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SENATE BILL 6457

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State of Washington

60th Legislature

2008 Regular Session

By Senators Keiser and Kohl-Welles; by request of Governor Gregoire

Read first time 01/16/08. Referred to Committee on Health & Long-Term Care.

1 AN ACT Relating to the adverse health events and incident reporting  
2 system; amending RCW 70.56.010, 70.56.010, 70.56.020, 70.56.030,  
3 70.56.040, and 70.56.050; reenacting and amending RCW 42.56.360 and  
4 42.56.360; providing an effective date; and providing an expiration  
5 date.

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

7 **Sec. 1.** RCW 70.56.010 and 2006 c 8 s 105 are each amended to read  
8 as follows:

9 The definitions in this section apply throughout this chapter  
10 unless the context clearly requires otherwise.

11 (1) "Adverse health event" or "adverse event" means the list of  
12 serious reportable events adopted by the national quality forum in  
13 2002, in its consensus report on serious reportable events in health  
14 care. The department shall update the list, through adoption of rules,  
15 as subsequent changes are made by the national quality forum. The term  
16 does not include an incident.

17 (2) "Ambulatory surgical facility" means any distinct entity that  
18 operates exclusively for the purpose of providing surgical services to

1 patients not requiring hospitalization, whether or not the facility is  
2 certified under Title XVIII of the federal social security act.

3 (3) "Childbirth center" means a facility licensed under chapter  
4 18.46 RCW.

5 (4) "Correctional medical facility" means a part or unit of a  
6 correctional facility operated by the department of corrections under  
7 chapter 72.10 RCW that provides medical services for lengths of stay in  
8 excess of twenty-four hours to offenders.

9 (5) "Department" means the department of health.

10 (6) "Health care worker" means an employee, independent contractor,  
11 licensee, or other individual who is directly involved in the delivery  
12 of health services in a medical facility.

13 (7) "Hospital" means a facility licensed under chapter 70.41 RCW.

14 (8) "Incident" means an event, occurrence, or situation involving  
15 the clinical care of a patient in a medical facility that:

16 (a) Results in unanticipated serious injury to a patient that is  
17 not related to the natural course of the patient's illness or  
18 underlying condition and does not constitute an adverse event; or

19 (b) Could have injured the patient but did not either cause an  
20 unanticipated injury or require the delivery of additional health care  
21 services to the patient.

22 "Incident" does not include an adverse event.

23 (9) "Independent entity" means that entity that the department of  
24 health contracts with under RCW 70.56.040 to receive notifications and  
25 reports of adverse events and incidents, and carry out the activities  
26 specified in RCW 70.56.040.

27 (10) "Medical facility" means a childbirth center, hospital,  
28 psychiatric hospital, or correctional medical facility. An ambulatory  
29 surgical facility shall be considered a medical facility for purposes  
30 of this chapter upon the effective date of any requirement for state  
31 registration or licensure of ambulatory surgical facilities.

32 (11) "Psychiatric hospital" means a hospital facility licensed as  
33 a psychiatric hospital under chapter 71.12 RCW.

34 **Sec. 2.** RCW 70.56.010 and 2007 c 273 s 20 are each amended to read  
35 as follows:

36 The definitions in this section apply throughout this chapter  
37 unless the context clearly requires otherwise.

1 (1) "Adverse health event" or "adverse event" means the list of  
2 serious reportable events adopted by the national quality forum in  
3 2002, in its consensus report on serious reportable events in health  
4 care. The department shall update the list, through adoption of rules,  
5 as subsequent changes are made by the national quality forum. The term  
6 does not include an incident.

7 (2) "Ambulatory surgical facility" means a facility licensed under  
8 chapter 70.230 RCW.

9 (3) "Childbirth center" means a facility licensed under chapter  
10 18.46 RCW.

11 (4) "Correctional medical facility" means a part or unit of a  
12 correctional facility operated by the department of corrections under  
13 chapter 72.10 RCW that provides medical services for lengths of stay in  
14 excess of twenty-four hours to offenders.

15 (5) "Department" means the department of health.

16 (6) "Health care worker" means an employee, independent contractor,  
17 licensee, or other individual who is directly involved in the delivery  
18 of health services in a medical facility.

19 (7) "Hospital" means a facility licensed under chapter 70.41 RCW.

20 (8) "Incident" means an event, occurrence, or situation involving  
21 the clinical care of a patient in a medical facility that:

22 (a) Results in unanticipated serious injury to a patient that is  
23 not related to the natural course of the patient's illness or  
24 underlying condition and does not constitute an adverse event; or

25 (b) Could have injured the patient but did not either cause an  
26 unanticipated injury or require the delivery of additional health care  
27 services to the patient.

28 "Incident" does not include an adverse event.

29 (9) "Independent entity" means that entity that the department of  
30 health contracts with under RCW 70.56.040 to receive notifications and  
31 reports of adverse events and incidents, and carry out the activities  
32 specified in RCW 70.56.040.

33 (10) "Medical facility" means a childbirth center, hospital,  
34 psychiatric hospital, or correctional medical facility. An ambulatory  
35 surgical facility shall be considered a medical facility for purposes  
36 of this chapter upon the effective date of any requirement for state  
37 registration or licensure of ambulatory surgical facilities.

1 (11) "Psychiatric hospital" means a hospital facility licensed as  
2 a psychiatric hospital under chapter 71.12 RCW.

3 **Sec. 3.** RCW 70.56.020 and 2006 c 8 s 106 are each amended to read  
4 as follows:

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

12 ~~(2) ((Each medical facility shall notify the department of health~~  
13 ~~regarding the occurrence of any adverse event and file a subsequent~~  
14 ~~report as provided in this section. Notification must be submitted to~~  
15 ~~the department within forty-eight hours of confirmation by the medical~~  
16 ~~facility that an adverse event has occurred. A subsequent report must~~  
17 ~~be submitted to the department within forty-five days after~~  
18 ~~confirmation by the medical facility that an adverse event has~~  
19 ~~occurred.))~~ When a medical facility confirms that an adverse event has  
20 occurred, it shall submit to the department of health:

- 21 (a) Notification of the event within forty-eight hours; and
- 22 (b) A report regarding the event within forty-five days.

23 The notification and report shall be submitted to the department  
24 using the internet-based system established under RCW 70.56.040(2).

25 (3) The notification and report shall be filed in a format  
26 specified by the department after consultation with medical facilities  
27 and the independent entity. The format shall identify the facility,  
28 but shall not include any identifying information for any of the health  
29 care professionals, facility employees, or patients involved. This  
30 provision does not modify the duty of a hospital to make a report to  
31 the department of health or a disciplinary authority if a licensed  
32 practitioner has committed unprofessional conduct as defined in RCW  
33 18.130.180.

34 (4) As part of the report filed under subsection (2)(b) of this  
35 section, the medical facility must conduct a root cause analysis of the  
36 event, describe the corrective action plan that will be implemented  
37 consistent with the findings of the analysis, or provide an explanation

1 of any reasons for not taking corrective action. The department shall  
2 adopt rules, in consultation with medical facilities and the  
3 independent entity, related to the form and content of the root cause  
4 analysis and corrective action plan. In developing the rules,  
5 consideration shall be given to existing standards for root cause  
6 analysis or corrective action plans adopted by the joint commission on  
7 accreditation of health facilities and other national or governmental  
8 entities.

9 (5) If, in the course of investigating a complaint received from an  
10 employee of a medical facility, the department determines that the  
11 facility has not (~~reported~~) provided notification of an adverse event  
12 or undertaken efforts to investigate the occurrence of an adverse  
13 event, the department shall direct the facility to (~~report~~) provide  
14 notification or to undertake an investigation of the event.

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

18 **Sec. 4.** RCW 70.56.030 and 2007 c 259 s 13 are each amended to read  
19 as follows:

20 (1) The department shall:

21 (a) Receive and investigate, where necessary, notifications and  
22 reports of adverse events, including root cause analyses and corrective  
23 action plans submitted as part of reports, and communicate to  
24 individual facilities the department's conclusions, if any, regarding  
25 an adverse event reported by a facility;

26 (b) Provide to the Washington state quality forum established in  
27 RCW 41.05.029 such information from the adverse (~~health events and~~  
28 ~~incidents reports made under this chapter~~) events notifications under  
29 RCW 70.56.020(2)(a), the adverse events reports under RCW  
30 70.56.020(2)(b), and the incidents notifications under RCW 70.56.040(5)  
31 as the department and the Washington state quality forum determine will  
32 assist in the Washington state quality forum's research regarding  
33 health care quality, evidence-based medicine, and patient safety.  
34 (~~Any~~) Shared information (~~must be aggregated and not~~) shall  
35 identify an individual medical facility. As determined by the  
36 department and the Washington state quality forum, selected shared

1 information, otherwise subject to public disclosure, may be  
2 disseminated on the Washington state quality forum's web site and  
3 through other appropriate means; ~~((and))~~

4 (c) Make available to the public the notifications of adverse  
5 events under RCW 70.56.020(2)(a) and notifications of incidents as  
6 defined in RCW 70.56.010(8)(a) under RCW 70.56.040(5); and

7 (d) Adopt rules as necessary to implement this chapter.

8 (2) The department may enforce the notification and reporting  
9 requirements of RCW 70.56.020 using its existing enforcement authority  
10 provided in chapter 18.46 RCW for childbirth centers, chapter 70.41 RCW  
11 for hospitals, and chapter 71.12 RCW for psychiatric hospitals.

12 **Sec. 5.** RCW 70.56.040 and 2006 c 8 s 108 are each amended to read  
13 as follows:

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

22 (2) The independent entity shall:

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

35 (b) Collect, analyze, and evaluate data regarding notifications and  
36 reports of adverse events and incidents, including the identification

1 of performance indicators and patterns in frequency or severity at  
2 certain medical facilities or in certain regions of the state;

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

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

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

22 (f) Monitor implementation of reporting systems addressing adverse  
23 events or their equivalent in other states and make recommendations to  
24 the governor and the legislature as necessary for modifications to this  
25 chapter to keep the system as nearly consistent as possible with  
26 similar systems in other states.

27 (3) The independent entity shall report no later than January 1,  
28 2008, and annually thereafter to the governor and the legislature on  
29 the activities under this chapter in the preceding year. The report  
30 shall include:

31 (a) The number of adverse events and incidents reported by medical  
32 facilities ~~((on a geographical basis))~~ and their outcomes. For each  
33 facility, the report shall identify the date of each occurrence of an  
34 adverse event or incident, as defined in RCW 70.56.010(8)(a), the type  
35 of adverse event or incident, as defined in RCW 70.56.010(8)(a), and  
36 other information as determined by the department to be relevant to  
37 establish context for consumers of health care. Such information may

1 include relevant descriptive information about the number and acuity  
2 level of patients at the medical facility and the medical facility's  
3 efforts to discover and prevent similar adverse events and incidents;

4 (b) The information derived from the data collected, including any  
5 recognized trends concerning patient safety; and

6 (c) Recommendations for statutory or regulatory changes that may  
7 help improve patient safety in the state.

8 The annual report shall be made available for public inspection and  
9 shall be posted on the department's and the independent entity's web  
10 site.

11 (4) The independent entity shall conduct all activities under this  
12 section in a manner that preserves the confidentiality of facilities,  
13 documents, materials, or information made confidential by RCW  
14 70.56.050.

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

27 **Sec. 6.** RCW 70.56.050 and 2006 c 8 s 110 are each amended to read  
28 as follows:

29 (1) When (~~a notification or report of an adverse event or incident~~  
30 ~~under RCW 70.56.020 or 70.56.040~~) notification of an adverse event  
31 under RCW 70.56.020(2)(a) or of an incident under RCW 70.56.040(5), or  
32 a report regarding an adverse event under RCW 70.56.020(2)(b) is made  
33 by or through a coordinated quality improvement program under RCW  
34 43.70.510 or 70.41.200, or by a peer review committee under RCW  
35 4.24.250, information and documents, including complaints and incident  
36 reports, created specifically for and collected and maintained by a  
37 quality improvement committee for the purpose of preparing a



1 notification (~~or report~~) of an adverse event or incident, (~~and~~) or  
2 a report regarding an adverse event, the (~~notification or~~) report  
3 itself, and the notification of an incident, as defined in RCW  
4 70.56.010(8)(b), shall be subject to the confidentiality protections of  
5 those laws and RCW (~~(42.17.310(1)(hh) and~~) 42.56.360(1)(c). The  
6 notification of an adverse event or an incident, as defined in RCW  
7 70.56.010(8)(a), shall be subject to public disclosure and not exempt  
8 from disclosure under chapter 42.56 RCW.

9 (2) When (~~a notification or report of an adverse event or incident~~  
10 ~~made by a health care worker under RCW 70.56.020 or 70.56.040~~)  
11 notification of an adverse event under RCW 70.56.020(2)(a) or of an  
12 incident under RCW 70.56.040(5), or a report regarding an adverse event  
13 under RCW 70.56.020(2)(b), made by a health care worker uses  
14 information and documents, including complaints and incident reports,  
15 created specifically for and collected and maintained by a quality  
16 improvement committee under RCW 43.70.510 or 70.41.200 or a peer review  
17 committee under RCW 4.24.250, (~~the~~) a notification (~~or~~) of an  
18 incident, as defined in RCW 70.56.010(8)(b), the report itself, and the  
19 information or documents used for the purpose of preparing (~~the~~)  
20 notifications or the report, shall be subject to the confidentiality  
21 protections of those laws and RCW (~~(42.17.310(1)(hh) and~~)  
22 42.56.360(1)(c). The notification of an adverse event or an incident,  
23 as defined in RCW 70.56.010(8)(a), shall be subject to public  
24 disclosure and not exempt from disclosure under chapter 42.56 RCW.

25 (3) Nothing in this section precludes the disclosure of information  
26 specified in RCW 70.56.040(3).

27 **Sec. 7.** RCW 42.56.360 and 2007 c 261 s 4 and 2007 c 259 s 49 are  
28 each reenacted and amended to read as follows:

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

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

33 (b) Information obtained by the board of pharmacy or the department  
34 of health and its representatives as provided in RCW 69.41.044,  
35 69.41.280, and 18.64.420;

36 (c) Information and documents created specifically for, and  
37 collected and maintained by a quality improvement committee under RCW

1 43.70.510 or 70.41.200, or by a peer review committee under RCW  
2 4.24.250, or by a quality assurance committee pursuant to RCW 74.42.640  
3 or 18.20.390, or by a hospital, as defined in RCW 43.70.056, for  
4 reporting of health care-associated infections under RCW 43.70.056,  
5 (~~and notifications or reports of adverse events or incidents made~~  
6 ~~under RCW 70.56.020 or 70.56.040,~~) a notification of an incident, as  
7 defined in RCW 70.56.010(8)(b), and reports regarding adverse events  
8 under RCW 70.56.020(2)(b), regardless of which agency is in possession  
9 of the information and documents;

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

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

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

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

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

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

36 (h) Information obtained by the department of health under chapter  
37 70.225 RCW.

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

3 **Sec. 8.** RCW 42.56.360 and 2007 c 273 s 25, 2007 c 261 s 4, and  
4 2007 c 259 s 49 are each reenacted and amended to read as follows:

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

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

9 (b) Information obtained by the board of pharmacy or the department  
10 of health and its representatives as provided in RCW 69.41.044,  
11 69.41.280, and 18.64.420;

12 (c) Information and documents created specifically for, and  
13 collected and maintained by a quality improvement committee under RCW  
14 43.70.510, 70.230.080, or 70.41.200, or by a peer review committee  
15 under RCW 4.24.250, or by a quality assurance committee pursuant to RCW  
16 74.42.640 or 18.20.390, or by a hospital, as defined in RCW 43.70.056,  
17 for reporting of health care-associated infections under RCW 43.70.056,  
18 (~~and notifications or reports of adverse events or incidents made~~  
19 ~~under RCW 70.56.020 or 70.56.040,)) a notification of an incident, as  
20 defined in RCW 70.56.010(8)(b), and reports regarding adverse events  
21 under RCW 70.56.020(2)(b), regardless of which agency is in possession  
22 of the information and documents;~~

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

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

36 (iii) If the requester initiates an action to compel disclosure

1 under this chapter, the submitting entity must be joined as a party to  
2 demonstrate the continuing need for confidentiality;

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

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

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

13 (h) Information obtained by the department of health under chapter  
14 70.225 RCW.

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

17 NEW SECTION. **Sec. 9.** Sections 1 and 7 of this act expire July 1,  
18 2009.

19 NEW SECTION. **Sec. 10.** Sections 2 and 8 of this act take effect  
20 July 1, 2009.

--- END ---