

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.

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 8, 2000

Mr. SPECTER (for himself, Mr. HARKIN, and Mr. INOUE) 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.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Error Reduc-

5 tion Act of 2000”.

6 **SEC. 2. FINDINGS AND PURPOSE.**

7 (a) FINDINGS.—Congress makes the following find-

8 ings:

1           (1) The United States has the finest health  
2           care system in the world. However, there is con-  
3           tinuing concern and fear among the public about the  
4           safety of the nation’s health care system as a result  
5           of a high occurrence of medical mistakes—the fifth  
6           leading cause of death.

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

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

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

18          (5) When using the lower estimate in paragraph  
19          (4), deaths due to medical errors still exceed the  
20          number of deaths attributable to motor vehicle acci-  
21          dents (43,458), breast cancer (42,297), or AIDS  
22          (16,516).

23          (6) Deaths from adverse drug events total more  
24          than 7,000 annually—exceeding the number of year-  
25          ly workplace injuries (6,000).

1           (7) The total national cost of preventable med-  
2           ical errors resulting in injury is estimated to be be-  
3           tween \$17,000,000,000 and \$29,000,000,000, from  
4           direct medical costs, lost productivity, and disability.

5           (8) One recent study found that about 2 out of  
6           every 100 admissions involves a preventable adverse  
7           drug event. If these findings are generalized, these  
8           adverse drug events affecting inpatients cost  
9           \$2,000,000,000 nationally.

10          (9) Medical errors are costly in terms of repeat  
11          tests and medical countermeasures, which also are  
12          subject to compounding errors. Purchasers and pa-  
13          tients pay for errors when insurance costs and co-  
14          payments are inflated by services that would not  
15          have been necessary had proper care been provided.

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

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

1 **SEC. 3. AMENDMENT TO PUBLIC HEALTH SERVICE ACT.**

2 Title IX of the Public Health Service Act (42 U.S.C.  
3 299 et seq.) is amended—

4 (1) by redesignating part C as part D;

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

7 (3) in section 938(1) (as so redesignated), by  
8 striking “921” and inserting “931”; and

9 (4) by inserting after part B the following:

10 **“PART C—REDUCING ERRORS IN HEALTH CARE**

11 **“SEC. 921. DEFINITIONS.**

12 “In this part:

13 “(1) ADVERSE EVENT.—The term ‘adverse  
14 event’ means an injury resulting from medical man-  
15 agement rather than the underlying condition of the  
16 patient.

17 “(2) ERROR.—The term ‘error’ means the fail-  
18 ure of a planned action to be completed as intended  
19 or the use of a wrong plan to achieve the desired  
20 outcome.

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

25 “(4) HEALTH CARE-RELATED ERROR.—The  
26 term “health care-related error” means a prevent-

1       able adverse event related to a health care interven-  
2       tion or a failure to intervene appropriately.

3               “(5) MEDICATION-RELATED ERROR.—The term  
4       ‘medication-related error’ means a preventable ad-  
5       verse event related to the administration of a medi-  
6       cation.

7               “(6) SAFETY.—The term ‘safety’ with respect  
8       to an individual means that such individual has a  
9       right to be free from preventable serious injury.

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

15       **“SEC. 922. ESTABLISHMENT OF STATE-BASED MEDICAL**  
16                               **ERROR REPORTING SYSTEMS.**

17              “(a) IN GENERAL.—The Secretary shall make grants  
18       available to States to enable such States to establish re-  
19       porting systems designed to reduce medical errors and im-  
20       prove health care quality.

21              “(b) REQUIREMENT.—

22                      “(1) IN GENERAL.—To be eligible to receive a  
23       grant under subsection (a), the State involved shall  
24       provide assurances to the Secretary that amounts re-  
25       ceived under the grant will be used to establish and

1 implement a medical error reporting system using  
2 guidelines (including guidelines relating to the con-  
3 fidentiality of the reporting system) developed by the  
4 Agency for Healthcare Research and Quality with  
5 input from interested, non-governmental parties in-  
6 cluding patient, consumer and health care provider  
7 groups.

8 “(2) GUIDELINES.—Not later than 90 days  
9 after the date of enactment of this part, the Agency  
10 for Healthcare Research and Quality shall develop  
11 and publish the guidelines described in paragraph  
12 (1).

13 “(c) DATA.—

14 “(1) AVAILABILITY.—A State that receives a  
15 grant under subsection (a) shall make the data pro-  
16 vided to the medical error reporting system involved  
17 available only to the Agency for Healthcare Research  
18 and Quality and may not otherwise disclose such in-  
19 formation.

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

23 “(d) APPLICATION.—To be eligible for a grant under  
24 this section, a State shall prepare and submit to the Sec-  
25 retary an application at such time, in such manner and

1 containing, such information as the Secretary shall re-  
2 quire.

3 **“SEC. 923. DEMONSTRATION PROJECTS TO REDUCE MED-**  
4 **ICAL ERRORS, IMPROVE PATIENT SAFETY,**  
5 **AND EVALUATE REPORTING.**

6 “(a) ESTABLISHMENT.—The Secretary, acting  
7 through the Director of the Agency for Healthcare Re-  
8 search and Quality and in conjunction with the Adminis-  
9 trator of the Health Care Financing Administration, may  
10 establish a program under which funding will be provided  
11 for not less than 15 demonstration projects, to be competi-  
12 tively awarded, in health care facilities and organizations  
13 in geographically diverse locations, including rural and  
14 urban areas (as determined by the Secretary), to deter-  
15 mine the causes of medical errors and to—

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

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

20 “(3) develop mechanisms that encourage report-  
21 ing, prompt review, and corrective action with re-  
22 spect to medical errors; and

23 “(4) develop methods to minimize any addi-  
24 tional paperwork burden on health care profes-  
25 sionals.

1 “(b) ACTIVITIES.—

2 “(1) IN GENERAL.—A health care provider par-  
3 ticipating in a demonstration project under sub-  
4 section (a) shall—

5 “(A) utilize all available and appropriate  
6 technologies to reduce the probability of future  
7 medical errors; and

8 “(B) carry out other activities consistent  
9 with subsection (a).

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

12 “(A) 5 of the demonstration projects per-  
13 mit the voluntary reporting by participating  
14 health care providers of any adverse events,  
15 sentinel events, health care-related errors, or  
16 medication-related errors to the Secretary;

17 “(B) 5 of the demonstration projects re-  
18 quire participating health care providers to re-  
19 port any adverse events, sentinel events, health  
20 care-related errors, or medication-related errors  
21 to the Secretary; and

22 “(C) 5 of the demonstration projects re-  
23 quire participating health care providers to re-  
24 port any adverse events, sentinel events, health  
25 care-related errors, or medication-related errors

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

3 “(3) CONFIDENTIALITY.—

4 “(A) IN GENERAL.—The Secretary and the  
5 participating grantee organization shall ensure  
6 that information reported under this section re-  
7 mains confidential.

8 “(B) USE.—The Secretary may use the in-  
9 formation reported under this section only for  
10 the purpose of evaluating the ability to reduce  
11 errors in the delivery of care. Such information  
12 shall not be used for enforcement purposes.

13 “(C) DISCLOSURE.—The Secretary may  
14 not disclose the information reported under this  
15 section.

16 “(D) NONADMISSIBILITY.—Information re-  
17 ported under this section shall be privileged,  
18 confidential, shall not be admissible as evidence  
19 or discoverable in any civil or criminal action or  
20 proceeding or subject to disclosure, and shall  
21 not be subject to the Freedom of Information  
22 Act (5 U.S.C. App). This paragraph shall apply  
23 to all information maintained by the reporting  
24 entity and the entities who receive such reports.

1       “(c) USE OF TECHNOLOGIES.—The Secretary shall  
2 encourage, as part of the demonstration projects con-  
3 ducted under subsection (a), the use of appropriate tech-  
4 nologies to reduce medical errors, such as hand-held elec-  
5 tronic prescription pads, training simulators for medical  
6 education, and bar-coding of prescription drugs and pa-  
7 tient bracelets.

8       “(d) DATABASE.—The Secretary shall provide for the  
9 establishment and operation of a national database of  
10 medical errors to be used as provided for by the Secretary.  
11 The information provided to the Secretary under sub-  
12 section (b)(2) shall be contained in the database.

13       “(e) EVALUATION.—The Secretary shall evaluate the  
14 progress of each demonstration project established under  
15 this section in reducing the incidence of medical errors and  
16 submit the results of such evaluations as part of the re-  
17 ports under section 926(b).

18       “(f) REPORTING.—Prior to October 1, of the third  
19 fiscal year for which funds are made available under this  
20 section, the Secretary shall prepare and submit to the ap-  
21 propriate committees of Congress an interim report con-  
22 cerning the results of such demonstration projects.

23 **“SEC. 924. PATIENT SAFETY IMPROVEMENT.**

24       “(a) IN GENERAL.—The Secretary shall provide in-  
25 formation to educate patients and family members about

1 their role in reducing medical errors. Such information  
2 shall be provided to all individuals who participate in Fed-  
3 erally-funded health care programs.

4 “(b) DEVELOPMENT OF PROGRAMS.—The Secretary  
5 shall develop programs that encourage patients to take a  
6 more active role in their medical treatment, including en-  
7 couraging patients to provide information to health care  
8 providers concerning pre-existing conditions and medica-  
9 tions.

10 **“SEC. 925. PRIVATE, NONPROFIT EFFORTS TO REDUCE**  
11 **MEDICAL ERRORS.**

12 “(a) IN GENERAL.—The Secretary shall make grants  
13 to health professional associations and other organizations  
14 to provide training in ways to reduce medical errors, in-  
15 cluding curriculum development, technology training, and  
16 continuing medical education.

17 “(b) APPLICATION.—To be eligible for a grant under  
18 this section, an entity shall prepare and submit to the Sec-  
19 retary an application at such time, in such manner and  
20 containing, such information as the Secretary shall re-  
21 quire.

22 **“SEC. 926. REPORT TO CONGRESS.**

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

1 of Congress a report concerning the costs associated with  
2 implementing a program that identifies factors that con-  
3 tribute to errors and which includes upgrading the health  
4 care computer systems and other technologies in the  
5 United States in order to reduce medical errors, including  
6 computerizing hospital systems for the coordination of  
7 prescription drugs and handling of laboratory specimens,  
8 and contains recommendation on ways in which to reduce  
9 those factors.

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

14 “(1) how successful each demonstration project  
15 was in reducing medical errors;

16 “(2) the data submitted by States under section  
17 922(c);

18 “(3) the best methods for reducing medical er-  
19 rors;

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

22 “(5) the manner in which other Federal agen-  
23 cies can share information on best practices in order  
24 to reduce medical errors in all Federal health care  
25 programs.

1 **“SEC. 927. AUTHORIZATION OF APPROPRIATIONS.**

2       “There is authorized to be appropriated such sums

3 as may be necessary to carry out this part.”.

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