 399 beds; and

8 (5) 400 beds or more.

9 (c) The department shall combine two or more categories
10 described by Subsection (b) if the number of hospitals in any
11 category falls below 40.

12 Sec. 241.203. ANNUAL REPORT. (a) This section applies only
13 to a hospital located in a county with a population of more than
14 350,000.

15 (b) On renewal of a license under this chapter, a hospital
16 shall submit to the department an annual report that lists the
17 number of occurrences at the hospital or at an outpatient facility
18 owned or operated by the hospital of each of the following
19 preventable adverse events during the preceding year:

20 (1) the unintended retention of a foreign object in a
21 patient after surgery or another procedure;

22 (2) death or serious disability of a patient caused by
23 an intravascular air embolism that occurs while the patient is
24 receiving care in the hospital, excluding a death associated with a
25 neurological procedure known to present a high risk of
26 intravascular air embolism;

27 (3) death or serious disability of a patient caused by

1 a hemolytic reaction resulting from the administration of ABO- or
2 HLA-incompatible blood or blood products;

3 (4) stage three or four pressure ulcers acquired after
4 admission to the hospital, excluding progression from stage two to
5 stage three if stage two was recognized on admission;

6 (5) death or serious disability caused by an electric
7 shock while a patient is receiving care in the hospital, excluding
8 an event involving a planned treatment such as electric
9 countershock;

10 (6) death or serious disability caused by a burn
11 incurred from any source while a patient is receiving care in the
12 hospital;

13 (7) death or serious disability caused by a fall or
14 trauma resulting in a fracture, dislocation, intracranial injury,
15 or crushing injury while a patient is receiving care in the
16 hospital;

17 (8) death or serious disability directly related to
18 the following manifestations of poor glycemic control, the onset of
19 which occurred while the patient was receiving care at the
20 hospital:

21 (A) diabetic ketoacidosis;

22 (B) nonketotic hyperosmolar coma;

23 (C) hypoglycemic coma;

24 (D) secondary diabetes with ketoacidosis; and

25 (E) secondary diabetes with hyperosmolarity;

26 (9) death or serious disability caused by a urinary
27 tract infection resulting from the insertion of a catheter by an

individual health care provider;

(10) death or serious disability caused by an infection resulting from the insertion of a vascular catheter by an individual health care provider;

(11) death or serious disability caused by a surgical site infection occurring as a result of the following procedures:

(A) a coronary artery bypass graft;

(B) bariatric surgery such as laparoscopic gastric bypass surgery, gastroenterostomy, and laparoscopic gastric restrictive surgery; and

(C) orthopedic procedures involving the spine, neck, shoulder, or elbow; and

(12) death or serious disability caused by a pulmonary embolism or deep vein thrombosis that occurred while the patient was receiving care at the hospital following an orthopedic procedure, including a total knee replacement or hip replacement.

(c) The department may not require the annual report to include any information other than the number of occurrences of each preventable adverse event listed in Subsection (b).

Sec. 241.204. ROOT CAUSE ANALYSIS AND ACTION PLAN. (a) In this section, "root cause analysis" means the process that identifies basic or causal factors underlying a variation in performance leading to a preventable adverse event listed in Section 241.203 and that:

(1) focuses primarily on systems and processes;

(2) progresses from special causes in clinical processes to common causes in organizational processes; and

1 (3) identifies potential improvements in processes or
2 systems.

3 (b) This section applies only to a hospital located in a
4 county with a population of more than 350,000.

5 (c) Not later than the 45th day after the date a hospital
6 becomes aware of the occurrence of a preventable adverse event
7 listed in Section 241.203, the hospital shall:

8 (1) conduct a root cause analysis of the event; and

9 (2) develop an action plan that identifies strategies
10 to reduce the risk of a similar event occurring in the future.

11 (d) The department may review a root cause analysis or
12 action plan related to a preventable adverse event listed in
13 Section 241.203 during a survey, inspection, or investigation of a
14 hospital.

15 (e) The department may not require a root cause analysis or
16 action plan to be submitted to the department.

17 (f) The department or an employee or agent of the department
18 may not in any form, format, or manner remove, copy, reproduce,
19 redact, or dictate from any part of a root cause analysis or action
20 plan.

21 Sec. 241.205. CONFIDENTIALITY; ABSOLUTE PRIVILEGE. (a)
22 Except as provided by Sections 241.206 and 241.207, all information
23 and materials obtained or compiled by the department under this
24 subchapter or compiled by a hospital under this subchapter,
25 including the root cause analysis, annual hospital report, action
26 plan, best practices report, department summary, and all related
27 information and materials, are confidential and:

1 (1) are not subject to disclosure under Chapter 552,
2 Government Code, or discovery, subpoena, or other means of legal
3 compulsion for release to any person, subject to Section
4 241.204(d); and

5 (2) may not be admitted as evidence or otherwise
6 disclosed in any civil, criminal, or administrative proceeding.

7 (b) The confidentiality protections under Subsection (a)
8 apply without regard to whether the information or materials are
9 obtained from or compiled by a hospital or an entity that has an
10 ownership or management interest in a hospital.

11 (c) The transfer of information or materials under this
12 subchapter is not a waiver of a privilege or protection granted
13 under law.

14 (d) Information reported by a hospital under this
15 subchapter and analyses, plans, records, and reports obtained,
16 prepared, or compiled by a hospital under this subchapter and all
17 related information and materials are subject to an absolute
18 privilege and may not be used in any form against the hospital or
19 the hospital's agents, employees, partners, assignees, or
20 independent contractors in any civil, criminal, or administrative
21 proceeding, regardless of the means by which a person came into
22 possession of the information, analysis, plan, record, report, or
23 related information or material. A court shall enforce this
24 privilege for all matters covered by this subsection.

25 (e) The provisions of this section regarding the
26 confidentiality of information or materials compiled or reported by
27 a hospital in compliance with or as authorized under this

1 subchapter do not restrict access, to the extent authorized by law,
2 by the patient or the patient's legally authorized representative
3 to records of the patient's medical diagnosis or treatment or to
4 other primary health records.

5 Sec. 241.206. ANNUAL DEPARTMENT SUMMARY. The department
6 annually shall compile and make available to the public a summary of
7 the preventable adverse events reported by hospitals as required by
8 Section 241.203. The summary may contain only aggregated
9 information and may not directly or indirectly identify:

10 (1) a specific hospital or group of hospitals;
11 (2) an individual; or
12 (3) a specific reported preventable adverse event or
13 the circumstances or individuals surrounding the event.

14 Sec. 241.207. BEST PRACTICES REPORT AND DEPARTMENT SUMMARY.
15 (a) A hospital located in a county with a population of more than
16 350,000 shall provide to the department at least one report of the
17 best practices and safety measures related to a reported
18 preventable adverse event.

19 (b) A hospital may provide to the department a report of
20 other best practices and the safety measures, such as marking a
21 surgical site and involving the patient in the marking process,
22 that are effective in improving patient safety.

23 (c) The department by rule may prescribe the form and format
24 of a best practices report. The department may not require a best
25 practices report to exceed one page in length. The department shall
26 accept, in lieu of a report in the form and format prescribed by the
27 department, a copy of a report submitted by a hospital to a patient

1 safety organization.

2 (d) The department periodically shall:

3 (1) review the best practices reports;

4 (2) compile a summary of the best practices reports
5 determined by the department to be effective and recommended as
6 best practices; and

7 (3) make the summary available to the public.

8 (e) The summary may not directly or indirectly identify:

9 (1) a specific hospital or group of hospitals;

10 (2) an individual; or

11 (3) a specific reported event or the circumstances or
12 individuals surrounding the event.

13 Sec. 241.208. PROHIBITION. The hospital annual report,
14 the department summary, or the best practices report may not
15 distinguish between a preventable adverse event that occurred at an
16 outpatient facility owned or operated by the hospital and a
17 preventable adverse event that occurred at a hospital facility.

18 Sec. 241.209. REPORT TO LEGISLATURE. (a) Not later than
19 December 1 of each even-numbered year, the commissioner of state
20 health services shall:

21 (1) evaluate the patient safety program established
22 under this subchapter; and

23 (2) report the results of the evaluation and make
24 recommendations to the legislature.

25 (b) The commissioner of state health services shall conduct
26 the evaluation in consultation with hospitals licensed under this
27 chapter.

1 (c) The evaluation must address:

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

5 (2) the degree to which the statewide summaries of
6 events compiled by the department were accessed by the public;

7 (3) the effectiveness of the department's best
8 practices summary in improving hospital patient care; and

9 (4) the impact of national studies on the
10 effectiveness of state or federal systems of reporting medical
11 errors.

12 Sec. 241.210. GIFTS, GRANTS, AND DONATIONS. The department
13 may accept and administer a gift, grant, or donation from any source
14 to carry out the purposes of this subchapter.

15 SECTION 2. Chapter 243, Health and Safety Code, is amended
16 by adding Subchapter B to read as follows:

17 SUBCHAPTER B. PATIENT SAFETY PROGRAM

18 Sec. 243.051. DEFINITION. In this subchapter, "serious
19 disability" means:

20 (1) a physical or mental impairment that substantially
21 limits one or more major life activities of an individual such as
22 seeing, hearing, speaking, walking, or breathing, or a loss of a
23 bodily function, if the impairment or loss lasts more than seven
24 days or is still present at the time of discharge from an ambulatory
25 surgical center; or

26 (2) loss of a body part.

27 Sec. 243.052. DUTIES OF DEPARTMENT. The department shall

1 develop a patient safety program for ambulatory surgical centers.

2 The program must:

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

5 (2) serve as an information clearinghouse for
6 ambulatory surgical centers concerning best practices and quality
7 improvement strategies.

8 Sec. 243.053. ANNUAL REPORT. (a) This section applies only
9 to an ambulatory surgical center located in a county with a
10 population of more than 350,000.

11 (b) On renewal of a license under this chapter, an
12 ambulatory surgical center shall submit to the department an annual
13 report that lists the number of occurrences at the center or at an
14 outpatient facility owned or operated by the center of each of the
15 following preventable adverse events during the preceding year:

16 (1) the unintended retention of a foreign object in a
17 patient after surgery or another procedure;

18 (2) death or serious disability of a patient caused by
19 an intravascular air embolism that occurs while the patient is
20 receiving care at the ambulatory surgical center, excluding a death
21 associated with a neurological procedure known to present a high
22 risk of intravascular air embolism;

23 (3) death or serious disability of a patient caused by
24 a hemolytic reaction resulting from the administration of ABO- or
25 HLA-incompatible blood or blood products;

26 (4) stage three or four pressure ulcers acquired after
27 admission to the ambulatory surgical center, excluding progression

1 from stage two to stage three if stage two was recognized on
2 admission;

3 (5) death or serious disability caused by an electric
4 shock while a patient is receiving care at the ambulatory surgical
5 center, excluding an event involving a planned treatment such as
6 electric countershock;

7 (6) death or serious disability caused by a burn
8 incurred from any source while a patient is receiving care at the
9 ambulatory surgical center;

10 (7) death or serious disability caused by a fall or
11 trauma resulting in a fracture, dislocation, intracranial injury,
12 or crushing injury while a patient is receiving care at the
13 ambulatory surgical center;

14 (8) death or serious disability directly related to
15 the following manifestations of poor glycemic control, the onset of
16 which occurred while the patient was receiving care at the
17 ambulatory surgical center:

18 (A) diabetic ketoacidosis;

19 (B) nonketotic hyperosmolar coma;

20 (C) hypoglycemic coma;

21 (D) secondary diabetes with ketoacidosis; and

22 (E) secondary diabetes with hyperosmolarity;

23 (9) death or serious disability caused by a urinary
24 tract infection resulting from the insertion of a catheter by an
25 individual health care provider;

26 (10) death or serious disability caused by an
27 infection resulting from the insertion of a vascular catheter by an

individual health care provider;

(11) death or serious disability caused by a surgical site infection occurring as a result of the following procedures:

(A) a coronary artery bypass graft;

(B) bariatric surgery such as laparoscopic gastric bypass surgery, gastroenterostomy, and laparoscopic gastric restrictive surgery; and

(C) orthopedic procedures involving the spine, neck, shoulder, or elbow; and

(12) death or serious disability caused by a pulmonary embolism or deep vein thrombosis that occurred while the patient was receiving care at the ambulatory surgical center following an orthopedic procedure, including a total knee replacement or hip replacement.

(c) The department may not require the annual report to include any information other than the number of occurrences of each preventable adverse event listed in Subsection (b).

Sec. 243.054. ROOT CAUSE ANALYSIS AND ACTION PLAN. (a) In this section, "root cause analysis" means the process that identifies basic or causal factors underlying a variation in performance leading to a preventable adverse event listed in Section 243.053 and that:

(1) focuses primarily on systems and processes;

(2) progresses from special causes in clinical processes to common causes in organizational processes; and

(3) identifies potential improvements in processes or systems.

1 (b) This section applies only to an ambulatory surgical
2 center located in a county with a population of more than 350,000.

3 (c) Not later than the 45th day after the date an ambulatory
4 surgical center becomes aware of the occurrence of a preventable
5 adverse event listed in Section 243.053, the center shall:

6 (1) conduct a root cause analysis of the event; and

7 (2) develop an action plan that identifies strategies
8 to reduce the risk of a similar event occurring in the future.

9 (d) The department may review a root cause analysis or
10 action plan related to a preventable adverse event listed in
11 Section 243.053 during a survey, inspection, or investigation of an
12 ambulatory surgical center.

13 (e) The department may not require a root cause analysis or
14 action plan to be submitted to the department.

15 (f) The department or an employee or agent of the department
16 may not in any form, format, or manner remove, copy, reproduce,
17 redact, or dictate from any part of a root cause analysis or action
18 plan.

19 Sec. 243.055. CONFIDENTIALITY; ABSOLUTE PRIVILEGE. (a)
20 Except as provided by Sections 243.056 and 243.057, all information
21 and materials obtained or compiled by the department under this
22 subchapter or compiled by an ambulatory surgical center under this
23 subchapter, including the root cause analysis, annual report of an
24 ambulatory surgical center, action plan, best practices report,
25 department summary, and all related information and materials, are
26 confidential and:

27 (1) are not subject to disclosure under Chapter 552,

1 Government Code, or discovery, subpoena, or other means of legal
2 compulsion for release to any person, subject to Section
3 243.054(d); and

4 (2) may not be admitted as evidence or otherwise
5 disclosed in any civil, criminal, or administrative proceeding.

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

11 (c) The transfer of information or materials under this
12 subchapter is not a waiver of a privilege or protection granted
13 under law.

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

25 (e) The provisions of this section regarding the
26 confidentiality of information or materials compiled or reported by
27 an ambulatory surgical center 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. 243.056. ANNUAL DEPARTMENT SUMMARY. The department annually shall compile and make available to the public a summary of the preventable adverse events reported by ambulatory surgical centers as required by Section 243.053. The summary may contain only aggregated information and may not directly or indirectly identify:

(1) a specific ambulatory surgical center or group of centers;

(2) an individual; or

(3) a specific reported preventable adverse event or the circumstances or individuals surrounding the event.

Sec. 243.057. BEST PRACTICES REPORT AND DEPARTMENT SUMMARY. (a) An ambulatory surgical center located in a county with a population of more than 350,000 shall provide to the department at least one report of best practices and safety measures related to a reported preventable adverse event.

(b) An ambulatory surgical center may provide to the department 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) The department by rule may prescribe the form and format of a best practices report. The department may not require a best

1 practices report to exceed one page in length. The department shall
2 accept, in lieu of a report in the form and format prescribed by the
3 department, a copy of a report submitted by an ambulatory surgical
4 center to a patient safety organization.

5 (d) The department periodically shall:

6 (1) review the best practices reports;

7 (2) compile a summary of the best practices reports
8 determined by the department to be effective and recommended as
9 best practices; and

10 (3) make the summary available to the public.

11 (e) The summary may not directly or indirectly identify:

12 (1) a specific ambulatory surgical center or group of
13 centers;

14 (2) an individual; or

15 (3) a specific reported event or the circumstances or
16 individuals surrounding the event.

17 Sec. 243.058. PROHIBITION. The annual report of an
18 ambulatory surgical center, the department summary, or the best
19 practices report may not distinguish between a preventable adverse
20 event that occurred at an outpatient facility owned or operated by
21 the center and a preventable adverse event that occurred at a center
22 facility.

23 Sec. 243.059. REPORT TO LEGISLATURE. (a) Not later than
24 December 1 of each even-numbered year, the commissioner of state
25 health services shall:

26 (1) evaluate the patient safety program established
27 under this subchapter; and

1 (2) report the results of the evaluation and make
2 recommendations to the legislature.

3 (b) The commissioner of state health services shall conduct
4 the evaluation in consultation with ambulatory surgical centers.

5 (c) The evaluation must address:

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

9 (2) the degree to which the statewide summaries of
10 events compiled by the department were accessed by the public;

11 (3) the effectiveness of the department's best
12 practices summary in improving patient care; and

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

16 Sec. 243.060. GIFTS, GRANTS, AND DONATIONS. The department
17 may accept and administer a gift, grant, or donation from any source
18 to carry out the purposes of this subchapter.

19 SECTION 3. (a) Not later than December 1, 2009, the
20 executive commissioner of the Health and Human Services Commission
21 shall adopt the rules necessary to implement the changes in law made
22 by this Act.

23 (b) Not later than January 1, 2010, the Department of State
24 Health Services, using existing resources available to the
25 department, shall establish a patient safety program as required
26 under Subchapter H, Chapter 241, Health and Safety Code, as added by
27 this Act, and under Subchapter B, Chapter 243, Health and Safety

1 Code, as added by this Act.

2 (c) Beginning July 1, 2010, a hospital or ambulatory
3 surgical center on renewal of a license under Chapter 241 or 243,
4 Health and Safety Code, shall submit the annual report required by
5 Section 241.203 or 243.053, Health and Safety Code, as added by this
6 Act.

7 SECTION 4. This Act takes effect September 1, 2009.