

CERTIFICATION OF ENROLLMENT

SUBSTITUTE SENATE BILL 6457

60th Legislature
2008 Regular Session

Passed by the Senate February 14, 2008
YEAS 47 NAYS 0

President of the Senate

Passed by the House March 4, 2008
YEAS 93 NAYS 0

Speaker of the House of Representatives

Approved

Governor of the State of Washington

CERTIFICATE

I, Thomas Hoemann, Secretary of the Senate of the State of Washington, do hereby certify that the attached is **SUBSTITUTE SENATE BILL 6457** as passed by the Senate and the House of Representatives on the dates hereon set forth.

Secretary

FILED

**Secretary of State
State of Washington**

SUBSTITUTE SENATE BILL 6457

Passed Legislature - 2008 Regular Session

State of Washington 60th Legislature 2008 Regular Session

By Senate Health & Long-Term Care (originally sponsored by Senators Keiser and Kohl-Welles; by request of Governor Gregoire)

READ FIRST TIME 02/07/08.

1 AN ACT Relating to the adverse health events and incident reporting
2 system; amending RCW 70.56.020, 70.56.040, and 70.56.050; reenacting
3 and amending RCW 42.56.360 and 42.56.360; providing an effective date;
4 and providing an expiration date.

5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

6 **Sec. 1.** RCW 70.56.020 and 2006 c 8 s 106 are each amended to read
7 as follows:

8 (1) The legislature intends to establish an adverse health events
9 and incident notification and reporting system that is designed to
10 facilitate quality improvement in the health care system, improve
11 patient safety, assist the public in making informed health care
12 choices, and decrease medical errors in a nonpunitive manner. The
13 notification and reporting system shall not be designed to punish
14 errors by health care practitioners or health care facility employees.

15 (2) ~~((Each medical facility shall notify the department of health~~
16 ~~regarding the occurrence of any adverse event and file a subsequent~~
17 ~~report as provided in this section. Notification must be submitted to~~
18 ~~the department within forty eight hours of confirmation by the medical~~
19 ~~facility that an adverse event has occurred. A subsequent report must~~

1 ~~be submitted to the department within forty five days after~~
2 ~~confirmation by the medical facility that an adverse event has~~
3 ~~occurred.)) When a medical facility confirms that an adverse event has
4 occurred, it shall submit to the department of health:~~

5 (a) Notification of the event, with the date, type of adverse
6 event, and any additional contextual information the facility chooses
7 to provide, within forty-eight hours; and

8 (b) A report regarding the event within forty-five days.

9 The notification and report shall be submitted to the department
10 using the internet-based system established under RCW 70.56.040(2). A
11 medical facility may amend the notification or report within sixty days
12 of the submission.

13 (3) The notification and report shall be filed in a format
14 specified by the department after consultation with medical facilities
15 and the independent entity. The format shall identify the facility,
16 but shall not include any identifying information for any of the health
17 care professionals, facility employees, or patients involved. This
18 provision does not modify the duty of a hospital to make a report to
19 the department of health or a disciplinary authority if a licensed
20 practitioner has committed unprofessional conduct as defined in RCW
21 18.130.180.

22 (4) As part of the report filed under subsection (2)(b) of this
23 section, the medical facility must conduct a root cause analysis of the
24 event, describe the corrective action plan that will be implemented
25 consistent with the findings of the analysis, or provide an explanation
26 of any reasons for not taking corrective action. The department shall
27 adopt rules, in consultation with medical facilities and the
28 independent entity, related to the form and content of the root cause
29 analysis and corrective action plan. In developing the rules,
30 consideration shall be given to existing standards for root cause
31 analysis or corrective action plans adopted by the joint commission on
32 accreditation of health facilities and other national or governmental
33 entities.

34 (5) If, in the course of investigating a complaint received from an
35 employee of a medical facility, the department determines that the
36 facility has not (~~reported~~) provided notification of an adverse event
37 or undertaken efforts to investigate the occurrence of an adverse

1 event, the department shall direct the facility to (~~report~~) provide
2 notification or to undertake an investigation of the event.

3 (6) The protections of RCW 43.70.075 apply to (~~reports~~)
4 notifications of adverse events that are submitted in good faith by
5 employees of medical facilities.

6 **Sec. 2.** RCW 70.56.040 and 2006 c 8 s 108 are each amended to read
7 as follows:

8 (1) The department shall contract with a qualified, independent
9 entity to receive notifications and reports of adverse events and
10 incidents, and carry out the activities specified in this section. In
11 establishing qualifications for, and choosing the independent entity,
12 the department shall strongly consider the patient safety organization
13 criteria included in the federal patient safety and quality improvement
14 act of 2005, P.L. 109-41, and any regulations adopted to implement this
15 chapter.

16 (2) The independent entity shall:

17 (a) In collaboration with the department of health, establish an
18 internet-based system for medical facilities and the health care
19 workers of a medical facility to submit notifications and reports of
20 adverse events and incidents, which shall be accessible twenty-four
21 hours a day, seven days a week. The system shall be a portal to report
22 both adverse events and incidents, and notifications and reports of
23 adverse events shall be immediately transmitted to the department. The
24 system shall be a secure system that protects the confidentiality of
25 personal health information and provider and facility specific
26 information submitted in notifications and reports, including
27 appropriate encryption and an accurate means of authenticating the
28 (~~identify [identity]~~) identity of users of the system. When the
29 system becomes operational, medical facilities shall submit all
30 notifications and reports by means of the system;

31 (b) Collect, analyze, and evaluate data regarding notifications and
32 reports of adverse events and incidents, including the identification
33 of performance indicators and patterns in frequency or severity at
34 certain medical facilities or in certain regions of the state;

35 (c) Develop recommendations for changes in health care practices
36 and procedures, which may be instituted for the purpose of reducing the
37 number or severity of adverse events and incidents;

1 (d) Directly advise reporting medical facilities of immediate
2 changes that can be instituted to reduce adverse events or incidents;

3 (e) Issue recommendations to medical facilities on a
4 facility-specific or on a statewide basis regarding changes, trends,
5 and improvements in health care practices and procedures for the
6 purpose of reducing the number and severity of adverse events or
7 incidents. Prior to issuing recommendations, consideration shall be
8 given to the following factors: Expectation of improved quality of
9 care, implementation feasibility, other relevant implementation
10 practices, and the cost impact to patients, payers, and medical
11 facilities. Statewide recommendations shall be issued to medical
12 facilities on a continuing basis and shall be published and posted on
13 a publicly accessible web site. The recommendations made to medical
14 facilities under this section shall not be considered mandatory for
15 licensure purposes unless they are adopted by the department as rules
16 pursuant to chapter 34.05 RCW; and

17 (f) Monitor implementation of reporting systems addressing adverse
18 events or their equivalent in other states and make recommendations to
19 the governor and the legislature as necessary for modifications to this
20 chapter to keep the system as nearly consistent as possible with
21 similar systems in other states.

22 (3)(a) The independent entity shall report no later than January 1,
23 2008, and annually thereafter to the governor and the legislature on
24 the activities under this chapter in the preceding year. The report
25 shall include:

26 ~~((a))~~ (i) The number of adverse events and incidents reported by
27 medical facilities, in the aggregate, on a geographical basis, and
28 ~~((their outcomes))~~ a summary of actions taken by facilities in response
29 to the adverse events or incidents;

30 ~~((b))~~ (ii) In the aggregate, the information derived from the
31 data collected, including any recognized trends concerning patient
32 safety; ~~((and~~

33 ~~((c))~~ (iii) Recommendations for statutory or regulatory changes
34 that may help improve patient safety in the state; and

35 (iv) Information, presented in the aggregate, to inform and educate
36 consumers and providers, on best practices and prevention tools that
37 medical facilities are implementing to prevent adverse events as well

1 as other patient safety initiatives medical facilities are undertaking
2 to promote patient safety.

3 (b) The annual report shall be made available for public inspection
4 and shall be posted on the department's and the independent entity's
5 web site.

6 (4) The independent entity shall conduct all activities under this
7 section in a manner that preserves the confidentiality of facilities,
8 documents, materials, or information made confidential by RCW
9 70.56.050.

10 (5) Medical facilities and health care workers may ~~((report))~~
11 provide notification of incidents to the independent entity. The
12 ~~((report))~~ notification shall be filed in a format specified by the
13 independent entity, after consultation with the department and medical
14 facilities, and shall identify the facility but shall not include any
15 identifying information for any of the health care professionals,
16 facility employees, or patients involved. This provision does not
17 modify the duty of a hospital to make a report to the department or a
18 disciplinary authority if a licensed practitioner has committed
19 unprofessional conduct as defined in RCW 18.130.180. The protections
20 of RCW 43.70.075 apply to ~~((reports))~~ notifications of incidents that
21 are submitted in good faith by employees of medical facilities.

22 **Sec. 3.** RCW 70.56.050 and 2006 c 8 s 110 are each amended to read
23 as follows:

24 (1)(a) When ~~((a notification or report of an adverse event or~~
25 ~~incident under RCW 70.56.020 or 70.56.040))~~ notification of an adverse
26 event under RCW 70.56.020(2)(a) or of an incident under RCW
27 70.56.040(5), or a report regarding an adverse event under RCW
28 70.56.020(2)(b) is made by or through a coordinated quality improvement
29 program under RCW 43.70.510 or 70.41.200, or by a peer review committee
30 under RCW 4.24.250, information and documents, including complaints and
31 incident reports, created specifically for and collected and maintained
32 by a quality improvement committee for the purpose of preparing a
33 notification ~~((or report))~~ of an adverse event or incident~~((, and))~~ or
34 a report regarding an adverse event, the ~~((notification or))~~ report
35 itself, and the notification of an incident, shall be subject to the
36 confidentiality protections of those laws and RCW ~~((42.17.310(1)(hh)~~
37 ~~and))~~ 42.56.360(1)(c).

1 (b) The notification of an adverse event under RCW 70.56.020(2)(a),
2 shall be subject to public disclosure and not exempt from disclosure
3 under chapter 42.56 RCW. Any public disclosure of an adverse event
4 notification must include any contextual information the medical
5 facility chose to provide under RCW 70.56.020(2)(a).

6 (2)(a) When (~~a notification or report of an adverse event or~~
7 ~~incident made by a health care worker under RCW 70.56.020 or~~
8 ~~70.56.040~~) notification of an adverse event under RCW 70.56.020(2)(a)
9 or of an incident under RCW 70.56.040(5), or a report regarding an
10 adverse event under RCW 70.56.020(2)(b), made by a health care worker
11 uses information and documents, including complaints and incident
12 reports, created specifically for and collected and maintained by a
13 quality improvement committee under RCW 43.70.510 or 70.41.200 or a
14 peer review committee under RCW 4.24.250, (~~the~~) a notification (~~or~~)
15 of an incident, the report itself, and the information or documents
16 used for the purpose of preparing (~~the~~) notifications or the report,
17 shall be subject to the confidentiality protections of those laws and
18 RCW (~~42.17.310(1)(hh) and~~) 42.56.360(1)(c).

19 (b) The notification of an adverse event under RCW 70.56.020(2)(a)
20 shall be subject to public disclosure and not exempt from disclosure
21 under chapter 42.56 RCW. Any public disclosure of an adverse event
22 notification must include any contextual information the medical
23 facility chose to provide under RCW 70.56.020(2)(a).

24 **Sec. 4.** RCW 42.56.360 and 2007 c 261 s 4 and 2007 c 259 s 49 are
25 each reenacted and amended to read as follows:

26 (1) The following health care information is exempt from disclosure
27 under this chapter:

28 (a) Information obtained by the board of pharmacy as provided in
29 RCW 69.45.090;

30 (b) Information obtained by the board of pharmacy or the department
31 of health and its representatives as provided in RCW 69.41.044,
32 69.41.280, and 18.64.420;

33 (c) Information and documents created specifically for, and
34 collected and maintained by a quality improvement committee under RCW
35 43.70.510 or 70.41.200, or by a peer review committee under RCW
36 4.24.250, or by a quality assurance committee pursuant to RCW 74.42.640
37 or 18.20.390, or by a hospital, as defined in RCW 43.70.056, for

1 reporting of health care-associated infections under RCW 43.70.056,
2 (~~and notifications or reports of adverse events or incidents made~~
3 ~~under RCW 70.56.020 or 70.56.040,~~) a notification of an incident under
4 RCW 70.56.040(5), and reports regarding adverse events under RCW
5 70.56.020(2)(b), regardless of which agency is in possession of the
6 information and documents;

7 (d)(i) Proprietary financial and commercial information that the
8 submitting entity, with review by the department of health,
9 specifically identifies at the time it is submitted and that is
10 provided to or obtained by the department of health in connection with
11 an application for, or the supervision of, an antitrust exemption
12 sought by the submitting entity under RCW 43.72.310;

13 (ii) If a request for such information is received, the submitting
14 entity must be notified of the request. Within ten business days of
15 receipt of the notice, the submitting entity shall provide a written
16 statement of the continuing need for confidentiality, which shall be
17 provided to the requester. Upon receipt of such notice, the department
18 of health shall continue to treat information designated under this
19 subsection (1)(d) as exempt from disclosure;

20 (iii) If the requester initiates an action to compel disclosure
21 under this chapter, the submitting entity must be joined as a party to
22 demonstrate the continuing need for confidentiality;

23 (e) Records of the entity obtained in an action under RCW 18.71.300
24 through 18.71.340;

25 (f) Except for published statistical compilations and reports
26 relating to the infant mortality review studies that do not identify
27 individual cases and sources of information, any records or documents
28 obtained, prepared, or maintained by the local health department for
29 the purposes of an infant mortality review conducted by the department
30 of health under RCW 70.05.170;

31 (g) Complaints filed under chapter 18.130 RCW after July 27, 1997,
32 to the extent provided in RCW 18.130.095(1); and

33 (h) Information obtained by the department of health under chapter
34 70.225 RCW.

35 (2) Chapter 70.02 RCW applies to public inspection and copying of
36 health care information of patients.

1 **Sec. 5.** RCW 42.56.360 and 2007 c 273 s 25, 2007 c 261 s 4, and
2 2007 c 259 s 49 are each reenacted and amended to read as follows:

3 (1) The following health care information is exempt from disclosure
4 under this chapter:

5 (a) Information obtained by the board of pharmacy as provided in
6 RCW 69.45.090;

7 (b) Information obtained by the board of pharmacy or the department
8 of health and its representatives as provided in RCW 69.41.044,
9 69.41.280, and 18.64.420;

10 (c) Information and documents created specifically for, and
11 collected and maintained by a quality improvement committee under RCW
12 43.70.510, 70.230.080, or 70.41.200, or by a peer review committee
13 under RCW 4.24.250, or by a quality assurance committee pursuant to RCW
14 74.42.640 or 18.20.390, or by a hospital, as defined in RCW 43.70.056,
15 for reporting of health care-associated infections under RCW 43.70.056,
16 (~~and notifications or reports of adverse events or incidents made~~
17 ~~under RCW 70.56.020 or 70.56.040,~~) a notification of an incident under
18 RCW 70.56.040(5), and reports regarding adverse events under RCW
19 70.56.020(2)(b), regardless of which agency is in possession of the
20 information and documents;

21 (d)(i) Proprietary financial and commercial information that the
22 submitting entity, with review by the department of health,
23 specifically identifies at the time it is submitted and that is
24 provided to or obtained by the department of health in connection with
25 an application for, or the supervision of, an antitrust exemption
26 sought by the submitting entity under RCW 43.72.310;

27 (ii) If a request for such information is received, the submitting
28 entity must be notified of the request. Within ten business days of
29 receipt of the notice, the submitting entity shall provide a written
30 statement of the continuing need for confidentiality, which shall be
31 provided to the requester. Upon receipt of such notice, the department
32 of health shall continue to treat information designated under this
33 subsection (1)(d) as exempt from disclosure;

34 (iii) If the requester initiates an action to compel disclosure
35 under this chapter, the submitting entity must be joined as a party to
36 demonstrate the continuing need for confidentiality;

37 (e) Records of the entity obtained in an action under RCW 18.71.300
38 through 18.71.340;

1 (f) Except for published statistical compilations and reports
2 relating to the infant mortality review studies that do not identify
3 individual cases and sources of information, any records or documents
4 obtained, prepared, or maintained by the local health department for
5 the purposes of an infant mortality review conducted by the department
6 of health under RCW 70.05.170;

7 (g) Complaints filed under chapter 18.130 RCW after July 27, 1997,
8 to the extent provided in RCW 18.130.095(1); and

9 (h) Information obtained by the department of health under chapter
10 70.225 RCW.

11 (2) Chapter 70.02 RCW applies to public inspection and copying of
12 health care information of patients.

13 NEW SECTION. **Sec. 6.** Section 4 of this act expires July 1, 2009.

14 NEW SECTION. **Sec. 7.** Section 5 of this act takes effect July 1,
15 2009.

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