

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

# H. R. 4889

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

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## 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  
5 “Patient Safety Improvement Act of 2002”.

6       (b) TABLE OF CONTENTS.—The table of contents of  
7 this 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. Reduction of medical errors using non-identifiable patient safety data reported to patient safety organization.

“Sec. 1184. Technical assistance.

“Sec. 1185. Interoperability standards for health care information technology systems.

Sec. 3. Medical Information Technology Advisory Board.

1 **SEC. 2. PATIENT SAFETY IMPROVEMENTS.**

2 (a) IN GENERAL.—Title XI of the Social Security Act  
3 is amended by adding at the end the following new part:

4 “PART D—PATIENT SAFETY IMPROVEMENTS

5 “VOLUNTARY REPORTING OF PATIENT SAFETY DATA;

6 DEFINITIONS

7 “SEC. 1181. (a) VOLUNTARY REPORTING.—The re-  
8 porting of patient safety data by health care providers  
9 under this part is voluntary.

10 “(b) DEFINITIONS.—In this part:

11 “(1) PATIENT SAFETY DATA.—The term ‘pa-  
12 tient safety data’ means—

13 “(A) any data, reports, records, memo-  
14 randa, analyses, deliberative work, statements,  
15 root cause analyses, or quality improvement  
16 processes that could result in improved patient  
17 safety or health care quality, that are—

18 “(i) collected or developed by a health  
19 care provider for the purpose of reporting  
20 to a patient safety organization;

1           “(ii) reported to a patient safety orga-  
2           nization for patient safety or quality im-  
3           provement processes;

4           “(iii) requested by a patient safety or-  
5           ganization (including the contents of such  
6           request);

7           “(iv) reported to a health care pro-  
8           vider by a patient safety organization;

9           “(v) collected or developed by a pa-  
10          tient safety organization; or

11          “(vi) reported among patient safety  
12          organizations; or

13          “(B) information related to corrective ac-  
14          tions taken in response to patient safety data;  
15          for the purpose of improving patient safety, health  
16          care quality, or health care outcomes.

17          “(2) PATIENT SAFETY ORGANIZATION.—

18                 “(A) IN GENERAL.—The term ‘patient  
19                 safety organization’ means a private or public  
20                 organization or component thereof that certifies  
21                 to the Secretary that it performs each of the ac-  
22                 tivities described in subparagraph (B) (which  
23                 are necessary for the proper management and  
24                 administration of such organization or compo-

1           nent) and meets the conflict of interest stand-  
2           ard under subparagraph (C).

3           “(B) ACTIVITIES DESCRIBED.—The activi-  
4           ties referred to in subparagraph (A) are the fol-  
5           lowing:

6                   “(i) The conduct, as its primary activi-  
7                   ty, of efforts to improve patient safety and  
8                   the quality of health care delivery by as-  
9                   sisting health care providers that report to  
10                  such organizations.

11                  “(ii) The collection and analysis of pa-  
12                  tient safety data that are voluntarily sub-  
13                  mitted by a health care provider.

14                  “(iii) The development and dissemina-  
15                  tion of information to health care providers  
16                  with respect to improving patient safety,  
17                  such as recommendations, protocols, or in-  
18                  formation regarding best practices.

19                  “(iv) The utilization of patient safety  
20                  data to carry out activities under this sub-  
21                  paragraph and for the purposes of encour-  
22                  aging a culture of safety and of providing  
23                  direct feedback and assistance to health  
24                  care providers to effectively minimize pa-  
25                  tient risk.

1           “(v) The maintenance of confiden-  
2           tiality with respect to individually identifi-  
3           able health information.

4           “(vi) The provision of appropriate se-  
5           curity measures with respect to patient  
6           safety data.

7           “(C) CONFLICT OF INTEREST STAND-  
8           ARD.—The conflict of interest standard referred  
9           to in subparagraph (A) for a patient safety or-  
10          ganization, with respect to a health care pro-  
11          vider, is that the organization does not use pa-  
12          tient safety data submitted under this part to  
13          take regulatory or enforcement actions it other-  
14          wise performs (or is responsible for performing)  
15          in relation to such provider.

16          “(3) HEALTH CARE PROVIDER.—The term  
17          ‘health care provider’ means—

18               “(A) a provider of services (as defined in  
19               section 1861(u), and including a hospital,  
20               skilled nursing facility, home health agency, and  
21               hospice program) that provides services for  
22               which payment may be made under part A of  
23               title XVIII;

24               “(B) a health care entity or individual that  
25               furnishes medical or other health services (as

1 defined in section 1861(s)) or other services de-  
2 scribed in section 1832(a)(2) for which payment  
3 may be made under part B of such title, includ-  
4 ing a physician (as defined in section 1861(r));  
5 and

6 “(C) a Medicare+Choice organization  
7 under part C of such title.

8 “CONFIDENTIALITY AND PEER REVIEW PROTECTIONS

9 “SEC. 1182. (a) IN GENERAL.—Notwithstanding any  
10 other provision of law, and subject to subsection (b), pa-  
11 tient safety data shall be privileged and confidential and  
12 shall not be—

13 “(1) subject to a civil, criminal, or administra-  
14 tive subpoena;

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

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

21 “(4) admitted as evidence or otherwise disclosed  
22 in any civil, criminal, or administrative proceeding;  
23 or

24 “(5) utilized in an adverse employment action  
25 or in the evaluation or decisions made in relation to  
26 accreditation, certification, credentialing or licensing

1 of an individual, that is based on such individual's  
2 participation in the development, collection, report-  
3 ing, or storage of patient safety data.

4 “(b) DISCLOSURE REQUIREMENTS.—Nothing in this  
5 section shall be construed to prohibit one or more of the  
6 following disclosures:

7 “(1) Disclosures by a health care provider in  
8 complying with authorized requests for the provision  
9 of patient safety information (such as a patient's  
10 medical record or other relevant information) that is  
11 in the control of such a health care provider and  
12 that has been developed, maintained, or exists sepa-  
13 rately from the process by which the health care pro-  
14 vider collects or develops information for reporting  
15 to a patient safety organization.

16 “(2) Disclosures by a health care provider or  
17 patient safety organization of patient safety data as  
18 part of a disciplinary proceeding relating to a health  
19 care provider, or a criminal proceeding, if such a  
20 disclosure of such patient safety data is—

21 “(A) material to the proceeding;

22 “(B) within the public interest; and

23 “(C) not available from any other source.

24 “(3) Disclosures by a health care provider or  
25 patient safety organization of relevant information

1 to the Food and Drug Administration, or to a per-  
2 son that is subject to the jurisdiction of such Admin-  
3 istration, with respect to an Administration-regu-  
4 lated product or activity for which that entity has  
5 responsibility, for the purposes of activities related  
6 to the quality, safety, or effectiveness of such Ad-  
7 ministration-regulated product or activity.

8 “(4) Disclosures by a health care provider or  
9 patient safety organization of information to which  
10 subsection (a) applies to carry out activities de-  
11 scribed in section 1181(b)(2)(B).

12 “(c) PENALTY.—It is unlawful for any person to dis-  
13 close any patient safety data in violation of the provisions  
14 of this section. Any person violating such provisions shall  
15 be subject to the same sanctions under section 1160(c)  
16 as a person who discloses any information described in  
17 section 1160(a).

18 “(d) NO LIMITATION OF OTHER PRIVILEGES.—  
19 Nothing in this section shall be construed to limit other  
20 privileges that are available under Federal or State laws  
21 that provide greater peer review or confidentiality protec-  
22 tions than the peer review and confidentiality protections  
23 provided for in this section.

24 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-  
25 tion shall be construed to alter or affect the implementa-

1 tion of any provision of section 264(e) of the Health Insur-  
2 ance Portability and Accountability Act of 1996 (Public  
3 Law 104–191; 110 Stat. 2033) or any regulation promul-  
4 gated under such section.

5 “(f) TREATMENT OF RESIDUAL PATIENT SAFETY  
6 DATA.—In the case of a patient safety organization which  
7 no longer qualifies as a patient safety organization under  
8 section 1181(b)(2) that received patient safety data from  
9 a health care provider, the organization shall return the  
10 data to the provider, if practicable, or destroy the data.

11 “REDUCTION OF MEDICAL ERRORS USING AGGREGATED  
12 NON-IDENTIFIABLE PATIENT SAFETY DATA RE-  
13 PORTED TO PATIENT SAFETY ORGANIZATION

14 “SEC. 1183. (a) ANALYSIS OF PATTERNS OF MED-  
15 ICAL ERRORS.—

16 “(1) IN GENERAL.—The Secretary shall estab-  
17 lish one or more mechanisms—

18 “(A) to analyze aggregate non-identifiable  
19 patient safety data (as defined in paragraph  
20 (3))—

21 “(i) to identify patterns of medical er-  
22 rors; and

23 “(ii) to disseminate to health care  
24 providers methods that can be systemati-  
25 cally employed; and

1           “(B) to analyze system changes adopted by  
2           patient safety organizations and health care  
3           providers;  
4           in order to reduce such errors and improve patient  
5           safety and health care quality.

6           “(2) PERIODIC REPORTS.—The Secretary shall  
7           periodically report to Congress on mechanisms es-  
8           tablished under paragraph (1) and on changes that  
9           should be made to the provisions of this part in  
10          order to best promote system-wide improvements in  
11          patient safety and quality.

12          “(3) NON-IDENTIFIABLE PATIENT SAFETY  
13          DATA DEFINED.—For purposes of this section, the  
14          term ‘non-identifiable patient safety data’ means pa-  
15          tient safety data voluntarily reported to a patient  
16          safety organization under this part that are pre-  
17          sented in a form and manner that prevent the iden-  
18          tification of any health care provider, patient, and  
19          the reporter of the data.

20          “(b) CONFIDENTIALITY.—Any patient safety data  
21          that are used under this section shall be privileged and  
22          confidential in the same manner as provided under section  
23          1182 with respect to such data reported to a patient safety  
24          organization.

1                                   “TECHNICAL ASSISTANCE

2           “SEC. 1184. The Secretary may provide technical as-  
3   sistance to patient safety organizations in providing rec-  
4   ommendations and advice to health care providers submit-  
5   ting patient safety data under this part. Such assistance  
6   shall include advice with respect to methodology, commu-  
7   nication, data collection, security, and confidentiality con-  
8   cerns.

9           “INTEROPERABILITY STANDARDS FOR HEALTH CARE  
10                                   INFORMATION TECHNOLOGY SYSTEMS

11           “SEC. 1185. (a) IN GENERAL.—By not later than 2  
12   years after the date of the enactment of this part, the Sec-  
13   retary shall develop (and shall periodically review and up-  
14   date) voluntary, national standards that promote the  
15   interoperability of health care information technology sys-  
16   tems across all health care settings.

17           “(b) CONSULTATION.—The Secretary shall develop  
18   and update such standards in consultation with—

19                   “(1) the National Committee for Vital and  
20   Health Statistics,

21                   “(2) the organizations referred to in section  
22   1172(c)(3)(B), and

23                   “(3) the Medical Information Technology Advi-  
24   sory Board (established under section 3 of the Pa-  
25   tient Safety Improvement Act of 2002).

1       “(c) DISSEMINATION.—The Secretary shall provide  
2 for the dissemination of the standards developed and up-  
3 dated under this section.”.

4 **SEC. 3. MEDICAL INFORMATION TECHNOLOGY ADVISORY**  
5 **BOARD.**

6       (a) ESTABLISHMENT.—

7           (1) IN GENERAL.—Not later than 3 months  
8 after the date of the enactment of this Act, the Sec-  
9 retary of Health and Human Services (in this sec-  
10 tion referred to as the “Secretary”) shall appoint an  
11 advisory board to be known as the “Medical Infor-  
12 mation Technology Advisory Board” (in this section  
13 referred to as the “MITAB”).

14           (2) CHAIRMAN; VICE CHAIRMAN.—The Sec-  
15 retary shall designate one member as chairman and  
16 one as vice chairman. The chairman shall be an indi-  
17 vidual affiliated with an organization having exper-  
18 tise creating American National Standards Institute  
19 (ANSI) accepted standards in health care informa-  
20 tion technology.

21       (b) COMPOSITION.—

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

24                   (A) experts from the fields of medical in-  
25 formation, information technology, medical con-

1           tinuous quality improvement, medical records  
2           security and privacy, individual and institu-  
3           tional health care clinical providers, health re-  
4           searchers, and health care purchasers;

5           (B) one or more staff experts from the  
6           Centers for Medicare & Medicaid Services;

7           (C) one or more staff experts from the  
8           Agency for Healthcare Research and Quality;

9           (D) one or more staff experts from the In-  
10          stitute of Medicine of the National Academy of  
11          Sciences;

12          (E) representatives of private organizations  
13          with expertise in medical infomatics;

14          (F) one or more staff experts of a public  
15          health agency;

16          (G) a representative of a teaching hospital;  
17          and

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

20          (2) TERMS OF APPOINTMENT.—The term of  
21          any appointment under paragraph (1) to the  
22          MITAB 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  
2 shall be filled in the same manner in which the origi-  
3 nal appointment was made not later than 30 days  
4 after the MITAB is given notice of the vacancy and  
5 shall not affect the power of the remaining members  
6 to execute 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) INITIAL REPORT.—No later than 30 months  
16 after the date of the enactment of this Act, the  
17 MITAB shall submit to Congress and the Secretary  
18 a report on the following:

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

21                   (B) Methods of implementing—

22                           (i) health care information technology  
23 interoperability standardization; and

24                           (ii) records security

1 (C) A recommendation for a common lexi-  
2 con for computer technology.

3 (2) SUBSEQUENT REPORTS.—During each of  
4 the 2 years after the year in which the report is sub-  
5 mitted under paragraph (1), the MITAB shall sub-  
6 mit to Congress and the Secretary an annual report  
7 relating to additional recommendations, best prac-  
8 tices, results of information technology improve-  
9 ments, analyses of private sector efforts to imple-  
10 ment the interoperability standards established in  
11 section 1185 of the Social Security Act, and such  
12 other matters as may help ensure the most rapid  
13 dissemination of best practices in health care infor-  
14 mation technology.

15 (d) GOALS.—The goals described in this subsection  
16 are the following:

17 (1) To maximize positive outcomes in clinical  
18 care—

19 (A) by providing decision support for diag-  
20 nosis and care; and

21 (B) by assisting in the emergency treat-  
22 ment of a patient presenting at a facility where  
23 there is no medical record of the patient.

24 (2) To contribute to (and be consistent with)  
25 the development of the patient assessment instru-

1       ment provided for under section 545 of the Medi-  
2       care, Medicaid, and SCHIP Benefits Improvement  
3       and Protection Act of 2000 (as enacted into law by  
4       section 1(a)(6) of Public Law 106–554), and to as-  
5       sist in minimizing the need for new and different  
6       records as patients move from provider to provider.

7               (3) To reduce or eliminate the need for redun-  
8       dant records, paperwork, and the repetitive taking of  
9       patient histories and administering of tests.

10              (4) To minimize medical errors, such as admin-  
11       istration of contraindicated drugs.

12              (5) To promote and ensure access to best prac-  
13       tices of medicine through support of research across  
14       institutions.

15              (6) To provide a compatible information tech-  
16       nology architecture that facilitates future quality  
17       and cost-saving needs and that avoids the financing  
18       and development of information technology systems  
19       that are not readily compatible.

20       (e) STAFF AND SUPPORT SERVICES.—

21              (1) EXECUTIVE DIRECTOR.—

22                      (A) APPOINTMENT.—The Chairman shall  
23       appoint an executive director of the MITAB.

1                   (B) COMPENSATION.—The executive direc-  
2                   tor shall be paid the rate of basic pay for level  
3                   V of the Executive Schedule.

4                   (2) STAFF.—With the approval of the MITAB,  
5                   the executive director may appoint such personnel as  
6                   the executive director considers appropriate.

7                   (3) APPLICABILITY OF CIVIL SERVICE LAWS.—  
8                   The staff of the MITAB shall be appointed without  
9                   regard to the provisions of title 5, United States  
10                  Code, governing appointments in the competitive  
11                  service, and shall be paid without regard to the pro-  
12                  visions of chapter 51 and subchapter III of chapter  
13                  53 of such title (relating to classification and Gen-  
14                  eral Schedule pay rates).

15                  (4) EXPERTS AND CONSULTANTS.—With the  
16                  approval of the MITAB, the executive director may  
17                  procure temporary and intermittent services under  
18                  section 3109(b) of title 5, United States Code.

19                  (5) PHYSICAL FACILITIES.—The Administrator  
20                  of the General Services Administration shall locate  
21                  suitable office space for the operation of the  
22                  MITAB. The facilities shall serve as the head-  
23                  quarters of the MITAB and shall include all nec-  
24                  essary equipment and incidentals required for the  
25                  proper functioning of the MITAB.

1 (f) POWERS.—

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

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

15 (3) TECHNICAL ASSISTANCE.—Upon the re-  
16 quest of the MITAB, the head of a Federal agency  
17 shall provide such technical assistance to the  
18 MITAB as the MITAB determines to be necessary  
19 to carry out its duties.

20 (4) USE OF MAILS.—The MITAB may use the  
21 United States mails in the same manner and under  
22 the same conditions as Federal agencies and shall,  
23 for purposes of the frank, be considered a commis-  
24 sion of Congress as described in section 3215 of title  
25 39, United States Code.

1           (5) OBTAINING INFORMATION.—The MITAB  
2           may secure directly from any Federal agency infor-  
3           mation necessary to enable it to carry out its duties,  
4           if the information may be disclosed under section  
5           552 of title 5, United States Code. Upon request of  
6           the Chairman of the MITAB, the head of such agen-  
7           cy shall furnish such information to the MITAB.

8           (6) ADMINISTRATIVE SUPPORT SERVICES.—  
9           Upon the request of the MITAB, the Administrator  
10          of General Services shall provide to the MITAB on  
11          a reimbursable basis such administrative support  
12          services as the MITAB may request.

13          (7) PRINTING.—For purposes of costs relating  
14          to printing and binding, including the cost of per-  
15          sonnel detailed from the Government Printing Of-  
16          fice, the MITAB shall be deemed to be a committee  
17          of the Congress.

18          (g) TERMINATION.—The MITAB shall terminate 30  
19          days after the date of submission of its final report under  
20          subsection (e)(2).

21          (h) AUTHORIZATION OF APPROPRIATIONS.—There  
22          are authorized to be appropriated to the Secretary of  
23          Health and Human Services such sums as are necessary  
24          to carry out this section.

○