CERTIFICATION OF ENROLLMENT

SUBSTITUTE SENATE BILL 6457

Chapter 136, Laws of 2008

60th Legislature
2008 Regular Session

ADVERSE HEALTH EVENTS REPORTING SYSTEM

EFFECTIVE DATE: 06/12/08 - Except section 5, which becomes effective 07/01/09.

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

BRAD OWEN

President of the Senate

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

FRANK CHOPP

Speaker of the House of Representatives

Approved March 25, 2008, 1:18 p.m.

CHRISTINE GREGOIRE

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.

THOMAS HOEMANN

Secretary

FILED

March 25, 2008

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.

AN ACT Relating to the adverse health events and incident reporting system; amending RCW 70.56.020, 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.

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

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

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

~~be submitted to the department within forty-five days after confirmation by the medical facility that an adverse event has occurred.~~)) 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). 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. 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, 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 ((~~reported~~)) provided notification of an adverse event or undertaken efforts to investigate the occurrence of an adverse

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

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

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

(1) 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) 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 ((~~identify [identity]~~)) 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 web site. 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 to the governor and the legislature on the activities under this chapter in the preceding year. The report shall include:

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

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

~~(c)~~)) (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 web site.

(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 ((~~report~~)) provide notification of incidents to the independent entity. The ((~~report~~)) 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 ((~~reports~~)) notifications of incidents that are submitted in good faith by employees of medical facilities.

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

(1)(a) 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 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 ((~~or report~~)) of an adverse event or incident((~~, and~~)) or a report regarding an adverse event, the ((~~notification or~~)) report itself, and the notification of an incident, shall be subject to the confidentiality protections of those laws and RCW ((~~42.17.310(1)(hh) and~~)) 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 ((~~a notification or report of an adverse event or incident 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 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, ((~~the~~)) a notification ((~~or~~)) of an incident, the report itself, and the information or documents used for the purpose of preparing ((~~the~~)) notifications or the report, shall be subject to the confidentiality protections of those laws and RCW ((~~42.17.310(1)(hh) and~~)) 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).

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

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

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

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

(c) Information and documents created specifically for, and 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 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

reporting of health care-associated infections under RCW 43.70.056, ((~~and notifications or reports of adverse events or incidents made under RCW 70.56.020 or 70.56.040,~~)) a notification of an incident under RCW 70.56.040(5), and reports regarding adverse events under RCW 70.56.020(2)(b), regardless of which agency is in possession 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 18.71.300 through 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;

(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 chapter 70.225 RCW.

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

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

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

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

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

(c) Information and documents created specifically for, and collected and maintained by a quality improvement committee under RCW 43.70.510, 70.230.080, or 70.41.200, or by a peer review committee under RCW 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 reporting of health care-associated infections under RCW 43.70.056, ((~~and notifications or reports of adverse events or incidents made under RCW 70.56.020 or 70.56.040,~~)) a notification of an incident under RCW 70.56.040(5), and reports regarding adverse events under RCW 70.56.020(2)(b), regardless of which agency is in possession 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 18.71.300 through 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;

(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 chapter 70.225 RCW.

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

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

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

Passed by the Senate February 14, 2008.
Passed by the House March 4, 2008.
Approved by the Governor March 25, 2008.
Filed in Office of Secretary of State March 25, 2008.