

107TH CONGRESS
2D SESSION

S. 2590

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

IN THE SENATE OF THE UNITED STATES

JUNE 5, 2002

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

A BILL

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

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 Quality Improvement Act”.

6 **SEC. 2. FINDINGS AND PURPOSES.**

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

1 (1) In 1999, the Institute of Medicine released
2 a report entitled *To Err is Human* that described
3 medical errors as the eighth leading cause of death
4 in the United States, with as many as 98,000 people
5 dying as a result of medical errors each year.

6 (2) To address these deaths and injuries due to
7 medical errors, the health care system must identify
8 and learn from such errors so that systems of care
9 can be improved.

10 (3) In their report, the Institute of Medicine
11 called on Congress to provide legal protections with
12 respect to information reported for the purposes of
13 quality improvement and patient safety.

14 (4) The Health, Education, Labor, and Pen-
15 sions Committee of the Senate held 4 hearings in
16 the 106th Congress and 1 hearing in the 107th Con-
17 gress on patient safety where experts in the field
18 supported the recommendation of the Institute of
19 Medicine for congressional action.

20 (5) Myriad public and private patient safety ini-
21 tiatives have begun. The Quality Interagency Coordi-
22 nation Taskforce has recommended steps to improve
23 patient safety that may be taken by each Federal
24 agency involved in health care and activities relating
25 to these steps are ongoing.

1 (6) The research on patient safety unequivocally calls for a learning environment, rather than a
2 punitive environment, in order to improve patient
3 safety.
4

5 (7) Voluntary data gathering systems are more
6 supportive than mandatory systems in creating the
7 learning environment referred to in paragraph (5) as
8 stated in the Institute of Medicine's report.

9 (8) Promising patient safety reporting systems
10 have been established throughout the United States
11 and the best ways to structure and use these systems
12 are currently being determined, largely through
13 projects funded by the Agency for Healthcare Research and Quality.
14

15 (9) The Department of Health and Human
16 Services has initiated several patient safety projects.
17 The Joint Commission on Accreditation of
18 Healthcare Organizations issued a patient safety
19 standard that went into effect on July 1, 2001, and
20 the peer review organizations are conducting ongoing
21 studies of clinical performance measurement of care
22 delivered to beneficiaries under the medicare program
23 under title XVIII of the Social Security Act.

24 (10) Many organizations currently collecting
25 patient safety data have expressed a need for legal

1 protections that will allow them to review protected
2 information so that they may collaborate in the de-
3 velopment and implementation of patient safety im-
4 provement strategies. Currently, the State peer re-
5 view protections provide inadequate conditions to
6 allow the sharing of information to promote patient
7 safety.

8 (11) In 2001, the Institute of Medicine released
9 a report entitled Crossing the Quality Chasm that
10 found that the United States health care system
11 does not consistently deliver high quality care to pa-
12 tients.

13 (b) PURPOSES.—It is the purpose of this Act to—

14 (1) encourage a culture of safety and quality in
15 the United States health care system by providing
16 for legal protection of information reported volun-
17 tarily for the purposes of quality improvement and
18 patient safety; and

19 (2) ensure accountability by raising standards
20 and expectations for continuous quality improve-
21 ments in patient safety through the actions of the
22 Secretary of Health and Human Services.

23 **SEC. 3. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.**

24 Title IX of the Public Health Service Act (42 U.S.C.
25 299 et seq.) is amended—

1 (1) in section 912(c), by inserting “, in accord-
2 ance with part C,” after “The Director shall”;

3 (2) by redesignating part C as part D;

4 (3) by redesignating sections 921 through 928,
5 as sections 931 through 938, respectively;

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

8 (5) by inserting after part B the following:

9 **“PART C—PATIENT SAFETY IMPROVEMENT**

10 **“SEC. 921. DEFINITIONS.**

11 “In this part:

12 “(1) NON-IDENTIFIABLE INFORMATION.—The
13 term ‘non-identifiable information’ means informa-
14 tion that is presented in a form and manner that
15 prevents the identification of any provider, patient,
16 and the reporter of patient safety data.

17 “(2) PATIENT SAFETY DATA.—The term ‘pa-
18 tient safety data’ means—

19 “(A) any data, reports, records, memo-
20 randa, analyses, deliberative work, statements,
21 root cause analyses, or quality improvement
22 processes that could result in improved patient
23 safety or health care quality, that are—

1 “(i) collected or developed by a pro-
2 vider for the purpose of reporting to a pa-
3 tient safety organization;

4 “(ii) reported to a patient safety orga-
5 nization for patient safety or quality im-
6 provement processes;

7 “(iii) requested by a patient safety or-
8 ganization (including the contents of such
9 request);

10 “(iv) reported to a provider by a pa-
11 tient safety organization;

12 “(v) collected or developed by a pa-
13 tient safety organization; or

14 “(vi) reported among patient safety
15 organizations, after obtaining authoriza-
16 tion; or

17 “(B) information related to corrective ac-
18 tions taken in response to patient safety data;
19 for the purpose of improving patient safety, health
20 care quality, or health care outcomes.

21 “(3) PATIENT SAFETY ORGANIZATION.—The
22 term ‘patient safety organization’ means a private or
23 public organization or component thereof that per-
24 forms the following activities (which are deemed to

1 be necessary for the proper management and admin-
2 istration of such organization or component thereof):

3 “(A) The conduct, as its primary activity,
4 of efforts to improve patient safety and the
5 quality of health care delivery.

6 “(B) The collection and analysis of patient
7 safety data that are voluntarily submitted by a
8 provider.

9 “(C) The development and dissemination
10 of information to providers with respect to im-
11 proving patient safety, such as recommenda-
12 tions, protocols, or information regarding best
13 practices.

14 “(D) The utilization of patient safety data
15 to carry out activities under this paragraph and
16 for the purposes of encouraging a culture of
17 safety and of providing direct feedback and as-
18 sistance to providers to effectively minimize pa-
19 tient risk.

20 “(E) The maintenance of confidentiality
21 with respect to individually identifiable health
22 information.

23 “(F) The provision of appropriate security
24 measures with respect to patient safety data.

1 “(G) The certification to the Agency that
2 the patient safety organization satisfies the cri-
3 teria of this paragraph for the period in which
4 the organization is carrying out such duties.

5 “(4) PROVIDER.—The term ‘provider’ means—

6 “(A) a provider of services (as defined in
7 section 1861(u) of the Social Security Act) and
8 a person furnishing any medical or other health
9 care services (as defined in section 1861(s)(1)
10 and (2) of such Act) through, or under the au-
11 thority of, such a provider of services;

12 “(B) a physician (as defined in section
13 1861(r) of such Act);

14 “(C) any other person, including a phar-
15 macist, who is engaged in the delivery of med-
16 ical or other health services (as defined in sec-
17 tion 1861(s)(1) and (2) of such Act) in a State
18 and who is required by State law or regulation
19 to be licensed or certified by the State to en-
20 gage in the delivery of such services in the
21 State;

22 “(D) a renal dialysis facility, ambulatory
23 surgical center, pharmacy, physician or health
24 care practitioner’s office, long term care facility,

1 behavioral health residential treatment facility,
2 or clinical laboratory; or

3 “(E) any other person or entity specified
4 in regulations by the Secretary after public no-
5 tice and comment.

6 **“SEC. 922. CONFIDENTIALITY AND PEER REVIEW PROTEC-**
7 **TIONS.**

8 “(a) IN GENERAL.—Notwithstanding any other pro-
9 vision of law, and subject to this section, patient safety
10 data shall be privileged and confidential.

11 “(b) SCOPE OF PRIVILEGE.—Subject to the provi-
12 sions of subsection (c), patient safety data to which sub-
13 section (a) applies shall not be—

14 “(1) subject to a civil, criminal, or administra-
15 tive subpoena;

16 “(2) subject to discovery in connection with a
17 civil, criminal, or administrative proceeding;

18 “(3) disclosed pursuant to section 552 of title
19 5, United States Code (commonly known as the
20 Freedom of Information Act) or any other similar
21 Federal or State law;

22 “(4) admitted as evidence or otherwise disclosed
23 in any civil, criminal, or administrative proceeding;
24 or

1 “(5) utilized in an adverse employment action
2 or in the evaluation of decisions made in relation to
3 accreditation, certification, credentialing or licensing
4 of an individual, that is based on such individual’s
5 participation in the development, collection, report-
6 ing, or storage of patient safety data in accordance
7 with this part.

8 “(c) DISCLOSURE REQUIREMENTS.—Nothing in this
9 section shall be construed to prohibit one or more of the
10 following disclosures (which are deemed to be necessary
11 for the proper management and administration of the pa-
12 tient safety organization):

13 “(1) Disclosures by a provider in complying
14 with authorized requests for the provision of infor-
15 mation to which subsection (a) applies (such as a
16 patient’s medical record or other relevant informa-
17 tion) that is in the control of such a provider and
18 that has been developed, maintained, or exists sepa-
19 rately from the process by which the provider col-
20 lects or develops information for reporting to a pa-
21 tient safety organization.

22 “(2) Disclosures by a provider or patient safety
23 organization of patient safety data as part of a dis-
24 ciplinary proceeding relating to a provider, or a

1 criminal proceeding, if such a disclosure of such pa-
2 tient safety data is—

3 “(A) material to the proceeding;

4 “(B) within the public interest; and

5 “(C) not available from any other source.

6 “(3) Disclosures by a provider or patient safety
7 organization of relevant information to the Food and
8 Drug Administration, or to a person that is subject
9 to the jurisdiction of such Administration, with re-
10 spect to an Administration-regulated product or ac-
11 tivity for which that entity has responsibility, for the
12 purposes of activities related to the quality, safety,
13 or effectiveness of such Administration-regulated
14 product or activity, subject to section 520(e) of the
15 Federal Food, Drug, and Cosmetic Act.

16 “(4) Disclosures by a provider or patient safety
17 organization of information to which subsection (a)
18 applies to carry out activities described in paragraph
19 (2)(A) (i) through (vi) or (3) of section 921.

20 “(d) TRANSFER OF INFORMATION.—The transfer of
21 any patient safety data by a provider to a patient safety
22 organization shall not be treated as a waiver of any privi-
23 lege or protection established under this part or estab-
24 lished under State law.

1 “(e) PENALTY.—Except as provided in subsection (c)
2 and as otherwise provided for in this section, it shall be
3 unlawful for any person to disclose any patient safety data
4 described in subsection (a). Any person violating the provi-
5 sions of this section shall, upon conviction, be fined in ac-
6 cordance with section 934(d).

7 “(f) NO LIMITATION OF OTHER PRIVILEGES.—Noth-
8 ing in this section shall be construed to limit other privi-
9 leges that are available under Federal or State laws that
10 provide greater peer review or confidentiality protections
11 than the peer review and confidentiality protections pro-
12 vided for in this section.

13 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
14 tion shall be construed to alter or affect the implementa-
15 tion of any provision of section 264(c) of the Health Insur-
16 ance Portability and Accountability Act of 1996 (Public
17 Law 104–191; 110 Stat. 2033) or any regulation promul-
18 gated under such section.

19 **“SEC. 923. NATIONAL DATABASE.**

20 “(a) AUTHORITY.—

21 “(1) IN GENERAL.—In conducting activities
22 under this part, the Secretary may provide for the
23 establishment and maintenance of a database to re-
24 ceive relevant non-identifiable patient safety data, or
25 may designate entities to collect relevant non-identi-

1 fiable patient safety data, that is voluntarily re-
2 ported by patient safety organizations upon the re-
3 quest of the Secretary.

4 “(2) USE OF DATA.—Data reported to any
5 database established or designated under paragraph
6 (1) shall be used to analyze regional variations and
7 national statistics related to patient safety and
8 health care quality. The information resulting from
9 such analyses may be included in the annual quality
10 reports prepared under section 913(b)(2).

11 “(b) STANDARDS.—In developing or designating a
12 database under subsection (a)(1), the Secretary may de-
13 termine common formats for the voluntary reporting of
14 non-identifiable patient safety data, including necessary
15 data elements, common and consistent definitions, and a
16 standardized computer interface for the processing of such
17 data. To the extent practicable, such standards shall be
18 consistent with the administrative simplification provisions
19 of part C of title XI of the Social Security Act.

20 “(c) CONFIDENTIALITY.—Any non-identifiable pa-
21 tient safety data that is transferred to the database under
22 this section shall be privileged and confidential.

23 **“SEC. 924. TECHNICAL ASSISTANCE.**

24 “The Secretary, acting through the Director, may
25 provide technical assistance to patient safety organiza-

1 tions. Such assistance shall include annual meetings for
 2 patient safety organizations to discuss methodology, com-
 3 munication, data collection, or privacy concerns.

4 **“SEC. 925. PROMOTING THE INTEGRATION OF HEALTH**
 5 **CARE INFORMATION TECHNOLOGY SYSTEMS.**

6 “(a) DEVELOPMENT.—Not later than 36 months
 7 after the date of enactment of the Patient Safety and
 8 Quality Improvement Act, the Secretary shall develop or
 9 adopt voluntary national standards that promote the inte-
 10 gration of health care information technology systems.

11 “(b) UPDATES.—The Secretary shall provide for the
 12 ongoing review and periodic updating of the standards de-
 13 veloped under subsection (a).

14 “(c) DISSEMINATION.—The Secretary shall provide
 15 for the dissemination of the standards developed and up-
 16 dated under this section.

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

18 “There is authorized to be appropriated such sums
 19 as may be necessary to carry out this part.”.

20 **SEC. 4. STUDIES AND REPORTS.**

21 (a) **MEDICAL TECHNOLOGIES AND THERAPIES.—**

22 (1) **IN GENERAL.—**The Secretary of Health and
 23 Human Services shall enter into a contract with an
 24 appropriate research organization for the conduct of
 25 a study to assess the impact of medical technologies

1 and therapies on patient safety, patient benefit,
2 health care quality, and the costs of care as well as
3 productivity growth. Such study shall determine—

4 (A) the extent to which the current health
5 care system's use of labor versus the use of
6 technology has contributed to increases in the
7 share of the gross domestic product that is de-
8 voted to health care and the impact of medical
9 technologies and therapies on such increases;

10 (B) the extent to which early and appro-
11 priate introduction and integration of innovative
12 medical technologies and therapies may affect
13 the overall productivity and quality of the
14 health care delivery systems of the United
15 States; and

16 (C) the relationship of such medical tech-
17 nologies and therapies to patient safety, patient
18 benefit, health care quality, and cost of care.

19 (2) REPORT.—Not later than 18 months after
20 the date of enactment of this Act, the Secretary of
21 Health and Human Services shall prepare and sub-
22 mit to the appropriate committees of Congress a re-
23 port containing the results of the study conducted
24 under paragraph (1).

1 (b) STATE LAWS RELATING TO PATIENT SAFETY
2 PEER REVIEW SYSTEMS.—

3 (1) SURVEY.—The Attorney General shall con-
4 duct a survey of State laws that relate to patient
5 safety data peer review systems, including laws that
6 establish an evidentiary privilege applicable to data
7 developed by such systems, and shall review the
8 manner in which such laws have been interpreted by
9 the courts.

10 (2) REPORT.—Not later than 9 months after
11 the date of enactment of this Act, the Attorney Gen-
12 eral shall prepare and submit to the Committee on
13 Health, Education, Labor, and Pensions of the Sen-
14 ate and the Committee on Energy and Commerce of
15 the House of Representatives, a report concerning
16 the results of the survey conducted under paragraph
17 (1).

○