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SENATE . . . . . No. 561

The Commonwealth of Massachusetts

In the Year Two Thousand Nine

An Act to Establish an Adverse Event Disclosure and Compensation Grant Program for Hospitals..

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. FINDINGS.

The Committee on Health Care Financing makes the following findings:

(1) Massachusetts ranks highest among states reporting medical malpractice insurance claims to a central state agency, with almost 20% of insurance payouts over $1 million.

(2) The increase in professional liability fees is one of the key factors driving the Commonwealth's perpetual shortage of practicing physicians, particularly in primary care.

(3) The 2008 Defensive Medicine Report issued by the Massachusetts Medical Society reported that the current medical liability system leads to "defensive medicine," or the practice of additional testing and procedures as a result of physicians' fear of lawsuits, which cost the state $1.4 billion in 2007.

(4) Only a minority of patients who sustain injuries from medical error receive compensation. Many patients never file a legal claim for minor injuries due to the expense, and many never discover that an error occurred. Patients receiving compensation only recuperate 36 cents on every dollar awarded.

(5) The current tort system places blame on individual physicians, when errors are often the result of system failures. This system encourages physicians to hide errors, discourages communication between physicians and patients, and prevents health care providers from using mistakes to improve the systematic delivery of medical care.

(6) Some hospital systems and insurance providers have implemented a system of early disclosure of medical errors. For example, at the University of Michigan, University of Illinois and Department of Veterans Affairs hospital in Lexington, physicians communicate all adverse events to patients, apologize, and when appropriate, negotiate compensation. Overall, these programs have accounted for fewer numbers of malpractice claims being filed, more patients being compensated for injuries, greater patient trust and satisfaction, and a significant reduction of hospital's malpractice reserves as well as the cost of defending cases.

SECTION 2. Chapter 6A of the general laws as appearing in the 2006 Official Edition, is hereby amended by adding the following new section:

Section 16E1/2. ADVERSE EVENT DISCLOSURE AND COMPENSATION PROGRAM

(a) Definitions

(1) DATABASE – The term ‘Database’ means the Patient Safety Database established within the Betsy Lehman Center.

(2) ADVERSE EVENT – The term ‘adverse event’ means an event which results in a serious adverse patient outcome that is clearly identifiable and measurable.

(3) PATIENT SAFETY DATA – The term ‘patient safety data’ means information requested by the Program Coordinator to be submitted by the Patient Safety Officer of a Program participant.

(4) PATIENT SAFETY OFFICER – The term ‘Patient Safety Officer’ means the individual designated by a Program Participant as being responsible for ensuring that the conditions for participation in the Program are met.

(5) PROGRAM – The term ‘Program’ means the Adverse Event Disclosure and Compensation Program.

(6) PROGRAM COORDINATOR – The term ‘Program Coordinator’ means the individual designated by the Betsy Lehman Center to manage the affairs of the Adverse Event Disclosure and Compensation Program.

(7) PROGRAM PARTICIPANT – The term ‘Program participant’ means a participant that meets the requirements of subsection (d).

(8) ROOT CAUSE ANALYSIS – The term ‘root cause analysis’ means an examination or investigation of an adverse event to determine if a preventable medical error took place or if the standard of care was not followed and to identify the causal factors that led to the adverse event.

(b) The director of the Betsy Lehman Center is hereby authorized to appoint a Program Coordinator to manage the affairs of the Adverse Event Disclosure and Compensation Program. The Program Coordinator shall:

(1) establish an Adverse Event and Compensation Program to provide for the disclosure of adverse events among Program Participants to patients and families and to reduce the incidence of events that adversely affect patient safety, improve patient's access to timely compensation, and reduce medical liability costs to health care providers;

(2) determine who is eligible for participation in the Program;

(3) develop a standardized application to be submitted by interested parties for entry into the Program;

(4) oversee the application process for entry into the Program and provide technical assistance to applicants and Program Participants;

(5) establish and maintain a Patient Safety Database to compile patient safety data from unidentifiable patients and physicians which is reported by Program Participants;

(6) analyze medical error trends and prepare annual reports in consultation with the Director to be submitted to the Joint Committee on Health Care Financing and the House and Senate Committees on Ways and Means;

(7) develop annual safety and training recommendations Program Participants that focus on the reduction of medical errors, improved patient safety, and increased quality of care;

(8) perform any other duties as determined necessary by the Director of the Betsy Lehman Center.

(c) The awarding of grants under the Medical Error and Compensation Pilot Program

(1) The Program Coordinator shall award grants to Program Participants to enable such participants to:

a. organize teams of providers to respond to situations requiring the communication of adverse events to patients and families, as well as to provide support to the health care providers involved. The teams will also provide for a liaison to maintain continuous contact with the patient and family upon determination of an adverse event, until the review and negotiation process is completed;

b. make a determination of all adverse events that are to be disclosed to patients and families;

c. develop training and education for all providers on the disclosure of adverse events;

d. employ a Patient Safety Officer responsible for monitoring the early disclosure program; and

e. procure information technology products, including hardware, software, and support services, to facilitate the reporting, collection and analysis of patient safety data as required.

(d) Participation in the Program is subject to eligibility and appropriations, and the Program Coordinator shall have sole authority to select participants.

(2) Eligible Participants. To be eligible to participate in the Program an entity shall be a hospital licensed under section 51 of chapter 111 of the general laws and shall meet the following criteria:

a. The hospital's primary coverage is self insured, or

b. The hospital's and physicians' insurance carriers, including risk retention groups and similar organizations, agree to participate in the program.

(3) An eligible hospital shall:

a. submit a completed application which includes a detailed comprehensive plan for implementation of the adverse event disclosure model to the Betsy Lehman Center at such time, in such manner, and containing such information as the program coordinator may require; and

b. agree to comply with the conditions of participation under subsection (e).

(e) Conditions of Participation. A Program Participant shall:

(1) designate a Patient Safety Officer to ensure that the conditions of participation described herein are met;

(2) submit cost analysis statements, in such manner as determined by the Program Coordinator, for the 2 fiscal years prior to the year of expected entry into the Program at the time of application and at the end of every year of participation in the Program, that outline all real and projected costs and savings related to the liability coverage and legal defense costs of doctors and other health care providers;

(3) adhere to the parameters of an adverse event disclosure model, as follows:

a. an adverse event shall be disclosed to the patient no later than 15 working days after its discovery;

b. following disclosure, the hospital and health care providers involved in the adverse event shall promptly offer a statement of apology;

c. following discovery of an adverse event, the team of providers shall immediately convene a root cause analysis;

d. upon completion of the root cause analysis, which shall be completed no more than 3 months after the occurrence of an adverse event, disclose any relevant information obtained in the course of the investigation to the patient and report that

(i) that the hospital was not at fault in the occurrence of the adverse event and therefore no compensation shall be offered; or

(ii) that the patient was harmed or injured as a result of a medical error or as a result of the relevant standard of care not being followed.

e. offer, at the time of disclosure of an incident or occurrence in which it was determined that a patient was harmed or injured as a result of medical error or as a result of the relevant standard of care not being followed, to:

(i) negotiate compensation with the patient involved in accordance with subsection (f);

(ii) share, where practicable, any efforts the health care provider will undertake to prevent reoccurrence.

(f) Negotiations

(1) If at the time of the disclosure of an incident or occurrence in which it was determined that a patient was harmed or injured as a result of medical error or as a result of the relevant standard of care not being followed, a patient elects to enter into an agreement for negotiations with a Program Participant as provided for in subsection (e), such negotiations shall, at a minimum, provide for the following:

a. the confidentiality of the proceedings;

b. written notification of a patient's right to legal counsel, which shall include an affirmative declaration that no coercive or otherwise inappropriate action was taken to dissuade a patient from utilizing counsel for the negotiations;

c. an agreement that if such negotiations end without an offer of compensation that is acceptable to both parties, any expression of regret or apology made by any member of the licensed hospital in the course of the negotiations, including an expression of regret or apology that is made in writing, orally or by conduct, does not constitute an admission of liability for any purpose in any subsequent civil action.

(2) Both parties may use legal representation to facilitate the negotiation of the terms of the settlement.

(3) With respect to negotiations under paragraph (1), the parties shall agree that if an agreement on the terms of compensation is not reached within 6 months from the date of the disclosure:

a. the patient may proceed directly to the judicial system for a resolution of the issues involved; or

b. the parties may sign an extension of the agreement to provide an additional 3-month negotiation period.

(4) Upon receipt of the final payment of the accepted settlement as negotiated under this subsection, the patient shall agree to the final settlement of the incident described in the report and findings of the root cause analysis and further litigation with respect to such matter shall be prohibited in Federal or State court.

(g) Submission of Patient Safety Data

(1) The purpose of creating a Patient Safety Database is to:

a. promote patient safety by identifying preventable errors and adverse events, and develop process changes to reduce their incidence in the future; and

b. encourage better exchange between health care providers and patients regarding preventable medical errors and transparency in the practice of medicine- including apologizing for errors - consistent with the goals of enhancing patient safety.

(2) The Betsy Lehman Center shall establish a Patient Safety Database, and the Patient Safety Officer of a Program Participant shall be required to prepare and submit to the Database:

a. any adverse events that occur within the hospital;

b. any legal action related to the medical liability of a hospital;

c. a summary of any report submitted to a Program Participant's Patient Safety Officer following a root cause analysis;

d. the terms of any agreement reached either through negotiations under subsection (f) or by other means;

e. any disciplinary actions taken against a physician or licensed hospital as a result of involvement in any incident or occurrence that is found to be the result of a medical error or the relevant standard of care not being followed; and

f. any other data as determined appropriate by the Betsy Lehman Center.

(3) Information submitted to the Database related to patients, physicians, and health care providers shall be kept strictly confidential.

(4) Access to the Patient Safety Database shall only be granted to the Betsy Lehman Center and the Department of Public Health.

(h) Study

(1) Beginning not more than 12 months after the implementation of an Adverse Event Disclosure and Compensation Pilot Program, the Betsy Lehman Center shall conduct an evaluation regarding the overall effectiveness of the program and grant and prepare a report for the Center. The evaluation shall include:

a. an analysis of the effect of the system on the number, nature, and costs of compensated events, as well as health care liability claims, and a comparison of this information among all Program Participants; and

b. a recommendation for an expansion of the program, a continuation of the program as is, or its discontinuation.

(i) Authorization of Appropriations

(1) There are authorized to be appropriated sums of $250,000 per Program Participant to carry out this section.