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S. 1784 Encourages Providers and Insurers to Voluntarily Report Medical Errors, Apologize and Make Good-faith Offers of Compensation

The Medical Error Disclosure and Compensation Act, or MEDiC Act, sponsored by Sens. Clinton and Obama, follows and builds on passage in July 2005 of the Patient Safety and Quality Improvement Act, which encourages providers to report medical errors by providing full legal privilege to patient-safety information transmitted to a federally-recognized "patient safety organization." (42 U.S.C.A. §299b-21-26)

The purpose of the MEDiC Act is to encourage a policy of robust disclosure of medical errors with thorough analysis and intervention, apologies for such errors, early compensation for patient injury and a corresponding reduction in the cost of medical liability insurance for doctors and hospitals. That we face an epidemic of medical errors is beyond dispute, "It is not pretty to say, but doctors and nurses make *preventable* mistakes that kill more people in the United States every year than workplace and automobile accidents combined." (Tom Baker, *The Medical Malpractice Myth*, 2005)

The National MEDiC program builds on a number of state and local efforts by encouraging the adoption of this model across the country and providing grant money and technical assistance for doctors, hospitals, insurers and health systems to help them implement the program. Overall these programs already in existence are reported to have resulted in greater patient satisfaction, fewer numbers of malpractice suits being filed and significantly reduced administrative and legal defense costs for providers, insurers and hospitals where such policies have been implemented.

While participation by providers is voluntary, the program provides grants to providers to fund program implementation; the program also protects providers against increased claims costs during their participation and provides for protection from further litigation in cases where settlements are successfully negotiated with the patient.

The program also takes innovative steps to study and analyze the information collected to improve patient safety and the quality of care. Three major studies are authorized: analysis of the material in the database to determine best practices for preventing medical errors, analysis of the medical liability insurance market, and examination of cases that were not successfully resolved by this program to determine reasons and trends.

The MEDiC program will be administered by HHS.

Office of Patient Safety and Healthcare Quality

The bill creates an Office of Patient Safety and Healthcare Quality within HHS, which in collaboration with the Agency for Healthcare Research and Quality shall increase patient safety and health care quality across healthcare settings. The Secretary of HHS shall appoint a Director whose duties will include administration of the program; participant eligibility determinations; oversight and development of standardized application forms; contract with independent entity for periodic evaluation of the program; establish and maintain database; adoption of standardized taxonomy for electronic reporting of patient safety data; survey federal and state patient safety reporting requirements to streamline and reduce duplication; allow qualified researchers access to the database; analyze the data directly and through use of outside entities; develop patient safety recommendations; maintain a publicly accessible website for patients and providers; and conduct the comprehensive studies provided for in the Act.

National Patient Safety Database

The Director shall in consultation with other Patient Safety Organizations; establish a National Patient Safety Database to collect confidential patient safety data from MEDiC Program participants. He shall develop an electronic interface, common terminology, for the comprehensive collection and analysis of patient safety data. Information collected shall be non-identifiable and confidential and access shall be provided only through application and approval by the Director.

National Medical Error Disclosure and Compensation Program

The goal of the Medical Error Disclosure and Compensation (MEDiC) Program is to:

- Improve the quality of health care by encouraging open, nonpunitive communication between patients and health care providers;
- Reduce rates of preventable medical errors;
- Ensure patients have access to fair compensation for medical injury, negligence, or malpractice;
- Reduce the cost of medical liability insurance for doctors, hospitals, health systems, and other health care providers.

Operation of Disclosure and Compensation Program

- **Eligibility**. To be a participant an entity must (1) be a health care provider, medical malpractice insurer, self insurer, risk retention group or any other alternative malpractice insurer; (2) designate a patient safety officer to ensure compliance with conditions of participation; (3) submit a completed application to the Director; and (4) agree to comply with the conditions of participation. The decision by the provider or insurer to participate is voluntary.

- **Conditions.** The conditions of participation include submission of application; submission of cost analysis statements for two fiscal years before participation and each year of participation that detail all costs and savings related to liability coverage and legal defense costs.

- **Allocation of Program Savings**. Participants agree to allocate not less than 50 percent of the annual savings for the first year of participation, not less than 40 percent of the second year savings, and not less than 30 percent of the third year and all succeeding years of participation to reduction of medical liability insurance premiums or activities that result in reduction of medical errors.

- **Health Care Provider's Duty to Report**. Health care providers within the program are required to report to the Patient Safety Officer (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. The act contains no sanctions for a failure to report a medical error or patient safety event.

- **Medical Error Broadly Defined**. 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.

- **Patient Safety Event Defined**. 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.

- **Root Cause Analysis**. Where appropriate, ensure that a root cause analysis of any report is performed within 90 days of the report.

- **Notify the Patient within 5 days**. 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 shall be disclosed to the patient not later than 5 business days after the completion of the root cause analysis.

- **Full Disclosure**. Upon the request of the patient, disclose all information on this matter that is contained in any report submitted to the patient safety officer.

- **Offer and Apology.** At time of disclosure, the program participant is required to offer to negotiate compensation, provide, at the discretion of the health care provider, an apology or expression of remorse and share any efforts the health care provider will undertake to prevent reoccurrence.

- **Negotiation Conditions**. If a patient elects to enter into an agreement for negotiations, that agreement shall provide (1) for confidentiality of the proceedings, (2) any apology or expression of remorse shall be inadmissible in any subsequent legal proceeding, (3) for written notification to patient of their right to legal counsel and that no inappropriate action was taken to dissuade them to forgo legal advice, (4) the parties may agree to the use of a neutral third party to facilitate the negotiation, and (5) that if negotiations are not concluded within 6 months (or an agreed one-time 3 month extension), the patient may

proceed directly to the judicial system for resolution. The decision by the patient to participate in the settlement process is voluntary.

- **Compensation**. The act contains no limits on the amount of compensation. Presumably the limits on compensation would be governed by the jurisdiction in which the claim arose.

- **Payment**. Upon agreement, payment shall be made within an agreed time frame.

- **Finality and Provider Protection**. Upon receipt of final payment, patient shall agree that further litigation with respect to the matter of the report and root cause analysis shall be prohibited in Federal or State court.

Act Provides Protection Against Loss for Participants

Of the total funds appropriated to carry out the National MEDiC program, there is a provision to hold in reserve twenty percent for the purpose of providing funding to Program participants if the total costs for the year of the cases handled under the Program during the grant period exceed the total costs that would have been incurred if such cases had not been handled under the Program.

Patient Safety Officer Reports to Database.

Required to submit to database (1) summary of findings of the root cause analysis within 5 days of its completion; (2) the terms of any agreement reached with the patient; (3) any awards given to patient as compensation whether obtained through negotiations or by other means; (4) any disciplinary actions taken against any health care provider as a result of this incident; and (5) other data required by the Director.

National MEDiC Grant Program

This section allows the Director to develop and oversee grant programs to encourage participation in the program and support patient safety initiatives. Program participants would be eligible for funding to develop and implement communication training programs to help health care providers learn how to effectively disclose medical errors and other patient safety events to patients; and procure information technology to facilitate reporting, analysis of patient safety date. Patient Safety Organizations and others deemed qualified may obtain grants to track and analyze local and regional patient safety trends and to develop guidelines for methods to reduce medical errors and improve patient safety.

The National Patient Safety and Fair Compensation Accountability Study

This is the first section requiring a major study, the Director, directly or through contract, to analyze the patient safety data in the Database and from other sources to determine performance and systems standards, tools and best practices for doctors and other health care providers necessary to prevent medical errors, improve patient safety, and increase accountability within the healthcare system. Such analysis will consider the value of increasing the transparency of patient safety data to include the identity of health care providers and provide recommendations for improvements to the peer review process. A report with recommendations resulting from this analysis shall be submitted to Congress and be made available to States, State medical boards, and the public.

The Medical Liability Insurance Study

This second study section requires the Director, directly or through contract, to analyze the medical liability insurance market 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. Such an analysis shall distinguish between types of carriers. A report with recommendations resulting from this analysis shall be submitted to Congress and be made available to States, State insurance regulators, and the public.

Study to Reduce the Incidence of Lawsuits Not Related to Medical Error

Finally, this section requires the Director, directly or through contract, to analyze the patient safety data in the Database to examine those cases that were not successfully negotiated through the Program, or of which the parties chose not to participate in the Program and to determine the reasons, trends, and impact of such outcomes on Program participants and patients. A report with recommendations resulting from this analysis shall be submitted to Congress and be made available to States and the public.

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