THE SENATE
TWENTY-SIXTH LEGISLATURE, 2011
STATE OF HAWAII

S.B. NO. 705

JAN 21 2011

A BILL FOR AN ACT

RELATING TO HEALTH.

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

SECTION 1. Chapter 321, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

"**PART . MEDICAL ERROR REPORTING AND DISCLOSURE**

§321-A Definitions. Wherever used in this part:

"Department" means the department of health.

"Hospital" or "licensee" means an acute care health care facility licensed under section 321-14.5.

"Medical harm event" is harm to a patient as a result of medical care or in a health care setting. It shall include the following categories of events:

(1) Surgical and related anesthesia events including unexpected complications and deaths, surgery performed on a wrong body part, surgery performed on the wrong patient, the wrong surgical procedure performed on a patient, and retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned

intervention and objects present prior to surgery that are intentionally retained;

(2) Medication events related to professional practice, or health care products, procedures, and systems, including but not limited to prescribing, prescription order communications, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use;

(3) Product or device events related to the use or function of a device in patient care in which the device is used or functions other than as intended, including but not limited to catheters, infusion pumps, or ventilators;

(4) Care management events including but not limited to stage three or four pressure ulcers acquired after admission to a health facility, failure to rescue, intravenous therapy injuries, and maternal death or serious disability associated with labor or delivery, including events that occur within forty-two days post-delivery;

(5) Environmental deaths, including but not limited to unintended electric shock, delivery of the wrong gas

or contaminated toxic substance, burns incurred from any source, patient falls, and harm associated with the use of restraints or bedrails; and

(6) Death of a previously healthy person while undergoing medical care.

§321-B Hospital requirements. (a) A hospital shall report a medical harm event to the department not later than five days after the event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, no later than twenty-four hours after the adverse event has been detected. The reports shall be made on a form prescribed by the department.

(b) The report shall indicate the level of medical harm to the patient, such as whether it resulted in serious injury or death, using the format developed by the department.

(c) On a quarterly basis, each hospital that has had no medical harm events to report during that quarter shall affirmatively declare this fact to the department, using a form developed by the department.

(d) Each hospital shall create facility-wide patient safety programs to routinely review patient records for medical

harm, analyze these events to determine if they were preventable, and implement changes to prevent similar harmful events. Each hospital shall provide an annual summary of its patient safety program to the department.

(e) Each hospital shall inform the patient, the party responsible for the patient, or an adult member of the immediate family in cases of death or serious bodily injury, of the medical harm event by the time the report is made to the department.

(f) Each hospital shall interview patients, family members, and parties responsible for the patient about medical harm events and document a detailed summary of that interview in the patient's medical record.

(g) If the medical harm event contributed to the death of a patient, the hospital shall include that event as a contributing cause on the patient's death certificate.

(h) If the hospital is a division or subsidiary of another entity that owns or operates multiple hospitals or related organizations, a report shall be made for each specific division or subsidiary and not aggregately for multiple hospitals.

(i) Nothing in this section shall be interpreted to change or otherwise affect hospital reporting requirements regarding reportable diseases or unusual occurrences, as otherwise provided by law.

§321-C Advisory committee. (a) The director of the department shall appoint an advisory committee, including representatives from public and private hospitals, direct care nursing staff, physicians, epidemiologists with expertise in patient safety, academic researchers, consumer organizations, health insurers, health maintenance organizations, organized labor, and purchasers of health insurance, such as employers. The advisory committee shall have a majority of members representing interests other than hospitals.

(b) The advisory committee shall assist the department in the development of all aspects of the department's methodology for collecting, analyzing, and disclosing the information collected under this part, including collection methods, formatting, evaluation of methods used, and the methods and means for release and dissemination.

(c) Meetings of the advisory committee shall be open to the public in accordance with chapter 92.

§321-D Methodologies for collecting, analyzing, and validating data. (a) The department shall, with the advice of the advisory committee established under section 321-C, develop guidelines for hospitals in identifying medical harm events.

(b) The department shall create standardized reporting formats for hospitals to use to comply with this part.

(c) In developing the methodology for collecting the data on medical harm events, the department and advisory committee shall use the forms developed by the Agency for Healthcare Research and Quality or a similar standardized collection method.

(d) In developing the methodology for analyzing the data, the department shall include a standardized method of categorizing the level of harm experienced by the patient, such as the National Coordinating Council for Medication Error Reporting and Prevention Index for Categorizing Medication Errors.

(e) The department shall at least quarterly check the accuracy of information reported by hospitals under this part by comparing the information with other available data such as

patient safety indicators from hospital patient discharge data, complaints filed with the hospital's licensing division, death certificates, inspection and survey reports, and medical malpractice information. The department shall annually conduct random reviews of hospital medical records.

(f) The data collection, analysis and validation methodologies shall be disclosed to the public.

(g) Every three years, the department shall have an independent audit conducted by a state university not affiliated with any hospital required to report under this part. The audit shall:

(1) Assess the accuracy of reporting by hospitals, especially seeking to identify underreporting;

(2) Be funded by the patient safety trust fund created in section 321-H; and

(3) Be available to the public on the department's website within one month of receiving the final report.

(h) The department shall adopt rules pursuant to chapter 91 to carry out the provisions of this part.

§321-E Public reports. (a) Each quarter, the department shall publish details of the fines assessed to hospitals under

section 321-I for failures to report medical harm events and shall issue a news release about that publication.

(b) The department shall annually submit a report to the legislature detailing medical harm events reported at each hospital required to report under this part. The report may include policy recommendations, as appropriate. The report shall:

(1) Be published on the department's website at the same time it is submitted to the legislature;

(2) Include hospital-specific information on the number and type of medical harm events reported, the level of harm to patients, fines assessed and enforcement actions taken, and the quarterly affirmation by hospitals in which no medical harm events have occurred;

(3) Provide information in a manner that stratifies the data based on characteristics of the hospitals, such as the number of patient admissions and patient days in each hospital; and

(4) Contain text written in plain language that includes a discussion of findings, conclusions, and trends concerning the overall patient safety in the State,

including a comparison to prior years, and the methods the department used to check for the accuracy of hospital reports.

(c) Each quarter, the department shall make information regarding outcomes of inspections and investigations readily accessible to the public on the department website.

(d) No hospital report or department public disclosure may contain information identifying a patient, employee, or licensed health care professional in connection with a specific infection incident.

(e) The first report required under subsection (b) shall be submitted and published no later than July 1, 2012. Following the initial report, the department shall publish these reports annually on July 1.

§321-F Privacy. A patient's right of confidentiality shall not be violated in any manner by carrying out the obligations imposed under this part. Patient social security numbers or any other information that could be used to identify an individual patient shall not be released, notwithstanding any other provision of law.

§321-G Protection for taking action. No hospital shall discharge, refuse to hire, refuse to serve, retaliate in any

manner, or take any adverse action against any employee, applicant for employment, or health care provider because the employee, applicant for employment, or health care provider takes or has taken any action to enforce this part.

§321-H Patient safety trust fund. (a) A patient safety trust fund is created independent of the general fund. All penalties assessed under section 321-I shall be deposited into the patient safety trust fund.

(b) Spending from the fund shall be used for regulatory oversight and public accountability for safe health care, including the audit specified under section 321-D.

§321-I Department actions and penalties. (a) In any case in which the department receives a report from a hospital pursuant to section 321-B, that indicates an ongoing threat or imminent danger of death or serious bodily harm, the department shall make an onsite inspection or investigation within forty-eight hours or two business days, whichever is greater, of the receipt of the report and shall complete that investigation within forty-five days.

(b) If a hospital fails to report a medical harm event pursuant to section 321-B, the department may assess the licensee a civil penalty in an amount not to exceed $100 for

each day that the adverse event is not reported following the initial five-day period or twenty-four-hour period, as applicable. If the licensee disputes a determination by the department regarding alleged failure to report an adverse event, the licensee may, within ten days, request a hearing. Penalties shall be paid when appeals pursuant to those provisions have been exhausted.

(c) The department shall be responsible for ensuring compliance with this part as a condition of licensure under section 321-14.5.

§321-J Oversight information. The department shall share data regarding medical harm events in hospitals with other requesting state agencies, with patient confidentiality maintained at all times.

§321-K Public awareness. The department shall promote public awareness regarding where and how consumers can file complaints about hospitals under this part, including implementing a requirement that information about filing complaints be posted in a visible manner:

(1) On the department's website;

(2) On each hospital's website;

(3) In public areas in hospital facilities;

(4) On all hospital correspondence and billing documents; and

(5) On all correspondence by the department's hospital licensing division and the division collecting data on medical harm events under this part."

SECTION 2. In codifying the new sections added by section 321 of this Act, the revisor of statutes shall substitute appropriate section numbers for the letters used in designating the new sections in this Act.

SECTION 3. This Act shall take effect upon its approval.

INTRODUCED BY:

S.B. NO. 705

Report Title:
Health; Medical Error Reporting and Disclosure; Patient Safety Trust Fund

Description:
Establishes medical error reporting and disclosure requirements. Creates an advisory board charged with the duty of developing methodologies to enhance medical error reporting. Establishes the patient safety trust fund.

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