

106TH CONGRESS
2D SESSION

S. 2738

To amend the Public Health Service Act to reduce medical mistakes and medication-related errors.

IN THE SENATE OF THE UNITED STATES

JUNE 15, 2000

Mr. JEFFORDS (for himself, Mr. FRIST, and Mr. ENZI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to reduce medical mistakes and medication-related errors.

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 “Patient Safety and
5 Errors Reduction Act”.

6 **SEC. 2. PURPOSES.**

7 It is the purpose of this Act to—

8 (1) promote the identification, evaluation, and
9 reporting of medical errors;

1 (2) raise standards and expectations for im-
2 provements in patient safety;

3 (3) reduce deaths, serious injuries, and other
4 medical errors through the implementation of safe
5 practices at the delivery level;

6 (4) develop error reduction systems with legal
7 protections to support the collection of information
8 under such systems;

9 (5) extend existing confidentiality and peer re-
10 view protections to the reports relating to medical
11 errors that are reported under such systems that are
12 developed for safety and quality improvement pur-
13 poses; and

14 (6) provide for the establishment of systems of
15 information collection, analysis, and dissemination to
16 enhance the knowledge base concerning patient safe-
17 ty.

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

19 Title IX of the Public Health Service Act (42 U.S.C.
20 299 et seq.) is amended—

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

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

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

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

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

3 **“SEC. 921. DEFINITIONS.**

4 “In this part:

5 “(1) ADVERSE EVENT.—The term ‘adverse
6 event’ means, with respect to the patient of a pro-
7 vider of services, an untoward incident, therapeutic
8 misadventure, or iatrogenic injury directly associated
9 with the provision of health care items and services
10 by a health care provider or provider of services.

11 “(2) CENTER.—The term ‘Center’ means the
12 Center for Quality Improvement and Patient Safety
13 established under section 922(b).

14 “(3) CLOSE CALL.—The term ‘close call’
15 means, with respect to the patient of a provider of
16 services, any event or situation that—

17 “(A) but for chance or a timely interven-
18 tion, could have resulted in an accident, injury,
19 or illness; and

20 “(B) is directly associated with the provi-
21 sion of health care items and services by a pro-
22 vider of services.

23 “(4) EXPERT ORGANIZATION.—The term ‘ex-
24 pert organization’ means a third party acting on be-
25 half of, or in conjunction with, a provider of services

1 to collect information about, or evaluate, a medical
2 event.

3 “(5) HEALTH CARE OVERSIGHT AGENCY.—The
4 term ‘health care oversight agency’ means an agen-
5 cy, entity, or person, including the employees and
6 agents thereof, that performs or oversees the per-
7 formance of any activities necessary to ensure the
8 safety of the health care system.

9 “(6) HEALTH CARE PROVIDER.—The term
10 ‘health care provider’ means—

11 “(A) any provider of services (as defined in
12 section 1861(u) of the Social Security Act); and

13 “(B) any person furnishing any medical or
14 other health care services as defined in section
15 1861(s)(1) and (2) of such Act through, or
16 under the authority of, a provider of services
17 described in subparagraph (A).

18 “(7) PROVIDER OF SERVICES.—The term ‘pro-
19 vider of services’ means a hospital, skilled nursing
20 facility, comprehensive outpatient rehabilitation fa-
21 cility, home health agency, renal dialysis facility, am-
22 bulatory surgical center, or hospice program, and
23 any other entity specified in regulations promulgated
24 by the Secretary.

1 “(8) PUBLIC HEALTH AUTHORITY.—The term
2 ‘public health authority’ means an agency or author-
3 ity of the United States, a State, a territory, a polit-
4 ical subdivision of a State or territory, and an In-
5 dian tribe that is responsible for public health mat-
6 ters as part of its official mandate.

7 “(9) MEDICAL EVENT.—The term ‘medical
8 event’ means, with respect to the patient of a pro-
9 vider of services, any sentinel event, adverse event,
10 or close call.

11 “(10) MEDICAL EVENT ANALYSIS ENTITY.—
12 The term ‘medical event analysis entity’ means an
13 entity certified under section 923(a).

14 “(11) ROOT CAUSE ANALYSIS.—

15 “(A) IN GENERAL.—The term ‘root cause
16 analysis’ means a process for identifying the
17 basic or contributing causal factors that under-
18 lie variation in performance associated with ad-
19 verse events or close calls that—

20 “(i) has the characteristics described
21 in subparagraph (B);

22 “(ii) includes participation by the
23 leadership of the organization and individ-
24 uals most closely involved in the processes
25 and systems under review;

1 “(iii) is internally consistent; and

2 “(iv) includes the consideration of rel-
3 evant literature.

4 “(B) CHARACTERISTICS.—The characteris-
5 tics described in this subparagraph include the
6 following:

7 “(i) The analysis is interdisciplinary
8 in nature and involves those individuals
9 who are responsible for administering the
10 reporting systems.

11 “(ii) The analysis focuses primarily on
12 systems and processes rather than indi-
13 vidual performance.

14 “(iii) The analysis involves a thorough
15 review of all aspects of the process and all
16 contributing factors involved.

17 “(iv) The analysis identifies changes
18 that could be made in systems and proc-
19 esses, through either redesign or develop-
20 ment of new processes or systems, that
21 would improve performance and reduce the
22 risk of adverse events or close calls.

23 “(12) SENTINEL EVENT.—The term ‘sentinel
24 event’ means, with respect to the patient of a pro-
25 vider of services, an unexpected occurrence that—

1 “(A) involves death or serious physical or
2 psychological injury (including loss of a limb);
3 and

4 “(B) is directly associated with the provi-
5 sion of health care items and services by a pro-
6 vider.

7 **“SEC. 922. RESEARCH TO IMPROVE THE QUALITY AND**
8 **SAFETY OF PATIENT CARE.**

9 “(a) IN GENERAL.—To improve the quality and safe-
10 ty of patient care, the Director shall—

11 “(1) conduct and support research, evaluations
12 and training, support demonstration projects, pro-
13 vide technical assistance, and develop and support
14 partnerships that will identify and determine the
15 causes of medical errors and other threats to the
16 quality and safety of patient care;

17 “(2) develop or identify and evaluate interven-
18 tions and strategies for preventing or reducing med-
19 ical errors and threats to the quality and safety of
20 patient care;

21 “(3) develop, in conjunction with experts in the
22 field, reporting requirements to provide consistency
23 throughout the errors reporting system;

24 “(4) develop approaches for the clinical man-
25 agement of complications from medical errors; and

1 “(5) establish mechanisms for the rapid dis-
2 semination of interventions and strategies developed
3 under this section for which there is scientific evi-
4 dence of effectiveness.

5 “(b) CENTER FOR QUALITY IMPROVEMENT AND PA-
6 TIENT SAFETY.—

7 “(1) ESTABLISHMENT.—The Director shall es-
8 tablish a center to be known as the Center for Qual-
9 ity Improvement and Patient Safety to assist the Di-
10 rector in carrying out the requirements of subsection
11 (a).

12 “(2) MISSION.—The Center shall—

13 “(A) provide national leadership for re-
14 search and other initiatives to improve the qual-
15 ity and safety of patient care;

16 “(B) develop public-private sector partner-
17 ships to improve the quality and safety of pa-
18 tient care; and

19 “(C) serve as a national resource for re-
20 search and learning from medical errors.

21 “(3) DUTIES.—

22 “(A) IN GENERAL.—In carrying out this
23 section, the Director, acting through the Cen-
24 ter, shall consult and develop partnerships, as
25 appropriate, with all segments of the health

1 care industry, including health care practi-
2 tioners and patients, those who manage health
3 care facilities, systems and plans, peer review
4 organizations, health care purchasers and pol-
5 icymakers, and other users of health care re-
6 search.

7 “(B) REQUIRED DUTIES.—In addition to
8 the broad responsibilities that the Director may
9 assign to the Center for research and related
10 activities that are designed to improve the qual-
11 ity of health care, the Director shall ensure that
12 the Center—

13 “(i) builds scientific knowledge and
14 understanding of the causes of medical er-
15 rors in all health care settings and identi-
16 fies or develops and validates effective
17 interventions and strategies to reduce er-
18 rors and improve the safety and quality of
19 patient care;

20 “(ii) promotes public and private sec-
21 tor research on patient safety by—

22 “(I) developing a national patient
23 safety research agenda;

1 “(II) identifying promising op-
2 portunities for preventing or reducing
3 medical errors; and

4 “(III) tracking the progress
5 made in addressing the highest pri-
6 ority research questions with respect
7 to patient safety;

8 “(iii) facilitates the development of
9 voluntary national patient safety goals by
10 convening all segments of the health care
11 industry and tracks the progress made in
12 meeting those goals;

13 “(iv) develops national patient safety
14 data for inclusion in the annual report on
15 the quality of health care required under
16 section 913(b)(2);

17 “(v) strengthens the ability of the
18 United States to learn from medical errors
19 by—

20 “(I) developing the necessary
21 tools and advancing the scientific
22 techniques for analysis of errors;

23 “(II) providing technical assist-
24 ance as appropriate to reporting sys-
25 tems; and

1 “(III) entering into contracts to
2 receive and analyze aggregate data
3 from public and private sector report-
4 ing systems;

5 “(vi) supporting dissemination and
6 communication activities to improve pa-
7 tient safety, including the development of
8 tools and methods for educating consumers
9 about patient safety; and

10 “(vii) undertaking other activities that
11 the Director determines are necessary to
12 enable the Center to fulfill its mission.

13 “(C) LIMITATION.—Aggregate data gath-
14 ered for the purposes described in this section
15 shall not include specific patient, health care
16 provider, or provider of service identifiers.

17 “(c) LEARNING FROM MEDICAL ERRORS.—

18 “(1) IN GENERAL.—To enhance the ability of
19 the health care community in the United States to
20 learn from medical errors and close calls, the Direc-
21 tor shall—

22 “(A) carry out activities to increase sci-
23 entific knowledge and understanding regarding
24 medical error reporting systems;

1 “(B) carry out activities to advance the
2 scientific knowledge regarding the tools and
3 techniques for analyzing medical errors and de-
4 termining their root causes;

5 “(C) carry out activities in partnership
6 with experts in the field to increase the capacity
7 of the health care community in the United
8 States to analyze patient safety data;

9 “(D) develop a confidential national safety
10 database of medical errors reports;

11 “(E) conduct and support research, using
12 the database developed under subparagraph
13 (D), into the causes and potential interventions
14 to decrease the incidence of medical errors and
15 close calls; and

16 “(F) ensure that information contained in
17 the national database developed under subpara-
18 graph (D) does not include specific patient,
19 health care provider, or provider of service iden-
20 tifiers.

21 “(2) NATIONAL PATIENT SAFETY DATABASE.—

22 The Director shall, in accordance with paragraph
23 (1)(D), establish a confidential national safety data-
24 base (to be known as the National Patient Safety
25 Database) of reports of medical errors and close

1 calls that can be used only for research to improve
2 the quality and safety of patient care. In developing
3 and managing the National Patient Safety Data-
4 base, the Director shall—

5 “(A) ensure that the database can only be
6 used for its intended purpose;

7 “(B) ensure that the database is as com-
8 prehensive as possible by aggregating data from
9 Federal, State, and private sector patient safety
10 reporting systems;

11 “(C) conduct and support research on the
12 most common medical errors and close calls,
13 their causes, and potential interventions to re-
14 duce medical errors and improve the quality
15 and safety of patient care;

16 “(D) report findings made by the Director,
17 based on the data in the database, to clinicians,
18 individuals who manage health care facilities,
19 systems, and plans, patients, and other individ-
20 uals who can act appropriately to improve pa-
21 tient safety; and

22 “(E) develop a rapid response capacity to
23 provide alerts when specific health care prac-
24 tices pose an imminent threat to patients or
25 health care workers.

1 “(3) CONFIDENTIALITY AND PEER REVIEW
2 PROTECTIONS.—Notwithstanding any other provi-
3 sion of law any information (including any data, re-
4 ports, records, memoranda, analyses, statements,
5 and other communications) developed by or on be-
6 half of a health care provider or provider of services
7 with respect to a medical event, that is contained in
8 the National Patient Safety Database shall be con-
9 fidential in accordance with section 925.

10 “(4) PATIENT SAFETY REPORTING SYSTEMS.—
11 The Director shall identify public and private sector
12 patient safety reporting systems and build scientific
13 knowledge and understanding regarding the most
14 effective—

15 “(A) components of patient safety report-
16 ing systems;

17 “(B) incentives intended to increase the
18 rate of error reporting;

19 “(C) approaches for undertaking root
20 cause analyses;

21 “(D) ways to provide feedback to those fil-
22 ing error reports;

23 “(E) techniques and tools for collecting, in-
24 tegrating, and analyzing patient safety data;
25 and

1 “(F) ways to provide meaningful informa-
2 tion to patients, consumers, and purchasers
3 that will enhance their understanding of patient
4 safety issues.

5 “(5) TRAINING.—The Director shall support
6 training initiatives to build the capacity of the health
7 care community in the United States to analyze pa-
8 tient safety data and to act on that data to improve
9 patient safety.

10 “(d) EVALUATION.—The Director shall recommend
11 strategies for measuring and evaluating the national
12 progress made in implementing safe practices and stand-
13 ards identified by the Center through the research and
14 analysis required under subsection (b) and through the
15 voluntary reporting system established under subsection
16 (c).

17 “(e) IMPLEMENTATION.—In implementing strategies
18 to carry out the functions described in subsections (b), (c),
19 and (d), the Director may contract with public or private
20 entities on a national or local level with appropriate exper-
21 tise.

22 **“SEC. 923. MEDICAL EVENT ANALYSIS ENTITIES.**

23 “(a) IN GENERAL.—The Director, based on informa-
24 tion collected under section 922(c), shall provide for the
25 certification of entities to collect and analyze information

1 on medical errors, and to collaborate with health care pro-
2 viders or providers of services in collecting information
3 about, or evaluating, certain medical events.

4 “(b) COMPATIBILITY OF COLLECTED DATA.—To en-
5 sure that data reported to the National Patient Safety
6 Database under section 922(c)(2) concerning medical er-
7 rors and close calls are comparable and useful on an ana-
8 lytic basis, the Director shall require that the entities de-
9 scribed in subsection (c) follow the recommendations re-
10 garding a common set of core measures for reporting that
11 are developed by the National Forum for Health Care
12 Quality Measurement and Reporting, or other voluntary
13 private standard-setting organization that is designated by
14 the Director taking into account existing measurement
15 systems and in conjunction with experts in the field.

16 “(c) DUTIES OF CERTIFIED ENTITIES.—

17 “(1) IN GENERAL.—An entity that is certified
18 under subsection (a) shall collect and analyze infor-
19 mation, consistent with the requirement of sub-
20 section (b), provided to the entity under section
21 924(a)(5) to improve patient safety.

22 “(2) INFORMATION TO BE REPORTED TO THE
23 ENTITY.—A medical event analysis entity shall, on a
24 periodic basis and in a format that is specified by

1 the Director, submit to the Director a report that
2 contains—

3 “(A) a description of the medical events
4 that were reported to the entity during the pe-
5 riod covered under the report;

6 “(B) a description of any corrective action
7 taken by providers of services with respect to
8 such medical events or any other measures that
9 are necessary to prevent similar events from oc-
10 ccurring in the future; and

11 “(C) a description of the systemic changes
12 that entities have identified, through an anal-
13 ysis of the medical events included in the re-
14 port, as being needed to improve patient safety.

15 “(3) COLLABORATION.—A medical event anal-
16 ysis entity that is collaborating with a health care
17 provider or provider of services to address close calls
18 and adverse events may, at the request of the health
19 care provider or provider of services—

20 “(A) provide expertise in the development
21 of root cause analyses and corrective action
22 plan relating to such close calls and adverse
23 events; or

1 “(B) collaborate with such provider of
2 services to identify on-going risk reduction ac-
3 tivities that may enhance patient safety.

4 “(d) CONFIDENTIALITY AND PEER REVIEW PROTEC-
5 TIONS.—Notwithstanding any other provision of law, any
6 information (including any data, reports, records, memo-
7 randa, analyses, statements, and other communications)
8 collected by a medical event analysis entity or developed
9 by or on behalf of such an entity under this part shall
10 be confidential in accordance with section 925.

11 “(e) TERMINATION AND RENEWAL.—

12 “(1) IN GENERAL.—The certification of an enti-
13 ty under this section shall terminate on the date
14 that is 3 years after the date on which such certifi-
15 cation was provided. Such certification may be re-
16 newed at the discretion of the Director.

17 “(2) NONCOMPLIANCE.—The Director may ter-
18 minate the certification of a medical event analysis
19 entity if the Director determines that such entity
20 has failed to comply with this section.

21 “(f) IMPLEMENTATION.—In implementing strategies
22 to carry out the functions described in subsection (c), the
23 Director may contract with public or private entities on
24 a national or local level with appropriate expertise.

1 **“SEC. 924. PROVIDER OF SERVICES SYSTEMS FOR REPORT-**
2 **ING MEDICAL EVENTS.**

3 “(a) INTERNAL MEDICAL EVENT REPORTING SYS-
4 TEMS.—Each provider of services that elects to participate
5 in a medical error reporting system under this part shall—

6 “(1) establish a system for—

7 “(A) identifying, collecting information
8 about, and evaluating medical events that occur
9 with respect to a patient in the care of the pro-
10 vider of services or a practitioner employed by
11 the provider of services, that may include—

12 “(i) the provision of a medically co-
13 herent description of each event so identi-
14 fied;

15 “(ii) the provision of a clear and thor-
16 ough accounting of the results of the inves-
17 tigation of such event under the system;
18 and

19 “(iii) a description of all corrective
20 measures taken in response to the event;
21 and

22 “(B) determining appropriate follow-up ac-
23 tions to be taken with respect to such events;

24 “(2) establish policies and procedures with re-
25 spect to when and to whom such events are to be
26 reported;

1 “(3) take appropriate follow-up action with re-
2 spect to such events; and

3 “(4) submit to the appropriate medical event
4 analysis entity information that contains descrip-
5 tions of the medical events identified under para-
6 graph (1)(A).

7 “(b) PROMOTING IDENTIFICATION, EVALUATION,
8 AND REPORTING OF CERTAIN MEDICAL EVENTS.—

9 “(1) IN GENERAL.—Notwithstanding any other
10 provision of law any information (including any
11 data, reports, records, memoranda, analyses, state-
12 ments, and other communications) developed by or
13 on behalf of a provider of services with respect to a
14 medical event pursuant to a system established
15 under subsection (a) shall be privileged in accord-
16 ance with section 925.

17 “(2) RULES OF CONSTRUCTION.—Nothing in
18 this subsection shall be construed as prohibiting—

19 “(A) disclosure of a patient’s medical
20 record to the patient;

21 “(B) a health care oversight agency or
22 public health authority from requiring a pro-
23 vider of services to transfer information to the
24 agency or authority to the extent required by
25 law; or

1 “(C) such an agency or authority from dis-
2 closing information transferred by a provider of
3 services to the public in a form that does not
4 identify or permit the identification of the
5 health care provider or provider of services or
6 patient.

7 **“SEC. 925. CONFIDENTIALITY.**

8 “(a) CONFIDENTIALITY AND PEER REVIEW PROTEC-
9 TIONS.—Notwithstanding any other provision of law—

10 “(1) any information (including any data, re-
11 ports, records, memoranda, analyses, statements,
12 and other communications) developed by or on be-
13 half of a health care provider or provider of services
14 with respect to a medical event, that is contained in
15 the National Patient Safety Database, collected by a
16 medical event analysis entity, or developed by or on
17 behalf of such an entity, or collected by a health
18 care provider or provider of services for use under
19 systems that are developed for safety and quality im-
20 provement purposes under this part—

21 “(A) shall be privileged, strictly confiden-
22 tial, and may not be disclosed by any other per-
23 son to which such information is transferred
24 without the authorization of the health care
25 provider or provider of services; and

1 “(B) shall—

2 “(i) be protected from disclosure by
3 civil, criminal, or administrative subpoena;

4 “(ii) not be subject to discovery or
5 otherwise discoverable in connection with a
6 civil, criminal, or administrative pro-
7 ceeding;

8 “(iii) not be subject to disclosure pur-
9 suant to section 552 of title 5, United
10 States Code (the Freedom of Information
11 Act) and any other similar Federal or
12 State statute or regulation; and

13 “(iv) not be admissible as evidence in
14 any civil, criminal, or administrative pro-
15 ceeding;

16 without regard to whether such information is
17 held by the provider or by another person to
18 which such information was transferred;

19 “(2) the transfer of any such information by a
20 provider of services to a health care oversight agen-
21 cy, an expert organization, a medical event analysis
22 entity, or a public health authority, shall not be
23 treated as a waiver of any privilege or protection es-
24 tablished under paragraph (1) or established under
25 State law.

1 “(b) PENALTY.—It shall be unlawful for any person
2 to disclose any information described in subsection (a)
3 other than for the purposes provided in such paragraph,
4 and any person violating the provisions of this section
5 shall, upon conviction, be fined in accordance with title
6 18, United States Code, and imprisoned for not more than
7 6 months, or both.

8 “(c) APPLICATION OF PROVISIONS.—The protections
9 provided under subsection (a) and the penalty provided for
10 under subsection (b) shall apply to any information (in-
11 cluding any data, reports, memoranda, analyses, state-
12 ments, and other communications) collected or developed
13 pursuant to research, including demonstration projects,
14 with respect to medical error reporting supported by the
15 Director under this part.

16 **“SEC. 926. AUTHORIZATION OF APPROPRIATIONS.**

17 “There is authorized to be appropriated to carry out
18 this part, \$50,000,000 for fiscal year 2001, and such sums
19 as may be necessary for subsequent fiscal years.”.

20 **SEC. 4. EFFECTIVE DATE.**

21 The amendments made by section 3 shall become ef-
22 fective on January 1 of the calendar year that begins after
23 the date of the enactment of this Act.

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