106TH CONGRESS
2D SESSION

S. 2038

To amend the Public Health Service Act to reduce accidental injury and death resulting from medical mistakes and to reduce medication-related errors, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 8, 2000

Mr. SPECTER (for himself, Mr. HARKIN, and Mr. INOUYE) 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 reduce accidental injury and death resulting from medical mistakes and to reduce medication-related errors, and for other purposes.

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 ''Medical Error Reduction Act of 2000''.

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress makes the following findings:

(1) The United States has the finest health care system in the world. However, there is continuing concern and fear among the public about the safety of the nation's health care system as a result of a high occurrence of medical mistakes—the fifth leading cause of death.

(2) One national study estimates that more than 100,000,000 Americans have experience with medical errors and 1 out 3 cases caused permanent harm, with half of the errors occurring in hospitals.

(3) Three of the top patient-safety issues were exposure to infection, level of care received, and the credentials of health care professionals.

(4) A recent large-scale study indicates that at least 44,000 Americans may die each year as a result of medical error. Another study suggests that this number may be as high as 98,000 Americans.

(5) When using the lower estimate in paragraph (4), deaths due to medical errors still exceed the number of deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).

(6) Deaths from adverse drug events total more than 7,000 annually—exceeding the number of yearly workplace injuries (6,000).

(7) The total national cost of preventable medical errors resulting in injury is estimated to be between $17,000,000,000 and $29,000,000,000, from direct medical costs, lost productivity, and disability.

(8) One recent study found that about 2 out of every 100 admissions involves a preventable adverse drug event. If these findings are generalized, these adverse drug events affecting inpatients cost $2,000,000,000 nationally.

(9) Medical errors are costly in terms of repeat tests and medical countermeasures, which also are subject to compounding errors. Purchasers and patients pay for errors when insurance costs and copayments are inflated by services that would not have been necessary had proper care been provided.

(10) Errors also erode trust in the health care system by patients who experience longer hospital stays or disabilities and physical and psychological discomfort. Health care professionals pay for errors with loss of morale and frustration at not being able to provide the best care possible.

(b) PURPOSE.—It is the purpose of this Act to ensure that individuals enjoy the right to be free from accidental injury, accidental death, and medication-related errors, including medication-related errors.

SEC. 3. AMENDMENT TO PUBLIC HEALTH SERVICE ACT.

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended—

(1) by redesignating part C as part D;

(2) by redesignating sections 921 through 928, as sections 931 through 938, respectively;

(3) in section 938(1) (as so redesignated), by striking ''921'' and inserting ''931''; and

(4) by inserting after part B the following:

''PART C—REDUCING ERRORS IN HEALTH CARE

''SEC. 921. DEFINITIONS.

''In this part:

''(1) ADVERSE EVENT.—The term 'adverse event' means an injury resulting from medical management rather than the underlying condition of the patient.

''(2) ERROR.—The term 'error' means the failure of a planned action to be completed as intended or the use of a wrong plan to achieve the desired outcome.

''(3) HEALTH CARE PROVIDER.—The term 'health care provider' means an individual or entity that provides medical services and is a participant in a demonstration program under this part.

''(4) HEALTH CARE-RELATED ERROR.—The term ''health care-related error'' means a prevent-

able adverse event related to a health care intervention or a failure to intervene appropriately.

''(5) MEDICATION-RELATED ERROR.—The term 'medication-related error' means a preventable adverse event related to the administration of a medication.

''(6) SAFETY.—The term 'safety' with respect to an individual means that such individual has a right to be free from preventable serious injury.

''(7) SENTINEL EVENT.—The term 'sentinel event' means an unexpected occurrence involving an individual that results in death or serious physical injury that is unrelated to the natural course of the individual's illness or underlying condition.

"SEC. 922. ESTABLISHMENT OF STATE-BASED MEDICAL ERROR REPORTING SYSTEMS.

''(a) IN GENERAL.—The Secretary shall make grants available to States to enable such States to establish reporting systems designed to reduce medical errors and improve health care quality.

''(b) REQUIREMENT.—

''(1) IN GENERAL.—To be eligible to receive a grant under subsection (a), the State involved shall provide assurances to the Secretary that amounts received under the grant will be used to establish and

implement a medical error reporting system using guidelines (including guidelines relating to the confidentiality of the reporting system) developed by the Agency for Healthcare Research and Quality with input from interested, non-governmental parties including patient, consumer and health care provider groups.

''(2) GUIDELINES.—Not later than 90 days after the date of enactment of this part, the Agency for Healthcare Research and Quality shall develop and publish the guidelines described in paragraph (1).

''(c) DATA.—

''(1) AVAILABILITY.—A State that receives a grant under subsection (a) shall make the data provided to the medical error reporting system involved available only to the Agency for Healthcare Research and Quality and may not otherwise disclose such information.

''(2) CONFIDENTIALITY.—Nothing in this part shall be construed to supersede any State law that is inconsistent with this part.

''(d) APPLICATION.—To be eligible for a grant under this section, a State shall prepare and submit to the Secretary an application at such time, in such manner and

containing, such information as the Secretary shall require.

"SEC. 923. DEMONSTRATION PROJECTS TO REDUCE MEDICAL ERRORS, IMPROVE PATIENT SAFETY, AND EVALUATE REPORTING.

''(a) ESTABLISHMENT.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality and in conjunction with the Administrator of the Health Care Financing Administration, may establish a program under which funding will be provided for not less than 15 demonstration projects, to be competitively awarded, in health care facilities and organizations in geographically diverse locations, including rural and urban areas (as determined by the Secretary), to determine the causes of medical errors and to—

''(1) use technology, staff training, and other methods to reduce such errors;

''(2) develop replicable models that minimize the frequency and severity of medical errors;

''(3) develop mechanisms that encourage reporting, prompt review, and corrective action with respect to medical errors; and

''(4) develop methods to minimize any additional paperwork burden on health care professionals.

''(b) ACTIVITIES.—

''(1) IN GENERAL.—A health care provider participating in a demonstration project under subsection (a) shall—

''(A) utilize all available and appropriate technologies to reduce the probability of future medical errors; and

''(B) carry out other activities consistent with subsection (a).

''(2) REPORTING TO PATIENTS.—In carrying out this section, the Secretary shall ensure that—

''(A) 5 of the demonstration projects permit the voluntary reporting by participating health care providers of any adverse events, sentinel events, health care-related errors, or medication-related errors to the Secretary;

''(B) 5 of the demonstration projects require participating health care providers to report any adverse events, sentinel events, health care-related errors, or medication-related errors to the Secretary; and

''(C) 5 of the demonstration projects require participating health care providers to report any adverse events, sentinel events, health care-related errors, or medication-related errors

to the Secretary and to the patient involved and a family member or guardian of the patient.

''(3) CONFIDENTIALITY.—

''(A) IN GENERAL.—The Secretary and the participating grantee organization shall ensure that information reported under this section remains confidential.

''(B) USE.—The Secretary may use the information reported under this section only for the purpose of evaluating the ability to reduce errors in the delivery of care. Such information shall not be used for enforcement purposes.

''(C) DISCLOSURE.—The Secretary may not disclose the information reported under this section.

''(D) NONADMISSIBILITY.—Information reported under this section shall be privileged, confidential, shall not be admissible as evidence or discoverable in any civil or criminal action or proceeding or subject to disclosure, and shall not be subject to the Freedom of Information Act (5 U.S.C. App). This paragraph shall apply to all information maintained by the reporting entity and the entities who receive such reports.

''(c) USE OF TECHNOLOGIES.—The Secretary shall encourage, as part of the demonstration projects conducted under subsection (a), the use of appropriate technologies to reduce medical errors, such as hand-held electronic prescription pads, training simulators for medical education, and bar-coding of prescription drugs and patient bracelets.

''(d) DATABASE.—The Secretary shall provide for the establishment and operation of a national database of medical errors to be used as provided for by the Secretary. The information provided to the Secretary under subsection (b)(2) shall be contained in the database.

''(e) EVALUATION.—The Secretary shall evaluate the progress of each demonstration project established under this section in reducing the incidence of medical errors and submit the results of such evaluations as part of the reports under section 926(b).

''(f) REPORTING.—Prior to October 1, of the third fiscal year for which funds are made available under this section, the Secretary shall prepare and submit to the appropriate committees of Congress an interim report concerning the results of such demonstration projects.

''SEC. 924. PATIENT SAFETY IMPROVEMENT.

''(a) IN GENERAL.—The Secretary shall provide information to educate patients and family members about

their role in reducing medical errors. Such information shall be provided to all individuals who participate in Federally-funded health care programs.

''(b) DEVELOPMENT OF PROGRAMS.—The Secretary shall develop programs that encourage patients to take a more active role in their medical treatment, including encouraging patients to provide information to health care providers concerning pre-existing conditions and medications.

''SEC. 925. PRIVATE, NONPROFIT EFFORTS TO REDUCE MEDICAL ERRORS.

''(a) IN GENERAL.—The Secretary shall make grants to health professional associations and other organizations to provide training in ways to reduce medical errors, including curriculum development, technology training, and continuing medical education.

''(b) APPLICATION.—To be eligible for a grant under this section, an entity shall prepare and submit to the Secretary an application at such time, in such manner and containing, such information as the Secretary shall require.

''SEC. 926. REPORT TO CONGRESS.

''(a) INITIAL REPORT.—Not later than 180 days after the date of enactment of this part, the Secretary shall prepare and submit to the appropriate committees

of Congress a report concerning the costs associated with implementing a program that identifies factors that contribute to errors and which includes upgrading the health care computer systems and other technologies in the United States in order to reduce medical errors, including computerizing hospital systems for the coordination of prescription drugs and handling of laboratory specimens, and contains recommendation on ways in which to reduce those factors.

''(b) OTHER REPORTS.—Not later than 180 days after the completion of all demonstration projects under section 923, the Secretary shall prepare and submit to the appropriate committees of Congress a report concerning—

''(1) how successful each demonstration project was in reducing medical errors;

''(2) the data submitted by States under section 922(c);

''(3) the best methods for reducing medical errors;

''(4) the costs associated with applying such best methods on a nationwide basis; and

''(5) the manner in which other Federal agencies can share information on best practices in order to reduce medical errors in all Federal health care programs.

"SEC. 927. AUTHORIZATION OF APPROPRIATIONS.

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

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