107TH CONGRESS
2D SESSION

S. 3029

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of accidental medical injury.

IN THE SENATE OF THE UNITED STATES

OCTOBER 2, 2002

Mr. KENNEDY 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 accidental medical injury.

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 Improvement and Medical Injury Reduction Act''.

SEC. 2. PURPOSE.

It is the purpose of this Act to improve patient safety by promoting the voluntary reporting of patient safety events and medical errors and other measures.

SEC. 3. PATIENT SAFETY IMPROVEMENTS.

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 E;

(3) by redesignating sections 921 through 928, as sections 941 through 948, respectively;

(4) in section 948(1) (as so redesignated), by striking "921" and inserting "941"; and

(5) by inserting after part B the following:

"PART C—PATIENT SAFETY IMPROVEMENT

"SEC. 921. DEFINITIONS.

"In this part:

"(1) CENTER.—The term 'Center' means the Center for Quality Improvement and Patient Safety established under section 922(a).

"(2) HEALTH CARE PROVIDER.—The term 'health care provider' means an individual or entity licensed or otherwise authorized under State law to provide health care services, including—

"(A) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, and hospice program;

"(B) a physician, physician assistant, nurse practitioner, clinical nurse specialist, cer-

tified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, or other individual health care practitioner;

''(C) a pharmacist; and

''(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, clinical laboratory, or community health center.

''(3) IDENTIFIABLE INFORMATION.—The term 'identifiable information' means information that is presented in a form and manner that allows the identification of any health care provider, patient, or reporter of patient safety information. With respect to patients, such information includes any individually identifiable health information as that term is defined in the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191; 110 Stat. 2033).

''(4) NATIONAL PATIENT SAFETY DATABASE.—The term 'National Patient Safety Database' means the database of nonidentifiable information concerning patient safety that is coordinated by, and

developed in collaboration with, the Director under section 922(c)(3)(B).

''(5) NATIONAL PATIENT SAFETY RESEARCH DEMONSTRATION SYSTEM.—The term 'National Patient Safety Research Demonstration System' means a system under which the Director will enter into voluntary agreements with a geographically and institutionally diverse group of eligible entities to collect data for the purpose of conducting research on patient safety under section 922(c)(3)(C).

''(6) NONIDENTIFIABLE INFORMATION.—The term 'nonidentifiable information' means information that is presented in a form and manner that prevents the identification of any health care provider, patient, or reporter of patient safety information. With respect to patients, such information must be de-identified consistent with the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033).

''(7) PATIENT SAFETY INFORMATION.—The term 'patient safety information' means any reports, records, memoranda, analyses, deliberative work, statements, or root cause analyses that are collected

or developed to improve patient safety or health care quality and that—

"(A) are developed by a health care provider for the purpose of reporting to a patient safety organization and that are reported on a timely basis to such an organization; or

"(B) are collected or developed by a patient safety organization or by the National Patient Safety Database or National Patient Safety Research Demonstration System, regardless of whether the information is transmitted to the health care provider that reported the original information.

"(8) PATIENT SAFETY ORGANIZATION.—The term 'patient safety organization' means a private or public organization, or component thereof, that is certified, through a process to be determined by the Director under section 925, to perform each of the following activities:

"(A) The conduct, as the organization or component's primary activity, of activities to improve patient safety and the quality of health care delivery.

''(B) The collection and analysis of patient safety information that is submitted by health care providers.

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

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

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

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

''(G) The submission of nonidentifiable information to the Agency consistent with standards established by the Director under section 924 for the National Patient Safety Database.

"SEC. 922. PRIVILEGE.

''(a) IN GENERAL.—Notwithstanding any other provision of law, patient safety information shall be privileged and confidential in accordance with this section.

''(b) SCOPE OF PRIVILEGE.—Subject to the succeeding provisions of this section, such information shall not be—

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

''(2) subject to discovery in connection with a civil 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; or

''(4) admitted as evidence or otherwise disclosed in any Federal or State civil or administrative proceeding.

''(c) EXCEPTIONS TO PRIVILEGE.—The privilege provided for under this section shall not apply to—

''(1) records of a patient's medical diagnosis and treatment, patient or hospital records, other primary health care information or other documents, records, or data that exist separately from the process of collecting or developing information for the purposes of this part;

''(2) information merely by reason of its inclusion, report, or the fact of its submission, to a patient safety organization, the National Patient Safety Database, or the National Patient Safety Research Demonstration System; and

''(3) information available from sources other than a report or submission made under this part, which may be discovered or admitted in a Federal or State civil or administrative proceeding, if discoverable or admissible under applicable Federal or State law.

''(d) DISCLOSURES.—Nothing in this section shall be construed to prohibit any of the following disclosures:

''(1) The disclosure of nonidentifiable information by a health care provider, patient safety organization, or the Director.

''(2) The disclosure of identifiable information by a health care provider or patient safety organization, if such disclosure—

''(A) is authorized by the provider for the purposes of improving quality and safety;

''(B) is to an entity or person subject to the requirements 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; and

''(C) is not in conflict with such section or any regulation promulgated under such section.

''(3) The disclosure of patient safety information by a provider or patient safety organization to the Food and Drug Administration.

''(e) RULES OF CONSTRUCTION.—

''(1) IN GENERAL.—Nothing in this section shall be construed to limit or extend other privileges that are available under Federal or State laws, including peer review and confidentiality protections.

''(2) CONSTRUCTION REGARDING USE OF PATIENT SAFETY INFORMATION.—

''(A) INTERNAL USE PERMITTED TO IMPROVE PATIENT SAFETY, QUALITY, AND EFFICIENCY.—Nothing in this part shall be construed to limit a health care provider from using patient safety information within the provider to improve patient safety, health care quality, or administrative efficiency of the provider.

''(B) TREATMENT.—Information that is collected as patient safety information is not disqualified from being treated as patient safety

information because of its use for the purposes described in subparagraph (A) and such use shall not constitute a waiver of any privilege or protection established under this section or under State law.

''(3) STATE MANDATORY REPORTING REQUIREMENTS.—Nothing in this part shall be construed as preempting or otherwise affecting any mandatory reporting requirement for health care providers under State law.

''(f) APPLICATION OF PRIVACY REGULATIONS.—For purposes of applying the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033)—

''(1) patient safety organizations that collect or receive identifiable information shall be treated as covered entities; and

''(2) activities of such organizations described in section 923(b)(2)(A) in relation to a health care provider are deemed to be health care operations of the provider.

Nothing in this section shall be construed to alter or affect the implementation of such regulation or such section 264(c).

''(g) WAIVERS.—

''(1) IN GENERAL.—Nothing in this part shall be construed as precluding a health care provider from waiving the privilege established under this section.

''(2) LIMITATION.—The disclosure of patient safety information pursuant to this part shall not constitute a waiver of any other Federal or State privilege.

''(h) CONTINUATION OF PRIVILEGE.—Patient safety information of an organization that is certified as a patient safety organization shall continue to be privileged and confidential, in accordance with this section, if the organization's certification is terminated or revoked or if the organization otherwise ceases to qualify as a patient safety organization until the information is otherwise disposed of in accordance with section 925(g).

''(i) PENALTY.—

''(1) PROHIBITION.—Except as provided in this part, and subject to paragraph (2), it shall be unlawful for any person to disclose patient safety information in violation of this section.

''(2) RELATION TO HIPAA.—The penalty under this subsection for a disclosure described in paragraph (1) shall not apply if the person making such

disclosure is subject to a penalty under 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, for such disclosure.

''(3) AMOUNT.—Any person who violates paragraph (1) shall be subject to a civil monetary penalty of not more than $25,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties are imposed and collected under subsection (a) of section 1128A of the Social Security Act.

''(j) SURVEY AND REPORT.—

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

''(2) REPORT.—Not later than 9 months after the date of enactment of this part, the Comptroller General shall prepare and submit to Congress a re-

port concerning the results of the survey conducted under paragraph (1).

"SEC. 923. REPORTER PROTECTION.

"(a) IN GENERAL.—A health care provider may not take an adverse employment action, as described in subsection (b), against an individual based upon the fact that the individual in good faith reported—

"(1) to the provider with the intention of having it reported to a patient safety organization, or

"(2) directly to a patient safety organization,

information that would constitute patient safety information if the provider were to have submitted it on a timely basis to a patient safety organization in accordance with this part.

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

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

"(2) an evaluation or decision made in relation to accreditation, certification, credentialing or licensing of the individual; and

"(3) a personnel action that is adverse to the individual concerned.

''(c) REMEDIES.—The provisions of the first sentence of section 1128A(a) of the Social Security Act shall apply with respect to a health care provider's violation of subsection (a) in the same manner as they apply to an act referred to in section 1128A(a)(7) of such Act.

''(d) PENALTY.—Any person who violated the provisions of this section shall be subject to a fine of not more than $25,000, imprisonment for not more than 6 months, or both, per disclosure and payment of the costs of prosecution.

''SEC. 924. CENTER FOR QUALITY IMPROVEMENT AND PATIENT SAFETY.

''(a) IN GENERAL.—The Director shall establish a center to be known as the Center for Quality Improvement and Patient Safety to carry out the duties described in subsection (b).

''(b) DUTIES.—

''(1) IN GENERAL.—The Center shall carry out the following duties:

''(A) Conduct and support research, demonstrations, and evaluations of the quality of health care and the promotion of patient safety, and the measurement of health care quality.

"(B) Develop, evaluate, and disseminate methods for identifying and promoting effective patient safety programs.

"(C) Provide for the certification and recertification of patient safety organizations in accordance with section 925.

"(D) Establish a National Patient Safety Database to collect, support, and coordinate the analysis of nonidentifiable information submitted to the Database in accordance with subsection (d).

"(E) Establish a National Patient Safety Research Demonstration System under which the Director will enter into voluntary agreements with a geographically and institutionally diverse group of eligible entities to collect data for the purpose of conducting research on patient safety.

"(F) Facilitate the development of consensus, including through annual meetings, among health care providers, patients, and other interested parties concerning patient safety and recommendations to improve patient safety.

''(G) Provide technical assistance and support to States that have (or are developing) medical errors reporting systems, assist States in developing standardized methods for data collection, and collect data from State reporting systems for inclusion in the National Patient Safety Database.

''(2) CONSULTATION.—In carrying out the duties under paragraph (1) (including the establishment of the Database), the Director shall consult with and develop partnerships, as appropriate, with health care organizations, health care providers, public and private sector entities, patient safety organizations, health care consumers, and other relevant experts to improve patient safety.

''(c) IMPLEMENTATION AND CONSULTATION.—In carrying out this section, the Director shall—

''(1) facilitate the development of patient safety goals and track the progress made in meeting those goals; and

''(2) ensure that information submitted by a patient safety organization to the National Patient Safety Database, as provided for under subsection (d), is comparable and useful for research and analysis and that the research findings and patient safe-

ty alerts that result from such analyses are presented in clear and consistent formats that enhance the usefulness of such alerts.

''(d) NATIONAL PATIENT SAFETY DATABASE.—

''(1) IN GENERAL.—The Director shall—

''(A) establish a National Patient Safety Database to collect nonidentifiable information concerning patient safety that is reported on a voluntary basis which shall be used to analyze national, regional, and State trends and patterns in patient safety and medical errors; and

''(B) establish common formats for the voluntary reporting of information under subparagraph (A), including the establishment of necessary data elements, common and consistent definitions, and a standardized computer interface for the processing of such data.

To the extent practicable, formats established under subparagraph (A) shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act

''(2) DATABASE.—In carrying out this subsection, the Director—

''(A) shall establish and modify as necessary criteria to determine the organizations

that may voluntarily contribute to, and the data that comprises, the National Patient Safety Database;

"(B) shall ensure that the National Patient Safety Database is only used by qualified entities or individuals for purposes of research, education, and enhancing patient safety as determined appropriate by the Director in accordance with criteria applied by the Director;

"(C) may enter into contracts for the administration of the Database with private and public entities with experience in the administration of similar databases;

"(D) shall ensure that the methodologies for the collection of nonidentifiable patient safety information for the National Patient Safety Database include the methodologies developed or recommended by the Patient Safety Task Force of the Department of Health and Human Services; and

"(E) may, to the extent practicable, facilitate the direct link of information between health care providers and patient safety organizations and between patient safety organiza-

tions and the National Patient Safety Database.

''(3) NATIONAL PATIENT SAFETY RESEARCH DEMONSTRATION SYSTEM.—

''(A) ESTABLISHMENT.—

''(i) IN GENERAL.—Not later than 1 year after the date of enactment of this part, the Director shall establish a National Patient Safety Research Demonstration System under which the Director will enter into voluntary agreements with a geographically and institutionally diverse group of eligible entities to collect information for the purpose of conducting research on patient safety. The Director may contract with other organizations to carry out this paragraph.

''(ii) PURPOSE.—The purpose of the demonstration system established under clause (i) is to conduct targeted research on patient safety and to test promising systems and methods of improving patient safety.

''(iii) NUMBER AND TYPES OF ORGANIZATIONS.—In carrying out clause (i), the

Director shall determine the number and types of health care organizations with which to enter into agreements, as well as the types of patient safety events the particular health care organizations with which the Director enters into an agreement should identify and the types of analyses that such organizations should perform.

''(B) ELIGIBILITY.—To be eligible to enter into an agreement under subparagraph (A) an entity shall—

''(i) be a health care organization; and

''(ii) prepare and submit to the Director an application at such time, in such manner, and containing such information as the Director may require.

''(C) SUBMISSION OF REPORTS.—

''(i) IN GENERAL.—A health care organization that enters into a voluntary agreement under subparagraph (A) shall, with respect to such organization, submit reports of patient safety events, or reports of specific types of patient safety events if so prescribed by the agreement, and shall

submit, if prescribed by the agreement, root cause analyses concerning such events (using standards developed by the Director), and corrective action plans to the Director.

''(ii) PROCESSING OF INFORMATION.—The Director shall process the reports submitted under clause (i) in the same manner as reports are processed through the National Patient Safety Database.

''(iii) PROVISION OF RECOMMENDATIONS.—The Director shall provide feedback concerning patient safety event reports directly to the health care organizations that are participating in the demonstration system under this paragraph.

''(D) TECHNICAL ASSISTANCE.—The Director shall provide health care organizations participating in the demonstration system under this paragraph with technical support and may provide technology support, including computer software and hardware, through the patient safety improvement grants under section 932 and section 934.

''(E) EVALUATION.—Upon the expiration of the 5-year period beginning on the date on which the demonstration system is established under this paragraph, the Director 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 that includes—

''(i) information on the types of data collected through the demonstration system;

''(ii) research conducted with data collected through the demonstration system; and

''(iii) the identification of promising systems and methods of reducing patient safety events.

''(F) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed to preempt Federal or State mandatory reporting or sentinel surveillance systems in effect on the date of enactment of this part, or Federal or State mandatory reporting or sentinel surveillance systems developed after such date of enactment.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out this section.

''SEC. 925. PATIENT SAFETY ORGANIZATIONS.

''(a) CERTIFICATION AND RECERTIFICATION.—

''(1) IN GENERAL.—The initial certification and recertification of a patient safety organization under section 924 shall be made under a process that is approved by the Director and is consistent with criteria published by the Director.

''(2) REVOCATION.—Such a certification or recertification of a patient safety organization may be revoked by the Director upon a showing of cause (including the disclosure of information in violation of section 922).

''(3) TERMINATION.—Such a certification provided for a patient safety organization shall terminate (subject to recertification) on the earlier of—

''(A) the date that is 3 years after the date on which such certification was provided; or

''(B) the date on which the Director revokes the certification.

''(b) ORGANIZATION REQUIREMENTS.—A patient safety organization shall meet the following criteria as conditions for certification:

''(1) The mission of the organization shall be to conduct activities to improve patient safety and the quality of health care delivery.

''(2) The organization shall collect and analyze patient safety information that is voluntarily reported by more than one health care provider on a local, regional, State, or national basis.

''(3) The organization shall have appropriately qualified staff, including licensed or certified medical professionals.

''(4) The organization is managed, controlled, and operated independently from health care providers that report patient safety information to it under this part, and the organization—

''(A) does not have a material familial or financial relationship (except for fees charged to health care providers) with any health care provider from whom it receives patient safety information;

''(B) does not otherwise have a conflict of interest with such a health care provider (as determined under regulations); and

''(C) is not a health insurer or other entity that offers a group health plan or health insur-

ance coverage, or a component of such an entity.

''(5) The organization seeks to collect data from health care providers in a standardized manner that permits valid comparisons of similar cases among similar health care providers.

''(6) The organization meets such other requirements as the Director may by regulation require.

''(c) LIMITATION ON USE OF PATIENT SAFETY INFORMATION BY PATIENT SAFETY ORGANIZATIONS.—A patient safety organization may not use patient safety information reported by a health care provider in accordance with this part to take regulatory or enforcement actions it otherwise performs (or is responsible for performing) in relation to such provider.

''(d) TECHNICAL ASSISTANCE.—The Director may provide technical assistance to patient safety organizations in providing recommendations and advice to health care providers reporting patient safety information under this part. Such assistance shall include advice with respect to methodology, communication, dissemination of information, data collection, security, and confidentiality concerns.

''(e) COMPONENT ORGANIZATIONS.—If a patient safety organization is a component of a larger organization, the patient safety organization shall—

''(1) maintain patient safety information within the component, separately from the rest of the larger organization, and establish appropriate security measures to maintain the confidentiality of the patient safety information;

''(2) not disclose patient safety information to the larger organization; and

''(3) not create a conflict of interest with the larger organization.

''(f) CONSTRUCTION.—Nothing in this part shall be construed to limit or discourage the reporting of information relating to patient safety within a health care provider.

''(g) TREATMENT OF INFORMATION.—If an organization no longer qualifies as a patient safety organization under this section, with respect to any patient safety information that such organization received from a health care provider, the organization shall comply with one of the following:

''(1) With the approval of the provider and another patient safety organization, the organization shall transfer such information to such other organization.

''(2) If practicable, the organization shall return the information to the provider.

''(3) The organization shall destroy the patient safety information.

"PART D—PATIENT SAFETY IMPROVEMENT GRANTS

"SEC. 931. GRANTS FOR COMMUNITY PARTNERSHIPS FOR HEALTH CARE IMPROVEMENT.

''(a) IN GENERAL.—The Secretary shall award grants to eligible entities to enable such entities to establish, enhance or improve community partnerships for health care improvement among providers within a community for the purpose of improving the quality of medical care, including the prescribing, dispensing, and use of prescription drugs, within such community.

''(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a) an entity shall—

''(1) be a—

''(A) hospital;

''(B) health care clinic;

''(C) skilled nursing facility;

''(D) non-profit entity, or component thereof, established for the purpose of establishing, enhancing or improving a community partnership for health care improvement; or

''(E) consortium of any of the entities described in subparagraphs (A) through (D); and

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may reasonably require, including assurances satisfactory to the Secretary that the community partnership for health care improvement in connection with which the entity is submitting the application does, at the time of application, or will, within a reasonable amount of time from the date of application, include the substantive participation of a broad range of entities (that may include providers, payers, patients, and governmental entities) involved in the delivery of health care within the community.

''(c) LIMITATIONS.—In carrying out subsection (a), the Secretary shall not—

''(1) award any single entity more than $2,000,000 in any single fiscal year; or

''(2) award grants under this section to any single entity for more than 3 fiscal years.

''(d) DEFINITION.—In this section, the term 'community partnership for health care improvement' means a formal cooperative arrangement including health care facilities and nonprofit organizations within a community that—

''(1) is entered into for the purpose of significantly reducing the incidence of patient safety events or significantly improving the quality of health care, including the appropriate use of prescription drugs, at health care facilities participating in such partnership using one or more quantifiable indicators of such improvement;

''(2) collects quantifiable data on the incidence of patient safety events or on the quality of health care in connection with one or more specific medical procedures conducted at the health care facilities participating in such partnerships;

''(3) makes available to the health care facilities participating in such partnership the data described in paragraph (2); and

''(4) promotes cooperation and communication among providers employed by the health care facilities participating in such partnership for the purposes described in paragraph (1).

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2003, and such sums as may be necessary for each subsequent fiscal year.

"SEC. 932. TECHNICAL STANDARDS FOR HEALTH CARE INFORMATION TECHNOLOGY SYSTEMS.

''(a) IN GENERAL.—By not later than 2 years after the date of the enactment of this part, the Secretary shall develop or adopt (and shall periodically review and update) voluntary, national standards—

''(1) that promote the interoperability of health care information technology systems across all health care settings; and

''(2) for computerized physician order entry systems, including standards relating to—

''(A) data formats or other methods of encoding medical information that facilitate transfer of data among such systems;

''(B) the protection of the confidentiality of individually identifiable health information contained within such systems from unauthorized access or disclosure;

''(C) procedures for issuing warnings when prescribing errors may be imminent;

''(D) procedures for ensuring that recommendations or warnings issued by such systems reflect good medical practice; and

''(E) other matters determined appropriate by the Secretary.

''(b) COST AND INCREASED EFFICIENCY.—In promulgating regulations to carry out this section, the Secretary shall take into account the cost that meeting the standards under subsection (a) would have on providing health care in the United States and the increased efficiencies in providing such care achieved under the standards.

''(c) CONSULTATION AND COORDINATION.—The Secretary shall develop and update the standards under subsection (a) in consultation with (and with coordination between)—

''(1) the National Committee for Vital and Health Statistics;

''(2) the Medical Information Technology Advisory Board (established under section 933); and

''(3) the Secretary of Veterans Affairs and the Secretary of Defense.

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

''(e) LIMITATION.—Effective beginning on the date that is 4 years after the date of enactment of this part, the Secretary may not purchase any health care information technology system unless such system conforms to the standards developed or adopted under subsection (a), to

the extent that such standards have been developed or adopted.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out this section.

''SEC. 933. MEDICAL INFORMATION TECHNOLOGY ADVISORY BOARD.

''(a) ESTABLISHMENT.—

''(1) IN GENERAL.—Not later than 3 months after the date of the enactment of this part, the Secretary shall appoint an advisory board to be known as the 'Medical Information Technology Advisory Board' (in this section referred to as the 'MITAB').

''(2) CHAIRPERSON.—The Secretary shall designate one member of the MITAB to serve as the chairperson. The chairperson shall be an individual affiliated with an organization having expertise creating American National Standards Institute (ANSI) accepted standards in health care information technology and a member of the National Committee for Vital and Health Statistics.

''(b) COMPOSITION.—

''(1) IN GENERAL.—The MITAB shall consist of not more than 17 members that include—

''(A) experts from the fields of medical information, information technology, medical continuous quality improvement, medical records security and privacy, individual and institutional health care clinical providers, health researchers, and health care purchasers;

''(B) one or more staff experts from each of the following: the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, and the Institute of Medicine of the National Academy of Sciences;

''(C) representatives of private organizations with expertise in medical informatics;

''(D) a representative of a teaching hospital;

''(E) one or more representatives of the health care information technology industry; and

''(F) a representative of an organization representing health care consumers.

''(2) TERMS OF APPOINTMENT.—The term of any appointment under paragraph (1) to the MITAB shall be for 2 years. Such an appointment may be renewed for one additional term.

''(3) MEETINGS.—The MITAB shall meet at the call of its chairperson or a majority of its members.

''(4) VACANCIES.—A vacancy on the MITAB shall be filled in the same manner in which the original appointment was made not later than 30 days after the MITAB is given notice of the vacancy and shall not affect the power of the remaining members to execute the duties of the MITAB.

''(5) COMPENSATION.—Members of the MITAB shall receive no additional pay, allowances, or benefits by reason of their service on the MITAB.

''(6) EXPENSES.—Each member of the MITAB shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

''(c) DUTIES.—

''(1) IN GENERAL.—The MITAB shall on an ongoing basis advise, and make recommendations to, the Secretary regarding medical information technology, including the following:

''(A) The best current practices in medical information technology.

''(B) Methods for the adoption (not later than 2 years after the date of the enactment of

this part) of a uniform health care information system interface between and among old and new computer systems.

''(C) Recommendations for health care vocabulary, messaging, and other technology standards (including a common lexicon for computer technology) necessary to achieve the interoperability of health care information systems for the purposes described in subparagraph (E).

''(D) Methods of implementing—

''(i) health care information technology interoperability standardization; and

''(ii) records security.

''(E) Methods to promote information exchange among health care providers so that long-term compatibility among information systems is maximized, in order to do one or more of the following:

''(i) To maximize positive outcomes in clinical care—

''(I) by providing decision support for diagnosis and care; and

''(II) by assisting in the emergency treatment of a patient presenting at a facility where there is no medical record for the patient.

''(ii) To contribute to (and be consistent with) the development of the patient assessment instrument provided for under section 545 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, and to assist in minimizing the need for new and different records as patients move from provider to provider.

''(iii) To reduce or eliminate the need for redundant records, paperwork, and the repetitive taking of patient histories and administering of tests.

''(iv) To minimize medical errors, such as administration of contraindicated drugs.

''(v) To provide a compatible information technology architecture that facilitates future quality and cost-saving needs and that avoids the financing and development

of information technology systems that are not readily compatible.

''(2) REPORTS.—

''(A) INITIAL REPORT.—Not later than 18 months after the date of the enactment of this part, the MITAB shall submit to Congress and the Secretary an initial report concerning the matters described in paragraph (1). The report shall include—

''(i) the practices described in paragraph (1)(A), including the status of health care information technology standards being developed by private sector and public-private groups;

''(ii) recommendations for accelerating the development of common health care terminology standards;

''(iii) recommendations for completing development of health care information system messaging standards; and

''(iv) progress toward meeting the deadline described in paragraph (1)(B) for adoption of methods described in such paragraph.

''(B) SUBSEQUENT REPORTS.—During each of the 2 years after the year in which the report is submitted under subparagraph (A), the MITAB shall submit to Congress and the Secretary an annual report relating to additional recommendations, best practices, results of information technology improvements, analyses of private sector efforts to implement the interoperability standards established in section 1184 of the Social Security Act, and such other matters as may help ensure the most rapid dissemination of best practices in health care information technology.

''(d) STAFF AND SUPPORT SERVICES.—

''(1) EXECUTIVE DIRECTOR.—

''(A) APPOINTMENT.—The Chairperson shall appoint an executive director of the MITAB.

''(B) COMPENSATION.—The executive director shall be paid the rate of basic pay for level V of the Executive Schedule.

''(2) STAFF.—With the approval of the MITAB, the executive director may appoint such personnel as the executive director considers appropriate.

''(3) APPLICABILITY OF CIVIL SERVICE LAWS.—The staff of the MITAB shall be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title (relating to classification and General Schedule pay rates).

''(4) EXPERTS AND CONSULTANTS.—With the approval of the MITAB, the executive director may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

''(e) POWERS.—

''(1) HEARINGS AND OTHER ACTIVITIES.—For the purpose of carrying out its duties, the MITAB may hold such hearings and undertake such other activities as the MITAB determines to be necessary to carry out its duties.

''(2) DETAIL OF FEDERAL EMPLOYEES.—Upon the request of the MITAB, the head of any Federal agency is authorized to detail, without reimbursement, any of the personnel of such agency to the MITAB to assist the MITAB in carrying out its duties. Any such detail shall not interrupt or otherwise

affect the civil service status or privileges of the Federal employee.

''(3) TECHNICAL ASSISTANCE.—Upon the request of the MITAB, the head of a Federal agency shall provide such technical assistance to the MITAB as the MITAB determines to be necessary to carry out its duties.

''(4) OBTAINING INFORMATION.—The MITAB may secure directly from any Federal agency information necessary to enable it to carry out its duties, if the information may be disclosed under section 552 of title 5, United States Code. Upon request of the Chairman of the MITAB, the head of such agency shall furnish such information to the MITAB.

''(f) TERMINATION.—The MITAB shall terminate 30 days after the date of submission of its final report under subsection (c)(2)(B).

''(g) TESTING.—The Secretary, in consultation with the MITAB, shall test the efficacy, usability, and scalability, of standards within a variety of clinical settings that may include a rural hospital or community health center, a community hospital, a children's hospital, and an urban academic center.

''(h) APPLICABILITY OF FACA.—The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the MITAB.

''(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary of Health and Human Services such sums as are necessary to carry out this section.

''SEC. 934. GRANTS FOR COMPUTERIZED PHYSICIAN ORDER ENTRY SYSTEMS.

''(a) IN GENERAL.—The Secretary may award grants to eligible entities to enable such entities to develop, install, or train personnel in the use of, computerized physician order entry systems.

''(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

''(1) be a nonprofit hospital, health care clinic, community health center, skilled nursing facility, or other nonprofit entity determined to be eligible by the Secretary;

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a description of the computerized medication prescribing system that the entity in-

tends to implement using amounts received under the grant; and

''(3) provide assurances that are satisfactory to the Secretary that any computerized physician order entry systems, for which amounts are to be expended under an award made under subsection (a), conform to the technical standards established by the Secretary for such systems under section 932(a)(2).

''(c) MATCHING REQUIREMENT.—

''(1) IN GENERAL.—The Secretary may not make a grant to an entity under subsection (a) unless that entity agrees that, with respect to the costs to be incurred by the entity in carrying out the activities for which the grant is being awarded, the entity will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount equal to $1 for each $2 of Federal funds provided under the grant.

''(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services. Amounts provided by the Federal Government, or services as-

sisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

''(d) STUDY.—

''(1) IN GENERAL.—The Secretary, acting through The Director of the Agency for Healthcare Research and Quality, shall support a study to assess existing scientific evidence regarding the effectiveness and cost-effectiveness of the use of electronic prescription programs intended to improve the efficiency of prescription ordering and the safe and effective use of prescription drugs. The study shall address the following:

''(A) The ability of such programs to reduce medical errors and improve the quality and safety of patient care.

''(B) The impact of the use of such programs on physicians, pharmacists, and patients, including such factors as direct and indirect costs, changes in productivity, and satisfaction.

''(C) The effectiveness of strategies for overcoming barriers to the use of electronic prescription programs.

''(2) REPORT.—The Secretary shall ensure that, not later than 18 months after the date of enactment of this part, a report containing the findings of the study under paragraph (1) is submitted to the appropriate committees of the Congress.

''(3) DISSEMINATION OF FINDINGS.—The Secretary shall disseminate the findings of the study under paragraph (1) to appropriate public and private entities.

''(e) DEFINITIONS.—In this section and section 932:

''(1) COMPUTERIZED PHYSICIAN ORDER ENTRY SYSTEM.—The term 'computerized physician order entry system' means an information technology system that—

''(A) shall—

''(i) permit a qualified practitioner who wishes to enter a medication order for a patient to enter such order via a computer that is linked to a database capable of accessing the medical record of the patient who is intended to receive such medication;

''(ii) incorporate prescribing error prevention software so that a warning (including documentation regarding the cause of

such warning) is generated by such system if a medication order is entered that is likely to lead to an adverse drug event; and

''(iii) require documented acknowledgment that a qualified practitioner entering a medication order that has generated the warning described in clause (ii) has read the appropriate documentation regarding the cause of such warning prior to overriding such warning; and

''(B) may allow for the electronic submission of prescriptions to pharmacies or pharmacy benefit managers and the processing of such submissions by pharmacies.

''(2) QUALIFIED PRACTITIONER.—The term 'qualified practitioner' means a practitioner licensed to administer prescription drugs.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $100,000,000 for fiscal year 2003, and such sums as may be necessary for each of fiscal years 2004 through 2007.

''SEC. 935. GRANTS FOR INFORMATICS SYSTEMS.

''(a) IN GENERAL.—The Secretary may establish a program to make grants to eligible entities for the purpose of assisting such entities in offsetting the costs related to

purchasing, leasing, licensing, developing, and implementing standardized clinical health care informatics systems, other than computerized prescriber order entry systems, that are designed to improve patient safety and reduce adverse events and health care complications resulting from medication errors.

''(b) COSTS DEFINED.—In this section, the term 'costs' includes total expenditures incurred for—

''(1) purchasing, leasing, licensing, and installing computer software and hardware;

''(2) making improvements to existing computer software and hardware;

''(3) purchasing or leasing communications capabilities necessary for clinical data access, storage, and exchange; and

''(4) providing education and training to eligible entity staff on computer patient safety information systems.

''(c) ELIGIBILITY.—To be eligible to receive a grant under this section, an entity shall—

''(1) be a hospital, health care clinic, community health center, skilled nursing facility, patient safety organization, or other entity determined to be eligible by the Secretary; and

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a description of the type of informatics system that the entity intends to implement using amounts received under the grant.

''(d) TYPES OF IMFORMATICS SYSTEMS.—

''(1) IN GENERAL.—Not later than 6 months after the date of enactment of this part, the Secretary shall identify the informatics systems, other than computerized physician order entry systems, and other information technology or telecommunications systems demonstrated to improve patient safety and reduce adverse events and health care complications resulting from medication errors, that may be adopted and applied by eligible entities through funds under this section.

''(2) SYSTEMS.—The systems described in paragraph (1) may include bar coding, software to collect and analyze medication errors, clinical decision-support systems, software to detect inappropriately prescribed drugs or doses, drug utilization review programs, and disease management systems.

''(e) MATCHING REQUIREMENT.—

''(1) IN GENERAL.—The Secretary may not make a grant to an entity under subsection (a) unless that entity agrees that, with respect to the costs to be incurred by the entity in carrying out the activities for which the grant is being awarded, the entity will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount equal to $1 for each $1 of Federal funds provided under the grant.

''(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

''(f) ADDITIONAL INFORMATION.—An eligible entity receiving a grant under this section shall furnish the Secretary with such information as the Secretary may require to—

''(1) evaluate the project for which the grant is made, including how the project has improved pa-

tient safety and has reduced patient safety events and health care complications resulting from medication errors; and

''(2) ensure that funding provided under the grant is expended for the purposes for which it is made.

''(g) REPORTS.—

''(1) INTERIM REPORTS.—

''(A) IN GENERAL.—The Secretary shall submit, at least annually, a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the grant program established under this section.

''(B) CONTENTS.—A report submitted pursuant to subparagraph (A) shall include information on—

''(i) the number of grants made;

''(ii) the nature of the projects for which funding is provided under the grant program;

''(iii) the geographic distribution of grant recipients; and

''(iv) such other matters as the Secretary determines appropriate.

''(2) FINAL REPORT.—Not later than 5 years after the date of enactment of this part, the Secretary shall submit a final report to the committees referred to in paragraph (1)(A) on the grant program.

''(h) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2003, and such sums as may be necessary for each subsequent fiscal year.''.

''SEC. 936. GRANTS FOR PATIENT SAFETY RESEARCH.

''(a) IN GENERAL.—The Secretary may conduct research and award grants to promote research on patient safety.

''(b) PROCESS.—The Secretary shall establish a formal process to gather information on priorities, methodologies and approaches for medical errors, including medication errors, and patient safety research. In gathering such information, the Secretary shall ensure that input is obtained from a wide range of individuals and organizations who will use and can benefit from the availability of such information.

''(c) COORDINATION.—The Secretary shall ensure that activities are carried out under subsection (a) in co-

operation and coordination with existing research initiatives, programs, and activities.

''(d) OTHER INDUSTRIES.—In carrying out this section, the Secretary shall consider the experiences of other industries in reducing errors within such industries and the processes that such industries employ to reduce errors.

''(e) ISSUES.—The issues to be addressed with respect to the research to be conducted and supported under this subsection may include—

''(1) the types and causes of errors in the provision of health care, both in the United States and internationally, such as those identified by the reporting system developed by the Linnaeus Collaboration and the United States Pharmacopeia;

''(2) the identification and comparison of trends in errors in geographically and demographically diverse health care facilities;

''(3) training requirements for health care professionals to ensure that such professionals provide quality health care generally, in specific settings, and for specific practices;

''(4) the development of effective communication methods and tools between disciplines to improve patient safety;

''(5) the use of interdisciplinary teams to improve patient safety;

''(6) the barriers to medical error reduction strategies;

''(7) the use of standardized processes in providing medication, including the application of these processes in demographically diverse health care facilities;

''(8) the application of a national standardized taxonomy for medication errors;

''(9) the effect of educational programs on the consistent application of standardized definitions, terminology, and formats; and

''(10) other areas determined appropriate by the Secretary.

''(f) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

''(1) be a patient safety organization, health care provider, health care provider association, research organization, university, or other entity determined to be eligible by the Secretary; and

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2003, and such sums as may be necessary for each subsequent fiscal year.''.

SEC. 4. REQUIRED USE OF PRODUCT IDENTIFICATION TECHNOLOGY.

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) in section 502, by adding at the end the following:

''(u) If it is a drug or biological product, unless it includes a unique product identifier for the drug or biological product as required by regulations under section 510(o).''; and

(2) in section 510, by adding at the end the following:

''(o)(1) The Secretary shall issue, and may periodically revise, regulations requiring the manufacturer of any drug or biological product, or the packager or labeler of a drug or biological product, to include a unique product identifier on the packaging of the drug or biological product.

''(2) For purposes of this subsection, the term 'unique product identifier' means an identification that—

''(A) is affixed by the manufacturer, labeler, or packager to each drug or biological product described in paragraph (1);

''(B) uniquely identifies the item and meets the standards required by this section; and

''(C) can be read by a scanning device or other technology acceptable to the Secretary.

''(3) A unique product identifier required by regulations issued or revised under paragraph (1) shall be based on—

''(A) the National Drug Code maintained by the Food and Drug Administration;

''(B) commercially accepted standards established by organizations that are accredited by the American National Standards Institute, such as the Health Industry Business Communication Council or the Uniform Code Council; or

''(C) other identification formats that the Secretary deems appropriate.

''(4) The Secretary may, at the Secretary's discretion, waive the requirements of this subsection, or add additional provisions that are necessary to safeguard the public health.''.

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