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108TH CONGRESS
1ST SESSION

H. R. 663

[Report No. 108-28]

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

MARCH 6, 2003

Additional sponsors: Mr. ISSA, Ms. ESHOO, Mr. GREEN of Texas, and Mr. STUPAK

MARCH 6, 2003

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on February 11, 2003]

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.**

4 *This Act may be cited as the “Patient Safety and*
5 *Quality Improvement Act”.*

6 **SEC. 2. FINDINGS AND PURPOSES.**

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

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

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

17 *(3) Myriad public and private patient safety*
18 *initiatives have begun. The Quality Interagency Co-*
19 *ordination Task Force has recommended steps to im-*
20 *prove patient safety that may be taken by each Fed-*
21 *eral agency involved in health care and activities re-*
22 *lating to these steps are ongoing.*

1 (4) *The Department of Health and Human Serv-*
2 *ices has initiated several patient safety projects. The*
3 *Joint Commission on Accreditation of Healthcare Or-*
4 *ganizations issued a patient safety standard that*
5 *went into effect on July 1, 2001, and the peer review*
6 *organizations are conducting ongoing studies of clin-*
7 *ical performance measurement of care delivered to*
8 *beneficiaries under the medicare program under title*
9 *XVIII of the Social Security Act.*

10 (5) *Several steps can be taken now to improve*
11 *patient safety. For example, according to the Centers*
12 *for Disease Control and Prevention, hand washing is*
13 *the single most important means of preventing the*
14 *spread of infection. Repeated studies indicate that*
15 *lack of or improper hand washing still contributes*
16 *significantly to disease transmission in health care*
17 *settings. Working with experts from the private sector,*
18 *the Centers for Disease Control and Prevention has*
19 *drafted “Guidelines for Hand Hygiene in Healthcare*
20 *Settings” setting forth recommendations to promote*
21 *improved hand hygiene practices and reduce trans-*
22 *mission of pathogenic microorganisms to patients and*
23 *personnel in health care settings.*

24 (6) *According to the Centers for Disease Control*
25 *and Prevention, nosocomial infections affect approxi-*

1 *mately 2 million patients annually in acute care fa-*
2 *ilities in the United States at an estimated direct*
3 *patient care cost of approximately \$3.5 billion each*
4 *year.*

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

10 *(8) The research on patient safety unequivocally*
11 *calls for a learning environment, where providers will*
12 *feel safe to report health care errors, in order to im-*
13 *prove patient safety.*

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

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

24 *(11) Many organizations currently collecting pa-*
25 *tient safety information have expressed a need for*

1 *protections that will allow them to review protected*
2 *information so that they may collaborate in the devel-*
3 *opment and implementation of patient safety im-*
4 *provement strategies. Currently, the State peer review*
5 *protections provide inadequate conditions to allow the*
6 *sharing of information to promote patient safety.*

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

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

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

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

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

22 *(a) IN GENERAL.—Title IX of the Public Health Serv-*
23 *ice Act (42 U.S.C. 299 et seq.) is amended—*

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

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

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

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

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

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

8 **“SEC. 921. DEFINITIONS.**

9 *“In this part:*

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

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

1 *sistent with the regulations promulgated pursuant to*
2 *section 264(c) of the Health Insurance Portability*
3 *and Accountability Act of 1996 (Public Law 104–191;*
4 *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 term*
11 *‘patient safety organization’ means a private or pub-*
12 *lic organization or component thereof that is certified,*
13 *through a process to be determined by the Secretary*
14 *under section 925, to perform each of the following ac-*
15 *tivities:*

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 of*
24 *evidence-based information to providers with re-*
25 *spect to improving patient safety, such as rec-*

1 *ommendations, protocols, or information regard-*
2 *ing 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 product’*
21 *means any document or communication (includ-*
22 *ing any information, report, record, memo-*
23 *randum, analysis, deliberative work, statement,*
24 *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 reason
17 of inclusion of a copy of the document or
18 communication involved in a submission to,
19 or the fact of submission of such a copy to,
20 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 facility,*
14 *home health agency, and hospice program;*

15 “(ii) *a physician, physician assistant,*
16 *nurse practitioner, clinical nurse specialist,*
17 *certified nurse midwife, psychologist, cer-*
18 *tified social worker, registered dietitian or*
19 *nutrition professional, physical or occupa-*
20 *tional therapist, or other individual health*
21 *care practitioner;*

22 “(iii) *a pharmacist; and*

23 “(iv) *a renal dialysis facility, ambula-*
24 *tory surgical center, pharmacy, physician*
25 *or health care practitioner’s office, long-*

1 *term care facility, behavioral health residen-*
2 *tial treatment facility, clinical laboratory,*
3 *or community health center; or*

4 *“(B) any other person or entity specified in*
5 *regulations by the Secretary after public notice*
6 *and comment.*

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

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

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

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

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

20 *“(4) required to be admitted as evidence or other-*
21 *wise disclosed in any State or Federal civil or admin-*
22 *istrative proceeding; or*

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

1 *creditation 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 indi-*
14 *vidual 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 pur-*
21 *poses of this subsection, an ‘adverse employment ac-*
22 *tion’ includes—*

23 “(A) *the failure to promote an individual or*
24 *provide any other employment-related benefit for*
25 *which the individual would otherwise be eligible;*

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

4 “(C) a personnel action that is adverse to
5 the individual concerned.

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

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

15 “(1) Voluntary disclosure of nonidentifiable in-
16 formation.

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

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

22 “(B) is to an entity or person subject to the
23 requirements of section 264(c) of the Health In-
24 surance Portability and Accountability Act of
25 1996 (Public Law 104–191; 110 Stat. 2033), or

1 *any regulation promulgated under such section;*
2 *and*

3 “(C) *is not in conflict with such section or*
4 *any regulation promulgated under such section.*

5 “(3) *Disclosure as required by law by a provider*
6 *to the Food and Drug Administration, or on a vol-*
7 *untary basis by a provider to a federally established*
8 *patient safety program, with respect to an Adminis-*
9 *tration-regulated product or activity for which that*
10 *entity has responsibility, for the purposes of activities*
11 *related to the quality, safety, or effectiveness of such*
12 *Administration-regulated product or activity.*

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

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

19 “(1) *The transfer of any patient safety work*
20 *product between a provider and a patient safety orga-*
21 *nization.*

22 “(2) *Disclosure of patient safety work product as*
23 *described in subsection (c).*

24 “(3) *The unauthorized disclosure of patient safe-*
25 *ty work product.*

1 “(e) *PENALTY.*—

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

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

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

23 “(4) *SUBSEQUENT DISCLOSURE.*—*Paragraph (1)*
24 *applies only to the first person that breaches confiden-*

1 *tiality with respect to particular patient safety work*
2 *product.*

3 “(f) *RELATION TO HIPAA.*—

4 “(1) *IN GENERAL.*—*For purposes of applying the*
5 *regulations promulgated pursuant to section 264(c) of*
6 *the Health Insurance Portability and Accountability*
7 *Act of 1996 (Public Law 104–191; 110 Stat. 2033)—*

8 “(A) *patient safety organizations shall be*
9 *treated as business associates; and*

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

14 “(2) *RULE OF CONSTRUCTION.*—*Nothing in this*
15 *section shall be construed to alter or affect the imple-*
16 *mentation of such regulations or such section 264(c).*

17 “(g) *NO LIMITATION OF OTHER PRIVILEGES.*—*Noth-*
18 *ing in this section shall be construed to affect privileges,*
19 *including peer review and confidentiality protections, that*
20 *are otherwise available under Federal or State laws.*

21 “(h) *NO LIMITATION ON CONTRACTS.*—*Nothing in this*
22 *section shall be construed to limit the power of a provider*
23 *and a patient safety organization, or a patient safety orga-*
24 *nization and the Agency or any National Patient Safety*
25 *Database, consistent with the provisions of this Act and*

1 *other applicable law, to enter into a contract requiring*
2 *greater confidentiality or delegating authority to make an*
3 *authorized disclosure.*

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

10 “(j) *CONTINUATION OF PRIVILEGE.—Patient safety*
11 *work product of an organization that is certified as a pa-*
12 *tient safety organization shall continue to be privileged and*
13 *confidential, in accordance with this section, if the organi-*
14 *zation’s certification is terminated or revoked or if the orga-*
15 *nization otherwise ceases to qualify as a patient safety orga-*
16 *nization.*

17 “(k) *REPORTS ON STRATEGIES TO IMPROVE PATIENT*
18 *SAFETY.—*

19 “(1) *DRAFT REPORT.—Not later than the date*
20 *that is 18 months after any National Patient Safety*
21 *Database is operational, the Secretary, in consulta-*
22 *tion with the Director, shall prepare a draft report on*
23 *effective strategies for reducing medical errors and in-*
24 *creasing patient safety. The draft report shall include*
25 *any measure determined appropriate by the Secretary*

1 to encourage the appropriate use of such strategies,
2 including use in any federally funded programs. The
3 Secretary shall make the draft report available for
4 public comment and submit the draft report to the In-
5 stitute of Medicine for review.

6 “(2) *FINAL REPORT.*—Not later than 1 year
7 after the date described in paragraph (1), the Sec-
8 retary shall submit a final report to the Congress that
9 includes, in an appendix, any findings by the Insti-
10 tute of Medicine concerning research on the strategies
11 discussed in the draft report and any modifications
12 made by the Secretary based on such findings.

13 **“SEC. 923. NATIONAL DATABASE.**

14 “(a) *AUTHORITY.*—

15 “(1) *IN GENERAL.*—In conducting activities
16 under this part, the Secretary shall provide for the es-
17 tablishment and maintenance of a database to receive
18 relevant nonidentifiable patient safety work product,
19 and may designate entities to collect relevant non-
20 identifiable patient safety work product that is volun-
21 tarily reported by patient safety organizations upon
22 the request of the Secretary. Any database established
23 or designated under this paragraph may be referred
24 to as a ‘National Patient Safety Database’.

1 “(2) *USE OF INFORMATION.*—*Information re-*
2 *ported to any National Patient Safety Database shall*
3 *be used to analyze national and regional statistics,*
4 *including trends and patterns of health care errors.*
5 *The information resulting from such analyses may be*
6 *included in the annual quality reports prepared*
7 *under section 913(b)(2).*

8 “(3) *ADVISORY ROLE.*—*The Secretary shall pro-*
9 *vide scientific support to patient safety organizations,*
10 *including the dissemination of methodologies and evi-*
11 *dence-based information related to root causes and*
12 *quality improvement.*

13 “(b) *STANDARDS.*—*In establishing or designating a*
14 *database under subsection (a)(1), the Secretary shall, in*
15 *consultation with representatives of patient safety organiza-*
16 *tions, the provider community, and the health information*
17 *technology industry, determine common formats for the vol-*
18 *untary reporting of nonidentifiable patient safety work*
19 *product, including necessary elements, common and con-*
20 *sistent definitions, and a standardized computer interface*
21 *for the processing of the work product. To the extent prac-*
22 *ticable, such standards shall be consistent with the adminis-*
23 *trative simplification provisions of part C of title XI of the*
24 *Social Security Act.*

1 “(c) *CERTAIN METHODOLOGIES FOR COLLECTION.*—
2 *The Secretary shall ensure that the methodologies for the*
3 *collection of nonidentifiable patient safety work product for*
4 *any National Patient Safety Database include the meth-*
5 *odologies developed or recommended by the Patient Safety*
6 *Task Force of the Department of Health and Human Serv-*
7 *ices.*

8 “(d) *FACILITATION OF INFORMATION EXCHANGE.*—*To*
9 *the extent practicable, the Secretary may facilitate the di-*
10 *rect link of information between providers and patient safe-*
11 *ty organizations and between patient safety organizations*
12 *and any National Patient Safety Database.*

13 “(e) *RESTRICTION ON TRANSFER.*—*Only nonidentifi-*
14 *able information may be transferred to any National Pa-*
15 *tient Safety Database.*

16 **“SEC. 924. TECHNICAL ASSISTANCE.**

17 “(a) *IN GENERAL.*—*The Secretary, acting through the*
18 *Director, may—*

19 “(1) *provide technical assistance to patient safe-*
20 *ty organizations, and to States with reporting sys-*
21 *tems for health care errors; and*

22 “(2) *provide guidance on the type of data to be*
23 *voluntarily submitted to any National Patient Safety*
24 *Database.*

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

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

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

9 *“(1) The mission of the patient safety organiza-*
10 *tion is to conduct activities that are to improve pa-*
11 *tient safety and the quality of health care delivery*
12 *and is not in conflict of interest with the providers*
13 *that contract with the patient safety organization.*

14 *“(2) The patient safety organization has appro-*
15 *priately qualified staff, including licensed or certified*
16 *medical professionals.*

17 *“(3) The patient safety organization, within any*
18 *2 year period, contracts with more than 1 provider*
19 *for the purpose of receiving and reviewing patient*
20 *safety work product.*

21 *“(4) The patient safety organization is not a*
22 *component of a health insurer or other entity that of-*
23 *fers a group health plan or health insurance coverage.*

24 *“(5) The patient safety organization is managed,*
25 *controlled, and operated independently from any pro-*

1 *vider that contracts with the patient safety organiza-*
2 *tion for reporting patient safety work product.*

3 *“(6) To the extent practical and appropriate, the*
4 *patient safety organization collects patient safety*
5 *work product from providers in a standardized man-*
6 *ner that permits valid comparisons of similar cases*
7 *among similar providers.*

8 *“(d) ADDITIONAL CRITERIA FOR COMPONENT ORGANI-*
9 *ZATIONS.—If a patient safety organization is a component*
10 *of another organization, the patient safety organization*
11 *must, in addition to meeting the criteria described in sub-*
12 *section (c), meet the following criteria as conditions of cer-*
13 *tification:*

14 *“(1) The patient safety organization maintains*
15 *patient safety work product separately from the rest*
16 *of the organization, and establishes appropriate secu-*
17 *rity measures to maintain the confidentiality of the*
18 *patient safety work product.*

19 *“(2) The patient safety organization does not*
20 *make an unauthorized disclosure under this Act of*
21 *patient safety work product to the rest of the organi-*
22 *zation in breach of confidentiality.*

23 *“(3) The mission of the patient safety organiza-*
24 *tion does not create a conflict of interest with the rest*
25 *of the organization.”.*

1 (b) *AUTHORIZATION OF APPROPRIATIONS.*—Section
 2 937 of the Public Health Service Act (as redesignated by
 3 subsection (a)) is amended by adding at the end the fol-
 4 lowing:

5 “(e) *PATIENT SAFETY AND QUALITY IMPROVEMENT.*—
 6 For the purpose of carrying out part C, there are authorized
 7 to be appropriated such sums as may be necessary for each
 8 of the fiscal years 2004 through 2008.”.

9 **SEC. 4. PROMOTING THE DIFFUSION AND INTEROPER-**
 10 **ABILITY OF INFORMATION TECHNOLOGY SYS-**
 11 **TEMS INVOLVED WITH HEALTH CARE DELIV-**
 12 **ERY.**

13 (a) *VOLUNTARY STANDARDS.*—

14 (1) *IN GENERAL.*—Not later than 18 months
 15 after the date of the enactment of this Act, the Sec-
 16 retary of Health and Human Services (in this section
 17 referred to as the “Secretary”) shall—

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

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

1 (i) the ability of such systems to cap-
2 ture and aggregate clinically specific data
3 to enable evidence-based medicine and other
4 applications that promote the electronic ex-
5 change of patient medical record informa-
6 tion; and

7 (ii) the cost that meeting such stand-
8 ards would have on providing health care in
9 the United States and the increased effi-
10 ciencies in providing such care achieved
11 under the standards;

12 (C) in developing or adopting such stand-
13 ards and to the extent practicable, test the effi-
14 cacy, usability, and scalability of proposed inter-
15 operability standards within a variety of clinical
16 settings, including an urban academic medical
17 center, a rural hospital, a community health cen-
18 ter, and a community hospital; and

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

21 (2) CONSULTATION.—In developing or adopting
22 standards under paragraph (1)(A), the Secretary
23 shall consider the recommendations of the National
24 Committee on Vital Health Statistics for the stand-
25 ardization of message formatting, coding, and vocabu-

1 *beler of a drug or biological product that is subject to regu-*
2 *lation by the Food and Drug Administration, to include*
3 *a unique product identifier on the packaging of the drug*
4 *or biological product.*

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

7 “(A) *is affixed by the manufacturer, labeler, or*
8 *packager to each drug or biological product described*
9 *in paragraph (1) at each packaging level;*

10 “(B) *uniquely identifies the item and meets the*
11 *standards required by this section; and*

12 “(C) *can be read by a scanning device or other*
13 *technology acceptable to the Secretary.*

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

17 “(A) *the National Drug Code maintained by the*
18 *Food and Drug Administration;*

19 “(B) *commercially accepted standards estab-*
20 *lished by organizations that are accredited by the*
21 *American National Standards Institute, such as the*
22 *Health Industry Business Communication Council or*
23 *the Uniform Code Council; or*

24 “(C) *other identification formats that the Sec-*
25 *retary deems appropriate.*

1 *fairly evaluated, including equipment or services.*
2 *Amounts provided by the Federal Government,*
3 *or services assisted or subsidized to any signifi-*
4 *cant extent by the Federal Government, may not*
5 *be included in determining the amount of such*
6 *non-Federal contributions.*

7 **(b) STUDY.—**

8 **(1) IN GENERAL.—***The Secretary, acting through*
9 *the Director of the Agency for Healthcare Research*
10 *and Quality, shall support a study to assess existing*
11 *scientific evidence regarding the effectiveness and cost-*
12 *effectiveness of the use of electronic prescription pro-*
13 *grams intended to improve the efficiency of prescrip-*
14 *tion ordering and the safe and effective use of pre-*
15 *scription drugs. The study shall address the following:*

16 **(A)** *The ability of such programs to reduce*
17 *medical errors and improve the quality and safe-*
18 *ty of patient care.*

19 **(B)** *The impact of the use of such programs*
20 *on physicians, pharmacists, and patients, in-*
21 *cluding such factors as direct and indirect costs,*
22 *changes in productivity, and satisfaction.*

23 **(C)** *The effectiveness of strategies for over-*
24 *coming barriers to the use of electronic prescrip-*
25 *tion programs.*

1 (2) *REPORT.*—*The Secretary shall ensure that,*
2 *not later than 18 months after the date of the enact-*
3 *ment of this Act, a report containing the findings of*
4 *the study under paragraph (1) is submitted to the ap-*
5 *propriate committees of the Congress.*

6 (3) *DISSEMINATION OF FINDINGS.*—*The Sec-*
7 *retary shall disseminate the findings of the study*
8 *under paragraph (1) to appropriate public and pri-*
9 *vate entities.*

10 (c) *DEVELOPMENT OF MODEL.*—*The Secretary, acting*
11 *through the Director of the Agency for Healthcare Research*
12 *and Quality, may develop an Internet-based mathematical*
13 *model that simulates the cost and effectiveness of electronic*
14 *prescription programs for qualified practitioners. The*
15 *model may be designed to allow qualified practitioners to*
16 *estimate, through an interactive interface, the impact of*
17 *electronic prescribing on their practices, including the re-*
18 *duction in drug-related health care errors.*

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

20 (1) *The term “electronic prescription pro-*
21 *gram”—*

22 (A) *means a program for the electronic sub-*
23 *mission and processing of prescriptions; and*

24 (B) *includes the hardware (including com-*
25 *puters and other electronic devices) and software*

1 *programs for the electronic submission of pre-*
2 *scriptions to pharmacies, the processing of such*
3 *submissions by pharmacies, and decision-support*
4 *programs.*

5 (2) *The term “qualified practitioner” means a*
6 *practitioner licensed by law to administer or dispense*
7 *prescription drugs.*

8 **SEC. 7. GRANTS TO HOSPITALS AND OTHER HEALTH CARE**

9 **PROVIDERS FOR INFORMATION TECH-**
10 **NOLOGIES.**

11 (a) *IN GENERAL.*—*The Secretary of Health and*
12 *Human Services (in this section referred to as the “Sec-*
13 *retary”)* shall make grants to hospitals and other health
14 *care providers (but not more than 1 grant to any 1 hospital*
15 *or provider) to pay the costs of acquiring or implementing*
16 *information technologies whose purposes are—*

17 (1) *to improve quality of care and patient safety;*
18 *and*

19 (2) *to reduce adverse events and health care com-*
20 *plications resulting from medication errors.*

21 (b) *SPECIAL CONSIDERATION.*—*In making grants*
22 *under subsection (a), the Secretary shall give special consid-*
23 *eration to applicants who seek to promote the following:*

1 (1) *Interoperability across hospital services or*
2 *departments using standards developed or adopted by*
3 *the Secretary under section 4.*

4 (2) *Electronic communication of patient data*
5 *across the spectrum of health care delivery.*

6 (3) *Computerized physician order entry or bar*
7 *coding applications.*

8 (4) *Electronic communication of patient data in*
9 *hospitals that provide services to underserved or low-*
10 *income populations.*

11 (5) *Improved clinical decisionmaking through*
12 *acquisition and implementation of decision-support*
13 *technologies.*

14 (c) *CERTAIN GRANT CONDITIONS.*—*A condition for the*
15 *receipt of a grant under subsection (a) is that the applicant*
16 *involved meet the following requirements:*

17 (1) *The applicant agrees to carry out a program*
18 *to measure, analyze, and report patient safety and*
19 *medical errors at the hospital or other health care*
20 *provider involved, to submit to the Secretary a de-*
21 *scription of the methodology that will be used, and to*
22 *have such program in effect as soon as practicable*
23 *after the application for the grant is approved, with-*
24 *out regard to whether information technologies under*
25 *the grant have been implemented.*

1 (2) *The applicant has arranged for an evalua-*
2 *tion that addresses the effectiveness and cost-effective-*
3 *ness of the information technology for which the grant*
4 *is provided and its impact on the quality and safety*
5 *of patient care, submitted the evaluation plan to the*
6 *Secretary, and received approval from the Secretary*
7 *of the applicant’s methodology.*

8 (3) *The applicant has or is developing a patient*
9 *safety evaluation system (as that term is defined in*
10 *section 921 of the Public Health Service Act (as*
11 *amended by section 3)) for reporting health care er-*
12 *rors to a patient safety organization.*

13 (4) *The applicant agrees to provide the Secretary*
14 *with such information as the Secretary may require*
15 *regarding the use of funds under this program or its*
16 *impact.*

17 (5) *The applicant provides assurances satisfac-*
18 *tory to the Secretary that any information technology*
19 *planned, acquired, or implemented with grant funds*
20 *under this section will be part of an information pro-*
21 *gram that—*

22 (A) *carries out the purposes described in*
23 *subsection (a); and*

1 (B) is comprehensive or will be expanded to
2 become comprehensive, regardless of whether Fed-
3 eral assistance is available for such expansion.

4 (d) *TECHNICAL ASSISTANCE TO GRANTEES.*—The Sec-
5 retary, acting through the Director of the Agency for
6 Healthcare Research and Quality, shall provide technical
7 assistance to applicants and grantees to ensure the appro-
8 priate evaluation of the information technologies for which
9 grants are awarded under this section, such as—

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

12 (2) developing mechanisms to ensure ongoing
13 communications between grantees and evaluators to
14 facilitate the identification and resolution of problems
15 as they arise, ensure mutual learning, and promote
16 the rapid dissemination of information;

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

19 (4) disseminating evidence-based information in
20 interim and final reports to patient safety organiza-
21 tions, as appropriate.

22 (e) *EVALUATION REPORTS BY GRANTEE.*—A condition
23 for the receipt of a grant under subsection (a) is that the
24 applicant agree to submit an interim and a final report
25 to the Secretary in accordance with this subsection.

1 (1) *INTERIM REPORT.*—Not later than 1 year
2 after the implementation of information technologies
3 under the grant is completed, the applicant will sub-
4 mit an interim report to the Secretary describing the
5 initial effectiveness of such technologies in carrying
6 out the purposes described in subsection (a).

7 (2) *FINAL REPORT.*—Not later than 3 years after
8 the implementation of information technologies under
9 the grant is completed, the applicant will submit a
10 final report to the Secretary describing the effective-
11 ness and cost-effectiveness of such technologies and ad-
12 dressing other issues determined to be important in
13 carrying out the purposes described in subsection (a).

14 (3) *RELATION TO DISBURSEMENT OF GRANT.*—
15 In disbursing a grant under subsection (a), the Sec-
16 retary shall withhold $\frac{1}{3}$ of the grant until the grantee
17 submits to the Secretary the report required in para-
18 graph (1).

19 (f) *REPORTS BY SECRETARY.*—

20 (1) *INTERIM REPORTS.*—

21 (A) *IN GENERAL.*—Through the fiscal year
22 preceding the fiscal year in which the final re-
23 port under paragraph (2) is prepared, the Sec-
24 retary shall submit to the Committee on Energy
25 and Commerce of the House of Representatives

1 *and the Committee on Health, Education, Labor,*
2 *and Pensions of the Senate periodic reports on*
3 *the grant program under subsection (a). Such re-*
4 *ports shall be submitted not less frequently than*
5 *once each fiscal year, beginning with fiscal year*
6 *2004.*

7 *(B) CONTENTS.—A report under subpara-*
8 *graph (A) shall include information on—*

9 *(i) the number of grants made;*

10 *(ii) the nature of the projects for which*
11 *funding is provided under the grant pro-*
12 *gram;*

13 *(iii) the geographic distribution of*
14 *grant recipients; and*

15 *(iv) such other matters as the Sec-*
16 *retary determines appropriate.*

17 *(2) FINAL REPORT.—Not later than 180 days*
18 *after the date on which the last of the reports is due*
19 *under subsection (e)(2), the Secretary shall submit a*
20 *final report to the committees referred to in para-*
21 *graph (1)(A) on the grant program under subsection*
22 *(a), together with such recommendations for legisla-*
23 *tion and administrative action as the Secretary deter-*
24 *mines appropriate.*

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

1 (1) *The term “costs”, with respect to information*
2 *technologies referred to in subsection (a), includes*
3 *total expenditures incurred for—*

4 (A) *purchasing, leasing, and installing com-*
5 *puter software and hardware, including hand-*
6 *held computer technologies;*

7 (B) *making improvements to existing com-*
8 *puter software and hardware; and*

9 (C) *purchasing or leasing communications*
10 *capabilities necessary for clinical data access,*
11 *storage, and exchange.*

12 (2) *The term “health care provider” has the same*
13 *meaning given to the term “provider” in section 921*
14 *of the Public Health Services Act (as amended by this*
15 *Act).*

16 (h) *TERMINATION OF GRANT AUTHORITIES.—The au-*
17 *thority of the Secretary to make grants under subsection*
18 *(a) terminates upon the expiration of fiscal year 2011.*

19 (i) *MATCHING FUNDS.—*

20 (1) *IN GENERAL.—With respect to the costs of a*
21 *grant to be carried out under this section, such grant*
22 *may be made only if the applicant agrees to make*
23 *available (directly or through donations from public*
24 *or private entities) non-Federal contributions toward*
25 *such costs in an amount that is not less than 50 per-*

1 *cent of such costs (\$1 for each \$1 of Federal funds*
2 *provided in the grant).*

3 (2) *DETERMINATION OF AMOUNTS CONTRIB-*
4 *UTED.—Amounts provided by the Federal Govern-*
5 *ment, or services assisted or subsidized to any signifi-*
6 *cant extent by the Federal Government, may not be*
7 *included in determining the amount of such non-Fed-*
8 *eral contributions.*

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

10 **UNDER SECTIONS 6 AND 7.**

11 *For the purpose of carrying out sections 6 and 7, there*
12 *are authorized to be appropriated \$25,000,000 for each of*
13 *fiscal years 2004 and 2005.*

Union Calendar No. 19

108TH CONGRESS
1ST SESSION

H. R. 663

[Report No. 108-28]

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.

MARCH 6, 2003

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed