HOUSE BILL 2670

State of Washington 60th Legislature 2008 Regular Session

By Representatives Campbell, Hunt, and Kenney; by request of Governor Gregoire

Read first time 01/15/08. Referred to Committee on Health Care & Wellness.

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

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

(2) "Ambulatory surgical facility" means any distinct entity thatoperates exclusively for the purpose of providing surgical services to

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

3 (3) "Childbirth center" means a facility licensed under chapter4 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 involving15 the clinical care of a patient in a medical facility that:

16 (a) Results in unanticipated <u>serious</u> 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

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

22 "Incident" does not include an adverse event.

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

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

32 (11) "Psychiatric hospital" means a hospital facility licensed as33 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 under8 chapter 70.230 RCW.

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

(4) "Correctional medical facility" means a part or unit of a correctional facility operated by the department of corrections under chapter 72.10 RCW that provides medical services for lengths of stay in 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.

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

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

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

28

"Incident" does not include an adverse event.

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

(10) "Medical facility" means a childbirth center, hospital, psychiatric hospital, or correctional medical facility. An ambulatory surgical facility shall be considered a medical facility for purposes of this chapter upon the effective date of any requirement for state registration or licensure of ambulatory surgical facilities. (11) "Psychiatric hospital" means a hospital facility licensed as
 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:

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

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

(a) Notification of the event within forty-eight hours; and

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

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

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

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

21

22

of any reasons for not taking corrective action. The department shall 1 2 adopt rules, in consultation with medical facilities and the independent entity, related to the form and content of the root cause 3 analysis and corrective action plan. In developing the rules, 4 5 consideration shall be given to existing standards for root cause analysis or corrective action plans adopted by the joint commission on 6 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 <u>notifications</u> 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:

(a) Receive and investigate, where necessary, notifications and reports of adverse events, including root cause analyses and corrective action plans submitted as part of reports, and communicate to individual facilities the department's conclusions, if any, regarding 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 incidents reports made under this chapter)) events notifications under 28 29 RCW 70.56.020(2)(a), the adverse events reports under RCW 70.56.020(2)(b), and the incidents notifications under RCW 70.56.040(5) 30 31 as the department and the Washington state quality forum determine will assist in the Washington state quality forum's research regarding 32 health care quality, evidence-based medicine, and patient safety. 33 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

p. 5

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

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

7

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

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

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

(1) The department shall contract with a qualified, independent 14 entity to receive notifications and reports of adverse events and 15 16 incidents, and carry out the activities specified in this section. In establishing qualifications for, and choosing the independent entity, 17 the department shall strongly consider the patient safety organization 18 criteria included in the federal patient safety and quality improvement 19 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 internet-based system for medical facilities and the health care 24 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 both adverse events and incidents, and notifications and reports of 28 adverse events shall be immediately transmitted to the department. The 29 system shall be a secure system that protects the confidentiality of 30 31 personal health information and provider and facility specific 32 information submitted in notifications and reports, including appropriate encryption and an accurate means of authenticating the 33 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

of performance indicators and patterns in frequency or severity at
 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;

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

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

(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:

(a) The number of adverse events and incidents reported by medical facilities ((on a geographical basis)) and their outcomes. For each facility, the report shall identify the date of each occurrence of an adverse event or incident, as defined in RCW 70.56.010(8)(a), the type of adverse event or incident, as defined in RCW 70.56.010(8)(a), and other information as determined by the department to be relevant to establish context for consumers of health care. Such information may 1 <u>include relevant descriptive information about the number and acuity</u>
2 <u>level of patients at the medical facility and the medical facility's</u>
3 <u>efforts to discover and prevent similar adverse events and incidents;</u>

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.

(5) Medical facilities and health care workers may ((report)) 15 provide notification of incidents to the independent entity. 16 The ((report)) notification shall be filed in a format specified by the 17 independent entity, after consultation with the department and medical 18 facilities, and shall identify the facility but shall not include any 19 identifying information for any of the health care professionals, 20 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 are submitted in good faith by employees of medical facilities. 26

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

p. 8

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

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)) notification of an adverse event under RCW 70.56.020(2)(a) or of an 11 incident under RCW 70.56.040(5), or a report regarding an adverse event 12 13 under RCW 70.56.020(2)(b), made by a health care worker uses 14 information and documents, including complaints and incident reports, created specifically for and collected and maintained by a quality 15 improvement committee under RCW 43.70.510 or 70.41.200 or a peer review 16 17 committee under RCW 4.24.250, ((the)) a notification ((or)) of an incident, as defined in RCW 70.56.010(8)(b), the report itself, and the 18 information or documents used for the purpose of preparing ((the)) 19 notifications or the report, shall be subject to the confidentiality 20 21 of those laws and RCW ((42.17.310(1)(hh) and)) protections 22 42.56.360(1)(c). The notification of an adverse event or an incident, as defined in RCW 70.56.010(8)(a), shall be subject to public 23 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

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

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

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

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

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

(f) Except for published statistical compilations and reports relating to the infant mortality review studies that do not identify individual cases and sources of information, any records or documents obtained, prepared, or maintained by the local health department for the purposes of an infant mortality review conducted by the department 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 chapter37 70.225 RCW.

(2) Chapter 70.02 RCW applies to public inspection and copying of
 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 disclosure6 under this chapter:

7 (a) Information obtained by the board of pharmacy as provided in8 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 collected and maintained by a quality improvement committee under RCW 13 43.70.510, 70.230.080, or 70.41.200, or by a peer review committee 14 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, ((and notifications or reports of adverse events or incidents made 18 under RCW 70.56.020 or 70.56.040,)) a notification of an incident, as 19 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 of the information and documents; 22

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

(ii) If a request for such information is received, the submitting entity must be notified of the request. Within ten business days of receipt of the notice, the submitting entity shall provide a written statement of the continuing need for confidentiality, which shall be provided to the requester. Upon receipt of such notice, the department of health shall continue to treat information designated under this 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;

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

(h) Information obtained by the department of health under chapter70.225 RCW.

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

17 <u>NEW SECTION.</u> Sec. 9. Sections 1 and 7 of this act expire July 1, 18 2009.

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

--- END ---