PLEASE NOTE: Legislative Information ***cannot*** perform research, provide legal advice, or interpret Maine law. For legal assistance, please contact a qualified attorney.

An Act To Permit Medical Providers an Opportunity To Express Regret for a Medical Error

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 14 MRSA §171 is enacted to read:

§ 171. Expression of regret or apology by health care provider

An expression of regret or apology or an explanation of how a medical error occurred made by or on behalf of a health care provider that is provided within 14 days of when the provider knew or should have known of the consequences of the error or made pursuant to Title 22, chapter 422 does not constitute a legal admission of liability and is inadmissible in a civil or administrative proceeding, including an arbitration or mediation proceeding. A health care provider who makes an expression of regret or apology or an explanation of how a medical error occurred within 14 days of when the provider knew or should have known of the consequences of the error or pursuant to Title 22, chapter 422 may not be examined with respect to the expression of regret, apology or explanation in any deposition or civil or administrative proceeding. For purposes of this section, "health care provider" has the same meaning as in Title 5, section 19201, subsection 2.

Sec. 2. 22 MRSA c. 422 is enacted to read:

CHAPTER 422

medical errors and patient safety

§ 2150-D. Definitions

As used in this chapter, unless the context indicates otherwise, the following terms have the following meanings.

1. Database. "Database" means the patient safety database established by the commissioner pursuant to section 2150-I.

2. Health care facility. "Health care facility" has the same meaning as in section 328, subsection 8.

3. Health care provider. "Health care provider" has the same meaning as in Title 5, section 19201, subsection 2.

4. Incident. "Incident" means an event, occurrence or situation involving the clinical care of a patient in a health care facility that could have injured the patient but did not cause an unanticipated injury or require the delivery of additional health care services to the patient.

5. Medical error. "Medical error" means an unexpected occurrence involving death or serious physical or psychological injury or the risk of death or serious physical or psychological injury or of which a recurrence may carry a significant chance of a serious adverse outcome involving the clinical care of a patient in a health care facility.

6. Patient safety event. "Patient safety event" means an occurrence, incident or process that contributes to or has the potential to contribute to a patient injury or degrades the ability of a health care provider to provide the appropriate standard of care.

7. Patient safety officer. "Patient safety officer" means the person designated by a program participant pursuant to section 2150-F, subsection 2, paragraph A, who is responsible for ensuring that the conditions for participation in the program are met.

8. Program. "Program" means the Medical Error Disclosure and Compensation Program established in section 2150-E.

9. Root cause analysis. "Root cause analysis" means an examination or investigation of an occurrence, event or incident 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 occurrence, event or incident.

§ 2150-E. Medical Error Disclosure and Compensation Program

The Medical Error Disclosure and Compensation Program is established.

1. Administration. The commissioner shall develop and review applications and determine eligibility for the program and administer the program to provide for the confidential disclosure of medical errors in order to improve patient safety and health care quality, reduce rates of preventable medical errors, ensure patient access to fair compensation for medical injury due to medical error, negligence or malpractice and reduce the cost of medical liability for doctors, health systems and other health care providers.

2. Grants. The commissioner may award a grant to a program participant to further the purposes of this section. In order to be eligible to receive a grant under this subsection, a program participant must submit an application to the commissioner, who shall designate the form, time and manner of the application. The commissioner may award a grant under this subsection to a program participant for the following purposes:

A. To develop and implement a communication program to help a health care provider disclose medical errors and other patient safety events to patients; or

B. To procure information technology products, including hardware, software and support services, to facilitate the reporting, collection and analysis of patient safety data required under this chapter.

§ 2150-F. Program participation

1. Program participants. The following may participate in the program:

A. A health care facility;

B. A health care provider; and

C. A provider of medical malpractice insurance for a health care provider, including:

(1) A mutual insurance company;

(2) A privately held or publicly traded liability insurance company;

(3) A self-insured hospital;

(4) A captive insurance company or provider covered by a captive insurance company; and

(5) A risk retention group or any other alternative malpractice insurance mechanism.

A program participant that is a medical liability insurer shall provide to all or a subset of its insured an opportunity to participate in the program.

2. Application requirements. A health care provider or health care facility shall submit a comprehensive plan to reduce the incidence of medical errors and improve patient safety as part of its application for participation in the program.

3. Participant requirements. A program participant shall:

A. Designate a patient safety officer to ensure that the conditions of participation established in this chapter are met; and

B. Allocate an amount not less than 50% of the projected annual savings for the first year of participation in the program, not less than 40% of the actual savings reported for the second year of participation in the program and not less than 30% of the actual savings reported for the third and subsequent years of participation in the program to:

(1) In the case of a program participant that is a medical liability insurer, reduce medical liability premiums for health care providers; or

(2) In the case of a program participant that is a health care facility or provider, promote activities that result in the reduction of medical errors or that otherwise improve patient safety.

§ 2150-G. Reporting

A program participant shall maintain and submit a report as follows.

1. Patient safety officer. A program participant shall submit to the patient safety officer a report of:

A. An incident or occurrence involving a patient that is thought to be either a medical error or a patient safety event; or

B. A legal action related to the medical liability of a health care facility or provider.

2. Submission to database. A program participant shall file a report submitted under subsection 1 to the database in a standardized format as designed by the commissioner.

3. Root cause analysis. A program participant shall perform a root cause analysis with respect to a report submitted under subsection 1 within 90 days after the report is submitted.

4. Disclosure to patient. If a patient is harmed or injured as a result of a medical error or as a result of the relevant standard of care not being followed, a program participant shall:

A. Disclose to the patient the report submitted under subsection 1, paragraph A with respect to the patient not later than 5 business days after the completion of the root cause analysis required under subsection 3; and

B. Upon the request of a patient who is the subject of a report submitted under subsection 1, paragraph A, disclose to the patient information contained in the report.

§ 2150-H. Negotiation

At the time of disclosure to a patient pursuant to section 2150-G, subsection 4, a program participant shall offer to negotiate compensation for the injury with the patient.

1. Compensation; apology. As part of negotiating under this section, a program participant:

A. Shall offer to the patient compensation for the harm or injury pursuant to subsection 2;

B. May, at the discretion of the health care facility or provider involved, apologize or express regret to the patient for the harm or injury; and

C. Shall share when practicable any efforts the health care facility or provider will undertake to prevent a recurrence of the harm or injury.

2. Terms of negotiation. If a patient elects to negotiate compensation with a program participant pursuant to this section, the following rules apply.

A. The negotiations are confidential.

B. An apology or expression of regret by the program participant is confidential and inadmissible in a civil or administrative proceeding pursuant to Title 14, section 171.

C. The program participant shall provide to the patient written notification of the patient's right to legal counsel. This notification must include an affirmative declaration that no action was taken to dissuade the patient from using counsel for the negotiations.

D. The parties may agree to the use of a neutral 3rd-party mediator to facilitate the negotiation.

E. If an agreement on compensation for the harm or injury is not reached within 6 months from the date of disclosure under section 2150-G, subsection 4:

(1) The patient may proceed directly to the judicial system for a resolution of the issues involved; or

(2) The parties may sign an agreement to extend the negotiations for an additional 3 months.

3. **Agreement.** Upon reaching an agreement for compensation under this section, the program participant shall provide the negotiated compensation to the patient within an agreed-upon time. The agreement must provide that, upon receipt by the patient of the final payment of the accepted settlement agreed to under this section, further litigation with respect to the underlying incident as described in the report and findings of the root cause analysis under section 2150-G in a court of any jurisdiction is prohibited.

§ 2150-I. Patient safety database

The commissioner shall develop a patient safety database.

1. **Structure of the database.** The commissioner shall consult with health care organizations, health care providers, patient safety organizations and health information technology organizations with relevant expertise to:

A. Adopt a standardized patient safety taxonomy for the database;

B. Develop for the database necessary elements, common and consistent definitions and a standardized electronic interface for the entry and processing of data by program participants; and

C. Allow for the comprehensive collection and analysis of the patient safety data submitted to the database pursuant to subsection 5.

2. **Confidentiality.** Information submitted to the database is privileged and confidential and protected from disclosure pursuant to section 1711-C. Inclusion of information in the database does not limit access to information otherwise discoverable.

3. **Access.** Access to the information contained within the database may be obtained only through application to and approval by the commissioner.

4. **Entries.** An entry into the database must:

A. Be presented in a form and manner that deletes, omits or renders illegible any information identifying a health care provider, patient or program participant;

B. Be in a standardized electronic format as determined by the commissioner; and

C. If related to a single occurrence or incident, be given a common identifier to link entries of related data.

5. Information required to be submitted. A patient safety officer shall prepare and enter into the database:

A. A report filed by a health care facility or provider under section 2150-G;

B. A summary of the findings of a root cause analysis filed pursuant to section 2150-G, subsection 3;

C. The terms of an agreement reached through a negotiation pursuant to section 2150-H;

D. The terms of an award given by a program participant to a patient for compensation for harm or injury, whether provided through a negotiation under section 2150-H or through any other means;

E. A disciplinary action taken against a health care facility or provider as a result of involvement in an incident or occurrence involving a patient that is thought to be a medical error or patient safety event; and

F. Any other information determined appropriate by the patient safety officer or the commissioner.

§ 2150-J. Rules

The commissioner may adopt rules to carry out the purposes of this section. Rules adopted pursuant to this section are major substantive rules pursuant to Title 5, chapter 375, subchapter 2-A.

Sec. 3. Appropriations and allocations. The following appropriations and allocations are made.

HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Medical Error Disclosure and Compensation Program

Initiative: Provides funds to issue grants to participants in the Medical Error Disclosure and Compensation Program to develop communication programs and procure information technology products to assist health care providers in disclosing medical errors and to improve patient safety.

GENERAL FUND	2007-08	2008-09
All Other	$75,000	$0
GENERAL FUND TOTAL	$75,000	$0

SUMMARY

This bill makes a one-time General Fund appropriation of $75,000 in fiscal year 2007-08 for the Commissioner of Health and Human Services to issue grants to develop communication programs and procure information technology products to assist health care providers in disclosing medical errors and to improve patient safety. This bill also makes privileged and immune from discovery an expression of regret or apology or an explanation of how a medical error occurred made by a health care provider if it is provided within 14 days of when the provider knew or should have known of the consequences of the error. This bill further establishes the Medical Error Disclosure and Compensation Program, which creates a system that allows health care providers, facilities and medical malpractice insurers to disclose medical errors and negotiate compensation with the subject patient without the threat of litigation, and directs the Commissioner of Health and Human Services to create a patient safety database.