HOUSE OF REPRESENTATIVES
TWENTY-SIXTH LEGISLATURE, 2011
STATE OF HAWAII

H.B. NO. 420

A BILL FOR AN ACT

RELATING TO MEDICAL HARM DISCLOSURE.

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 HARM DISCLOSURE ACT**

§321-A Definitions. As used in this part, unless the context clearly requires otherwise:

"Department" means the department of health.

"Director" means the director of health.

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

"Medical harm event" means harm to a patient as a result of medical care or in a health care setting, including but not limited to the National Quality Forum's list of serious reportable events, and including the following categories of events:

(1) Surgical and related anesthesia events including:

(A) Unexpected complications and deaths;

(B) Surgery performed on a wrong body part;

(C) Surgery performed on the wrong patient;

(D) The wrong surgical procedure performed on a patient; and

(E) 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:

(A) Stage three or four pressure ulcers acquired after admission to a hospital;

(B) Failure to rescue;

(C) Intravenous injuries; and

(D) 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:

(A) Unintended electric shock;

(B) Delivery of the wrong gas or contaminated toxic substance;

(C) Burns incurred from any source;

(D) Patient falls; and

(E) 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; reports. (a) Each 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, not later than twenty-four hours after the adverse event has been

detected. The report shall be made in a format prescribed by the department.

(b) The report shall indicate the level of medical harm to the patient, such as whether the event 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 report format 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 required under subsection (a) 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 in the aggregate 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.

§321-C Advisory committee. (a) The director 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.

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

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

(c) In developing the methodology for collecting the data on medical harm events, the department and the advisory committee shall use the forms developed by the Agency for Healthcare Research and Quality as "common formats" 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 Errors Reporting and Prevention Index for Categorizing Errors.

(e) The department shall check the accuracy of information reported by hospitals under this part on a quarterly basis by comparing the information with other available data such as patient safety indicators from hospital patient discharge data, complaints filed with the department, 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 conduct an independent audit to:

(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 the department's receiving the final report.

(h) The department shall adopt rules in accordance with chapter 91 to carry out this part.

§321-E Public reports. (a) Each quarter, the department shall publish details of the fines assessed to hospitals for failure to report medical harm events under section 321-I and shall issue a news release about that publication.

(b) The department shall submit an annual report to the legislature detailing medical harm events reported at each hospital required to report under this part and include policy recommendations, as necessary. 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 conducted pursuant to its regulatory duties under this part 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 annual report required under subsection (b) shall be submitted and published no later than December 31, 2012.

§321-F Privacy. It is the expressed intent of the legislature that a patient's right of confidentiality shall not be violated in any manner. Any other law to the contrary notwithstanding, patient social security numbers or any other

information that could be used to identify an individual patient shall not be released.

§321-G No retaliation. 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 in furtherance of the enforcement of the provisions of this part.

§321-H Patient safety trust fund. (a) There is created the patient safety trust fund outside the state treasury to be administered by the department into which shall be deposited moneys from:

(1) The annual patient safety surcharge on licensing fees charged to hospitals subject to this part; and

(2) Penalties assessed under section 321-I.

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

§321-I Department actions; penalties. (a) If 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 of greater duration, 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 under section 321-B(a). If the licensee disputes a determination by the department regarding alleged failure to report an adverse event, the licensee, within ten days, may request a hearing. Penalties shall be paid when appeals have been concluded and denied.

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

§321-J Filing of complaints. Notice to the public on how to file complaints regarding medical harm events shall be made available:

(1) On the department's website;

(2) On each hospital's website;

(3) In public posting areas in hospitals;

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

(5) On all department correspondence relating to the collection of data on medical harm events under this part."

SECTION 2. Section 321-14.5, Hawaii Revised Statutes, is amended to read as follows:

"~~[+]~~§321-14.5~~[+]~~ **Hospitals; licensing.** (a) All hospitals shall be licensed by the department to ensure the health, safety, and welfare of the individuals placed therein.

(b) The director shall adopt rules in accordance with chapter 91 that shall provide for the licensing of hospitals.

(c) The rules may provide that accreditation by the joint commission on accreditation of healthcare organizations demonstrates a hospital's compliance with all licensing inspections required by rules for the year in which the joint commission on accreditation of healthcare organizations accreditation is issued. The rules may exempt a hospital from a licensing inspection for the year in which a joint commission on

accreditation of healthcare organizations accreditation is issued under the following conditions:

(1) The hospital provides a certified copy of the hospital's official joint commission on accreditation of healthcare organizations accreditation report to the department;

(2) The hospital holds full accreditation by the joint commission on accreditation of healthcare organizations; and

(3) The hospital holds a current and valid license.

(d) The rules shall provide that the department may conduct inspections and investigations of exempt hospitals to investigate complaints, follow up on adverse accreditation findings, or conduct periodic validation surveys.

(e) Information contained in reports of survey and official accreditation letters made by the joint commission on accreditation of healthcare organizations used in determining compliance with licensing requirements shall be public information.

(f) All other records maintained by the department shall be governed by chapter 92F.

(g) Each hospital subject to this section shall comply with part as a condition of licensing under this section."

SECTION 3. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 4. This Act shall take effect upon its approval.

INTRODUCED BY: Calvin K.Y. Say (By Request)

JAN 21 2011

H.B. NO. 420

Report Title:
Medical Harm Disclosure

Description:
Requires hospitals to comply with medical harm disclosure provisions as a condition of licensing. Requires hospitals to report medical harm events to the DOH.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.