

109TH CONGRESS
1ST SESSION

H. R. 3205

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

JULY 12, 2005

Mr. BILIRAKIS (for himself, Mr. DEAL of Georgia, Mr. BROWN of Ohio, and Mr. WAXMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Patient Safety and Quality Improvement Act”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings and purposes.

Sec. 3. Amendments to Public Health Service Act.

Sec. 4. Promoting the diffusion and interoperability of information technology systems involved with health care delivery.

Sec. 5. Required use of product identification technology.

Sec. 6. Grants for electronic prescription programs.

Sec. 7. Grants to hospitals and other health care providers for information technologies.

Sec. 8. Authorization of appropriations for grants under sections 6 and 7.

1 **SEC. 2. FINDINGS AND PURPOSES.**

2 (a) FINDINGS.—The Congress finds as follows:

3 (1) In 1999, the Institute of Medicine released
4 a report entitled “To Err Is Human” that described
5 medical errors as the 8th leading cause of death in
6 the United States, with as many as 98,000 people
7 dying as a result of medical errors each year.

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

12 (3) Myriad public and private patient safety ini-
13 tiatives have begun. The Quality Interagency Coordi-
14 nation Task Force has recommended steps to im-
15 prove patient safety that may be taken by each Fed-
16 eral agency involved in health care and activities re-
17 lating to these steps are ongoing.

18 (4) The Department of Health and Human
19 Services has initiated several patient safety projects.
20 The Joint Commission on Accreditation of
21 Healthcare Organizations issued a patient safety

1 standard that went into effect on July 1, 2001, and
2 the peer review organizations are conducting ongoing
3 studies of clinical performance measurement of care
4 delivered to beneficiaries under the medicare pro-
5 gram under title XVIII of the Social Security Act.

6 (5) Several steps can be taken now to improve
7 patient safety. For example, according to the Cen-
8 ters for Disease Control and Prevention, hand wash-
9 ing is the single most important means of preventing
10 the spread of infection. Repeated studies indicate
11 that lack of or improper hand washing still contrib-
12 utes significantly to disease transmission in health
13 care settings. Working with experts from the private
14 sector, the Centers for Disease Control and Preven-
15 tion has drafted “Guidelines for Hand Hygiene in
16 Healthcare Settings” setting forth recommendations
17 to promote improved hand hygiene practices and re-
18 duce transmission of pathogenic microorganisms to
19 patients and personnel in health care settings.

20 (6) According to the Centers for Disease Con-
21 trol and Prevention, nosocomial infections affect ap-
22 proximately 2 million patients annually in acute care
23 facilities in the United States at an estimated direct
24 patient care cost of approximately \$3.5 billion each
25 year.

1 (7) The Congress encourages the continuation
2 and acceleration of private sector efforts to take im-
3 mediate steps to improve patient safety and recog-
4 nizes the need for action in the public sector to com-
5 plement these efforts.

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

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

14 (10) Promising patient safety reporting systems
15 have been established throughout the United States,
16 and the best ways to structure and use these sys-
17 tems are currently being determined, largely through
18 projects funded by the Agency for Healthcare Re-
19 search and Quality.

20 (11) Many organizations currently collecting
21 patient safety information have expressed a need for
22 protections that will allow them to review protected
23 information so that they may collaborate in the de-
24 velopment and implementation of patient safety im-
25 provement strategies. Currently, the State peer re-

1 view protections provide inadequate conditions to
2 allow the sharing of information to promote patient
3 safety.

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

9 (b) PURPOSES.—The purposes of this Act are—

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

15 (2) to ensure accountability by raising stand-
16 ards and expectations for continuous quality im-
17 provements in patient safety through the actions of
18 the Secretary of Health and Human Services.

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

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

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

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

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

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

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

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

7 **“SEC. 921. DEFINITIONS.**

8 “In this part:

9 “(1) IDENTIFIABLE INFORMATION.—The term
10 ‘identifiable information’ means information that is
11 presented in a form and manner that allows the
12 identification of any provider, patient, or reporter of
13 patient safety work product. With respect to pa-
14 tients, such information includes any individually
15 identifiable health information as that term is de-
16 fined in the regulations promulgated pursuant to
17 section 264(c) of the Health Insurance Portability
18 and Accountability Act of 1996 (Public Law 104–
19 191; 110 Stat. 2033).

20 “(2) NONIDENTIFIABLE INFORMATION.—The
21 term ‘nonidentifiable information’ means informa-
22 tion that is presented in a form and manner that
23 prevents the identification of any provider, patient,
24 or reporter of patient safety work product. With re-
25 spect to patients, such information must be de-iden-

1 tified consistent with the regulations promulgated
2 pursuant to section 264(c) of the Health Insurance
3 Portability and Accountability Act of 1996 (Public
4 Law 104–191; 110 Stat. 2033).

5 “(3) PATIENT SAFETY EVALUATION SYSTEM.—
6 The term ‘patient safety evaluation system’ means a
7 process that involves the collection, management, or
8 analysis of information for submission to or by a pa-
9 tient safety organization.

10 “(4) PATIENT SAFETY ORGANIZATION.—The
11 term ‘patient safety organization’ means a private or
12 public organization or component thereof that is cer-
13 tified, through a process to be determined by the
14 Secretary under section 925, to perform each of the
15 following activities:

16 “(A) The conduct, as the organization or
17 component’s primary activity, of efforts to im-
18 prove patient safety and the quality of health
19 care delivery.

20 “(B) The collection and analysis of patient
21 safety work product that is submitted by pro-
22 viders.

23 “(C) The development and dissemination
24 of evidence-based information to providers with
25 respect to improving patient safety, such as rec-

1 ommendations, protocols, or information re-
2 garding best practices.

3 “(D) The utilization of patient safety work
4 product to carry out activities limited to those
5 described under this paragraph and for the pur-
6 poses of encouraging a culture of safety and of
7 providing direct feedback and assistance to pro-
8 viders to effectively minimize patient risk.

9 “(E) The maintenance of confidentiality
10 with respect to identifiable information.

11 “(F) The provision of appropriate security
12 measures with respect to patient safety work
13 product.

14 “(G) The submission of nonidentifiable in-
15 formation to the Agency consistent with stand-
16 ards established by the Secretary under section
17 923(b) for any National Patient Safety Data-
18 base.

19 “(5) PATIENT SAFETY WORK PRODUCT.—

20 “(A) The term ‘patient safety work prod-
21 uct’ means any document or communication
22 (including any information, report, record,
23 memorandum, analysis, deliberative work, state-
24 ment, or root cause analysis) that—

1 “(i) except as provided in subpara-
2 graph (B), is developed by a provider for
3 the purpose of reporting to a patient safety
4 organization, and is reported to a patient
5 safety organization;

6 “(ii) is created by a patient safety or-
7 ganization; or

8 “(iii) would reveal the deliberations or
9 analytic process of a patient safety evalua-
10 tion system (as defined in paragraph (3)).

11 “(B)(i) Patient safety work product de-
12 scribed in subparagraph (A)(i)—

13 “(I) does not include any separate in-
14 formation described in clause (ii); and

15 “(II) shall not be construed to include
16 such separate information merely by rea-
17 son of inclusion of a copy of the document
18 or communication involved in a submission
19 to, or the fact of submission of such a copy
20 to, a patient safety organization.

21 “(ii) Separate information described in this
22 clause is a document or communication (includ-
23 ing a patient’s medical record or any other pa-
24 tient or hospital record) that is developed or

1 maintained, or exists, separately from any pa-
2 tient safety evaluation system.

3 “(C) Information available from sources
4 other than a patient safety work product under
5 this section may be discovered or admitted in a
6 civil or administrative proceeding, if discover-
7 able or admissible under applicable law.

8 “(6) PROVIDER.—The term ‘provider’ means—

9 “(A) an individual or entity licensed or
10 otherwise authorized under State law to provide
11 health care services, including—

12 “(i) a hospital, nursing facility, com-
13 prehensive outpatient rehabilitation facil-
14 ity, home health agency, and hospice pro-
15 gram;

16 “(ii) a physician, physician assistant,
17 nurse practitioner, clinical nurse specialist,
18 certified nurse midwife, nurse anesthetist,
19 psychologist, certified social worker, reg-
20 istered dietitian or nutrition professional,
21 physical or occupational therapist, or other
22 individual health care practitioner;

23 “(iii) a pharmacist; and

24 “(iv) a renal dialysis facility, ambula-
25 tory surgical center, pharmacy, physician

1 or health care practitioner’s office, long-
2 term care facility, behavioral health resi-
3 dential treatment facility, clinical labora-
4 tory, or community health center; or

5 “(B) any other person or entity specified
6 in regulations by the Secretary after public no-
7 tice and comment.

8 **“SEC. 922. PRIVILEGE FOR PATIENT SAFETY WORK PROD-**
9 **UCT.**

10 “(a) PRIVILEGE.—Notwithstanding any other provi-
11 sion of law and subject to subsection (c), patient safety
12 work product shall not be—

13 “(1) subject to a civil or administrative sub-
14 poena or order;

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

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

21 “(4) required to be admitted as evidence or oth-
22 erwise disclosed in any State or Federal civil or ad-
23 ministrative proceeding; or

24 “(5) if the patient safety work product is identi-
25 fiable information and is received by a national ac-

1 accreditation organization in its capacity as a patient
2 safety organization—

3 “(A) used by a national accreditation orga-
4 nization in an accreditation action against the
5 provider that reported the information;

6 “(B) shared by such organization with its
7 survey team; or

8 “(C) required as a condition of accredita-
9 tion by a national accreditation association.

10 “(b) REPORTER PROTECTION.—

11 “(1) IN GENERAL.—A provider may not use
12 against an individual in an adverse employment ac-
13 tion described in paragraph (2) the fact that the in-
14 dividual in good faith reported information—

15 “(A) to the provider with the intention of
16 having the information reported to a patient
17 safety organization; or

18 “(B) directly to a patient safety organiza-
19 tion.

20 “(2) ADVERSE EMPLOYMENT ACTION.—For
21 purposes of this subsection, an ‘adverse employment
22 action’ includes—

23 “(A) the failure to promote an individual
24 or provide any other employment-related benefit

1 for which the individual would otherwise be eli-
2 gible;

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

6 “(C) a personnel action that is adverse to
7 the individual concerned.

8 “(3) REMEDIES.—Any provider that violates
9 this subsection shall be subject to a civil monetary
10 penalty of not more than \$20,000 for each such vio-
11 lation involved. Such penalty shall be imposed and
12 collected in the same manner as civil money pen-
13 alties under subsection (a) of section 1128A of the
14 Social Security Act are imposed and collected.

15 “(c) DISCLOSURES.—Nothing in this section pro-
16 hibits any of the following disclosures:

17 “(1) Voluntary disclosure of nonidentifiable in-
18 formation.

19 “(2) Voluntary disclosure of identifiable infor-
20 mation by a provider or patient safety organization,
21 if such disclosure—

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

24 “(B) is to an entity or person subject to
25 the requirements of section 264(c) of the

1 Health Insurance Portability and Accountability
2 Act of 1996 (Public Law 104–191; 110 Stat.
3 2033), or any regulation promulgated under
4 such section; and

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

7 “(3) Disclosure as required by law by a pro-
8 vider to the Food and Drug Administration, or on
9 a voluntary basis by a provider to a federally estab-
10 lished patient safety program, with respect to an Ad-
11 ministration-regulated product or activity for which
12 that entity has responsibility, for the purposes of ac-
13 tivities related to the quality, safety, or effectiveness
14 of such Administration-regulated product or activity.

15 “(4) Disclosures of patient safety work product
16 in accordance with this part by a provider to a pa-
17 tient safety organization.

18 “(d) EFFECT OF TRANSFER, DISCLOSURE.—The fol-
19 lowing shall not be treated as a waiver of any privilege
20 or protection established under this part:

21 “(1) The transfer of any patient safety work
22 product between a provider and a patient safety or-
23 ganization.

24 “(2) Disclosure of patient safety work product
25 as described in subsection (c).

1 “(3) The unauthorized disclosure of patient
2 safety work product.

3 “(e) PENALTY.—

4 “(1) PROHIBITION.—Except as provided in this
5 part, and subject to paragraphs (2) and (4), it shall
6 be unlawful for any person to disclose patient safety
7 work product in violation of this section, if such dis-
8 closure constitutes a negligent or knowing breach of
9 confidentiality.

10 “(2) RELATION TO HIPAA.—The penalty under
11 paragraph (3) for a disclosure in violation of para-
12 graph (1) does not apply if the person would be sub-
13 ject to a penalty under section 264(c) of the Health
14 Insurance Portability and Accountability Act of
15 1996 (Public Law 104–191; 110 Stat. 2033), or any
16 regulation promulgated under such section, for the
17 same disclosure.

18 “(3) AMOUNT.—Any person who violates para-
19 graph (1) shall be subject to a civil monetary penalty
20 of not more than \$10,000 for each such violation in-
21 volved. Such penalty shall be imposed and collected
22 in the same manner as civil money penalties under
23 subsection (a) of section 1128A of the Social Secu-
24 rity Act are imposed and collected.

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

5 “(f) RELATION TO HIPAA.—

6 “(1) IN GENERAL.—For purposes of applying
7 the regulations promulgated pursuant to section
8 264(c) of the Health Insurance Portability and Ac-
9 countability Act of 1996 (Public Law 104–191; 110
10 Stat. 2033)—

11 “(A) patient safety organizations shall be
12 treated as business associates; and

13 “(B) activities of such organizations de-
14 scribed in section 921(4) in relation to a pro-
15 vider are deemed to be health care operations
16 (as defined in such regulations) of the provider.

17 “(2) RULE OF CONSTRUCTION.—Nothing in
18 this section shall be construed to alter or affect the
19 implementation of such regulations or such section
20 264(c).

21 “(g) NO LIMITATION OF OTHER PRIVILEGES.—

22 Nothing in this section shall be construed to affect privi-
23 leges, including peer review and confidentiality protec-
24 tions, that are otherwise available under Federal or State
25 laws.

1 “(h) NO LIMITATION ON CONTRACTS.—Nothing in
2 this section shall be construed to limit the power of a pro-
3 vider and a patient safety organization, or a patient safety
4 organization and the Agency or any National Patient
5 Safety Database, consistent with the provisions of this Act
6 and other applicable law, to enter into a contract requiring
7 greater confidentiality or delegating authority to make an
8 authorized disclosure.

9 “(i) RELATION TO STATE REPORTING REQUIRE-
10 MENTS.—Nothing in this part shall be construed as pre-
11 empting or otherwise affecting any State law requiring a
12 provider to report information, including information de-
13 scribed in section 921(5)(B), that is not patient safety
14 work product.

15 “(j) CONTINUATION OF PRIVILEGE.—Patient safety
16 work product of an organization that is certified as a pa-
17 tient safety organization shall continue to be privileged
18 and confidential, in accordance with this section, if the or-
19 ganization’s certification is terminated or revoked or if the
20 organization otherwise ceases to qualify as a patient safety
21 organization.

22 “(k) REPORTS ON STRATEGIES TO IMPROVE PA-
23 TIENT SAFETY.—

24 “(1) DRAFT REPORT.—Not later than the date
25 that is 18 months after any National Patient Safety

1 Database is operational, the Secretary, in consulta-
2 tion with the Director, shall prepare a draft report
3 on effective strategies for reducing medical errors
4 and increasing patient safety. The draft report shall
5 include any measure determined appropriate by the
6 Secretary to encourage the appropriate use of such
7 strategies, including use in any federally funded pro-
8 grams. The Secretary shall make the draft report
9 available for public comment and submit the draft
10 report to the Institute of Medicine for review.

11 “(2) FINAL REPORT.—Not later than 1 year
12 after the date described in paragraph (1), the Sec-
13 retary shall submit a final report to the Congress
14 that includes, in an appendix, any findings by the
15 Institute of Medicine concerning research on the
16 strategies discussed in the draft report and any
17 modifications made by the Secretary based on such
18 findings.

19 **“SEC. 923. NATIONAL PATIENT SAFETY DATABASE.**

20 “(a) AUTHORITY.—

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

1 evant nonidentifiable patient safety work product
2 that is voluntarily reported by patient safety organi-
3 zations upon the request of the Secretary. Any data-
4 base established or designated under this paragraph
5 may be referred to as a ‘National Patient Safety
6 Database’.

7 “(2) USE OF INFORMATION.—Information re-
8 ported to any National Patient Safety Database
9 shall be used to analyze national and regional statis-
10 tics, including trends and patterns of health care er-
11 rors. The information resulting from such analyses
12 may be included in the annual quality reports pre-
13 pared under section 913(b)(2).

14 “(3) ADVISORY ROLE.—The Secretary shall
15 provide scientific support to patient safety organiza-
16 tions, including the dissemination of methodologies
17 and evidence-based information related to root
18 causes and quality improvement.

19 “(b) STANDARDS.—In establishing or designating a
20 database under subsection (a)(1), the Secretary shall, in
21 consultation with representatives of patient safety organi-
22 zations, the provider community, and the health informa-
23 tion technology industry, determine common formats for
24 the voluntary reporting of nonidentifiable patient safety
25 work product, including necessary elements, common and

1 consistent definitions, and a standardized computer inter-
2 face for the processing of the work product. To the extent
3 practicable, such standards shall be consistent with the
4 administrative simplification provisions of part C of title
5 XI of the Social Security Act.

6 “(c) CERTAIN METHODOLOGIES FOR COLLECTION.—
7 The Secretary shall ensure that the methodologies for the
8 collection of nonidentifiable patient safety work product
9 for any National Patient Safety Database include the
10 methodologies developed or recommended by the Patient
11 Safety Task Force of the Department of Health and
12 Human Services.

13 “(d) FACILITATION OF INFORMATION EXCHANGE.—
14 To the extent practicable, the Secretary may facilitate the
15 direct link of information between providers and patient
16 safety organizations and between patient safety organiza-
17 tions and any National Patient Safety Database.

18 “(e) RESTRICTION ON TRANSFER.—Only nonidentifi-
19 able information may be transferred to any National Pa-
20 tient Safety Database.

21 **“SEC. 924. TECHNICAL ASSISTANCE.**

22 “(a) IN GENERAL.—The Secretary, acting through
23 the Director, may—

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

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

7 “(b) ANNUAL MEETINGS.—Assistance provided
8 under subsection (a) may include annual meetings for pa-
9 tient safety organizations to discuss methodology, commu-
10 nication, information collection, or privacy concerns.

11 **“SEC. 925. CERTIFICATION OF PATIENT SAFETY ORGANIZA-**
12 **TIONS.**

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

17 “(b) PROCESS.—The process established under sub-
18 section (a) shall include the following:

19 “(1) Certification of patient safety organiza-
20 tions by the Secretary or by such other national or
21 State governmental organizations as the Secretary
22 determines appropriate.

23 “(2) If the Secretary allows other governmental
24 organizations to certify patient safety organizations
25 under paragraph (1), the Secretary shall establish a

1 process for approving such organizations. Any such
2 approved organization shall conduct certifications
3 and reviews in accordance with this section.

4 “(3) A review of each certification under para-
5 graph (1) (including a review of compliance with
6 each criterion in this section and any related imple-
7 menting standards as determined by the Secretary
8 through rulemaking) not less often than every 3
9 years, as determined by the Secretary.

10 “(4) Revocation of any such certification by the
11 Secretary or other such governmental organization
12 that issued the certification, upon a showing of
13 cause.

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

16 “(1) The mission of the patient safety organiza-
17 tion is to conduct activities that are to improve pa-
18 tient safety and the quality of health care delivery
19 and is not in conflict of interest with the providers
20 that contract with the patient safety organization.

21 “(2) The patient safety organization has appro-
22 priately qualified staff, including licensed or certified
23 medical professionals.

24 “(3) The patient safety organization, within any
25 2 year period, contracts with more than 1 provider

1 for the purpose of receiving and reviewing patient
2 safety work product.

3 “(4) The patient safety organization is not a
4 component of a health insurer or other entity that
5 offers a group health plan or health insurance cov-
6 erage.

7 “(5) The patient safety organization is man-
8 aged, controlled, and operated independently from
9 any provider that contracts with the patient safety
10 organization for reporting patient safety work prod-
11 uct.

12 “(6) To the extent practical and appropriate,
13 the patient safety organization collects patient safety
14 work product from providers in a standardized man-
15 ner that permits valid comparisons of similar cases
16 among similar providers.

17 “(d) ADDITIONAL CRITERIA FOR COMPONENT ORGA-
18 NIZATIONS.—If a patient safety organization is a compo-
19 nent of another organization, the patient safety organiza-
20 tion must, in addition to meeting the criteria described
21 in subsection (c), meet the following criteria as conditions
22 of certification:

23 “(1) The patient safety organization maintains
24 patient safety work product separately from the rest
25 of the organization, and establishes appropriate se-

1 security measures to maintain the confidentiality of
2 the patient safety work product.

3 “(2) The patient safety organization does not
4 make an unauthorized disclosure under this Act of
5 patient safety work product to the rest of the orga-
6 nization in breach of confidentiality.

7 “(3) The mission of the patient safety organiza-
8 tion does not create a conflict of interest with the
9 rest of the organization.”.

10 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
11 937 of the Public Health Service Act (as redesignated by
12 subsection (a)) is amended by adding at the end the fol-
13 lowing:

14 “(e) PATIENT SAFETY AND QUALITY IMPROVE-
15 MENT.—For the purpose of carrying out part C, there are
16 authorized to be appropriated such sums as may be nec-
17 essary for each of the fiscal years 2006 through 2010.”.

18 **SEC. 4. PROMOTING THE DIFFUSION AND INTEROPER-**
19 **ABILITY OF INFORMATION TECHNOLOGY SYS-**
20 **TEMS INVOLVED WITH HEALTH CARE DELIV-**
21 **ERY.**

22 (a) VOLUNTARY STANDARDS.—

23 (1) IN GENERAL.—Not later than 18 months
24 after the date of the enactment of this Act, the Sec-

1 retary of Health and Human Services (in this sec-
2 tion referred to as the “Secretary”) shall—

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

8 (B) in developing or adopting such stand-
9 ards, take into account—

10 (i) the ability of such systems to cap-
11 ture and aggregate clinically specific data
12 to enable evidence-based medicine and
13 other applications that promote the elec-
14 tronic exchange of patient medical record
15 information; and

16 (ii) the cost that meeting such stand-
17 ards would have on providing health care
18 in the United States and the increased effi-
19 ciencies in providing such care achieved
20 under the standards;

21 (C) in developing or adopting such stand-
22 ards and to the extent practicable, test the effi-
23 cacy, usability, and scalability of proposed inter-
24 operability standards within a variety of clinical
25 settings, including an urban academic medical

1 center, a rural hospital, a community health
2 center, and a community hospital; and

3 (D) submit a report to the Congress con-
4 taining recommendations on such standards.

5 (2) CONSULTATION.—In developing or adopting
6 standards under paragraph (1)(A), the Secretary
7 shall consider the recommendations of the National
8 Committee on Vital Health Statistics for the stand-
9 ardization of message formatting, coding, and vocab-
10 ulary for interoperability of information technology
11 systems involved with health care delivery. The Sec-
12 retary shall consult with representatives of the
13 health information technology industry and the pro-
14 vider community who are involved with the develop-
15 ment of interoperability standards.

16 (b) UPDATES.—The Secretary shall provide for the
17 ongoing review and periodic updating of the standards de-
18 veloped under subsection (a).

19 **SEC. 5. REQUIRED USE OF PRODUCT IDENTIFICATION**
20 **TECHNOLOGY.**

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

23 (1) in section 502, by adding at the end the fol-
24 lowing:

1 “(x) If it is a drug or biological product, unless it
2 includes a unique product identifier for the drug or bio-
3 logical product as required by regulations under section
4 510(q).”; and

5 (2) in section 510, by adding at the end the fol-
6 lowing:

7 “(q)(1) The Secretary shall issue, and may periodi-
8 cally revise, regulations requiring the manufacturer of any
9 drug or biological product that is subject to regulation by
10 the Food and Drug Administration, or the packager or
11 labeler of a drug or biological product that is subject to
12 regulation by the Food and Drug Administration, to in-
13 clude a unique product identifier on the packaging of the
14 drug or biological product.

15 “(2) For purposes of this subsection, the term
16 ‘unique product identifier’ means an identification that—

17 “(A) is affixed by the manufacturer, labeler, or
18 packager to each drug or biological product de-
19 scribed in paragraph (1) at each packaging level;

20 “(B) uniquely identifies the item and meets the
21 standards required by this section; and

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

1 “(3) A unique product identifier required by regula-
2 tions issued or revised under paragraph (1) shall be based
3 on—

4 “(A) the National Drug Code maintained by
5 the Food and Drug Administration;

6 “(B) commercially accepted standards estab-
7 lished by organizations that are accredited by the
8 American National Standards Institute, such as the
9 Health Industry Business Communication Council or
10 the Uniform Code Council; or

11 “(C) other identification formats that the Sec-
12 retary deems appropriate.

13 “(4) The Secretary may, at the Secretary’s discre-
14 tion, waive the requirements of this section, or add addi-
15 tional provisions that are necessary to safeguard the pub-
16 lic health.”

17 **SEC. 6. GRANTS FOR ELECTRONIC PRESCRIPTION PRO-**
18 **GRAMS.**

19 (a) GRANTS.—

20 (1) IN GENERAL.—The Secretary of Health and
21 Human Services (in this section referred to as the
22 “Secretary”) may make grants to qualified practi-
23 tioners for the purpose of establishing electronic pre-
24 scription programs.

25 (2) MATCHING FUNDS.—

1 (A) IN GENERAL.—With respect to the
2 costs of establishing an electronic prescription
3 program, a condition for the receipt of a grant
4 under paragraph (1) is that the qualified practi-
5 tioner involved agree to make available (directly
6 or through donations from public or private en-
7 tities) non-Federal contributions toward such
8 costs in an amount that is not less than 50 per-
9 cent of such costs.

10 (B) DETERMINATION OF AMOUNT CON-
11 TRIBUTED.—Non-Federal contributions re-
12 quired in subparagraph (A) may be in cash or
13 in kind, fairly evaluated, including equipment or
14 services. Amounts provided by the Federal Gov-
15 ernment, or services assisted or subsidized to
16 any significant extent by the Federal Govern-
17 ment, may not be included in determining the
18 amount of such non-Federal contributions.

19 (b) STUDY.—

20 (1) IN GENERAL.—The Secretary, acting
21 through the Director of the Agency for Healthcare
22 Research and Quality, shall support a study to as-
23 sess existing scientific evidence regarding the effec-
24 tiveness and cost-effectiveness of the use of elec-
25 tronic prescription programs intended to improve the

1 efficiency of prescription ordering and the safe and
2 effective use of prescription drugs. The study shall
3 address the following:

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

7 (B) The impact of the use of such pro-
8 grams on physicians, pharmacists, and patients,
9 including such factors as direct and indirect
10 costs, changes in productivity, and satisfaction.

11 (C) The effectiveness of strategies for over-
12 coming barriers to the use of electronic pre-
13 scription programs.

14 (2) REPORT.—The Secretary shall ensure that,
15 not later than 18 months after the date of the enact-
16 ment of this Act, a report containing the findings of
17 the study under paragraph (1) is submitted to the
18 appropriate committees of the Congress.

19 (3) DISSEMINATION OF FINDINGS.—The Sec-
20 retary shall disseminate the findings of the study
21 under paragraph (1) to appropriate public and pri-
22 vate entities.

23 (c) DEVELOPMENT OF MODEL.—The Secretary, act-
24 ing through the Director of the Agency for Healthcare Re-
25 search and Quality, may develop an Internet-based mathe-

1 matical model that simulates the cost and effectiveness of
2 electronic prescription programs for qualified practi-
3 tioners. The model may be designed to allow qualified
4 practitioners to estimate, through an interactive interface,
5 the impact of electronic prescribing on their practices, in-
6 cluding the reduction in drug-related health care errors.

7 (d) DEFINITIONS.—For purposes of this section:

8 (1) The term “electronic prescription pro-
9 gram”—

10 (A) means a program for the electronic
11 submission and processing of prescriptions; and

12 (B) includes the hardware (including com-
13 puters and other electronic devices) and soft-
14 ware programs for the electronic submission of
15 prescriptions to pharmacies, the processing of
16 such submissions by pharmacies, and decision-
17 support programs.

18 (2) The term “qualified practitioner” means a
19 practitioner licensed by law to administer or dis-
20 pensate prescription drugs.

21 **SEC. 7. GRANTS TO HOSPITALS AND OTHER HEALTH CARE**
22 **PROVIDERS FOR INFORMATION TECH-**
23 **NOLOGIES.**

24 (a) IN GENERAL.—The Secretary of Health and
25 Human Services (in this section referred to as the “Sec-

1 retary”) shall make grants to hospitals and other health
2 care providers (but not more than 1 grant to any 1 hos-
3 pital or provider) to pay the costs of acquiring or imple-
4 menting information technologies whose purposes are—

5 (1) to improve quality of care and patient safe-
6 ty; and

7 (2) to reduce adverse events and health care
8 complications resulting from medication errors.

9 (b) SPECIAL CONSIDERATION.—In making grants
10 under subsection (a), the Secretary shall give special con-
11 sideration to applicants who seek to promote the following:

12 (1) Interoperability across hospital services or
13 departments using standards developed or adopted
14 by the Secretary under section 4.

15 (2) Electronic communication of patient data
16 across the spectrum of health care delivery.

17 (3) Computerized physician order entry or bar
18 coding applications.

19 (4) Electronic communication of patient data in
20 hospitals that provide services to underserved or low-
21 income populations.

22 (5) Improved clinical decisionmaking through
23 acquisition and implementation of decision-support
24 technologies.

1 (c) CERTAIN GRANT CONDITIONS.—A condition for
2 the receipt of a grant under subsection (a) is that the ap-
3 plicant involved meet the following requirements:

4 (1) The applicant agrees to carry out a pro-
5 gram to measure, analyze, and report patient safety
6 and medical errors at the hospital or other health
7 care provider involved, to submit to the Secretary a
8 description of the methodology that will be used, and
9 to have such program in effect as soon as prac-
10 ticable after the application for the grant is ap-
11 proved, without regard to whether information tech-
12 nologies under the grant have been implemented.

13 (2) The applicant has arranged for an evalua-
14 tion that addresses the effectiveness and cost-effec-
15 tiveness of the information technology for which the
16 grant is provided and its impact on the quality and
17 safety of patient care, submitted the evaluation plan
18 to the Secretary, and received approval from the
19 Secretary of the applicant's methodology.

20 (3) The applicant has or is developing a patient
21 safety evaluation system (as that term is defined in
22 section 921 of the Public Health Service Act (as
23 amended by section 3)) for reporting health care er-
24 rors to a patient safety organization.

1 (4) The applicant agrees to provide the Sec-
2 retary with such information as the Secretary may
3 require regarding the use of funds under this pro-
4 gram or its impact.

5 (5) The applicant provides assurances satisfac-
6 tory to the Secretary that any information tech-
7 nology planned, acquired, or implemented with grant
8 funds under this section will be part of an informa-
9 tion program that—

10 (A) carries out the purposes described in
11 subsection (a); and

12 (B) is comprehensive or will be expanded
13 to become comprehensive, regardless of whether
14 Federal assistance is available for such expan-
15 sion.

16 (d) TECHNICAL ASSISTANCE TO GRANTEES.—The
17 Secretary, acting through the Director of the Agency for
18 Healthcare Research and Quality, shall provide technical
19 assistance to applicants and grantees to ensure the appro-
20 priate evaluation of the information technologies for which
21 grants are awarded under this section, such as—

22 (1) reviewing and providing technical assistance
23 on the applicant’s proposed evaluation;

24 (2) developing mechanisms to ensure ongoing
25 communications between grantees and evaluators to

1 facilitate the identification and resolution of prob-
2 lems as they arise, ensure mutual learning, and pro-
3 mote the rapid dissemination of information;

4 (3) reviewing the interim and final reports re-
5 quired under subsection (e); and

6 (4) disseminating evidence-based information in
7 interim and final reports to patient safety organiza-
8 tions, as appropriate.

9 (e) EVALUATION REPORTS BY GRANTEE.—A condi-
10 tion for the receipt of a grant under subsection (a) is that
11 the applicant agree to submit an interim and a final report
12 to the Secretary in accordance with this subsection.

13 (1) INTERIM REPORT.—Not later than 1 year
14 after the implementation of information technologies
15 under the grant is completed, the applicant will sub-
16 mit an interim report to the Secretary describing the
17 initial effectiveness of such technologies in carrying
18 out the purposes described in subsection (a).

19 (2) FINAL REPORT.—Not later than 3 years
20 after the implementation of information technologies
21 under the grant is completed, the applicant will sub-
22 mit a final report to the Secretary describing the ef-
23 fectiveness and cost-effectiveness of such tech-
24 nologies and addressing other issues determined to

1 be important in carrying out the purposes described
2 in subsection (a).

3 (3) RELATION TO DISBURSEMENT OF GRANT.—

4 In disbursing a grant under subsection (a), the Sec-
5 retary shall withhold $\frac{1}{3}$ of the grant until the grant-
6 ee submits to the Secretary the report required in
7 paragraph (1).

8 (f) REPORTS BY SECRETARY.—

9 (1) INTERIM REPORTS.—

10 (A) IN GENERAL.—Through the fiscal year
11 preceding the fiscal year in which the final re-
12 port under paragraph (2) is prepared, the Sec-
13 retary shall submit to the Committee on Energy
14 and Commerce of the House of Representatives
15 and the Committee on Health, Education,
16 Labor, and Pensions of the Senate periodic re-
17 ports on the grant program under subsection
18 (a). Such reports shall be submitted not less
19 frequently than once each fiscal year, beginning
20 with fiscal year 2004.

21 (B) CONTENTS.—A report under subpara-
22 graph (A) shall include information on—

23 (i) the number of grants made;

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

4 (iii) the geographic distribution of
5 grant recipients; and

6 (iv) such other matters as the Sec-
7 retary determines appropriate.

8 (2) FINAL REPORT.—Not later than 180 days
9 after the date on which the last of the reports is due
10 under subsection (e)(2), the Secretary shall submit
11 a final report to the committees referred to in para-
12 graph (1)(A) on the grant program under subsection
13 (a), together with such recommendations for legisla-
14 tion and administrative action as the Secretary de-
15 termines appropriate.

16 (g) DEFINITIONS.—For purposes of this section:

17 (1) The term “costs”, with respect to informa-
18 tion technologies referred to in subsection (a), in-
19 cludes total expenditures incurred for—

20 (A) purchasing, leasing, and installing
21 computer software and hardware, including
22 hand-held computer technologies;

23 (B) making improvements to existing com-
24 puter software and hardware; and

1 (C) purchasing or leasing communications
2 capabilities necessary for clinical data access,
3 storage, and exchange.

4 (2) The term “health care provider” has the
5 same meaning given to the term “provider” in sec-
6 tion 921 of the Public Health Services Act (as
7 amended by this Act).

8 (h) TERMINATION OF GRANT AUTHORITIES.—The
9 authority of the Secretary to make grants under sub-
10 section (a) terminates upon the expiration of fiscal year
11 2013.

12 (i) MATCHING FUNDS.—

13 (1) IN GENERAL.—With respect to the costs of
14 a grant to be carried out under this section, such
15 grant may be made only if the applicant agrees to
16 make available (directly or through donations from
17 public or private entities) non-Federal contributions
18 toward such costs in an amount that is not less than
19 50 percent of such costs (\$1 for each \$1 of Federal
20 funds provided in the grant).

21 (2) DETERMINATION OF AMOUNTS CONTRIB-
22 UTED.—Amounts provided by the Federal Govern-
23 ment, or services assisted or subsidized to any sig-
24 nificant extent by the Federal Government, may not

1 be included in determining the amount of such non-
2 Federal contributions.

3 **SEC. 8. AUTHORIZATION OF APPROPRIATIONS FOR GRANTS**

4 **UNDER SECTIONS 6 AND 7.**

5 For the purpose of carrying out sections 6 and 7,
6 there are authorized to be appropriated \$25,000,000 for
7 each of fiscal years 2006 and 2007.

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