109TH CONGRESS
1ST SESSION

S. 1784

To amend the Public Health Service Act to promote a culture of safety within the health care system through the establishment of a National Medical Error Disclosure and Compensation Program.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 28, 2005

Mrs. CLINTON (for herself and Mr. OBAMA) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Public Health Service Act to promote a culture of safety within the health care system through the establishment of a National Medical Error Disclosure and Compensation Program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''National Medical Error Disclosure and Compensation Act'' or the ''National MEDiC Act''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) In 1999, the Institute of Medicine released a report entitled ''To Err is Human'' that found medical errors to be the eighth leading cause of death in the United States, with as many as 98,000 people dying each year as a result of medical errors.

(2) To reduce deaths and injuries due to medical errors, the health care system must identify and learn how to prevent such errors so that health care quality can be improved.

(3) The goals of the liability system are to identify causes of medical error, remediate those causes to prevent reoccurrence, and to compensate those injured by medical negligence. Studies have shown, however, that only one medical malpractice claim is filed for every 8 medical injuries, and the average duration of malpractice claim resolution is between 4 and 8 years. Thus, the current health care liability system has been found to be an inefficient and sometimes ineffective mechanism for initiating or resolving claims of medical error, medical negligence, or malpractice.

(4) The current liability system has also been shown to be a deterrent to the timely sharing of information among health care professionals, as well as between health care professionals and patients,

which impedes efforts to improve patient safety and quality of care.

(5) Solutions to the patient safety, litigation, and medical liability insurance problems have been elusive. A middle ground solution that meets the basic needs of all stakeholders including patients, health care providers, insurers, purchasers, and attorneys is desperately needed.

(6) Some hospital systems and private medical liability insurance companies have adopted a policy of robust disclosure of medical errors, apologies for such errors, and early compensation for patient injury. For example, a Department of Veterans Affairs hospital in Lexington, Kentucky, the University of Michigan Health System, and the private insurer Copic Insurance Company in Colorado have adopted such policies and have reported significantly decreased legal expenses and smaller claim payouts. Overall, these policies have resulted in fewer numbers of malpractice suits being filed, more patients being compensated for injuries, greater patient trust and satisfaction, and significantly reduced administrative and legal defense costs for providers, insurers, and hospitals where such policies are in place.

SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.), as amended by the Patient Safety and Quality Improvement Act of 2005 (Public Law 109–41), is amended—

(1) by redesignating part D as part E;

(2) by redesignating sections 931 through 938 as sections 941 through 948, respectively;

(3) in section 948(1) (as so redesignated), by striking ''931'' and inserting ''941''; and

(4) by inserting after part C the following:

''PART D—MEDICAL ERROR DISCLOSURE AND COMPENSATION

''SEC. 931. DEFINITIONS.

''In this part:

''(1) DATABASE.—The term 'Database' means the National Patient Safety Database established under section 934.

''(2) HEALTH CARE PROVIDER.—The term 'health care provider' means a person or entity licensed or otherwise authorized under State law to provide health care services, including—

''(A) a hospital, health plan, community clinic, nursing facility, comprehensive rehabilitation facility, home health agency, hospice pro-

gram, renal dialysis facility, ambulatory surgical center, pharmacy, doctor's or health care practitioner's office, long-term care facility, behavior health residential treatment facility, clinical laboratory, or health center;

"(B) a doctor, nurse, physician assistant, nurse practitioner, clinical nurse specialist, certified nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; and

"(C) any other health care professional specified in regulations promulgated by the Secretary.

"(3) IDENTIFIABLE PATIENT SAFETY WORK PRODUCT.—The term 'identifiable patient safety work product' means patient safety work product that—

"(A) is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product;

''(B) constitutes individually identifiable health information as that term is defined in the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996; or

''(C) is presented in a form and manner that allows the identification of an individual who reported information in the manner specified in section 922(e) or 935.

''(4) MEDICAL ERROR.—The term 'medical error' means an unexpected occurrence involving death or serious physical or psychological injury, or the risk of such injury, including any process variation of which recurrence may carry significant chance of a serious adverse outcome.

''(5) NONIDENTIFIABLE PATIENT SAFETY WORK PRODUCT.—The term 'nonidentifiable patient safety work product' has the meaning given such term in section 921.

''(6) OFFICE.—The term 'Office' means the Office of Patient Safety and Health Care Quality established under section 933, which shall be a certified patient safety organization as defined under part C.

''(7) PATIENT SAFETY DATA.—The term 'patient safety data' means information requested by the Director of the Office to be submitted by the patient safety officer of a Program participant as described in section 935(e).

''(8) PATIENT SAFETY EVENT.—The term 'patient safety event' means an occurrence, incident, or process that either contributes to, or has the potential to contribute to, a patient injury or degrades the ability of health care providers to provide the appropriate standard of care.

''(9) 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.

''(10) PATIENT SAFETY ORGANIZATION.—The term 'patient safety organization' has the meaning given such term in section 921.

''(11) PATIENT SAFETY WORK PRODUCT.—The term 'patient safety work product' has the meaning given such term in section 921.

''(12) PROGRAM.—The term 'Program' means the National Medical Error Disclosure and Com-

pensation (MEDiC) Program, established under section 935.

''(13) PROGRAM PARTICIPANT.—The term 'Program participant' means a participant that meets the requirements of section 935(b).

''(14) ROOT CAUSE ANALYSIS.—The term 'root cause analysis' means an examination or investigation of an occurrence, event, or incident to determine if a preventable medical error took place or the standard of care was not followed and to identify the causal factors that led to such occurrence, event, or incident.

''SEC. 932. PURPOSE AND GOALS.

''It is the purpose of this part to promote a culture of safety within hospitals, health systems, clinics, and other sites of health care, through the establishment of a National Medical Error Disclosure and Compensation (MEDiC) Program (referred to in this part as the 'Program'). It shall be a goal of the Program to—

''(1) improve the quality of health care by encouraging open communication between patients and health care providers about medical errors and other patient safety events;

''(2) reduce rates of preventable medical errors;

''(3) ensure patients have access to fair compensation for medical injury due to medical error, negligence, or malpractice; and

''(4) reduce the cost of medical liability insurance for doctors, hospitals, health systems, and other health care providers.

''SEC. 933. OFFICE OF PATIENT SAFETY AND HEALTH CARE QUALITY.

''(a) IN GENERAL.—The Secretary shall establish within the Office of the Secretary, an Office of Patient Safety and Health Care Quality to collaborate with the Director of the Agency for Health Care Research and Quality to improve patient safety and reduce medical error across the health care system. The Office shall be headed by a Director to be appointed by the Secretary.

''(b) ACTIVITIES.—The activities of the Office shall be deemed patient safety activities, as defined in section 921.

''(c) DUTIES.—The Director of the Office shall—

''(1) establish and administer the Program;

''(2) determine who is eligible for participation in the Program in accordance with section 935;

''(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 under section 935 and provide technical assistance to Program applicants and Program participants;

''(5) contract with an independent entity for the purpose of evaluating the Program at least once every two years, with the results of such evaluations being disseminated to Program participants, Congress, and the public;

''(6) establish and maintain, in consultation with patient safety organizations, health care quality organizations, health care providers, and the health information technology industry, a National Patient Safety Database as provided for in section 934 to receive nonidentifiable patient safety work product as described in the reporting requirements for Program participants under section 935(c)(10);

''(7) determine and adopt a standardized patient safety taxonomy, necessary elements, common and consistent definitions, and standardized formats for the electronic reporting of patient safety data to the Database as described in section 934(e);

''(8) survey Federal, State, and local requirements for the reporting of patient safety data and

work to streamline and reduce duplication of such requirements;

''(9) grant patient safety organizations, researchers, and other qualified individuals and institutions access to the Database as determined appropriate through the evaluation of completed applications submitted to the Office for such purpose;

''(10) analyze, directly or through a contract with a patient safety organization, all data entered into the Database and provide Program participants, Congress, and the public with medical error trend reports and other analyses as determined appropriate by the Director on a quarterly basis;

''(11) develop, directly or through a contract with a patient safety organization, safety and training recommendations for health care providers that focus on the reduction of medical errors, improved patient safety, and increased quality of care on at least a yearly basis;

''(12) maintain a publicly accessible Internet website to provide patients and health care providers with information concerning the Program and the Database;

''(13) conduct, directly or through a contract, the National MEDiC Accountability Study, as de-

scribed in section 937, the Medical Liability Insurance Study, as described in section 938, and a study to reduce the incidence of lawsuits not related to medical error, as described in section 939; and

''(14) perform any other duties for the administration of the Program as determined necessary by the Secretary.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, such sums as may be necessary for each fiscal year to carry out the activities of the Office.

''SEC. 934. NATIONAL PATIENT SAFETY DATABASE.

''(a) IN GENERAL.—The Director of the Office shall, in accordance with section 933(c)(6), establish a National Patient Safety Database that shall—

''(1) adopt standardized patient safety taxonomy in consultation with the Joint Commission on Accreditation of the Healthcare Organizations and other entities with relevant expertise;

''(2) include necessary elements, common and consistent definitions, and a standardized electronic interface for the entry and processing of the data by Program participants, as developed by the Director in consultation with patient safety organizations,

health care providers, and the health information technology industry;

''(3) allow for the comprehensive collection and analysis of the patient safety data required to be submitted by all Program participants as described in section 935(e); and

''(4) include patient safety data required to be submitted by Program participants as described in section 935(e) as nonidentifiable patient safety work product and privileged and confidential in accordance with section 922.

''(b) LIMITATION.—Information submitted to the Database shall be confidential and protected from disclosure in accordance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

''(c) ACCESS.—Access to the patient safety data contained within the Database shall only be provided through application to and approval by the Director.

''SEC. 935. NATIONAL MEDICAL ERROR DISCLOSURE AND COMPENSATION (MEDIC) PROGRAM.

''(a) ESTABLISHMENT.—The Secretary, acting through the Director of the Office, shall establish a National Medical Error Disclosure and Compensation (MEDiC) Program to provide for the confidential disclo-

sure of medical errors and patient safety events 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, hospitals, health systems, and other health care providers.

''(b) ELIGIBLE PARTICIPANTS.—To be eligible to participate in the Program an entity shall—

''(1)(A) be a health care provider as defined in section 931(2)(A);

''(B)(i) provide, in whole or part, medical malpractice insurance for doctors and other designated health care providers, including—

''(I) mutual insurance companies;

''(II) privately held or publically traded liability insurance companies;

''(III) self-insured hospitals;

''(IV) captive insurance companies or providers covered by captive insurance companies; and

''(V) risk-retention groups and any other alternative malpractice insurance mechanisms; or

''(ii) in the case of a Program participant that is a medical liability insurer, provide to all, or a subset of, the insured of such insurer, an opportunity to participate in the Program; or

''(C) be any other entity determined to be eligible by the Director;

''(2) designate a patient safety officer to ensure that the conditions of participation described in subsection (c) are met;

''(3) submit a completed application to the Office at such time, in such manner, and containing such information as the Director may require; and

''(4) agree to comply with the conditions of participation under subsection (c).

''(c) CONDITIONS OF PARTICIPATION.—A Program participant shall, directly or indirectly—

''(1) submit a comprehensive plan, as part of the application for participation in the Program, to reduce the incidence of medical errors and improve patient safety;

''(2) submit cost analysis statements, in such manner as determined by the Director, 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) allocate an amount equal to not less than 50 percent of the projected annual savings for the first year of participation in the Program, not less than 40 percent of the actual savings reported for the second year, and not less than 30 percent of the actual savings reported for the third and each subsequent year of participation to—

''(A) in the case of a Program participant that is a medical liability insurer, the reduction of medical liability premiums for doctors or other designated health care providers as defined in section 931; or

''(B) in the case of a Program participant that is a health care provider as defined in section 931(2)(A), activities that result in the reduction of medical errors or that otherwise improve patient safety;

''(4) require health care providers included in the Program by the Program participant and as outlined in the Program participant application, to submit to the patient safety officer a report of—

''(A) any incident or occurrence involving a patient that is thought to either be a medical error or patient safety event; and

''(B) any legal action related to the medical liability of a health care provider;

''(5) ensure that the reports filed under paragraph (4) are submitted to the Database in a standardized format as designated by the Director;

''(6) where appropriate, ensure that a root cause analysis of any report submitted to the patient safety officer as described in paragraph (4) is performed within 90 days of the filing of a report under such paragraph;

''(7) ensure that if a patient was harmed or injured as the result of a medical error, or as a result of the relevant standard of care not being followed, an account of the incident or occurrence, as described in paragraph (4)(A) shall be disclosed to the patient not later than 5 business days after the completion of root cause analysis;

''(8) disclose information contained in any report submitted to the patient safety officer as described in paragraph (4)(A) upon the request of the patient with respect to whom the report has been filed;

''(9) 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—

''(A) negotiate compensation with the patient involved in accordance with subsection (d);

''(B) provide, at the discretion of the health care provider involved, an apology or expression of remorse; and

''(C) share, where practicable, any efforts the health care provider will undertake to prevent reoccurrence; and

''(10) prepare and submit entries to the Database as required by the Director of the Office and in accordance with subsection (e).

''(d) NEGOTIATIONS.—

''(1) TERMS.—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

(c)(9), such negotiations shall, at a minimum, provide for the following:

''(A) The confidentiality of the proceedings.

''(B) An agreement that any apology or expression of remorse by a doctor or other designated health care provider at any time during the negotiations shall be kept confidential and shall not be used in any subsequent legal proceedings as an admission of guilt if such negotiations end without an offer of compensation that is acceptable to both parties.

''(C) 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.

''(2) NEUTRAL THIRD PARTY MEDIATOR.—Both parties may agree to the use of a neutral third party mediator to facilitate the negotiation of the terms of the settlement.

''(3) TIMEFRAME FOR NEGOTIATIONS.—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 required under subsection (c)(7) to the patient—

"(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) PAYMENT.—Upon reaching an agreement under this subsection, the Program participant shall provide the negotiated compensation to the patient within an agreed upon timeframe.

"(5) FINALITY.—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 under subsection (c)(7), and further litigation with respect to such matter shall be prohibited in Federal or State court.

"(e) SUBMISSION OF PATIENT SAFETY DATA.—

"(1) IN GENERAL.—All entries into the Database shall—

''(A) contain only non-identifiable patient safety work product;

''(B) be in a standardized electronic format to be determined by the Director; and

''(C) if related to a single occurrence or incident, be given a common identifier to link entries of related data.

''(2) REPORTING REQUIREMENTS.—The patient safety officer of a Program participant shall be required to prepare and enter into the Database—

''(A) reports, containing only nonidentifiable patient safety work product, filed by a health care provider under subsection (c)(4) and a summary of the findings of the root cause analysis with respect to such report within 5 business days of the completion of the root cause analysis;

''(B) the terms of any agreement reached through negotiations under subsection (d);

''(C) any awards given by a Program participant to a patient as compensation for harm or injury whether obtained through negotiations under subsection (d) or by other means;

''(D) any disciplinary actions taken against a health care provider as a result of involve-

ment in any incident or occurrence involving a patient that is thought to be a medical error or patient safety event, or legal action for which a report under subsection (c)(4) was filed; or

''(E) other data as determined appropriate by the Director.

''(3) PRIVILEGE AND CONFIDENTIALITY.—The provisions of section 922 shall apply to patient safety data submitted under this subsection.

''SEC. 936. NATIONAL MEDIC GRANT PROGRAM.

''(a) IN GENERAL.—The Director of the Office shall award grants—

''(1) to Program participants, to enable such participants to—

''(A) develop and implement communication programs to help health care providers disclose medical errors and other patient safety events to patients; and

''(B) procure information technology products, including hardware, software, and support services, to facilitate the reporting, collection, and analysis of patient safety data as required under this part; and

''(2) to patient safety organizations and qualified institutions or individuals, to enable the—

''(A) tracking and analysis of local and regional patient safety trends; and

''(B) development and dissemination of training guidelines and other recommendations for doctors and other designated health care providers that focus on methods to reduce medical errors and improve patient safety and quality of care.

''(b) APPLICATION.—To be eligible to receive a grant under this section, a Program participant, patient safety organization, or qualified institution or individuals shall submit to the Director of the Office an application at such time, in such manner, and containing such information as the Director may require.

''(c) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There are authorized to be appropriated, such sums as may be necessary to carry out this section.

''(2) RESERVES.—The Secretary shall reserve 20 percent of the funds appropriated under paragraph (1) to provide funding to Program participants if the Secretary determines that the total costs of the cases handled under the Program for the year exceed the total costs that would have been incurred

if such cases had not been handled under the Program.

"SEC. 937. THE NATIONAL MEDIC ACCOUNTABILITY STUDY.

"(a) IN GENERAL.—The Director of the Office shall conduct, directly or through a contract with patient safety organizations or qualified individuals or institutions, an analysis of the patient safety data in the Database and other available data to determine performance and systems standards, tools, and best practices (including peer-review) for doctors and other health care providers necessary to prevent medical errors, improve patient safety, and increase accountability within the health care system. Such analysis shall also consider the value of increasing the transparency of the patient safety data to include the identity of health care providers and provide recommendations for improvements to the peer review process.

"(b) REPORT AND RECOMMENDATIONS.—Not later than 2 years after the date of enactment of the National MEDiC Act, the Director of the Office shall submit to Congress and make available to States, State medical boards, and the public a report that describes the results of the study carried out under subsection (a) and contains recommendations for Congress based on the findings of the report.

"SEC. 938. MEDICAL LIABILITY INSURANCE STUDY.

"(a) IN GENERAL.—The Director of the Office shall conduct, directly or through contract with patient safety organizations or qualified individuals or institutions, an analysis of the medical liability insurance market that distinguishes between types of carriers to determine historic and current legal costs related to medical liability, factors leading to increased legal costs related to medical liability, and which, if any, State medical liability insurance reforms have led to stabilization or reduction in medical liability premiums.

"(b) REPORT AND RECOMMENDATIONS.—Not later than 2 years after the date of enactment of the National MEDiC Act, the Director of the Office shall submit to Congress and make available to the States, State insurance regulators, and the public a report that describes the results of the study carried out under subsection (a) and contains recommendations for Congress based on the findings of the report.

"SEC. 939. STUDY TO REDUCE THE INCIDENCE OF LAWSUITS NOT RELATED TO MEDICAL ERROR.

"(a) IN GENERAL.—The Director of the Office shall conduct, directly or through a contract with patient safety organizations or qualified individuals and institutions, an analysis of the patient safety data in the Database to examine cases that were not successfully negotiated through

the Program, or of which the parties (including providers and patients) chose not to participate in the Program and to determine the reasons, trends, and impact on the Program participants and patients.

''(b) REPORT AND RECOMMENDATIONS.—

''(1) IN GENERAL.—Not later than 5 years after the date of enactment of the National MEDiC Act, the Director of the Office shall submit to Congress and make available to the States, and the public a report that describes the results of the study carried out under subsection (a) and contains recommendations for Congress based on the findings of the report.

''(2) INTERIM REPORTS.—The Director of the Office shall submit periodic interim reports to Congress (and make such reports available to the States and the public) before the submission on the report under paragraph (1) that describes the progress and findings made in carrying out the study under subsection (a).

''SEC. 940. AUTHORIZATION OF APPROPRIATIONS.

''There are authorized to be appropriated, such sums as may be necessary to carry out this part.''.

(b) CONFORMING AMENDMENT.—Section 921(7)(A)(i)(II) is amended by inserting '', including ac-

tivities under section 935(e)'' after ''patient safety activities''.

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