108TH CONGRESS
1ST SESSION

S. 720

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

MARCH 26, 2003

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

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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.

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 ''Patient Safety and Quality Improvement Act''.

SEC. 2. FINDINGS AND PURPOSES.

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

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

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

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

(4) The Health, Education, Labor, and Pensions Committee of the Senate held 4 hearings in the 106th Congress and 1 hearing in the 107th Congress on patient safety where experts in the field supported the recommendation of the Institute of Medicine for congressional action.

(5) Myriad public and private patient safety initiatives have begun. The Quality Interagency Coordination Taskforce has recommended steps to improve patient safety that may be taken by each Federal agency involved in health care and activities relating to these steps are ongoing.

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

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

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

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

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

protections that will allow them to review protected information so that they may collaborate in the development and implementation of patient safety improvement strategies. Currently, the State peer review protections provide inadequate conditions to allow the sharing of information to promote patient safety.

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

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

(1) encourage a culture of safety and quality in the United States health care system by providing for legal protection of information reported voluntarily for the purposes of quality improvement and patient safety; and

(2) ensure accountability by raising standards and expectations for continuous quality improvements in patient safety through the actions of the Secretary of Health and Human Services.

SEC. 3. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.

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

(1) in section 912(c), by inserting ", in accordance with part C," after "The Director shall";

(2) by redesignating part C as part D;

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

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

(5) by inserting after part B the following:

"PART C—PATIENT SAFETY IMPROVEMENT

"SEC. 921. DEFINITIONS.

"In this part:

"(1) NON-IDENTIFIABLE INFORMATION.—The term 'non-identifiable information' means information that is presented in a form and manner that prevents the identification of any provider, patient, and the reporter of patient safety data.

"(2) PATIENT SAFETY DATA.—The term 'patient safety data' means—

"(A) any data, reports, records, memoranda, analyses, deliberative work, statements, root cause analyses, or quality improvement processes that could result in improved patient safety or health care quality, that are—

''(i) collected or developed by a provider for the purpose of reporting to a patient safety organization;

''(ii) reported to a patient safety organization for patient safety or quality improvement processes;

''(iii) requested by a patient safety organization (including the contents of such request);

''(iv) reported to a provider by a patient safety organization;

''(v) collected or developed by a patient safety organization; or

''(vi) reported among patient safety organizations, after obtaining authorization; or

''(B) information related to corrective actions taken in response to patient safety data;

for the purpose of improving patient safety, health care quality, or health care outcomes.

''(3) PATIENT SAFETY ORGANIZATION.—The term 'patient safety organization' means a private or public organization or component thereof that performs the following activities (which are deemed to

be necessary for the proper management and administration of such organization or component thereof):

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

''(B) The collection and analysis of patient safety data that are voluntarily submitted by a provider.

''(C) The development and dissemination of information to providers with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

''(D) The utilization of patient safety data to carry out activities under this paragraph and for the purposes of encouraging a culture of safety and of providing direct feedback and assistance to providers to effectively minimize patient risk.

''(E) The maintenance of confidentiality with respect to individually identifiable health information.

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

''(G) The certification to the Agency that the patient safety organization satisfies the criteria of this paragraph for the period in which the organization is carrying out such duties.

''(4) PROVIDER.—The term 'provider' means—

''(A) a provider of services (as defined in section 1861(u) of the Social Security Act) and a person furnishing any medical or other health care services (as defined in section 1861(s)(1) and (2) of such Act) through, or under the authority of, such a provider of services;

''(B) a physician (as defined in section 1861(r) of such Act);

''(C) any other person, including a pharmacist, who is engaged in the delivery of medical or other health services (as defined in section 1861(s)(1) and (2) of such Act) in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State;

''(D) a renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility,

behavioral health residential treatment facility, or clinical laboratory; or

''(E) any other person or entity specified in regulations by the Secretary after public notice and comment.

''SEC. 922. CONFIDENTIALITY AND PEER REVIEW PROTECTIONS.

''(a) IN GENERAL.—Notwithstanding any other provision of law, and subject to this section, patient safety data shall be privileged and confidential.

''(b) SCOPE OF PRIVILEGE.—Subject to the provisions of subsection (c), patient safety data to which subsection (a) applies shall not be—

''(1) subject to a civil, criminal, or administrative subpoena;

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

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

''(4) admitted as evidence or otherwise disclosed in any civil, criminal, or administrative proceeding; or

''(5) utilized in an adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing or licensing of an individual, that is based on such individual's participation in the development, collection, reporting, or storage of patient safety data in accordance with this part.

''(c) DISCLOSURE REQUIREMENTS.—Nothing in this section shall be construed to prohibit one or more of the following disclosures (which are deemed to be necessary for the proper management and administration of the patient safety organization):

''(1) Disclosures by a provider in complying with authorized requests for the provision of information to which subsection (a) applies (such as a patient's medical record or other relevant information) that is in the control of such a provider and that has been developed, maintained, or exists separately from the process by which the provider collects or develops information for reporting to a patient safety organization.

''(2) Disclosures by a provider or patient safety organization of patient safety data as part of a disciplinary proceeding relating to a provider, or a

criminal proceeding, if such a disclosure of such patient safety data is—

"(A) material to the proceeding;

"(B) within the public interest; and

"(C) not available from any other source.

"(3) Disclosures by a provider or patient safety organization of relevant information to the Food and Drug Administration, or to a person that is subject to the jurisdiction of such Administration, with respect to an Administration-regulated product or activity for which that entity has responsibility, for the purposes of activities related to the quality, safety, or effectiveness of such Administration-regulated product or activity, subject to section 520(c) of the Federal Food, Drug, and Cosmetic Act.

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

"(d) TRANSFER OF INFORMATION.—The transfer of any patient safety data by a provider to a patient safety organization shall not be treated as a waiver of any privilege or protection established under this part or established under State law.

''(e) PENALTY.—Except as provided in subsection (c) and as otherwise provided for in this section, it shall be unlawful for any person to disclose any patient safety data described in subsection (a). Any person violating the provisions of this section shall, upon conviction, be fined in accordance with section 934(d).

''(f) NO LIMITATION OF OTHER PRIVILEGES.—Nothing in this section shall be construed to limit other privileges that are available under Federal or State laws that provide greater peer review or confidentiality protections than the peer review and confidentiality protections provided for in this section.

''(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to alter or affect the implementation of any provision of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) or any regulation promulgated under such section.

''SEC. 923. NATIONAL DATABASE.

''(a) AUTHORITY.—

''(1) IN GENERAL.—In conducting activities under this part, the Secretary may provide for the establishment and maintenance of a database to receive relevant non-identifiable patient safety data, or may designate entities to collect relevant non-identi-

fiable patient safety data, that is voluntarily reported by patient safety organizations upon the request of the Secretary.

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

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

''(c) CONFIDENTIALITY.—Any non-identifiable patient safety data that is transferred to the database under this section shall be privileged and confidential.

''SEC. 924. TECHNICAL ASSISTANCE.

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

tions. Such assistance shall include annual meetings for patient safety organizations to discuss methodology, communication, data collection, or privacy concerns.

''SEC. 925. PROMOTING THE INTEGRATION OF HEALTH CARE INFORMATION TECHNOLOGY SYSTEMS.

''(a) DEVELOPMENT.—Not later than 36 months after the date of enactment of the Patient Safety and Quality Improvement Act, the Secretary shall develop or adopt voluntary national standards that promote the integration of health care information technology systems.

''(b) UPDATES.—The Secretary shall provide for the ongoing review and periodic updating of the standards developed under subsection (a).

''(c) DISSEMINATION.—The Secretary shall provide for the dissemination of the standards developed and updated under this section.

''SEC. 926. AUTHORIZATION OF APPROPRIATIONS.

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

SEC. 4. STUDIES AND REPORTS.

(a) MEDICAL TECHNOLOGIES AND THERAPIES.—

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

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

(A) the extent to which the current health care system's use of labor versus the use of technology has contributed to increases in the share of the gross domestic product that is devoted to health care and the impact of medical technologies and therapies on such increases;

(B) the extent to which early and appropriate introduction and integration of innovative medical technologies and therapies may affect the overall productivity and quality of the health care delivery systems of the United States; and

(C) the relationship of such medical technologies and therapies to patient safety, patient benefit, health care quality, and cost of care.

(2) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report containing the results of the study conducted under paragraph (1).

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

(1) SURVEY.—The Attorney General shall conduct a survey of State laws that relate to patient safety data peer review systems, including laws that establish an evidentiary privilege applicable to data developed by such systems, and shall review the manner in which such laws have been interpreted by the courts.

(2) REPORT.—Not later than 9 months after the date of enactment of this Act, the Attorney General shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the results of the survey conducted under paragraph (1).

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