109TH CONGRESS
1ST SESSION

S. 544

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 8, 2005

Mr. JEFFORDS (for himself, Mr. GREGG, Mr. ENZI, Mr. BINGAMAN, Mr. FRIST, and Mrs. MURRAY) 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 of 2005''.

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 (6) 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) Many organizations currently collecting patient safety data have expressed a need for legal protections that will allow them to review protected information and collaborate in the development and implementation of patient safety improvement strategies. Currently, the State peer review protections are inadequate to allow the sharing of information to promote patient safety.

(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.

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 934(d) (as so redesignated), by striking the second sentence and inserting the following: "Penalties provided for under this section shall be imposed and collected by the Secretary using the administrative and procedural processes used to impose and collect civil money penalties under section 1128A of the Social Security Act (other than subsections (a) and (b), the second sentence of subsection (f), and subsections (i), (m), and (n)), unless

the Secretary determines that a modification of procedures would be more suitable or reasonable to carry out this subsection and provides for such modification by regulation.'';

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

(6) by inserting after part B the following:

''PART C—PATIENT SAFETY IMPROVEMENT

''SEC. 921. DEFINITIONS.

''In this part:

''(1) NON-IDENTIFIABLE INFORMATION.—

''(A) IN GENERAL.—The term 'non-identifiable information' means, with respect to information, that the information is presented in a form and manner that prevents the identification of a provider, a patient, or a reporter of patient safety data.

''(B) IDENTIFIABILITY OF PATIENT.—For purposes of subparagraph (A), the term 'presented in a form and manner that prevents the identification of a patient' means, with respect to information that has been subject to rules promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), that the

information has been de-identified so that it is no longer individually identifiable health information as defined in such rules.

''(2) PATIENT SAFETY DATA.—

''(A) IN GENERAL.—The term 'patient safety data' means—

''(i) any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements that are—

''(I) collected or developed by a provider for reporting to a patient safety organization, provided that they are reported to the patient safety organization within 60 days;

''(II) requested by a patient safety organization (including the contents of such request), if they are reported to the patient safety organization within 60 days;

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

''(IV) collected by a patient safety organization from another patient

safety organization, or developed by a patient safety organization;

that could result in improved patient safety, health care quality, or health care outcomes; or

''(ii) any deliberative work or process with respect to any patient safety data described in clause (i).

''(B) LIMITATION.—

''(i) COLLECTION.—If the original material from which any data, reports, records, memoranda, analyses (such as root case analyses), or written or oral statements referred to in subclause (I) or (IV) of subparagraph (A)(i) are collected and is not patient safety data, the act of such collection shall not make such original material patient safety data for purposes of this part.

''(ii) SEPARATE DATA.—The term 'patient safety data' shall not include information (including a patient's medical record, billing and discharge information or any other patient or provider record) that is collected or developed separately

from and that exists separately from patient safety data. Such separate information or a copy thereof submitted to a patient safety organization shall not itself be considered as patient safety data. Nothing in this part, except for section 922(f)(1), shall be construed to limit—

"(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

"(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

"(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

"(3) PATIENT SAFETY ORGANIZATION.—The term 'patient safety organization' means a private or

public entity or component thereof that is currently listed by the Secretary pursuant to section 924(c).

''(4) PATIENT SAFETY ORGANIZATION ACTIVITIES.—The term 'patient safety organization activities' means the following activities, which are deemed to be necessary for the proper management and administration of a patient safety organization:

''(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 submitted by more than one 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 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 procedures to preserve confidentiality with respect to patient safety data.

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

''(G) The utilization of qualified staff.

''(5) PERSON.—The term 'person' includes Federal, State, and local government agencies.

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

''(A) a person licensed or otherwise authorized under State law to provide health care services, including—

''(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

''(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutri-

tion professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

''(B) any other person specified in regulations promulgated by the Secretary.

''SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTECTIONS.

''(a) PRIVILEGE.—Notwithstanding any other provision of Federal, State, or local law, patient safety data shall be privileged and, subject to the provisions of subsection (c)(1), shall not be—

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

''(2) subject to discovery in connection with a Federal, State, or local 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, State, or local law;

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

''(5) utilized in a disciplinary proceeding against a provider.

''(b) CONFIDENTIALITY.—Notwithstanding any other provision of Federal, State, or local law, and subject to the provisions of subsections (c) and (d), patient safety data shall be confidential and shall not be disclosed.

''(c) EXCEPTIONS TO PRIVILEGE AND CONFIDENTIALITY.—Nothing in this section shall be construed to prohibit one or more of the following uses or disclosures:

''(1) Disclosure by a provider or patient safety organization of relevant patient safety data for use in a criminal proceeding only after a court makes an in camera determination that such patient safety data contains evidence of a wanton and criminal act to directly harm the patient.

''(2) Voluntary disclosure of non-identifiable patient safety data by a provider or a patient safety organization.

''(d) PROTECTED DISCLOSURE AND USE OF INFORMATION.—Nothing in this section shall be construed to prohibit one or more of the following uses or disclosures:

''(1) Disclosure of patient safety data by a person that is a provider, a patient safety organization, or a contractor of a provider or patient safety organization, to another such person, to carry out patient safety organization activities.

''(2) Disclosure of patient safety data by a provider or patient safety organization to grantees or contractors carrying out patient safety research, evaluation, or demonstration projects authorized by the Director.

''(3) Disclosure of patient safety data by a provider to an accrediting body that accredits that provider.

''(4) Voluntary disclosure of patient safety data by a patient safety organization to the Secretary for public health surveillance if the consent of each provider identified in, or providing, such data is obtained prior to such disclosure. Nothing in the preceding sentence shall be construed to prevent the release of patient safety data that is provided by, or that relates solely to, a provider from which the consent described in such sentence is obtained because one or more other providers do not provide such consent with respect to the disclosure of patient safety data that relates to such nonconsenting providers. Consent for the future release of patient safety data for such purposes may be requested by the patient safety organization at the time the data is submitted.

''(5) Voluntary disclosure of patient safety data by a patient safety organization to State of local government agencies for public health surveillance if the consent of each provider identified in, or providing, such data is obtained prior to such disclosure. Nothing in the preceding sentence shall be construed to prevent the release of patient safety data that is provided by, or that relates solely to, a provider from which the consent described in such sentence is obtained because one or more other providers do not provide such consent with respect to the disclosure of patient safety data that relates to such nonconsenting providers. Consent for the future release of patient safety data for such purposes may be requested by the patient safety organization at the time the data is submitted.

''(e) CONTINUED PROTECTION OF INFORMATION AFTER DISCLOSURE.—

''(1) IN GENERAL.—Except as provided in paragraph (2), patient safety data that is used or disclosed shall continue to be privileged and confidential as provided for in subsections (a) and (b), and the provisions of such subsections shall apply to such data in the possession or control of—

''(A) a provider or patient safety organization that possessed such data before the use or disclosure; or

''(B) a person to whom such data was disclosed.

''(2) EXCEPTION.—Notwithstanding paragraph (1), and subject to paragraph (3)—

''(A) if patient safety data is used or disclosed as provided for in subsection (c)(1), and such use or disclosure is in open court, the confidentiality protections provided for in subsection (b) shall no longer apply to such data; and

''(B) if patient safety data is used or disclosed as provided for in subsection (c)(2), the privilege and confidentiality protections provided for in subsections (a) and (b) shall no longer apply to such data.

''(3) CONSTRUCTION.—Paragraph (2) shall not be construed as terminating or limiting the privilege or confidentiality protections provided for in subsection (a) or (b) with respect to data other than the specific data used or disclosed as provided for in subsection (c).

''(f) LIMITATION ON ACTIONS.—

''(1) PATIENT SAFETY ORGANIZATIONS.—Except to enforce disclosures pursuant to subsection (c)(1), no action may be brought or process served against a patient safety organization to compel disclosure of information collected or developed under this part whether or not such information is patient safety data unless such information is specifically identified, is not patient safety data, and cannot otherwise be obtained.

''(2) PROVIDERS.—An accrediting body shall not take an accrediting action against a provider based on the good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety data in accordance with this part. An accrediting body may not require a provider to reveal its communications with any patient safety organization established in accordance with this part.

''(g) REPORTER PROTECTION.—

''(1) IN GENERAL.—A provider may not take an adverse employment action, as described in paragraph (2), against an individual based upon the fact that the individual in good faith reported information—

"(A) to the provider with the intention of having the information reported to a patient safety organization; or

"(B) directly to a patient safety organization.

"(2) ADVERSE EMPLOYMENT ACTION.—For purposes of this subsection, an 'adverse employment action' includes—

"(A) loss of employment, the failure to promote an individual, or the failure to provide any other employment-related benefit for which the individual would otherwise be eligible; or

"(B) an adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual.

"(h) ENFORCEMENT.—

"(1) PROHIBITION.—Except as provided in subsections (c) and (d) and as otherwise provided for in this section, it shall be unlawful for any person to negligently or intentionally disclose any patient safety data, and any such person shall, upon adjudication, be assessed in accordance with section 934(d).

"(2) RELATION TO HIPAA.—The penalty provided for under paragraph (1) shall not apply if the defendant would otherwise be subject to a penalty

under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) or under section 1176 of the Social Security Act (42 U.S.C. 1320d–5) for the same disclosure.

''(3) EQUITABLE RELIEF.—

''(A) IN GENERAL.—Without limiting remedies available to other parties, a civil action may be brought by any aggrieved individual to enjoin any act or practice that violates subsection (g) and to obtain other appropriate equitable relief (including reinstatement, back pay, and restoration of benefits) to redress such violation.

''(B) AGAINST STATE EMPLOYEES.—An entity that is a State or an agency of a State government may not assert the privilege described in subsection (a) unless before the time of the assertion, the entity or, in the case of and with respect to an agency, the State has consented to be subject to an action as described by this paragraph, and that consent has remained in effect.

''(i) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

''(1) limit other privileges that are available under Federal, State, or local laws that provide greater confidentiality protections or privileges than the privilege and confidentiality protections provided for in this section;

''(2) limit, alter, or affect the requirements of Federal, State, or local law pertaining to information that is not privileged or confidential under this section;

''(3) 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), section 1176 of the Social Security Act (42 U.S.C. 1320d–5), or any regulation promulgated under such sections;

''(4) limit the authority of any provider, patient safety organization, or other person to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with subsection (c) or (d); and

''(5) prohibit a provider from reporting a crime to law enforcement authorities, regardless of whether knowledge of the existence of, or the description of, the crime is based on patient safety data, so long as

the provider does not disclose patient safety data in making such report.

"SEC. 923. PATIENT SAFETY NETWORK OF DATABASES.

"(a) IN GENERAL.—The Secretary shall maintain a patient safety network of databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other persons. The network of databases shall have the capacity to accept, aggregate, and analyze nonidentifiable patient safety data voluntarily reported by patient safety organizations, providers, or other persons.

"(b) NETWORK OF DATABASE STANDARDS.—The Secretary may determine common formats for the reporting to the patient safety network of databases maintained under subsection (a) of nonidentifiable 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.

"SEC. 924. PATIENT SAFETY ORGANIZATION CERTIFICATION AND LISTING.

"(a) CERTIFICATION.—

''(1) INITIAL CERTIFICATION.—Except as provided in paragraph (2), an entity that seeks to be a patient safety organization shall submit an initial certification to the Secretary that the entity intends to perform the patient safety organization activities.

''(2) DELAYED CERTIFICATION OF COLLECTION FROM MORE THAN ONE PROVIDER.—An entity that seeks to be a patient safety organization may—

''(A) submit an initial certification that it intends to perform patient safety organization activities other than the activities described in subparagraph (B) of section 921(4); and

''(B) within 2 years of submitting the initial certification under subparagraph (A), submit a supplemental certification that it performs the patient safety organization activities described in subparagraphs (A) through (F) of section 921(4).

''(3) EXPIRATION AND RENEWAL.—

''(A) EXPIRATION.—An initial certification under paragraph (1) or (2)(A) shall expire on the date that is 3 years after it is submitted.

''(B) RENEWAL.—

''(i) IN GENERAL.—An entity that seeks to remain a patient safety organiza-

tion after the expiration of an initial certification under paragraph (1) or (2)(A) shall, within the 3-year period described in subparagraph (A), submit a renewal certification to the Secretary that the entity performs the patient safety organization activities described in section 921(4).

''(ii) TERM OF RENEWAL.—A renewal certification under clause (i) shall expire on the date that is 3 years after the date on which it is submitted, and may be renewed in the same manner as an initial certification.

''(b) ACCEPTANCE OF CERTIFICATION.—Upon the submission by an organization of an initial certification pursuant to subsection (a)(1) or (a)(2)(A), a supplemental certification pursuant to subsection (a)(2)(B), or a renewal certification pursuant to subsection (a)(3)(B), the Secretary shall review such certification and—

''(1) if such certification meets the requirements of subsection (a)(1), (a)(2)(A), (a)(2)(B), or (a)(3)(B), as applicable, the Secretary shall notify the organization that such certification is accepted; or

''(2) if such certification does not meet such requirements, as applicable, the Secretary shall notify the organization that such certification is not accepted and the reasons therefor.

''(c) LISTING.—

''(1) IN GENERAL.—Except as otherwise provided in this subsection, the Secretary shall compile and maintain a current listing of patient safety organizations with respect to which the Secretary has accepted a certification pursuant to subsection (b).

''(2) REMOVAL FROM LISTING.—The Secretary shall remove from the listing under paragraph (1)—

''(A) an entity with respect to which the Secretary has accepted an initial certification pursuant to subsection (a)(2)(A) and which does not submit a supplemental certification pursuant to subsection (a)(2)(B) that is accepted by the Secretary;

''(B) an entity whose certification expires and which does not submit a renewal application that is accepted by the Secretary; and

''(C) an entity with respect to which the Secretary revokes the Secretary's acceptance of the entity's certification, pursuant to subsection (d).

''(d) REVOCATION OF ACCEPTANCE.—

''(1) IN GENERAL.—Except as provided in paragraph (2), if the Secretary determines (through a review of patient safety organization activities) that a patient safety organization does not perform one of the patient safety organization activities described in subparagraph (A) through (F) of section 921(4), the Secretary may, after notice and an opportunity for a hearing, revoke the Secretary's acceptance of the certification of such organization.

''(2) DELAYED CERTIFICATION OF COLLECTION FROM MORE THAN ONE PROVIDER.—A revocation under paragraph (1) may not be based on a determination that the organization does not perform the activity described in section 921(4)(B) if—

''(A) the listing of the organization is based on its submittal of an initial certification under subsection (a)(2)(A);

''(B) the organization has not submitted a supplemental certification under subsection (a)(2)(B); and

''(C) the 2-year period described in subsection (a)(2)(B) has not expired.

''(e) NOTIFICATION OF REVOCATION OR REMOVAL FROM LISTING.—

''(1) SUPPLYING CONFIRMATION OF NOTIFICATION TO PROVIDERS.—Within 15 days of a revocation under subsection (d)(1), a patient safety organization shall submit to the Secretary a confirmation that the organization has taken all reasonable actions to notify each provider whose patient safety data is collected or analyzed by the organization of such revocation.

''(2) PUBLICATION.—Upon the revocation of an acceptance of an organization's certification under subsection (d)(1), or upon the removal of an organization from the listing under subsection (c)(2), the Secretary shall publish notice of the revocation or removal in the Federal Register.

''(f) STATUS OF DATA AFTER REMOVAL FROM LISTING.—

''(1) NEW DATA.—With respect to the privilege and confidentiality protections described in section 922, data submitted to an organization within 30 days after the organization is removed from the listing under subsection (c)(2) shall have the same status as data submitted while the organization was still listed.

''(2) PROTECTION TO CONTINUE TO APPLY.—If the privilege and confidentiality protections de-

scribed in section 922 applied to data while an organization was listed, or during the 30-day period described in paragraph (1), such protections shall continue to apply to such data after the organization is removed from the listing under subsection (c)(2).

''(g) DISPOSITION OF DATA.—If the Secretary removes an organization from the listing as provided for in subsection (c)(2), with respect to the patient safety data that the organization received from providers, the organization shall—

''(1) with the approval of the provider and another patient safety organization, transfer such data to such other organization;

''(2) return such data to the person that submitted the data; or

''(3) if returning such data to such person is not practicable, destroy such data.

''SEC. 925. TECHNICAL ASSISTANCE.

''The Secretary, acting through the Director, may provide technical assistance to patient safety organizations, including convening annual meetings for patient safety organizations to discuss methodology, communication, data collection, or privacy concerns.

''SEC. 926. PROMOTING THE INTEROPERABILITY 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 of 2005, the Secretary shall develop or adopt voluntary standards that promote the electronic exchange of health care information.

''(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. 927. 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) IN GENERAL.—The Secretary of Health and Human Services shall enter into a contract (based upon a competitive contracting process) 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 examine—

(1) the extent to which factors, such as the use of labor and technological advances, have 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;

(2) 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

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

(b) 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 subsection (a).

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