SENATE BILL 383

50TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2011

INTRODUCED BY

Stephen H. Fischmann

AN ACT

RELATING TO PUBLIC HEALTH; ENACTING THE MEDICAL HARM DISCLOSURE ACT; PROVIDING FOR DATA COLLECTION; PROVIDING FOR REPORTING OF MEDICAL HARM EVENTS; ESTABLISHING THE PATIENT SAFETY FUND; AMENDING A SECTION OF THE PUBLIC HEALTH ACT TO ALLOW THE DEPARTMENT OF HEALTH TO ADD A PATIENT SAFETY SURCHARGE TO LICENSURE FEES; MAKING AN APPROPRIATION.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

SECTION 1. [NEW MATERIAL] SHORT TITLE.--Sections 1 through 11 of this act may be cited as the "Medical Harm Disclosure Act".

SECTION 2. [NEW MATERIAL] DEFINITIONS.--As used in the Medical Harm Disclosure Act:

A. "advisory committee" means the medical event advisory committee;

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B. "department" means the department of health;

C. "health facility" means a public hospital, profit or nonprofit private hospital, general or special hospital, outpatient facility, nursing home or intermediate care facility licensed by the department;

D. "medical harm event" is an occurrence of harm, other than a hospital-acquired infection as that term is defined in the Hospital-Acquired Infection Act, to a patient as a result of medical care; and

E. "secretary" means the secretary of health.

SECTION 3. [NEW MATERIAL] HEALTH FACILITIES--MEDICAL HARM--REQUIREMENTS.--

A. A health facility 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 event has been detected. A report shall be made in a manner that the department prescribes by rule.

B. A report pursuant to this section shall indicate the level of medical harm to the patient, including whether the medical harm resulted in serious injury or death.

C. On a quarterly basis, a health facility that has had no medical harm events to report during that quarter shall affirmatively declare this fact to the department in a manner

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the department prescribes by rule.

D. A health facility 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. A health facility shall provide an annual summary of its patient safety program to the department.

E. A health facility shall inform the patient and, to the extent permitted by state and federal law, the patient's agent, parent or guardian or surrogate appointed pursuant to the Uniform Health-Care Decisions Act of the medical harm event by the time the report is made to the department.

F. A health facility shall interview the patient and the family members and parties responsible for the patient about a medical harm event 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 health facility shall include that event as a contributing cause on the patient's death certificate.

H. If the health facility is a division or subsidiary of another entity that owns or operates multiple health facilities or related organizations, a report of each medical harm event shall be made for each specific division or subsidiary and not aggregately for multiple health facilities.

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I. Nothing in this section shall be interpreted to change or otherwise affect reporting requirements regarding hospital-acquired infections pursuant to the Hospital-Acquired Infections Act.

SECTION 4. [NEW MATERIAL] ADVISORY COMMITTEE--APPOINTMENT--MEMBERSHIP--DUTIES.--

A. The "medical event advisory committee" is created in the department to advise the department in carrying out the provisions of the Medical Harm Disclosure Act. Members of the advisory committee shall include:

(1) a consumer of health care services;

(2) a representative of the New Mexico association for professionals in infection control and epidemiology;

(3) a representative of the New Mexico hospital association;

(4) a representative of the New Mexico medical review association;

(5) a local representative of the society for healthcare epidemiology of America;

(6) a representative of the department's infectious disease epidemiology bureau;

(7) a member of the New Mexico state association of health underwriters;

(8) a member of a consumer advocacy

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organization;

(9) a researcher in epidemiology or infectious disease from a state institution of higher learning;

(10) a member of the board of nursing; and

(11) a member of the New Mexico medical board or the board of osteopathic medical examiners.

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 pursuant to the Medical Harm Disclosure Act, including collection methods, formatting, evaluation of methods used and the methods and means for release and dissemination.

C. Advisory committee meetings shall be held in accordance with the Open Meetings Act.

SECTION 5. [NEW MATERIAL] METHODOLOGIES FOR COLLECTING, ANALYZING AND VALIDATING DATA.--

A. In consultation with the advisory committee, the department shall promulgate rules to establish guidelines for health facilities to identify medical harm events.

B. The department shall promulgate rules to create standardized reporting formats for health facilities to use when reporting pursuant to the Medical Harm Disclosure Act, provided that the department and advisory committee shall use the forms developed by the agency for healthcare research and

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quality or similar standardized collection methods.

C. The department shall promulgate rules to develop the methodology for analyzing data collected pursuant to the Medical Harm Disclosure Act, including a standardized method of categorizing the level of harm experienced by the patient based upon the national coordinating council for medication errors reporting and prevention's index for categorizing errors.

D. At least once per calendar quarter, the department shall check the accuracy of information that a health facilities report made pursuant to the Medical Harm Disclosure Act by comparing that information with other available data, including patient safety indicators from patient discharge data, complaints filed with licensing bodies, death certificates, inspection and survey reports and medical malpractice information. The department shall annually conduct random reviews of health facility medical records.

E. The department shall disclose to the public its methodologies for data collection, analysis and validation pursuant to the Medical Harm Disclosure Act.

F. Every three years, the department shall have an independent audit conducted by a state university not affiliated with any health facility that is required to report under the Medical Harm Disclosure Act. The audit shall:

(1) assess the accuracy of reporting by health facilities, including any underreporting;

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(2) be funded by the patient safety fund; and

(3) be available to the public on the department's web site within one month of receiving the final report.

SECTION 6. [NEW MATERIAL] PUBLIC REPORTING.--

A. Once each calendar quarter, the department shall publish details of the fines assessed to health facilities pursuant to Section 9 of the Medical Harm Disclosure Act for failure to report medical harm events and shall issue a news release about that publication.

B. The department shall annually submit a report to the appropriate interim legislative committees detailing medical harm events reported at each health facility required to report pursuant to the Medical Harm Disclosure Act. The report shall include policy recommendations as the department deems necessary. The report shall:

(1) be published on the department's web site at the same time it is submitted to the appropriate interim legislative committees;

(2) include health-facility-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 affirmations by health facilities in which no medical harm events have occurred;

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(3) provide information in a manner that stratifies the data based on characteristics of the health facilities, such as number of patient admissions and patient days in each health facility; 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 the accuracy of health facility reports.

C. Once each calendar quarter, the department shall make information regarding outcomes of inspections and investigations conducted pursuant to its regulatory duties pursuant to the Public Health Act readily accessible to the public on the department's web site.

D. No report or public disclosure shall contain information identifying a patient, employee or licensed health care professional in connection with a specific infection incident. All reporting shall be made in compliance with state and federal privacy laws.

E. The report required pursuant to Subsection B of this section shall be submitted and published no later than October 1, 2011 and October 1 of each year thereafter.

SECTION 7. [NEW MATERIAL] PROTECTION FOR TAKING ACTION.--A health facility shall not discharge, refuse to hire, refuse to serve, in any manner retaliate against or take any adverse

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action against any employee, applicant for employment or health care provider because such employee, applicant for employment or health care provider takes or has taken any action in furtherance of the enforcement of the provisions of the Medical Harm Disclosure Act.

SECTION 8. [NEW MATERIAL] PATIENT SAFETY FUND--CREATION--DISTRIBUTION.--The "patient safety fund" is created in the state treasury. Money in the fund shall consist of deposits of the annual patient safety surcharge on licensing fees the department charges to health facilities required to report pursuant to the Medical Harm Disclosure Act, as well as appropriations, contributions, grants and statutory revenues directed to the fund. Money in the fund is appropriated to the department, which shall administer the fund for carrying out its duties pursuant to the Medical Harm Disclosure Act. Disbursements from the fund shall be by warrants of the secretary of finance and administration drawn pursuant to vouchers signed by the secretary of health or the secretary of health's authorized representative. Money in the fund shall not revert at the end of a fiscal year.

SECTION 9. [NEW MATERIAL] ENFORCEMENT--PENALTIES.--

A. When the department receives a report from a health facility pursuant to Section 3 of the Medical Harm Disclosure Act that indicates an ongoing threat or imminent danger of death or serious bodily harm, the department shall

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make an on-site inspection or investigation within forty-eight hours or two business days, whichever is greater, of the receipt of the report. The department shall complete the inspection or investigation within forty-five days.

B. The department shall ensure compliance with the Medical Harm Disclosure Act as a condition of licensure under the Public Health Act and shall enforce such compliance according to the provisions of the Public Health Act. If a health facility fails to report a medical harm event pursuant to Section 3 of the Medical Harm Disclosure Act or otherwise fails to comply with the provisions of that act, the department shall proceed as in matters of noncompliance with any licensing requirement pursuant to the provisions of Sections 24-1-5 and 24-1-5.2 NMSA 1978.

SECTION 10. [NEW MATERIAL] INTRADEPARTMENTAL INFORMATION SHARING.--The health facility licensing and certification bureau of the department's division of health improvement and the department staff assigned to collect data on medical harm events pursuant to the Medical Harm Disclosure Act shall share data regarding medical harm events in health facilities and maintain patient confidentiality.

SECTION 11. [NEW MATERIAL] PUBLIC OUTREACH.--The department shall promote public awareness regarding where and how consumers can file complaints about health facilities and shall ensure that information about filing complaints is posted

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in a readily accessible manner:

A. on the department's web site;

B. on each licensed health facility's web site;

C. in public areas in health care facilities;

D. on all health facility correspondence and billing documents; and

E. on all correspondence by the licensing and certification bureau of the department's division of health improvement and the departmental subdivision assigned to collect data on medical harm events pursuant to the Medical Harm Disclosure Act.

SECTION 12. Section 24-1-5 NMSA 1978 (being Laws 1973, Chapter 359, Section 5, as amended) is amended to read:

"24-1-5. LICENSURE OF HEALTH FACILITIES--HEARINGS--APPEALS.--

A. A health facility shall not be operated without a license issued by the department. If a health facility is found to be operating without a license, in order to protect human health or safety, the secretary may issue a cease-and-desist order. The health facility may request a hearing that shall be held in the manner provided in this section. The department may also proceed pursuant to the Health Facility Receivership Act.

B. The department is authorized to make inspections and investigations and to prescribe rules it deems necessary or

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desirable to promote the health, safety and welfare of persons using health facilities.

C. Except as provided in Subsection F of this section, upon receipt of an application for a license to operate a health facility, the department shall promptly inspect the health facility to determine if it is in compliance with all rules of the department. Applications for hospital licenses shall include evidence that the bylaws or rules of the hospital apply equally to osteopathic and medical physicians. The department shall consolidate the applications and inspections for a hospital that also operates as a hospital-based primary care clinic.

D. Upon inspection of a health facility, if the department finds a violation of its rules, the department may deny the application for a license, whether initial or renewal, or it may issue a temporary license. A temporary license shall not be issued for a period exceeding one hundred twenty days, nor shall more than two consecutive temporary licenses be issued.

E. A one-year nontransferable license shall be issued to any health facility complying with all rules of the department. The license shall be renewable for successive one-year periods, upon filing of a renewal application, if the department is satisfied that the health facility is in compliance with all rules of the department or, if not in

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compliance with a rule, has been granted a waiver or variance of that rule by the department pursuant to procedures, conditions and guidelines adopted by rule of the department. Licenses shall be posted in a conspicuous place on the licensed premises, except that child care centers that receive no state or federal funds may apply for and receive from the department a waiver from the requirement that a license be posted or kept on the licensed premises.

F. A health facility that has been inspected and licensed by the department [~~and~~], that has received certification for participation in federal reimbursement programs and that has been fully accredited by the joint commission on accreditation of health care organizations or the American osteopathic association shall be granted a license renewal based on that accreditation. Health facilities receiving less than full accreditation by the joint commission on the accreditation of health care organizations or by the American osteopathic association may be granted a license renewal based on that accreditation. License renewals shall be issued upon application submitted by the health facility upon forms prescribed by the department. This subsection does not limit in any way the department's various duties and responsibilities under other provisions of the Public Health Act or under any other subsection of this section, including any of the department's responsibilities for the health and

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safety of the public.

G. The department may charge a reasonable fee not to exceed twelve dollars ($12.00) per bed for an inpatient health facility or three hundred dollars ($300) for any other health facility for each license application, whether initial or renewal, of an annual license or the second consecutive issuance of a temporary license. In addition to licensure fees charged pursuant to this section, the department may charge a reasonable "patient safety surcharge" not to exceed one dollar ($1.00) per bed for an inpatient health facility or five dollars ($5.00) for any other health facility for each license application or renewal of an annual license or the second consecutive issuance of a temporary license. The department shall deposit patient safety surcharge funds that it collects in the patient safety fund, and distributions from that fund shall be used to carry out the department's duties pursuant to the Medical Harm Disclosure Act. Fees collected shall not be refundable. All fees collected pursuant to licensure applications shall be deposited with the state treasurer for credit in a designated department recurring account for use in health facility licensure and certification operations.

H. The department may revoke or suspend the license of a health facility or may impose on a health facility an intermediate sanction and a civil monetary penalty provided in Section 24-1-5.2 NMSA 1978 after notice and an opportunity for

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a hearing before a hearing officer designated by the department to hear the matter and, except for child care centers and facilities, may proceed pursuant to the Health Facility Receivership Act upon a determination that the health facility is not in compliance with any rule of the department. If immediate action is required to protect human health and safety, the secretary may suspend a license or impose an intermediate sanction pending a hearing, provided the hearing is held within five working days of the suspension or imposition of the sanction, unless waived by the licensee, and, except for child care centers and facilities, may proceed ex parte pursuant to the Health Facility Receivership Act.

I. The department shall schedule a hearing pursuant to Subsection H of this section if the department receives a request for a hearing from a licensee:

(1) within ten working days after receipt by the licensee of notice of suspension, revocation, imposition of an intermediate sanction or civil monetary penalty or denial of an initial or renewal application;

(2) within four working days after receipt by the licensee of an emergency suspension order or emergency intermediate sanction imposition and notice of hearing if the licensee wishes to waive the early hearing scheduled and request a hearing at a later date; or

(3) within five working days after receipt of

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a cease-and-desist order.

The department shall also provide timely notice to the licensee of the date, time and place of the hearing, identity of the hearing officer, subject matter of the hearing and alleged violations.

J. A hearing held pursuant to provisions of this section shall be conducted in accordance with adjudicatory hearing rules and procedures adopted by rule of the department. The licensee has the right to be represented by counsel, to present all relevant evidence by means of witnesses and books, papers, documents, records, files and other evidence and to examine all opposing witnesses who appear on any matter relevant to the issues. The hearing officer has the power to administer oaths on request of any party and issue subpoenas and subpoenas duces tecum prior to or after the commencement of the hearing to compel discovery and the attendance of witnesses and the production of relevant books, papers, documents, records, files and other evidence. Documents or records pertaining to abuse, neglect or exploitation of a resident, client or patient of a health facility or other documents, records or files in the custody of the human services department or the office of the state long-term care ombudsman at the aging and long-term services department that are relevant to the alleged violations are discoverable and admissible as evidence in any hearing.

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K. Any party may appeal the final decision of the department pursuant to the provisions of Section 39-3-1.1 NMSA 1978.

L. A complaint about a health facility received by the department pursuant to this section shall be promptly investigated and appropriate action shall be taken if substantiated. The department shall develop a health facilities protocol in conjunction with the human services department, the protective services division of the children, youth and families department, the office of the state long-term care ombudsman and other appropriate agencies to ensure the health, safety and rights of individuals in health facilities. The health facilities protocol shall require:

(1) cross-reference among agencies pursuant to this subsection of an allegation of abuse, neglect or exploitation;

(2) an investigation, within the strict priority time frames established by each protocol member's rules, of an allegation or referral of abuse, neglect or exploitation after the department has made a good cause determination that abuse, neglect or exploitation occurred;

(3) an agency to share its investigative information and findings with other agencies, unless otherwise prohibited by law; and

(4) require the receiving agency to accept the

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information provided pursuant to Paragraph (3) of this subsection as potential evidence to initiate and conduct investigations.

M. A complaint received by the department pursuant to this section shall not be disclosed publicly in a manner as to identify any individuals or health facilities if upon investigation the complaint is unsubstantiated.

N. Notwithstanding any other provision of this section, when there are reasonable grounds to believe that a child is in imminent danger of abuse or neglect while in the care of a child care facility, whether or not licensed, or upon the receipt of a report pursuant to Section 32A-4-3 NMSA 1978, the department shall consult with the owner or operator of the child care facility. Upon a finding of probable cause, the department shall give the owner or operator notice of its intent to suspend operation of the child care facility and provide an opportunity for a hearing to be held within three working days, unless waived by the owner or operator. Within seven working days from the day of notice, the secretary shall make a decision, and, if it is determined that any child is in imminent danger of abuse or neglect in the child care facility, the secretary may suspend operation of the child care facility for a period not in excess of fifteen days. Prior to the date of the hearing, the department shall make a reasonable effort to notify the parents of children in the child care facility of

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the notice and opportunity for hearing given to the owner or operator.

O. Nothing contained in this section or in the Public Health Act shall authorize either the secretary or the department to make any inspection or investigation or to prescribe any rules concerning group homes as defined in Section 9-8-13 NMSA 1978 except as are reasonably necessary or desirable to promote the health and safety of persons using group homes."

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