I

108TH CONGRESS
1ST SESSION

H. R. 663

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 affect patient safety, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 11, 2003

Mr. BILIRAKIS (for himself, Mr. BROWN of Ohio, Mr. TAUZIN, Mr. DINGELL, Mr. BARTON of Texas, Mr. WAXMAN, Mr. UPTON, Mr. MARKEY, Mr. GREENWOOD, Mr. TOWNS, Mr. BURR, Mr. PALLONE, Mr. WHITFIELD, Mr. GORDON, Mr. NORWOOD, Mr. DEUTSCH, Mr. TERRY, Mr. RUSH, Mr. ROGERS of Michigan, Mr. ENGEL, Mr. WYNN, Ms. MCCARTHY of Missouri, Mr. STRICKLAND, Mrs. CAPPS, Mr. JOHN, and Ms. HARMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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 affect patient safety, and for other purposes.

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.—The Congress finds as follows:

(1) In 1999, the Institute of Medicine released a report entitled ''To Err Is Human'' that described medical errors as the 8th 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) Myriad public and private patient safety initiatives have begun. The Quality Interagency Coordination Task Force 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.

(4) 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.

(5) Several steps can be taken now to improve patient safety. For example, according to the Centers for Disease Control and Prevention, hand washing is the single most important means of preventing the spread of infection. Repeated studies indicate that lack of or improper hand washing still contributes significantly to disease transmission in health care settings. Working with experts from the private sector, the Centers for Disease Control and Prevention has drafted ''Guidelines for Hand Hygiene in Healthcare Settings'' setting forth recommendations to promote improved hand hygiene practices and reduce transmission of pathogenic microorganisms to patients and personnel in health care settings.

(6) According to the Centers for Disease Control and Prevention, nosocomial infections affect approximately 2 million patients annually in acute care facilities in the United States at an estimated direct patient care cost of approximately $3.5 billion each year.

(7) The Congress encourages the continuation and acceleration of private sector efforts to take immediate steps to improve patient safety and recognizes the need for action in the public sector to complement these efforts.

(8) The research on patient safety unequivocally calls for a learning environment, where providers will feel safe to report health care errors, in order to improve patient safety.

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

(10) 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.

(11) Many organizations currently collecting patient safety information have expressed a need for 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.

(12) 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.—The purposes of this Act are—

(1) to encourage a culture of safety and quality in the United States health care system by providing for a health care errors reporting system that both protects information and improves patient safety and quality of health care; and

(2) to 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.

(a) IN GENERAL.—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) IDENTIFIABLE INFORMATION.—The term 'identifiable information' means information that is presented in a form and manner that allows the identification of any provider, patient, or reporter of patient safety work product. 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).

''(2) NONIDENTIFIABLE INFORMATION.—The term 'nonidentifiable information' means information that is presented in a form and manner that prevents the identification of any provider, patient, or reporter of patient safety work product. 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).

''(3) PATIENT SAFETY EVALUATION SYSTEM.—The term 'patient safety evaluation system' means a

process that involves the collection, management, or analysis of information for submission to or by a patient safety organization.

''(4) 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 Secretary under section 925, to perform each of the following activities:

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

''(B) The collection and analysis of patient safety work product that is submitted by providers.

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

''(D) The utilization of patient safety work product 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 providers to effectively minimize patient risk.

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

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

''(G) The submission of nonidentifiable information to the Agency consistent with standards established by the Secretary under section 923(b) for any National Patient Safety Database.

''(5) PATIENT SAFETY WORK PRODUCT.—

''(A) The term 'patient safety work product' means any document or communication (including any information, report, record, memorandum, analysis, deliberative work, statement, or root cause analysis) that—

''(i) except as provided in subparagraph (B), is developed by a provider for the purpose of reporting to a patient safety organization, and is reported to a patient safety organization;

''(ii) is created by a patient safety organization; or

"(iii) would reveal the deliberations or analytic process of a patient safety evaluation system (as defined in paragraph (3)).

"(B)(i) Patient safety work product described in subparagraph (A)(i)—

"(I) does not include any separate information described in clause (ii); and

"(II) shall not be construed to include such separate information merely by reason of inclusion of a copy of the document or communication involved in a submission to, or the fact of submission of such a copy to, a patient safety organization.

"(ii) Separate information described in this clause is a document or communication (including a patient's medical record or any other patient or hospital record) that is developed or maintained, or exists, separately from any patient safety evaluation system.

"(C) Information available from sources other than a patient safety work product under this section may be discovered or admitted in a civil or administrative proceeding, if discoverable or admissible under applicable law.

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

''(A) an individual or entity 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, and hospice program;

''(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, or other individual health care practitioner;

''(iii) a pharmacist; and

''(iv) 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; or

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

"SEC. 922. PRIVILEGE FOR PATIENT SAFETY WORK PRODUCT.

"(a) PRIVILEGE.—Notwithstanding any other provision of law and subject to subsection (c), patient safety work product shall not be—

"(1) subject to a civil or administrative subpoena or order;

"(2) subject to discovery in connection with a civil or administrative proceeding;

"(3) subject to disclosure 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) required to be admitted as evidence or otherwise disclosed in any State or Federal civil or administrative proceeding; or

"(5) if the patient safety work product is identifiable information and is received by a national accreditation organization in its capacity as a patient safety organization—

"(A) used by a national accreditation organization in an accreditation action against the provider that reported the information;

"(B) shared by such organization with its survey team; or

''(C) required as a condition of accreditation by a national accreditation association.

''(b) REPORTER PROTECTION.—

''(1) IN GENERAL.—A provider may not use against an individual in an adverse employment action described in paragraph (2) 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) the failure to promote an individual or provide any other employment-related benefit for which the individual would otherwise be eligible;

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

''(C) a personnel action that is adverse to the individual concerned.

''(3) REMEDIES.—Any provider that violates this subsection shall be subject to a civil monetary penalty of not more than $20,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected.

''(c) DISCLOSURES.—Nothing in this section prohibits any of the following disclosures:

''(1) Voluntary disclosure of nonidentifiable information.

''(2) Voluntary disclosure of identifiable information by a 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) Disclosure as required by law by a provider to the Food and Drug Administration, or on a voluntary basis by a provider to a federally established patient safety program, 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.

''(4) Disclosures of patient safety work product in accordance with this part by a provider to a patient safety organization.

''(d) EFFECT OF TRANSFER, DISCLOSURE.—The following shall not be treated as a waiver of any privilege or protection established under this part:

''(1) The transfer of any patient safety work product between a provider and a patient safety organization.

''(2) Disclosure of patient safety work product as described in subsection (c).

''(3) The unauthorized disclosure of patient safety work product.

''(e) PENALTY.—

''(1) PROHIBITION.—Except as provided in this part, and subject to paragraphs (2) and (4), it shall be unlawful for any person to disclose patient safety

work product in violation of this section, if such disclosure constitutes a negligent or knowing breach of confidentiality.

''(2) RELATION TO HIPAA.—The penalty under paragraph (3) for a disclosure in violation of paragraph (1) does not apply if the person would be 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 the same disclosure.

''(3) AMOUNT.—Any person who violates paragraph (1) shall be subject to a civil monetary penalty of not more than $10,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected.

''(4) SUBSEQUENT DISCLOSURE.—Paragraph (1) applies only to the first person that breaches confidentiality with respect to particular patient safety work product.

''(f) RELATION TO HIPAA.—

''(1) IN GENERAL.—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)—

"(A) patient safety organizations shall be treated as business associates; and

"(B) activities of such organizations described in section 921(4) in relation to a provider are deemed to be health care operations (as defined in such regulations) of the provider.

"(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to alter or affect the implementation of such regulations or such section 264(c).

"(g) NO LIMITATION OF OTHER PRIVILEGES.—Nothing in this section shall be construed to affect privileges, including peer review and confidentiality protections, that are otherwise available under Federal or State laws.

"(h) NO LIMITATION ON CONTRACTS.—Nothing in this section shall be construed to limit the power of a provider and a patient safety organization, or a patient safety organization and the Agency or any National Patient Safety Database, consistent with the provisions of this Act and other applicable law, to enter into a contract requiring

greater confidentiality or delegating authority to make an authorized disclosure.

''(i) RELATION TO STATE REPORTING REQUIREMENTS.—Nothing in this part shall be construed as preempting or otherwise affecting any State law requiring a provider to report information, including information described in section 921(5)(B), that is not patient safety work product.

''(j) CONTINUATION OF PRIVILEGE.—Patient safety work product 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.

''(k) REPORTS ON STRATEGIES TO IMPROVE PATIENT SAFETY.—

''(1) DRAFT REPORT.—Not later than the date that is 18 months after any National Patient Safety Database is operational, the Secretary, in consultation with the Director, shall prepare a draft report on effective strategies for reducing medical errors and increasing patient safety. The draft report shall include any measure determined appropriate by the Secretary to encourage the appropriate use of such

strategies, including use in any federally funded programs. The Secretary shall make the draft report available for public comment and submit the draft report to the Institute of Medicine for review.

''(2) FINAL REPORT.—Not later than 1 year after the date described in paragraph (1), the Secretary shall submit a final report to the Congress that includes, in an appendix, any findings by the Institute of Medicine concerning research on the strategies discussed in the draft report and any modifications made by the Secretary based on such findings.

''SEC. 923. NATIONAL DATABASE.

''(a) AUTHORITY.—

''(1) IN GENERAL.—In conducting activities under this part, the Secretary shall provide for the establishment and maintenance of a database to receive relevant nonidentifiable patient safety work product, and may designate entities to collect relevant nonidentifiable patient safety work product that is voluntarily reported by patient safety organizations upon the request of the Secretary. Any database established or designated under this paragraph may be referred to as a 'National Patient Safety Database'.

''(2) USE OF INFORMATION.—Information reported to any National Patient Safety Database shall be used to analyze national and regional statistics, including trends and patterns of health care errors. The information resulting from such analyses may be included in the annual quality reports prepared under section 913(b)(2).

''(3) ADVISORY ROLE.—The Secretary shall provide scientific support to patient safety organizations, including the dissemination of methodologies and evidence-based information related to root causes and quality improvement.

''(b) STANDARDS.—In establishing or designating a database under subsection (a)(1), the Secretary shall, in consultation with representatives of patient safety organizations, the provider community, and the health information technology industry, determine common formats for the voluntary reporting of nonidentifiable patient safety work product, including necessary elements, common and consistent definitions, and a standardized computer interface for the processing of the work product. 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) CERTAIN METHODOLOGIES FOR COLLECTION.—The Secretary shall ensure that the methodologies for the collection of nonidentifiable patient safety work product for any National Patient Safety Database include the methodologies developed or recommended by the Patient Safety Task Force of the Department of Health and Human Services.

''(d) FACILITATION OF INFORMATION EXCHANGE.—To the extent practicable, the Secretary may facilitate the direct link of information between providers and patient safety organizations and between patient safety organizations and any National Patient Safety Database.

''(e) RESTRICTION ON TRANSFER.—Only nonidentifiable information may be transferred to any National Patient Safety Database.

''SEC. 924. TECHNICAL ASSISTANCE.

''(a) IN GENERAL.—The Secretary, acting through the Director, may—

''(1) provide technical assistance to patient safety organizations, and to States with reporting systems for health care errors; and

''(2) provide guidance on the type of data to be voluntarily submitted to any National Patient Safety Database.

''(b) ANNUAL MEETINGS.—Assistance provided under subsection (a) may include annual meetings for patient safety organizations to discuss methodology, communication, information collection, or privacy concerns.

"SEC. 925. CERTIFICATION OF PATIENT SAFETY ORGANIZATIONS.

''(a) IN GENERAL.—Not later than 6 months after the date of enactment of the Patient Safety and Quality Improvement Act, the Secretary shall establish a process for certifying patient safety organizations.

''(b) PROCESS.—The process established under subsection (a) shall include the following:

''(1) Certification of patient safety organizations by the Secretary or by such other national or State governmental organizations as the Secretary determines appropriate.

''(2) If the Secretary allows other governmental organizations to certify patient safety organizations under paragraph (1), the Secretary shall establish a process for approving such organizations. Any such approved organization shall conduct certifications and reviews in accordance with this section.

''(3) A review of each certification under paragraph (1) (including a review of compliance with each criterion in this section and any related imple-

menting standards as determined by the Secretary through rulemaking) not less often than every 3 years, as determined by the Secretary.

''(4) Revocation of any such certification by the Secretary or other such governmental organization that issued the certification, upon a showing of cause.

''(c) CRITERIA.—A patient safety organization must meet the following criteria as conditions of certification:

''(1) The mission of the patient safety organization is to conduct activities that are to improve patient safety and the quality of health care delivery and is not in conflict of interest with the providers that contract with the patient safety organization.

''(2) The patient safety organization has appropriately qualified staff, including licensed or certified medical professionals.

''(3) The patient safety organization, within any 2 year period, contracts with more than 1 provider for the purpose of receiving and reviewing patient safety work product.

''(4) The patient safety organization is not a component of a health insurer or other entity that offers a group health plan or health insurance coverage.

''(5) The patient safety organization is managed, controlled, and operated independently from any provider that contracts with the patient safety organization for reporting patient safety work product.

''(6) To the extent practical and appropriate, the patient safety organization collects patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.

''(d) ADDITIONAL CRITERIA FOR COMPONENT ORGANIZATIONS.—If a patient safety organization is a component of another organization, the patient safety organization must, in addition to meeting the criteria described in subsection (c), meet the following criteria as conditions of certification:

''(1) The patient safety organization maintains patient safety work product separately from the rest of the organization, and establishes appropriate security measures to maintain the confidentiality of the patient safety work product.

''(2) The patient safety organization does not make an unauthorized disclosure under this Act of patient safety work product to the rest of the organization in breach of confidentiality.

''(3) The mission of the patient safety organization does not create a conflict of interest with the rest of the organization.''.

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 937 of the Public Health Service Act (as redesignated by subsection (a)) is amended by adding at the end the following:

''(e) PATIENT SAFETY AND QUALITY IMPROVEMENT.—For the purpose of carrying out part C, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2013.''.

SEC. 4. PROMOTING THE DIFFUSION AND INTEROPERABILITY OF INFORMATION TECHNOLOGY SYSTEMS INVOLVED WITH HEALTH CARE DELIVERY.

(a) VOLUNTARY STANDARDS.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall—

(A) develop or adopt voluntary national standards that promote the interoperability of information technology systems involved with health care delivery, including but not limited to computerized physician order entry;

(B) in developing or adopting such standards, take into account—

(i) the ability of such systems to capture and aggregate clinically specific data to enable evidence-based medicine and other applications that promote the electronic exchange of patient medical record information; and

(ii) the cost that meeting such standards would have on providing health care in the United States and the increased efficiencies in providing such care achieved under the standards;

(C) in developing or adopting such standards and to the extent practicable, test the efficacy, usability, and scalability of proposed interoperability standards within a variety of clinical settings, including an urban academic medical center, a rural hospital, a community health center, and a community hospital; and

(D) submit a report to the Congress containing recommendations on such standards.

(2) CONSULTATION.—In developing or adopting standards under paragraph (1)(A), the Secretary shall consider the recommendations of the National

Committee on Vital Health Statistics for the standardization of message formatting, coding, and vocabulary for interoperability of information technology systems involved with health care delivery. The Secretary shall consult with representatives of the health information technology industry and the provider community who are involved with the development of interoperability standards.

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

SEC. 5. 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:

''(w) 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(q).''; and

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

''(q)(1) The Secretary shall issue, and may periodically revise, regulations requiring the manufacturer of any

drug or biological product that is subject to regulation by the Food and Drug Administration, or the packager or labeler of a drug or biological product that is subject to regulation by the Food and Drug Administration, 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) at each packaging level;

''(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 section, or add additional provisions that are necessary to safeguard the public health.''.

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