Chapter 70.56 RCW ADVERSE HEALTH EVENTS AND INCIDENT REPORTING SYSTEM

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- RCW 70.56.010 Definitions. The definitions in this section apply throughout this chapter 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 a facility licensed under chapter 70.230 RCW.
- (3) "Childbirth center" means a facility licensed under chapter 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.
 - (5) "Department" means the department of health.
- (6) "Health care worker" means an employee, independent contractor, licensee, or other individual who is directly involved in the delivery of health services in a medical facility.
 - (7) "Hospital" means a facility licensed under chapter 70.41 RCW.
- (8) "Incident" means an event, occurrence, or situation involving the clinical care of a patient in a medical facility that:
- (a) Results in unanticipated 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.
 - "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. [2007 c 273 § 20; 2006 c 8 § 105.]

Effective date—Implementation—2007 c 273: See RCW 70.230.900 and 70.230.901.

RCW 70.56.020 Notification of adverse health events— Notification and report required—Rules. (1) The legislature intends to establish an adverse health events and incident notification and reporting system that is designed to facilitate quality improvement in the health care system, improve patient safety, assist the public in making informed health care choices, and decrease medical errors in a nonpunitive manner. The notification and reporting system shall not be designed to punish errors by health care practitioners or health care facility employees.

- (2) When a medical facility confirms that an adverse event has occurred, it shall submit to the department of health:
- (a) Notification of the event, with the date, type of adverse event, and any additional contextual information the facility chooses to provide, 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) if the system is operational.

- (c) A medical facility may amend the notification or report within sixty days of the submission.
- (3) The notification and report shall be filed in a format specified by the department after consultation with medical facilities and the independent entity if an independent entity has been contracted for under RCW 70.56.040(1). The format shall identify the facility, but shall not include any identifying information for any of the health care professionals, facility employees, or patients involved. This provision does not modify the duty of a hospital to make a report to the department of health or a disciplinary authority if a licensed practitioner has committed unprofessional conduct as defined in RCW 18.130.180.
- (4) As part of the report filed under subsection (2)(b) of 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 of any reasons for not taking corrective action. The department shall adopt rules, in consultation with medical facilities and the independent entity if an independent entity has been contracted for under RCW 70.56.040(1), related to the form and content of the root cause analysis and corrective action plan. In developing the rules, consideration shall be given to existing standards for root cause analysis or corrective action plans adopted by the joint commission on accreditation of health facilities and other national or governmental entities.
- (5) If, in the course of investigating a complaint received from an employee of a medical facility, the department determines that the facility has not provided notification of an adverse event or

undertaken efforts to investigate the occurrence of an adverse event, the department shall direct the facility to provide notification or to undertake an investigation of the event.

(6) The protections of RCW 43.70.075 apply to notifications of adverse events that are submitted in good faith by employees of medical facilities. [2009 c 495 § 12; 2008 c 136 § 1; 2006 c 8 § 106.1

Effective date—2009 c 495: See note following RCW 43.20.050.

RCW 70.56.030 Department of health—Duties—Rules. (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; and
 - (b) Adopt rules as necessary to implement this chapter.
- (2) The department may enforce the reporting requirements of RCW 70.56.020 using its existing enforcement authority provided in chapter 18.46 RCW for childbirth centers, chapter 70.41 RCW for hospitals, and chapter 71.12 RCW for psychiatric hospitals. [2009 c 495 § 13; 2009 c 488 § 1; 2007 c 259 § 13; 2006 c 8 § 107.]

Reviser's note: This section was amended by 2009 c 488 § 1 and by 2009 c 495 § 13, each without reference to the other. Both amendments are incorporated in the publication of this section under RCW 1.12.025(2). For rule of construction, see RCW 1.12.025(1).

Effective date—2009 c 495: See note following RCW 43.20.050.

Subheadings not law—2007 c 259: See note following RCW 7.70.060.

- RCW 70.56.040 Contract with independent entity—Duties of independent entity—Establishment of notification and reporting system —Annual reports to governor, legislature. (1) To the extent funds are appropriated specifically for this purpose, the department shall contract with a qualified, independent entity to receive notifications and reports of adverse events and incidents, and carry out the activities specified in this section. In establishing qualifications for, and choosing the independent entity, the department shall strongly consider the patient safety organization criteria included in the federal patient safety and quality improvement act of 2005, P.L. 109-41, and any regulations adopted to implement this chapter.
- (2) If an independent entity is contracted for under subsection (1) of this section, the independent entity shall:
- (a) In collaboration with the department of health, establish an internet-based system for medical facilities and the health care workers of a medical facility to submit notifications and reports of adverse events and incidents, which shall be accessible twenty-four 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 adverse events shall be immediately transmitted to the department. The system shall be a secure system that protects the confidentiality of

personal health information and provider and facility specific information submitted in notifications and reports, including appropriate encryption and an accurate means of authenticating the identity of users of the system. When the system becomes operational, medical facilities shall submit all notifications and reports by means of the system;

- (b) Collect, analyze, and evaluate data regarding notifications and 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:
- (c) Develop recommendations for changes in health care practices and procedures, which may be instituted for the purpose of reducing the number or severity of adverse events and incidents;
- (d) Directly advise reporting medical facilities of immediate changes that can be instituted to reduce adverse events or incidents;
- (e) Issue recommendations to medical facilities on a facility-specific or on a statewide basis regarding changes, trends, and improvements in health care practices and procedures for the purpose of reducing the number and severity of adverse events or incidents. Prior to issuing recommendations, consideration shall be given to the following factors: Expectation of improved quality of care, implementation feasibility, other relevant implementation practices, and the cost impact to patients, payers, and medical facilities. Statewide recommendations shall be issued to medical facilities on a continuing basis and shall be published and posted on a publicly accessible website. The recommendations made to medical facilities under this section shall not be considered mandatory for licensure purposes unless they are adopted by the department as rules 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) (a) The independent entity shall report no later than January 1, 2008, and annually thereafter in any year that an independent entity is contracted for under subsection (1) of this section to the governor and the legislature on the activities under this chapter in the preceding year. The report shall include:
- (i) The number of adverse events and incidents reported by medical facilities, in the aggregate, on a geographical basis, and a summary of actions taken by facilities in response to the adverse events or incidents;
- (ii) In the aggregate, the information derived from the data collected, including any recognized trends concerning patient safety;
- (iii) Recommendations for statutory or regulatory changes that may help improve patient safety in the state; and
- (iv) Information, presented in the aggregate, to inform and educate consumers and providers, on best practices and prevention tools that medical facilities are implementing to prevent adverse events as well as other patient safety initiatives medical facilities are undertaking to promote patient safety.
- (b) The annual report shall be made available for public inspection and shall be posted on the department's and the independent entity's website.

- (4) The independent entity shall conduct all activities under this section in a manner that preserves the confidentiality of facilities, documents, materials, or information made confidential by RCW 70.56.050.
- (5) Medical facilities and health care workers may provide notification of incidents to the independent entity. The notification shall be filed in a format specified by the independent entity, after consultation with the department and medical facilities, and shall identify the facility but shall not include any identifying information for any of the health care professionals, facility employees, or patients involved. This provision does not modify the duty of a hospital to make a report to the department or a disciplinary authority if a licensed practitioner has committed unprofessional conduct as defined in RCW 18.130.180. The protections of RCW 43.70.075 apply to notifications of incidents that are submitted in good faith by employees of medical facilities. [2009 c 495 § 14; 2008 c 136 § 2; 2006 c 8 § 108.]

Effective date—2009 c 495: See note following RCW 43.20.050.

RCW 70.56.050 Confidentiality of notifications and reports.

- (1) (a) When notification of an adverse event under RCW 70.56.020(2)(a) or of an incident under RCW 70.56.040(5), or a report regarding an adverse event under RCW 70.56.020(2)(b) is made by or through a coordinated quality improvement program under RCW 43.70.510 or 70.41.200, or by a peer review committee under RCW 4.24.250, information and documents, including complaints and incident reports, created specifically for and collected and maintained by a quality improvement committee for the purpose of preparing a notification of an adverse event or incident or a report regarding an adverse event, the report itself, and the notification of an incident, shall be subject to the confidentiality protections of those laws and RCW 42.56.360(1)(c).
- (b) The notification of an adverse event under RCW 70.56.020(2)(a), shall be subject to public disclosure and not exempt from disclosure under chapter 42.56 RCW. Any public disclosure of an adverse event notification must include any contextual information the medical facility chose to provide under RCW 70.56.020(2)(a).
- (2) (a) When notification of an adverse event under RCW 70.56.020(2)(a) or of an incident under RCW 70.56.040(5), or a report regarding an adverse event under RCW 70.56.020(2)(b), made by a health care worker uses information and documents, including complaints and incident reports, created specifically for and collected and maintained by a quality improvement committee under RCW 43.70.510 or 70.41.200 or a peer review committee under RCW 4.24.250, a notification of an incident, the report itself, and the information or documents used for the purpose of preparing notifications or the report, shall be subject to the confidentiality protections of those laws and RCW 42.56.360(1)(c).
- (b) The notification of an adverse event under RCW 70.56.020(2)(a) shall be subject to public disclosure and not exempt from disclosure under chapter 42.56 RCW. Any public disclosure of an adverse event notification must include any contextual information the medical facility chose to provide under RCW 70.56.020(2)(a). [2008 c 136 § 3; 2006 c 8 § 110.]

RCW 70.56.900 Findings—Intent—Part headings and subheadings not law—Severability—2006 c 8. See notes following RCW 5.64.010.