

## Union Calendar No. 117

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 3205

[Report No. 109-197]

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.

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### 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

JULY 27, 2005

Additional sponsors: Mr. MURPHY, Mr. BAIRD, Mr. WHITFIELD, Ms. ESHOO, Mr. BISHOP of Georgia, Mr. BURGESS, Mr. NORWOOD, Mr. WALDEN of Oregon, Mr. UPTON, Mrs. BONO, Mrs. DRAKE, Mr. GENE GREEN of Texas, Mr. EMANUEL, Mr. PICKERING, and Mr. MCDERMOTT

JULY 27, 2005

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 July 12, 2005]

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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.

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 “Pa-*  
 5 *tient Safety and Quality Improvement Act of 2005”.*

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. Amendments to Public Health Service Act.*

*“PART C—PATIENT SAFETY IMPROVEMENT*

*“Sec. 921. Definitions.*

*“Sec. 922. Privilege and confidentiality protections.*

*“Sec. 923. Network of patient safety databases.*

*“Sec. 924. Patient safety organization certification and listing.*

*“Sec. 925. Technical assistance.*

*“Sec. 926. Severability.*

8 **SEC. 2. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.**

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

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

13 (2) *by redesignating part C as part D;*

14 (3) *by redesignating sections 921 through 928, as*  
 15 *sections 931 through 938, respectively;*

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

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

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

2       **“SEC. 921. DEFINITIONS.**

3       *“In this part:*

4               *“(1) HIPAA CONFIDENTIALITY REGULATIONS.—*

5       *The term ‘HIPAA confidentiality regulations’ means*  
6       *regulations promulgated under section 264(c) of the*  
7       *Health Insurance Portability and Accountability Act*  
8       *of 1996 (Public Law 104–191; 110 Stat. 2033).*

9               *“(2) IDENTIFIABLE PATIENT SAFETY WORK*  
10       *PRODUCT.—The term ‘identifiable patient safety work*  
11       *product’ means patient safety work product that—*

12               *“(A) is presented in a form and manner*  
13       *that allows the identification of any provider*  
14       *that is a subject of the work product, or any pro-*  
15       *viders that participate in activities that are a*  
16       *subject of the work product;*

17               *“(B) constitutes individually identifiable*  
18       *health information as that term is defined in the*  
19       *HIPAA confidentiality regulations; or*

20               *“(C) is presented in a form and manner*  
21       *that allows the identification of an individual*  
22       *who reported information in the manner speci-*  
23       *fied in section 922(e).*

24               *“(3) NONIDENTIFIABLE PATIENT SAFETY WORK*  
25       *PRODUCT.—The term ‘nonidentifiable patient safety*  
26       *work product’ means patient safety work product that*

1        *is not identifiable patient safety work product (as de-*  
2        *fin ed in paragraph (2)).*

3                *“(4) PATIENT SAFETY ORGANIZATION.—The term*  
4        *‘patient safety organization’ means a private or pub-*  
5        *lic entity or component thereof that is listed by the*  
6        *Secretary pursuant to section 924(d).*

7                *“(5) PATIENT SAFETY ACTIVITIES.—The term*  
8        *‘patient safety activities’ means the following activi-*  
9        *ties:*

10                *“(A) Efforts to improve patient safety and*  
11        *the quality of health care delivery.*

12                *“(B) The collection and analysis of patient*  
13        *safety work product.*

14                *“(C) The development and dissemination of*  
15        *information with respect to improving patient*  
16        *safety, such as recommendations, protocols, or*  
17        *information regarding best practices.*

18                *“(D) The utilization of patient safety work*  
19        *product for the purposes of encouraging a culture*  
20        *of safety and of providing feedback and assist-*  
21        *ance to effectively minimize patient risk.*

22                *“(E) The maintenance of procedures to pre-*  
23        *serve confidentiality with respect to patient safe-*  
24        *ty work product.*

1           “(F) *The provision of appropriate security*  
2           *measures with respect to patient safety work*  
3           *product.*

4           “(G) *The utilization of qualified staff.*

5           “(H) *Activities related to the operation of a*  
6           *patient safety evaluation system and to the pro-*  
7           *vision of feedback to participants in a patient*  
8           *safety evaluation system.*

9           “(6) *PATIENT SAFETY EVALUATION SYSTEM.—*  
10          *The term ‘patient safety evaluation system’ means the*  
11          *collection, management, or analysis of information*  
12          *for reporting to or by a patient safety organization.*

13          “(7) *PATIENT SAFETY WORK PRODUCT.—*

14          “(A) *IN GENERAL.—Except as provided in*  
15          *subparagraph (B), the term ‘patient safety work*  
16          *product’ means any data, reports, records,*  
17          *memoranda, analyses (such as root cause anal-*  
18          *yses), or written or oral statements—*

19                 “(i) *which—*

20                         “(I) *are assembled or developed by*  
21                         *a provider for reporting to a patient*  
22                         *safety organization and are reported to*  
23                         *a patient safety organization; or*

1                   “(II) are developed by a patient  
2                   safety organization for the conduct of  
3                   patient safety activities;

4                   and which could result in improved patient  
5                   safety, health care quality, or health care  
6                   outcomes; or

7                   “(i) which identify or constitute the  
8                   deliberations or analysis of, or identify the  
9                   fact of reporting pursuant to, a patient  
10                  safety evaluation system.

11                  “(B) CLARIFICATION.—

12                  “(i) Information described in subpara-  
13                  graph (A) does not include a patient’s med-  
14                  ical record, billing and discharge informa-  
15                  tion, or any other original patient or pro-  
16                  vider record.

17                  “(ii) Information described in sub-  
18                  paragraph (A) does not include information  
19                  that is collected, maintained, or developed  
20                  separately, or exists separately, from a pa-  
21                  tient safety evaluation system. Such sepa-  
22                  rate information or a copy thereof reported  
23                  to a patient safety organization shall not by  
24                  reason of its reporting be considered patient  
25                  safety work product.

1           “(iii) *Nothing in this part shall be*  
2           *construed to limit—*

3                   “(I) *the discovery of or admissi-*  
4                   *bility of information described in this*  
5                   *subparagraph in a criminal, civil, or*  
6                   *administrative proceeding;*

7                   “(II) *the reporting of information*  
8                   *described in this subparagraph to a*  
9                   *Federal, State, or local governmental*  
10                  *agency for public health surveillance,*  
11                  *investigation, or other public health*  
12                  *purposes or health oversight purposes;*  
13                  *or*

14                  “(III) *a provider’s recordkeeping*  
15                  *obligation with respect to information*  
16                  *described in this subparagraph under*  
17                  *Federal, State, or local law.*

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

19                   “(A) *an individual or entity licensed or*  
20                   *otherwise authorized under State law to provide*  
21                   *health care services, including—*

22                           “(i) *a hospital, nursing facility, com-*  
23                           *prehensive outpatient rehabilitation facility,*  
24                           *home health agency, hospice program, renal*  
25                           *dialysis facility, ambulatory surgical center,*

1           *pharmacy, physician or health care practi-*  
2           *tioner's office, long term care facility, be-*  
3           *havior health residential treatment facility,*  
4           *clinical laboratory, or health center; or*

5           *“(ii) a physician, physician assistant,*  
6           *nurse practitioner, clinical nurse specialist,*  
7           *certified registered nurse anesthetist, cer-*  
8           *tified nurse midwife, psychologist, certified*  
9           *social worker, registered dietitian or nutri-*  
10          *tion professional, physical or occupational*  
11          *therapist, pharmacist, or other individual*  
12          *health care practitioner; or*

13          *“(B) any other individual or entity speci-*  
14          *fied in regulations promulgated by the Secretary.*

15   **“SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTEC-**  
16                    **TIONS.**

17          *“(a) PRIVILEGE.—Notwithstanding any other provi-*  
18          *sion of Federal, State, or local law, and subject to subsection*  
19          *(c), patient safety work product shall be privileged and shall*  
20          *not be—*

21                *“(1) subject to a Federal, State, or local civil,*  
22                *criminal, or administrative subpoena or order, in-*  
23                *cluding in a Federal, State, or local civil or adminis-*  
24                *trative disciplinary proceeding against a provider;*

1           “(2) *subject to discovery in connection with a*  
2           *Federal, State, or local civil, criminal, or administra-*  
3           *tive proceeding, including in a Federal, State, or*  
4           *local civil or administrative disciplinary proceeding*  
5           *against a provider;*

6           “(3) *subject to disclosure pursuant to section 552*  
7           *of title 5, United States Code (commonly known as*  
8           *the Freedom of Information Act) or any other similar*  
9           *Federal, State, or local law;*

10           “(4) *admitted as evidence in any Federal, State,*  
11           *or local governmental civil proceeding, criminal pro-*  
12           *ceeding, administrative rulemaking proceeding, or ad-*  
13           *ministrative adjudicatory proceeding, including any*  
14           *such proceeding against a provider; or*

15           “(5) *admitted in a professional disciplinary pro-*  
16           *ceeding of a professional disciplinary body established*  
17           *or specifically authorized under State law.*

18           “(b) *CONFIDENTIALITY OF PATIENT SAFETY WORK*  
19           *PRODUCT.—Notwithstanding any other provision of Fed-*  
20           *eral, State, or local law, and subject to subsection (c), pa-*  
21           *tient safety work product shall be confidential and shall not*  
22           *be disclosed.*

23           “(c) *EXCEPTIONS.—Except as provided in subsection*  
24           *(g)(3)—*

1           “(1) *EXCEPTIONS FROM PRIVILEGE AND CON-*  
2           *FIDENTIALITY.—Subsections (a) and (b) shall not*  
3           *apply to (and shall not be construed to prohibit) one*  
4           *or more of the following disclosures:*

5                   “(A) *Disclosure of relevant patient safety*  
6                   *work product for use in a criminal proceeding,*  
7                   *but only after a court makes an in camera deter-*  
8                   *mination that such patient safety work product*  
9                   *contains evidence of a criminal act and that*  
10                   *such patient safety work product is material to*  
11                   *the proceeding and not reasonably available from*  
12                   *any other source.*

13                   “(B) *Disclosure of patient safety work prod-*  
14                   *uct to the extent required to carry out subsection*  
15                   *(f)(4)(A).*

16                   “(C) *Disclosure of identifiable patient safety*  
17                   *work product if authorized by each provider*  
18                   *identified in such work product.*

19           “(2) *EXCEPTIONS FROM CONFIDENTIALITY.—*  
20           *Subsection (b) shall not apply to (and shall not be*  
21           *construed to prohibit) one or more of the following*  
22           *disclosures:*

23                   “(A) *Disclosure of patient safety work prod-*  
24                   *uct to carry out patient safety activities.*

1           “(B) Disclosure of nonidentifiable patient  
2 safety work product.

3           “(C) Disclosure of patient safety work prod-  
4 uct to grantees, contractors, or other entities car-  
5 rying out research, evaluation, or demonstration  
6 projects authorized, funded, certified, or other-  
7 wise sanctioned by rule or other means by the  
8 Secretary, for the purpose of conducting research  
9 to the extent that disclosure of protected health  
10 information would be allowed for such purpose  
11 under the HIPAA confidentiality regulations.

12           “(D) Disclosure by a provider to the Food  
13 and Drug Administration with respect to a  
14 product or activity regulated by the Food and  
15 Drug Administration.

16           “(E) Voluntary disclosure of patient safety  
17 work product by a provider to an accrediting  
18 body that accredits that provider.

19           “(F) Disclosures that the Secretary may de-  
20 termine, by rule or other means, are necessary  
21 for business operations and are consistent with  
22 the goals of this part.

23           “(G) Disclosure of patient safety work prod-  
24 uct to law enforcement authorities relating to the  
25 commission of a crime (or to an event reasonably

1           *believed to be a crime) if the person making the*  
2           *disclosure believes, reasonably under the cir-*  
3           *cumstances, that the patient safety work product*  
4           *that is disclosed is necessary for criminal law*  
5           *enforcement purposes.*

6           “(H) *With respect to a person other than a*  
7           *patient safety organization, the disclosure of pa-*  
8           *tient safety work product that does not include*  
9           *materials that—*

10                   “(i) *assess the quality of care of an*  
11                   *identifiable provider; or*

12                   “(ii) *describe or pertain to one or more*  
13                   *actions or failures to act by an identifiable*  
14                   *provider.*

15           “(3) *EXCEPTION FROM PRIVILEGE.—Subsection*  
16           *(a) shall not apply to (and shall not be construed to*  
17           *prohibit) voluntary disclosure of nonidentifiable pa-*  
18           *tient safety work product.*

19           “(d) *CONTINUED PROTECTION OF INFORMATION*  
20 *AFTER DISCLOSURE.—*

21                   “(1) *IN GENERAL.—Patient safety work product*  
22                   *that is disclosed under subsection (c) shall continue to*  
23                   *be privileged and confidential as provided for in sub-*  
24                   *sections (a) and (b), and such disclosure shall not be*  
25                   *treated as a waiver of privilege or confidentiality,*

1 *and the privileged and confidential nature of such*  
2 *work product shall also apply to such work product*  
3 *in the possession or control of a person to whom such*  
4 *work product was disclosed.*

5 “(2) *EXCEPTION.*—*Notwithstanding paragraph*  
6 *(1), and subject to paragraph (3)—*

7 “(A) *if patient safety work product is dis-*  
8 *closed in a criminal proceeding, the confiden-*  
9 *tiality protections provided for in subsection (b)*  
10 *shall no longer apply to the work product so dis-*  
11 *closed; and*

12 “(B) *if patient safety work product is dis-*  
13 *closed as provided for in subsection (c)(2)(B) (re-*  
14 *lating to disclosure of nonidentifiable patient*  
15 *safety work product), the privilege and confiden-*  
16 *tiality protections provided for in subsections (a)*  
17 *and (b) shall no longer apply to such work prod-*  
18 *uct.*

19 “(3) *CONSTRUCTION.*—*Paragraph (2) shall not*  
20 *be construed as terminating or limiting the privilege*  
21 *or confidentiality protections provided for in sub-*  
22 *section (a) or (b) with respect to patient safety work*  
23 *product other than the specific patient safety work*  
24 *product disclosed as provided for in subsection (c).*

25 “(4) *LIMITATIONS ON ACTIONS.*—

1           “(A) *PATIENT SAFETY ORGANIZATIONS.*—

2                   “(i) *IN GENERAL.*—*A patient safety or-*  
3                   *ganization shall not be compelled to disclose*  
4                   *information collected or developed under*  
5                   *this part whether or not such information is*  
6                   *patient safety work product unless such in-*  
7                   *formation is identified, is not patient safety*  
8                   *work product, and is not reasonably avail-*  
9                   *able from another source.*

10                   “(ii) *NONAPPLICATION.*—*The limita-*  
11                   *tion contained in clause (i) shall not apply*  
12                   *in an action against a patient safety orga-*  
13                   *nization or with respect to disclosures pur-*  
14                   *suant to subsection (c)(1).*

15                   “(B) *PROVIDERS.*—*An accrediting body*  
16                   *shall not take an accrediting action against a*  
17                   *provider based on the good faith participation of*  
18                   *the provider in the collection, development, re-*  
19                   *porting, or maintenance of patient safety work*  
20                   *product in accordance with this part. An accred-*  
21                   *iting body may not require a provider to reveal*  
22                   *its communications with any patient safety or-*  
23                   *ganization established in accordance with this*  
24                   *part.*

25                   “(e) *REPORTER PROTECTION.*—

1           “(1) *IN GENERAL.*—A provider may not take an  
2           *adverse employment action, as described in para-*  
3           *graph (2), against an individual based upon the fact*  
4           *that the individual in good faith reported informa-*  
5           *tion—*

6                     “(A) *to the provider with the intention of*  
7                     *having the information reported to a patient*  
8                     *safety organization; or*

9                     “(B) *directly to a patient safety organiza-*  
10                    *tion.*

11           “(2) *ADVERSE EMPLOYMENT ACTION.*—*For pur-*  
12           *poses of this subsection, an ‘adverse employment ac-*  
13           *tion’ includes—*

14                    “(A) *loss of employment, the failure to pro-*  
15                    *mote an individual, or the failure to provide any*  
16                    *other employment-related benefit for which the*  
17                    *individual would otherwise be eligible; or*

18                    “(B) *an adverse evaluation or decision*  
19                    *made in relation to accreditation, certification,*  
20                    *credentialing, or licensing of the individual.*

21           “(f) *ENFORCEMENT.*—

22                    “(1) *CIVIL MONETARY PENALTY.*—*Subject to*  
23                    *paragraphs (2) and (3), a person who discloses iden-*  
24                    *tifiable patient safety work product in knowing or*  
25                    *reckless violation of subsection (b) shall be subject to*

1       *a civil monetary penalty of not more than \$10,000*  
2       *for each act constituting such violation.*

3               “(2) *PROCEDURE.*—*The provisions of section*  
4       *1128A of the Social Security Act, other than sub-*  
5       *sections (a) and (b) and the first sentence of sub-*  
6       *section (c)(1), shall apply to civil money penalties*  
7       *under this subsection in the same manner as such*  
8       *provisions apply to a penalty or proceeding under*  
9       *section 1128A of the Social Security Act.*

10              “(3) *RELATION TO HIPAA.*—*Penalties shall not*  
11       *be imposed both under this subsection and under the*  
12       *regulations issued pursuant to section 264(c)(1) of the*  
13       *Health Insurance Portability and Accountability Act*  
14       *of 1996 (42 U.S.C. 1320d–2 note) for a single act or*  
15       *omission.*

16              “(4) *EQUITABLE RELIEF.*—

17                      “(A) *IN GENERAL.*—*Without limiting rem-*  
18       *edies available to other parties, a civil action*  
19       *may be brought by any aggrieved individual to*  
20       *enjoin any act or practice that violates sub-*  
21       *section (e) and to obtain other appropriate equi-*  
22       *table relief (including reinstatement, back pay,*  
23       *and restoration of benefits) to redress such viola-*  
24       *tion.*

1           “(B) *AGAINST STATE EMPLOYEES.*—An en-  
2           tity that is a State or an agency of a State gov-  
3           ernment may not assert the privilege described  
4           in subsection (a) unless before the time of the as-  
5           sertion, the entity or, in the case of and with re-  
6           spect to an agency, the State has consented to be  
7           subject to an action described in subparagraph  
8           (A), and that consent has remained in effect.

9           “(g) *RULE OF CONSTRUCTION.*—Nothing in this sec-  
10          tion shall be construed—

11           “(1) to limit the application of other Federal,  
12          State, or local laws that provide greater privilege or  
13          confidentiality protections than the privilege and con-  
14          fidentiality protections provided for in this section;

15           “(2) to limit, alter, or affect the requirements of  
16          Federal, State, or local law pertaining to information  
17          that is not privileged or confidential under this sec-  
18          tion;

19           “(3) except as provided in subsection (i), to alter  
20          or affect the implementation of any provision of the  
21          HIPAA confidentiality regulations or section 1176 of  
22          the Social Security Act (or regulations promulgated  
23          under such section);

24           “(4) to limit the authority of any provider, pa-  
25          tient safety organization, or other entity to enter into

1       *a contract requiring greater confidentiality or dele-*  
2       *gating authority to make a disclosure or use in ac-*  
3       *cordance with this section;*

4             “(5) *as preempting or otherwise affecting any*  
5       *State law requiring a provider to report information*  
6       *that is not patient safety work product; or*

7             “(6) *to limit, alter, or affect any requirement for*  
8       *reporting to the Food and Drug Administration in-*  
9       *formation regarding the safety of a product or activ-*  
10       *ity regulated by the Food and Drug Administration.*

11       “(h) *CLARIFICATION.—Nothing in this part prohibits*  
12       *any person from conducting additional analysis for any*  
13       *purpose regardless of whether such additional analysis in-*  
14       *volves issues identical to or similar to those for which infor-*  
15       *mation was reported to or assessed by a patient safety orga-*  
16       *nization or a patient safety evaluation system.*

17       “(i) *CLARIFICATION OF APPLICATION OF HIPAA CON-*  
18       *FIDENTIALITY REGULATIONS TO PATIENT SAFETY ORGANI-*  
19       *ZATIONS.—For purposes of applying the HIPAA confiden-*  
20       *tiality regulations—*

21             “(1) *patient safety organizations shall be treated*  
22       *as business associates; and*

23             “(2) *patient safety activities of such organiza-*  
24       *tions in relation to a provider are deemed to be health*

1       *care operations (as defined in such regulations) of the*  
2       *provider.*

3       “(j) *REPORTS ON STRATEGIES TO IMPROVE PATIENT*  
4 *SAFETY.*—

5               “(1) *DRAFT REPORT.*—*Not later than the date*  
6       *that is 18 months after any network of patient safety*  
7       *databases is operational, the Secretary, in consulta-*  
8       *tion with the Director, shall prepare a draft report on*  
9       *effective strategies for reducing medical errors and in-*  
10       *creasing patient safety. The draft report shall include*  
11       *any measure determined appropriate by the Secretary*  
12       *to encourage the appropriate use of such strategies,*  
13       *including use in any federally funded programs. The*  
14       *Secretary shall make the draft report available for*  
15       *public comment and submit the draft report to the In-*  
16       *stitute of Medicine for review.*

17               “(2) *FINAL REPORT.*—*Not later than 1 year*  
18       *after the date described in paragraph (1), the Sec-*  
19       *retary shall submit a final report to the Congress.*

20       “**SEC. 923. NETWORK OF PATIENT SAFETY DATABASES.**

21               “(a) *IN GENERAL.*—*The Secretary shall facilitate the*  
22       *creation of, and maintain, a network of patient safety data-*  
23       *bases that provides an interactive evidence-based manage-*  
24       *ment resource for providers, patient safety organizations,*  
25       *and other entities. The network of databases shall have the*

1 *capacity to accept, aggregate across the network, and ana-*  
2 *lyze nonidentifiable patient safety work product voluntarily*  
3 *reported by patient safety organizations, providers, or other*  
4 *entities. The Secretary shall assess the feasibility of pro-*  
5 *viding for a single point of access to the network for quali-*  
6 *fied researchers for information aggregated across the net-*  
7 *work and, if feasible, provide for implementation.*

8       “(b) *DATA STANDARDS.—The Secretary may deter-*  
9 *mine common formats for the reporting to and among the*  
10 *network of patient safety databases maintained under sub-*  
11 *section (a) of nonidentifiable patient safety work product,*  
12 *including necessary work product elements, common and*  
13 *consistent definitions, and a standardized computer inter-*  
14 *face for the processing of such work product. To the extent*  
15 *practicable, such standards shall be consistent with the ad-*  
16 *ministrative simplification provisions of part C of title XI*  
17 *of the Social Security Act.*

18       “(c) *USE OF INFORMATION.—Information reported to*  
19 *and among the network of patient safety databases under*  
20 *subsection (a) shall be used to analyze national and re-*  
21 *gional statistics, including trends and patterns of health*  
22 *care errors. The information resulting from such analyses*  
23 *shall be made available to the public and included in the*  
24 *annual quality reports prepared under section 913(b)(2).*

1 **“SEC. 924. PATIENT SAFETY ORGANIZATION CERTIFI-**  
2 **CATION AND LISTING.**

3 *“(a) CERTIFICATION.—*

4 *“(1) INITIAL CERTIFICATION.—An entity that*  
5 *seeks to be a patient safety organization shall submit*  
6 *an initial certification to the Secretary that the enti-*  
7 *ty—*

8 *“(A) has policies and procedures in place to*  
9 *perform each of the patient safety activities de-*  
10 *scribed in section 921(5); and*

11 *“(B) upon being listed under subsection (d),*  
12 *will comply with the criteria described in sub-*  
13 *section (b).*

14 *“(2) SUBSEQUENT CERTIFICATIONS.—An entity*  
15 *that is a patient safety organization shall submit*  
16 *every 3 years after the date of its initial listing under*  
17 *subsection (d) a subsequent certification to the Sec-*  
18 *retary that the entity—*

19 *“(A) is performing each of the patient safe-*  
20 *ty activities described in section 921(5); and*

21 *“(B) is complying with the criteria de-*  
22 *scribed in subsection (b).*

23 *“(b) CRITERIA.—*

24 *“(1) IN GENERAL.—The following are criteria for*  
25 *the initial and subsequent certification of an entity as*  
26 *a patient safety organization:*

1           “(A) *The mission and primary activity of*  
2 *the entity are to conduct activities that are to*  
3 *improve patient safety and the quality of health*  
4 *care delivery.*

5           “(B) *The entity has appropriately qualified*  
6 *staff (whether directly or through contract), in-*  
7 *cluding licensed or certified medical profes-*  
8 *sionals.*

9           “(C) *The entity, within each 24-month pe-*  
10 *riod that begins after the date of the initial list-*  
11 *ing under subsection (d), has bona fide contracts,*  
12 *each of a reasonable period of time, with more*  
13 *than 1 provider for the purpose of receiving and*  
14 *reviewing patient safety work product.*

15           “(D) *The entity is not, and is not a compo-*  
16 *nent of, a health insurance issuer (as defined in*  
17 *section 2791(b)(2)).*

18           “(E) *The entity shall fully disclose—*

19                   “(i) *any financial, reporting, or con-*  
20 *tractual relationship between the entity and*  
21 *any provider that contracts with the entity;*  
22 *and*

23                   “(ii) *if applicable, the fact that the en-*  
24 *tity is not managed, controlled, and oper-*

1            *ated independently from any provider that*  
2            *contracts with the entity.*

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

8            *“(G) The utilization of patient safety work*  
9            *product for the purpose of providing direct feed-*  
10           *back and assistance to providers to effectively*  
11           *minimize patient risk.*

12           *“(2) ADDITIONAL CRITERIA FOR COMPONENT OR-*  
13           *GANIZATIONS.—If an entity that seeks to be a patient*  
14           *safety organization is a component of another organi-*  
15           *zation, the following are additional criteria for the*  
16           *initial and subsequent certification of the entity as a*  
17           *patient safety organization:*

18           *“(A) The entity maintains patient safety*  
19           *work product separately from the rest of the or-*  
20           *ganization, and establishes appropriate security*  
21           *measures to maintain the confidentiality of the*  
22           *patient safety work product.*

23           *“(B) The entity does not make an unau-*  
24           *thorized disclosure under this part of patient*

1           *safety work product to the rest of the organiza-*  
2           *tion in breach of confidentiality.*

3           “(C) *The mission of the entity does not cre-*  
4           *ate a conflict of interest with the rest of the orga-*  
5           *nization.*

6           “(c) *REVIEW OF CERTIFICATION.—*

7           “(1) *IN GENERAL.—*

8           “(A) *INITIAL CERTIFICATION.—Upon the*  
9           *submission by an entity of an initial certifi-*  
10          *cation under subsection (a)(1), the Secretary*  
11          *shall determine if the certification meets the re-*  
12          *quirements of subparagraphs (A) and (B) of such*  
13          *subsection.*

14          “(B) *SUBSEQUENT CERTIFICATION.—Upon*  
15          *the submission by an entity of a subsequent cer-*  
16          *tification under subsection (a)(2), the Secretary*  
17          *shall review the certification with respect to re-*  
18          *quirements of subparagraphs (A) and (B) of such*  
19          *subsection.*

20          “(2) *NOTICE OF ACCEPTANCE OR NON-ACCEPT-*  
21          *ANCE.—If the Secretary determines that—*

22                 “(A) *an entity’s initial certification meets*  
23                 *requirements referred to in paragraph (1)(A), the*  
24                 *Secretary shall notify the entity of the accept-*  
25                 *ance of such certification; or*

1           “(B) *an entity’s initial certification does*  
2           *not meet such requirements, the Secretary shall*  
3           *notify the entity that such certification is not ac-*  
4           *cepted and the reasons therefor.*

5           “(3) *DISCLOSURES REGARDING RELATIONSHIP*  
6           *TO PROVIDERS.—The Secretary shall consider any*  
7           *disclosures under subsection (b)(1)(E) by an entity*  
8           *and shall make public findings on whether the entity*  
9           *can fairly and accurately perform the patient safety*  
10           *activities of a patient safety organization. The Sec-*  
11           *retary shall take those findings into consideration in*  
12           *determining whether to accept the entity’s initial cer-*  
13           *tification and any subsequent certification submitted*  
14           *under subsection (a) and, based on those findings,*  
15           *may deny, condition, or revoke acceptance of the enti-*  
16           *ty’s certification.*

17           “(d) *LISTING.—The Secretary shall compile and*  
18           *maintain a listing of entities with respect to which there*  
19           *is an acceptance of a certification pursuant to subsection*  
20           *(c)(2)(A) that has not been revoked under subsection (e) or*  
21           *voluntarily relinquished.*

22           “(e) *REVOCATION OF ACCEPTANCE OF CERTIFI-*  
23           *CATION.—*

24           “(1) *IN GENERAL.—If, after notice of deficiency,*  
25           *an opportunity for a hearing, and a reasonable op-*

1 *portunity for correction, the Secretary determines*  
2 *that a patient safety organization does not meet the*  
3 *certification requirements under subsection (a)(2), in-*  
4 *cluding subparagraphs (A) and (B) of such sub-*  
5 *section, the Secretary shall revoke the Secretary's ac-*  
6 *ceptance of the certification of such organization.*

7 “(2) *SUPPLYING CONFIRMATION OF NOTIFICA-*  
8 *TION TO PROVIDERS.—Within 15 days of a revocation*  
9 *under paragraph (1), a patient safety organization*  
10 *shall submit to the Secretary a confirmation that the*  
11 *organization has taken all reasonable actions to no-*  
12 *tify each provider whose patient safety work product*  
13 *is collected or analyzed by the organization of such*  
14 *revocation.*

15 “(3) *PUBLICATION OF DECISION.—If the Sec-*  
16 *retary revokes the certification of an organization*  
17 *under paragraph (1), the Secretary shall—*

18 “(A) *remove the organization from the list-*  
19 *ing maintained under subsection (d); and*

20 “(B) *publish notice of the revocation in the*  
21 *Federal Register.*

22 “(f) *STATUS OF DATA AFTER REMOVAL FROM LIST-*  
23 *ING.—*

24 “(1) *NEW DATA.—With respect to the privilege*  
25 *and confidentiality protections described in section*

1 922, data submitted to an entity within 30 days after  
2 the entity is removed from the listing under sub-  
3 section (e)(3)(A) shall have the same status as data  
4 submitted while the entity was still listed.

5 “(2) *PROTECTION TO CONTINUE TO APPLY.*—If  
6 the privilege and confidentiality protections described  
7 in section 922 applied to patient safety work product  
8 while an entity was listed, or to data described in  
9 paragraph (1), such protections shall continue to  
10 apply to such work product or data after the entity  
11 is removed from the listing under subsection (e)(3)(A).

12 “(g) *DISPOSITION OF WORK PRODUCT AND DATA.*—  
13 If the Secretary removes a patient safety organization from  
14 the listing as provided for in subsection (e)(3)(A), with re-  
15 spect to the patient safety work product or data described  
16 in subsection (f)(1) that the patient safety organization re-  
17 ceived from another entity, such former patient safety orga-  
18 nization shall—

19 “(1) with the approval of the other entity and a  
20 patient safety organization, transfer such work prod-  
21 uct or data to such patient safety organization;

22 “(2) return such work product or data to the en-  
23 tity that submitted the work product or data; or

1           “(3) if returning such work product or data to  
2           such entity is not practicable, destroy such work  
3           product or data.

4   **“SEC. 925. TECHNICAL ASSISTANCE.**

5           *“The Secretary, acting through the Director, may pro-  
6           vide technical assistance to patient safety organizations, in-  
7           cluding convening annual meetings for patient safety orga-  
8           nizations to discuss methodology, communication, data col-  
9           lection, or privacy concerns.*

10   **“SEC. 926. SEVERABILITY.**

11           *“If any provision of this part is held to be unconstitu-  
12           tional, the remainder of this part shall not be affected.”.*

13           **(b) AUTHORIZATION OF APPROPRIATIONS.—***Section  
14           937 of the Public Health Service Act (as redesignated by  
15           subsection (a)) is amended by adding at the end the fol-  
16           lowing:*

17           **“(e) PATIENT SAFETY AND QUALITY IMPROVEMENT.—**  
18           *For the purpose of carrying out part C, there are authorized  
19           to be appropriated such sums as may be necessary for each  
20           of the fiscal years 2006 through 2010.”.*

21           **(c) GAO STUDY ON IMPLEMENTATION.—**

22           **(1) STUDY.—***The Comptroller General of the  
23           United States shall conduct a study on the effective-  
24           ness of part C of title IX of the Public Health Service*

1     *Act (as added by subsection (a)) in accomplishing the*  
2     *purposes of such part.*

3             (2) *REPORT.—Not later than February 1, 2010,*  
4     *the Comptroller General shall submit a report on the*  
5     *study conducted under paragraph (1). Such report*  
6     *shall include such recommendations for changes in*  
7     *such part as the Comptroller General deems appro-*  
8     *priate.*

Union Calendar No. 117

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

**H. R. 3205**

[Report No. 109-197]

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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.

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JULY 27, 2005

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