

## Union Calendar No. 468

107<sup>TH</sup> CONGRESS  
2D SESSION**H. R. 4889****[Report No. 107-714, Part I]**

To amend title XI of the Social Security Act to improve patient safety.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 6, 2002

Mrs. JOHNSON of Connecticut (for herself, Mr. THOMAS, Mr. HOUGHTON, Mr. FLETCHER, Mrs. MORELLA, Mr. HAYWORTH, Mr. WELLER, and Mr. CAMP) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

OCTOBER 1, 2002

Reported from the Committee on Ways and Means with an amendment

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

OCTOBER 1, 2002

Referral to the Committee on Energy and Commerce extended for a period ending not later than October 4, 2002

OCTOBER 4, 2002

Referral to the Committee on Energy and Commerce extended for a period ending not later than October 11, 2002

OCTOBER 11, 2002

Additional sponsors: Mr. HERGER, Mr. LEWIS of Kentucky, Mr. ENGLISH, Mr. SMITH of New Jersey, and Mr. PORTMAN

OCTOBER 11, 2002

Committee on Energy and Commerce discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

# A BILL

To amend title XI of the Social Security Act to improve patient safety.

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 Improvement Act of 2002”.*

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

*Sec. 1. Short title; table of contents.*

*Sec. 2. Patient safety improvements.*

*“PART D—PATIENT SAFETY IMPROVEMENTS*

*“Sec. 1181. Voluntary reporting of patient safety data; definitions.*

*“Sec. 1182. Confidentiality and peer review protections.*

*“Sec. 1183. Center for Quality Improvement and Patient Safety.*

*“Sec. 1184. Interoperability standards for health care information tech-*  
*nology systems.*

*“Sec. 1185. Voluntary adoption of methods to improve patient safety.*

*“Sec. 1186. Evaluation and report.*

*Sec. 3. Medical Information Technology Advisory Board.*

8 **SEC. 2. PATIENT SAFETY IMPROVEMENTS.**

9 *Title XI of the Social Security Act is amended by add-*  
 10 *ing at the end the following new part:*

1           “*PART D—PATIENT SAFETY IMPROVEMENTS*

2           “*VOLUNTARY REPORTING OF PATIENT SAFETY DATA;*

3                                 *DEFINITIONS*

4           “*SEC. 1181. (a) COLLECTION AND VOLUNTARY RE-*  
5   *PORTING OF PATIENT SAFETY DATA.—In order to improve*  
6   *patient safety and the quality of health care delivery, a*  
7   *health care provider (as defined in subsection (d)) may vol-*  
8   *untarily collect and develop patient safety data (as defined*  
9   *in subsection (e)) and report such data to one or more pa-*  
10   *tient safety organizations (as defined in subsection (f)) in*  
11   *a manner that is confidential and privileged (as described*  
12   *in section 1182).*

13          “*(b) USE OF PATIENT SAFETY DATA BY PATIENT*  
14   *SAFETY ORGANIZATIONS.—Patient safety organizations*  
15   *shall analyze the patient safety data reported and develop*  
16   *(and report back to health care providers) information to*  
17   *improve patient safety and the quality of health care deliv-*  
18   *ery and shall submit non-identifiable information derived*  
19   *from such data in a uniform manner to the Center for*  
20   *Quality Improvement and Patient Safety (for inclusion in*  
21   *the Patient Safety Database, if applicable). Such non-iden-*  
22   *tifiable information may be disclosed and shared with other*  
23   *patient safety organizations. Identifiable patient safety*  
24   *data may be disclosed to other patient safety organizations*

1 *with the explicit authorization for each such disclosure by*  
 2 *the reporting provider involved.*

3 “(c) *FUNCTIONS OF CENTER.—The Center for Quality*  
 4 *Improvement and Patient Safety conducts patient safety*  
 5 *activities consistent with section 1183.*

6 “(d) *HEALTH CARE PROVIDERS COVERED.—For pur-*  
 7 *poses of this part, the term ‘health care provider’ means—*

8 “(1) *a provider of services (as defined in section*  
 9 *1861(u) and including a hospital, skilled nursing fa-*  
 10 *cility, home health agency, and hospice program) that*  
 11 *provides services for which payment may be made*  
 12 *under part A of title XVIII and the provider’s em-*  
 13 *ployees;*

14 “(2) *a health care entity or individual that fur-*  
 15 *nishes medical or other health services (as defined in*  
 16 *section 1861(s)), other services described in section*  
 17 *1832(a)(2), or other items and services for which pay-*  
 18 *ment may be made under such title, including a phy-*  
 19 *sician (as defined in section 1861(r)); and*

20 “(3) *an organization offering a plan under part*  
 21 *C of title XVIII.*

22 “(e) *PATIENT SAFETY DATA COVERED.—*

23 “(1) *IN GENERAL.—For purposes of this part,*  
 24 *the term ‘patient safety data’ means any data, re-*  
 25 *ports, records, memoranda, analyses, deliberative*

1 *work, statements, or root cause analyses that are col-*  
2 *lected or developed to improve patient safety or health*  
3 *care quality and that—*

4 *“(A) are collected or developed by a health*  
5 *care provider for the purpose of reporting to a*  
6 *patient safety organization and that are reported*  
7 *on a timely basis to such an organization;*

8 *“(B) are collected or developed by a patient*  
9 *safety organization or by (or on behalf of) the*  
10 *Center for Quality Improvement and Patient*  
11 *Safety, regardless of whether the data are trans-*  
12 *mitted to the health care provider that reported*  
13 *the original data; or*

14 *“(C) describes corrective actions taken by a*  
15 *health care provider in response to the provider’s*  
16 *reporting of data to that organization, regardless*  
17 *of whether the organization has transmitted*  
18 *under subsection (f)(2) information to the health*  
19 *care provider that reported the original data,*  
20 *and that are reported on a timely basis to such*  
21 *an organization.*

22 *“(2) CONSTRUCTION REGARDING USE OF*  
23 *DATA.—*

24 *“(A) INTERNAL USE PERMITTED TO IM-*  
25 *PROVE PATIENT SAFETY, QUALITY, AND EFFI-*

1        *CIENCY.—Nothing in this part shall be construed*  
2        *to limit or discourage a health care provider*  
3        *from developing and using patient safety data*  
4        *within the provider to improve patient safety,*  
5        *health care quality, or administrative efficiency*  
6        *of the provider.*

7                *“(B) TREATMENT.—Information that is col-*  
8        *lected or developed as patient safety data is not*  
9        *disqualified from being treated as patient safety*  
10       *data because of its development or use for the*  
11       *purposes described in subparagraph (A) and*  
12       *such development or use shall not constitute a*  
13       *waiver of any privilege or protection established*  
14       *under section 1182 or under State law.*

15        *“(f) QUALIFICATIONS OF PATIENT SAFETY ORGANIZA-*  
16       *TIONS.—*

17                *“(1) IN GENERAL.—For purposes of this part,*  
18        *the term ‘patient safety organization’ means a private*  
19        *or public organization that conducts activities to im-*  
20        *prove patient safety and the quality of health care de-*  
21        *livery by assisting health care providers that report*  
22        *to such organizations and that has been certified by*  
23        *the Secretary as—*

24                *“(A) performing each of the activities de-*  
25        *scribed in paragraph (2); and*

1           “(B) meets the other requirements of para-  
2           graphs (3) through (5).

3           “(2) *ACTIVITIES DESCRIBED.*—*The activities re-*  
4           *ferred to in paragraph (1)(A) are the following:*

5           “(A) *The collection and analysis of patient*  
6           *safety data that are voluntarily reported by more*  
7           *than one health care provider on a local, re-*  
8           *gional, State, or national basis.*

9           “(B) *The development and dissemination of*  
10          *information to health care providers and other*  
11          *patient safety organizations with respect to im-*  
12          *proving patient safety, such as recommendations,*  
13          *protocols, or information regarding best prac-*  
14          *tices.*

15          “(C) *The utilization of patient safety data*  
16          *to carry out activities under this paragraph to*  
17          *improve patient safety and to provide assistance*  
18          *to health care providers to minimize patient*  
19          *risk.*

20          “(3) *CONDUCT OF ACTIVITIES.*—*In conducting*  
21          *activities under paragraph (2), a patient safety orga-*  
22          *nization shall—*

23                 “(A) *maintain confidentiality with respect*  
24                 *to individually identifiable health information;*

1           “(B) submit non-identifiable information to  
2           the Center for Quality Improvement and Patient  
3           Safety in a format established by the Secretary;  
4           and

5           “(C) maintain appropriate security meas-  
6           ures with respect to patient safety data.

7           “(4) ORGANIZATION REQUIREMENTS.—The re-  
8           quirements of this paragraph for an organization are  
9           that—

10           “(A) the organization is managed, con-  
11           trolled, and operated independently from health  
12           care providers which report patient safety data  
13           to it under this part;

14           “(B) if the organization no longer qualifies  
15           as a patient safety organization, with respect to  
16           any patient safety data that it received from a  
17           health care provider, the organization shall do  
18           one of the following:

19           “(i) with the approval of the provider  
20           and another patient safety organization,  
21           transfer such data to such other organiza-  
22           tion;

23           “(ii) if practicable, return the data to  
24           the provider; or

25           “(iii) destroy the patient safety data;



1           “(C) if the organization charges a fee for the  
2           activities it performs with respect to health care  
3           providers, the fee shall be uniform among all  
4           classes or types of health care providers (taking  
5           into account the size of the health care provider);

6           “(D) the organization seeks to collect data  
7           from health care providers in a standardized  
8           manner that permits valid comparisons of simi-  
9           lar cases among similar health care providers;  
10          and

11          “(E) the organization meets such other re-  
12          quirements as the Secretary may by regulation  
13          require.

14          For purposes of subparagraph (A), an organization is  
15          controlled by a health care provider if the provider is  
16          able to significantly influence or direct the actions or  
17          policies of the organization.

18          “(5) *LIMITATION ON USE OF PATIENT SAFETY*  
19          *DATA BY PATIENT SAFETY ORGANIZATIONS.*—A pa-  
20          tient safety organization may not use patient safety  
21          data reported by a health care provider in accordance  
22          with this part to take regulatory or enforcement ac-  
23          tions it otherwise performs (or is responsible for per-  
24          forming) in relation to such provider.

1           “(6) *TECHNICAL ASSISTANCE.*—*The Secretary*  
2           *may provide technical assistance to patient safety or-*  
3           *ganizations in providing recommendations and ad-*  
4           *vice to health care providers reporting patient safety*  
5           *data under this part. Such assistance shall include*  
6           *advice with respect to methodology, communication,*  
7           *dissemination of information, data collection, secu-*  
8           *urity, and confidentiality concerns.*

9           “(g) *CONSTRUCTION.*—*Nothing in this part shall be*  
10          *construed to limit or discourage the reporting of informa-*  
11          *tion relating to patient safety within a health care provider.*

12          “*CONFIDENTIALITY AND PEER REVIEW PROTECTIONS*

13          “*SEC. 1182. (a) IN GENERAL.*—*Notwithstanding any*  
14          *other provision of law, patient safety data shall be privi-*  
15          *leged and confidential in accordance with this section.*

16          “(b) *SCOPE OF PRIVILEGE.*—*Subject to the succeeding*  
17          *provisions of this section, such data shall not be—*

18                  “(1) *subject to a civil or administrative sub-*  
19                  *poena;*

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

22                  “(3) *disclosed pursuant to section 552 of title 5,*  
23                  *United States Code (commonly known as the Freedom*  
24                  *of Information Act) or any other similar Federal or*  
25                  *State law; or*

1           “(4) admitted as evidence or otherwise disclosed  
2           in any civil or administrative proceeding.

3           “(c) *CLARIFICATION OF SCOPE.*—The privilege estab-  
4           lished by this section with respect to patient safety data  
5           described in section 1181(e)(1)(A) shall apply to informa-  
6           tion, such as records of a patient’s medical diagnosis and  
7           treatment, other primary health care information, and  
8           other information, to the extent that such information was  
9           collected or developed for the purpose specified in such sec-  
10          tion and is reported in accordance with such section. Such  
11          privilege shall not apply to information merely by reason  
12          of its inclusion, or the fact of its submission, in a report  
13          under such section. Information available from sources  
14          other than a report made under such section may be discov-  
15          ered or admitted in a civil or administrative proceeding,  
16          if discoverable or admissible under applicable state law.

17          “(d) *INFORMATION NOT SUBJECT TO PRIVILEGE.*—  
18          The privilege established by this section shall not apply to  
19          one or more of the following:

20               “(1) *MEDICAL RECORDS AND OTHER PRIMARY*  
21               *HEALTH RECORDS.*—Records of a patient’s medical  
22               diagnosis and treatment and other primary health  
23               records of a health care provider. Such privilege shall  
24               not apply to such information by reason of its inclu-  
25               sion within patient safety data.

1           “(2) *FDA.*—*Relevant information disclosed by a*  
 2           *health care provider or patient safety organization to*  
 3           *the Food and Drug Administration, or to a person*  
 4           *that is subject to the jurisdiction of such Administra-*  
 5           *tion, with respect to an Administration-regulated*  
 6           *product or activity for which that entity has responsi-*  
 7           *bility, for the purposes of activities related to quality,*  
 8           *safety, or effectiveness of such Administration-regu-*  
 9           *lated product or activity, subject to section 520(c) of*  
 10           *the Federal Food, Drug, and Cosmetic Act.*

11           “(3) *NON-IDENTIFIABLE INFORMATION USED BY*  
 12           *DATABASE.*—*Non-identifiable information from a pa-*  
 13           *tient safety organization to the Patient Safety Data-*  
 14           *base and the further disclosure of such data by the*  
 15           *Center for Quality Improvement and Patient Safety.*

16           “(e) *REPORTER PROTECTION.*—

17           “(1) *IN GENERAL.*—*A health care provider may*  
 18           *not use against an individual in an adverse employ-*  
 19           *ment action described in paragraph (2) the fact that*  
 20           *the individual in good faith reported—*

21                   “(A) *to the provider with the intention of*  
 22                   *having it reported to a patient safety organiza-*  
 23                   *tion, or*

24                   “(B) *directly to a patient safety organiza-*  
 25                   *tion,*

1        *information that would constitute patient safety data*  
 2        *under section 1181(e)(1)(A) if the provider were to*  
 3        *have submitted it on a timely basis to a patient safe-*  
 4        *ty organization in accordance with such section.*

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

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

11                      *“(B) an evaluation or decision made in re-*  
 12        *lation to accreditation, certification,*  
 13        *credentialing or licensing of the individual; and*

14                      *“(C) a personnel action that is adverse to*  
 15        *the individual concerned.*

16                *“(3) REMEDIES.—The provisions of the first sen-*  
 17        *tence of section 1128A(a) shall apply with respect to*  
 18        *a health care provider’s violation of paragraph (1) in*  
 19        *the same manner as they apply to an act referred to*  
 20        *in section 1128A(a)(7).*

21                *“(f) PENALTY.—It is unlawful for any person to dis-*  
 22        *close any patient safety data in violation of the provisions*  
 23        *of this section. Any person violating such provisions shall*  
 24        *be subject to the same sanctions under section 1160(c) (re-*  
 25        *lating to, upon conviction, a fine of not more than \$1,000,*

1 *imprisonment for not more than 6 months, or both, per dis-*  
 2 *closure and payment of the costs of prosecution) as a person*  
 3 *who discloses any information described in section 1160(a).*

4 “(g) *RULES OF CONSTRUCTION.*—

5 “(1) *NO LIMITATION OF OTHER PRIVILEGES.*—

6 *Subject to paragraph (2), nothing in this section shall*  
 7 *be construed as affecting other privileges that are*  
 8 *available under Federal or State laws that provide*  
 9 *greater peer review or confidentiality protections than*  
 10 *the peer review and confidentiality protections pro-*  
 11 *vided for in this section.*

12 “(2) *NO EFFECT ON STATE MANDATORY REPORT-*  
 13 *ING REQUIREMENTS.*—*Nothing in this part shall be*  
 14 *construed as preempting or otherwise affecting any*  
 15 *State law mandatory reporting requirement for health*  
 16 *care providers.*

17 “(h) *APPLICATION OF PRIVACY REGULATIONS.*—*For*  
 18 *purposes of applying the regulations promulgated pursuant*  
 19 *to section 264(c) of the Health Insurance Portability and*  
 20 *Accountability Act of 1996 (Public Law 104–191; 110 Stat.*  
 21 *2033)*—

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

24 “(2) *activities of such organizations described in*  
 25 *section 1181(f)(2)(A) in relation to a health care pro-*

1        *vider are deemed to be health care operations of the*  
2        *provider; and*

3                *“(3) the disclosure of identifiable information*  
4        *under the voluntary program under this part by such*  
5        *an organization shall be treated as necessary for the*  
6        *proper management and administration of the orga-*  
7        *nization.*

8        *Nothing in this section shall be construed to alter or affect*  
9        *the implementation of such regulation or such section*  
10       *264(c).*

11        *“(i) WAIVERS.—Nothing in this part shall be con-*  
12       *strued as precluding a health care provider from waiving*  
13       *the privilege or confidentiality protections under this sec-*  
14       *tion. Disclosure of patient safety data under subsection*  
15       *(d)(2) shall not constitute a waiver of any privilege or pro-*  
16       *tection established under this section or under State law.*

17        *“(j) CONTINUATION OF PRIVILEGE.—Patient safety*  
18       *data of an organization that is certified as a patient safety*  
19       *organization shall continue to be privileged and confiden-*  
20       *tial, in accordance with this section, if the organization’s*  
21       *certification is terminated or revoked or if the organization*  
22       *otherwise ceases to qualify as a patient safety organization*  
23       *until the data are otherwise disposed of in accordance with*  
24       *section 1181(f)(4).*

25        *“(k) SURVEY AND REPORT.—*

9                   “(2) *REPORT*.—Not later than 9 months after the  
10                   date of enactment of this section, the Comptroller  
11                   General shall prepare and submit to Congress a re-  
12                   port concerning the results of the survey conducted  
13                   under paragraph (1).

16 “SEC. 1183. (a) IN GENERAL.—The Secretary, acting  
17 through the Director of the Agency for Healthcare Research  
18 and Quality, shall ensure that the Center for Quality Im-  
19 provement and Patient Safety (in this section referred to  
20 as the ‘Center’) supports public and private sector initia-  
21 tives to improve patient safety for items and services fur-  
22 nished through health care providers.

24 “(1) IN GENERAL.—The Secretary, acting  
25 through the Director, shall ensure that the Center car-  
26 ries out the following duties:



1           “(A) *Provide for the certification and recer-*  
2           *tification of patient safety organizations in ac-*  
3           *cordance with subsection (d).*

4           “(B) *Collect and disseminate information*  
5           *related to patient safety.*

6           “(C) *Establish a Patient Safety Database to*  
7           *collect, support, and coordinate the analysis of*  
8           *non-identifiable information submitted to the*  
9           *Database in accordance with subsection (e).*

10          “(D) *Facilitate the development of con-*  
11          *sensus among health care providers, patients,*  
12          *and other interested parties concerning patient*  
13          *safety and recommendations to improve patient*  
14          *safety.*

15          “(E) *Provide technical assistance to States*  
16          *that have (or are developing) medical errors re-*  
17          *porting systems, assist States in developing*  
18          *standardized methods for data collection, and*  
19          *collect data from State reporting systems for in-*  
20          *clusion in the Patient Safety Database.*

21          “(2) *CONSULTATION.—In carrying out the duties*  
22          *under paragraph (1) (including the establishment of*  
23          *the Database), the Secretary shall consult with and*  
24          *develop partnerships, as appropriate, with health care*  
25          *organizations, health care providers, public and pri-*

1        *vate sector entities, patient safety organizations,*  
 2        *health care consumers, and other relevant experts to*  
 3        *improve patient safety.*

4        “(c) *CERTIFICATION AND RECERTIFICATION PROC-*  
 5        *ESS.—*

6                “(1) *IN GENERAL.—The initial certification and*  
 7        *recertification of a patient safety organization under*  
 8        *subsection (b)(1)(A) shall be made under a process*  
 9        *that is approved by the Secretary and is consistent*  
 10        *with criteria published by the Secretary.*

11               “(2) *REVOCATION.—Such a certification or re-*  
 12        *certification may be revoked by the Secretary upon a*  
 13        *showing of cause (including the disclosure of data in*  
 14        *violation of section 1182).*

15               “(3) *TERMINATION.—Such a certification pro-*  
 16        *vided for a patient safety organization shall termi-*  
 17        *nate (subject to recertification) on the earlier of—*

18                        “(A) *the date that is 3 years after the date*  
 19                        *on which such certification was provided; or*

20                        “(B) *the date on which the Secretary re-*  
 21                        *vokes the certification.*

22               “(d) *IMPLEMENTATION AND CONSULTATION.—In car-*  
 23        *rying out subsection (c)(1), the Secretary shall—*

1           “(1) *facilitate the development of patient safety*  
2           *goals and track the progress made in meeting those*  
3           *goals; and*

4           “(2) *ensure that data submitted by a patient*  
5           *safety organization to the Patient Safety Database, as*  
6           *provided for under subsection (e), are comparable and*  
7           *useful for research and analysis and that the research*  
8           *findings and patient safety alerts that result from*  
9           *such analyses are presented in clear and consistent*  
10          *formats that enhance the usefulness of such alerts.*

11          “(e) *PATIENT SAFETY DATABASE.—*

12                 “(1) *IN GENERAL.—The Secretary, acting*  
13                 *through the Director, shall—*

14                         “(A) *establish a Patient Safety Database to*  
15                         *collect non-identifiable information concerning*  
16                         *patient safety that is reported on a voluntary*  
17                         *basis; and*

18                         “(B) *establish common formats for the vol-*  
19                         *untary reporting of data under subparagraph*  
20                         *(A), including the establishment of necessary*  
21                         *data elements, common and consistent defini-*  
22                         *tions, and a standardized computer interface for*  
23                         *the processing of such data.*

24                 “(2) *DATABASE.—In carrying out this sub-*  
25                 *section, the Secretary—*

1           “(A) shall establish and modify as necessary  
 2           criteria to determine the organizations that may  
 3           voluntarily contribute to, and the data that com-  
 4           prises, the Patient Safety Database;

5           “(B) shall ensure that the Patient Safety  
 6           Database is only used by qualified entities or in-  
 7           dividuals as determined appropriate by the Sec-  
 8           retary in accordance with criteria applied by the  
 9           Secretary; and

10          “(C) may enter into contracts for the ad-  
 11          ministration of the Database with private and  
 12          public entities with experience in the adminis-  
 13          tration of similar databases.

14          “(3) NON-IDENTIFIABLE INFORMATION.—For  
 15          purposes of this part, the term ‘non-identifiable infor-  
 16          mation’ means information that is presented in a  
 17          form and manner that prevents the identification of  
 18          any health care provider, patient, and the reporter of  
 19          the information.

20          “(f) AUTHORIZATION OF APPROPRIATIONS.—There are  
 21          authorized to be appropriated such sums as may be nec-  
 22          essary for each fiscal year to carry out this section.

23          “INTEROPERABILITY STANDARDS FOR HEALTH CARE  
 24          INFORMATION TECHNOLOGY SYSTEMS

25          “SEC. 1184. (a) IN GENERAL.—By not later than 2  
 26          years after the date of the enactment of this part, the Sec-

1    *retary shall develop or adopt (and shall periodically review*  
 2    *and update) voluntary, national standards that promote*  
 3    *the interoperability of health care information technology*  
 4    *systems across all health care settings. In promulgating reg-*  
 5    *ulations to carry out this section, the Secretary shall take*  
 6    *into account the cost that meeting such standards would*  
 7    *have on providing health care in the United States and the*  
 8    *increased efficiencies in providing such care achieved under*  
 9    *the standards.*

10        *“(b) CONSULTATION AND COORDINATION.—The Sec-*  
 11    *retary shall develop and update such standards in consulta-*  
 12    *tion with (and with coordination between)—*

13                *“(1) the National Committee for Vital and*  
 14        *Health Statistics, and*

15                *“(2) the Medical Information Technology Advi-*  
 16        *sory Board (established under section 3 of the Patient*  
 17        *Safety Improvement Act of 2002).*

18        *“(c) DISSEMINATION.—The Secretary shall provide for*  
 19    *the dissemination of the standards developed and updated*  
 20    *under this section.*

21        *“(d) AUTHORIZATION OF APPROPRIATIONS.—There*  
 22    *are authorized to be appropriated such sums as may be nec-*  
 23    *essary for each fiscal year to carry out this section.*

1 “VOLUNTARY ADOPTION OF METHODS TO IMPROVE PATIENT  
2 SAFETY

3 “SEC. 1185. *The Secretary shall encourage health care*  
4 *providers to adopt appropriate evidence-based methods to*  
5 *improve patient safety. Such methods shall not constitute*  
6 *national practice guidelines.*

7 “EVALUATION AND REPORT

8 “SEC. 1186. (a) *EVALUATION.—The Comptroller Gen-*  
9 *eral of the United States shall conduct a comprehensive*  
10 *evaluation of the implementation of this part. Such evalua-*  
11 *tion shall include an examination of the following:*

12 “(1) *The health care providers that reported pa-*  
13 *tient safety data under this part and the patient safe-*  
14 *ty organizations to which they reported the informa-*  
15 *tion.*

16 “(2) *What types of events were so reported on.*

17 “(3) *The usefulness of the analyses, information,*  
18 *and recommendations provided by patient safety or-*  
19 *ganizations in response to such reported information.*

20 “(4) *The response of health care providers to*  
21 *such analyses, information, and recommendations, in-*  
22 *cluding a survey of providers to obtain estimates of*  
23 *the percentage of providers by category who have*  
24 *adopted specific error-reduction methods and, if ap-*  
25 *plicable, reasons for not adopting specific practices.*

1           “(5) *The effectiveness of the program under this*  
 2           *part in reducing medical errors.*

3           “(b) *REPORT.—Not later than 5 years after the date*  
 4           *the provisions of this part are first implemented, the Comp-*  
 5           *troller General shall submit to Congress a report on the*  
 6           *evaluation conducted under subsection (a).’’.*

7   **SEC. 3. MEDICAL INFORMATION TECHNOLOGY ADVISORY**  
 8           **BOARD.**

9           (a) *ESTABLISHMENT.—*

10           (1) *IN GENERAL.—Not later than 3 months after*  
 11           *the date of the enactment of this Act, the Secretary of*  
 12           *Health and Human Services (in this section referred*  
 13           *to as the “Secretary”) shall appoint an advisory*  
 14           *board to be known as the “Medical Information Tech-*  
 15           *nology Advisory Board” (in this section referred to as*  
 16           *the “MITAB”).*

17           (2) *CHAIRMAN.—The Secretary shall designate*  
 18           *one member as chairman. The chairman shall be an*  
 19           *individual affiliated with an organization having ex-*  
 20           *pertise creating American National Standards Insti-*  
 21           *tute (ANSI) accepted standards in health care infor-*  
 22           *mation technology and a member of the National*  
 23           *Committee for Vital and Health Statistics.*

24           (b) *COMPOSITION.—*

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

3                     (A) *experts from the fields of medical infor-*  
4                     *mation, information technology, medical contin-*  
5                     *uous quality improvement, medical records secu-*  
6                     *rity and privacy, individual and institutional*  
7                     *health care clinical providers, health researchers,*  
8                     *and health care purchasers;*

9                     (B) *one or more staff experts from each of*  
10                    *the following: the Centers for Medicare & Med-*  
11                    *icaid Services, the Agency for Healthcare Re-*  
12                    *search and Quality, and the Institute of Medi-*  
13                    *cine of the National Academy of Sciences;*

14                    (C) *representatives of private organizations*  
15                    *with expertise in medical infomatics;*

16                    (D) *a representative of a teaching hospital;*  
17                    *and*

18                    (E) *one or more representatives of the health*  
19                    *care information technology industry.*

20           (2) *TERMS OF APPOINTMENT.*—*The term of any*  
21           *appointment under paragraph (1) to the MITAB*  
22           *shall be for the life of the MITAB.*

23           (3) *MEETINGS.*—*The MITAB shall meet at the*  
24           *call of its chairman or a majority of its members.*



1           (4) *VACANCIES.*—*A vacancy on the MITAB shall*  
2           *be filled in the same manner in which the original*  
3           *appointment was made not later than 30 days after*  
4           *the MITAB is given notice of the vacancy and shall*  
5           *not affect the power of the remaining members to exe-*  
6           *cute the duties of the MITAB.*

7           (5) *COMPENSATION.*—*Members of the MITAB*  
8           *shall receive no additional pay, allowances, or bene-*  
9           *fits by reason of their service on the MITAB.*

10          (6) *EXPENSES.*—*Each member of the MITAB*  
11          *shall receive travel expenses and per diem in lieu of*  
12          *subsistence in accordance with sections 5702 and*  
13          *5703 of title 5, United States Code.*

14          (c) *DUTIES.*—

15               (1) *IN GENERAL.*—*The MITAB shall on an ongo-*  
16               *ing basis advise, and make recommendations to, the*  
17               *Secretary regarding medical information technology,*  
18               *including the following:*

19                       (A) *The best current practices in medical*  
20                       *information technology.*

21                       (B) *Methods for the adoption (not later*  
22                       *than 2 years after the date of the enactment of*  
23                       *this section) of a uniform health care informa-*  
24                       *tion system interface between and among old*  
25                       *and new computer systems.*

1           (C) *Recommendations for health care vocab-*  
2           *ulary, messaging, and other technology standards*  
3           *(including a common lexicon for computer tech-*  
4           *nology) necessary to achieve the interoperability*  
5           *of health care information systems for the pur-*  
6           *poses described in subparagraph (E).*

7           (D) *Methods of implementing—*

8                 (i) *health care information technology*  
9                 *interoperability standardization; and*

10                (ii) *records security.*

11           (E) *Methods to promote information ex-*  
12           *change among health care providers so that long-*  
13           *term compatibility among information systems*  
14           *is maximized, in order to do one or more of the*  
15           *following:*

16                (i) *To maximize positive outcomes in*  
17                *clinical care—*

18                         (I) *by providing decision support*  
19                         *for diagnosis and care; and*

20                         (II) *by assisting in the emergency*  
21                         *treatment of a patient presenting at a*  
22                         *facility where there is no medical*  
23                         *record for the patient.*

24                (ii) *To contribute to (and be consistent*  
25                *with) the development of the patient assess-*

ment instrument provided for under section 545 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, and to assist in minimizing the need for new and different records as patients move from provider to provider.

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

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

(v) To provide a compatible information technology architecture that facilitates future quality and cost-saving needs and that avoids the financing and development of information technology systems that are not readily compatible.

(2) *REPORTS.*—

(A) *INITIAL REPORT.*—No later than 18 months after the date of the enactment of this Act, the MITAB shall submit to Congress and the Secretary an initial report concerning the matters described in paragraph (1). The report shall include—

1                   (i) the practices described in para-  
2                   graph (1)(A), including the status of health  
3                   care information technology standards being  
4                   developed by private sector and public-pri-  
5                   vate groups;

6                   (ii) recommendations for accelerating  
7                   the development of common health care ter-  
8                   minology standards;

9                   (iii) recommendations for completing  
10                  development of health care information sys-  
11                  tem messaging standards; and

12                  (iv) progress toward meeting the dead-  
13                  line described in paragraph (1)(B) for  
14                  adoption of methods described in such para-  
15                  graph.

16                  (B) *SUBSEQUENT REPORTS.*—During each  
17                  of the 2 years after the year in which the report  
18                  is submitted under subparagraph (A), the  
19                  MITAB shall submit to Congress and the Sec-  
20                  retary an annual report relating to additional  
21                  recommendations, best practices, results of infor-  
22                  mation technology improvements, analyses of  
23                  private sector efforts to implement the interoper-  
24                  ability standards established in section 1184 of  
25                  the Social Security Act, and such other matters

1           *as may help ensure the most rapid dissemination*  
 2           *of best practices in health care information tech-*  
 3           *nology.*

4           *(d) STAFF AND SUPPORT SERVICES.—*

5           *(1) EXECUTIVE DIRECTOR.—*

6                   *(A) APPOINTMENT.—The Chairman shall*  
 7                   *appoint an executive director of the MITAB.*

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

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

14           *(3) APPLICABILITY OF CIVIL SERVICE LAWS.—*  
 15           *The staff of the MITAB shall be appointed without re-*  
 16           *gard to the provisions of title 5, United States Code,*  
 17           *governing appointments in the competitive service,*  
 18           *and shall be paid without regard to the provisions of*  
 19           *chapter 51 and subchapter III of chapter 53 of such*  
 20           *title (relating to classification and General Schedule*  
 21           *pay rates).*

22           *(4) EXPERTS AND CONSULTANTS.—With the ap-*  
 23           *proval of the MITAB, the executive director may pro-*  
 24           *cure temporary and intermittent services under sec-*  
 25           *tion 3109(b) of title 5, United States Code.*

1       (e) *POWERS.*—

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

7               (2) *DETAIL OF FEDERAL EMPLOYEES.*—*Upon the*  
8       *request of the MITAB, the head of any Federal agency*  
9       *is authorized to detail, without reimbursement, any of*  
10       *the personnel of such agency to the MITAB to assist*  
11       *the MITAB in carrying out its duties. Any such de-*  
12       *tail shall not interrupt or otherwise affect the civil*  
13       *service status or privileges of the Federal employee.*

14              (3) *TECHNICAL ASSISTANCE.*—*Upon the request*  
15       *of the MITAB, the head of a Federal agency shall pro-*  
16       *vide such technical assistance to the MITAB as the*  
17       *MITAB determines to be necessary to carry out its*  
18       *duties.*

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

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

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

7       (h) *AUTHORIZATION OF APPROPRIATIONS.*—*There are*  
8 *authorized to be appropriated to the Secretary of Health*  
9 *and Human Services such sums as are necessary to carry*  
10 *out this section.*





**Union Calendar No. 468**

107<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**H. R. 4889**

**[Report No. 107-714, Part I]**

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**A BILL**

To amend title XI of the Social Security Act to  
improve patient safety.

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OCTOBER 11, 2002

Committee on Energy and Commerce discharged; com-  
mitted to the Committee of the Whole House on the  
State of the Union and ordered to be printed