

BILL THOMAS, CALIFORNIA,  
CHAIRMAN

PHILIP M. CRANE, ILLINOIS  
E. CLAY SHAW, JR., FLORIDA  
NANCY L. JOHNSON, CONNECTICUT  
AMO HOUGHTON, NEW YORK  
WALLY HERGER, CALIFORNIA  
JIM McCRERY, LOUISIANA  
DAVE CAMP, MICHIGAN  
JIM RAMSTAD, MINNESOTA  
JIM NUSSLE, IOWA  
SAM JOHNSON, TEXAS  
JENNIFER DUNN, WASHINGTON  
MAC COLLINS, GEORGIA  
ROB PORTMAN, OHIO  
PHILIP S. ENGLISH, PENNSYLVANIA  
WES WATKINS, OKLAHOMA  
J.D. HAYWORTH, ARIZONA  
JERRY WELLER, ILLINOIS  
KENNY HULSHOF, MISSOURI  
SCOTT McINNIS, COLORADO  
RON LEWIS, KENTUCKY  
MARK FOLEY, FLORIDA  
KEVIN BRADY, TEXAS  
PAUL RYAN, WISCONSIN

# Congress of the United States

## House of Representatives

COMMITTEE ON WAYS AND MEANS

1102 LONGWORTH HOUSE OFFICE BUILDING  
(202) 225-3625

Washington, DC 20515-6348

<http://waysandmeans.house.gov>

September 13, 2002

CHARLES B. RANGEL, NEW YORK,  
RANKING MINORITY MEMBER

FORTNEY PETE STARK, CALIFORNIA  
ROBERT T. MATSUI, CALIFORNIA  
WILLIAM J. COYNE, PENNSYLVANIA  
SANDER M. LEVIN, MICHIGAN  
BENJAMIN L. CARDIN, MARYLAND  
JIM McDERMOTT, WASHINGTON  
GERALD D. KLECZKA, WISCONSIN  
JOHN LEWIS, GEORGIA  
RICHARD E. NEAL, MASSACHUSETTS  
MICHAEL R. McNULTY, NEW YORK  
WILLIAM J. JEFFERSON, LOUISIANA  
JOHN S. TANNER, TENNESSEE  
XAVIER BECERRA, CALIFORNIA  
KAREN L. THURMAN, FLORIDA  
LLOYD DOGGETT, TEXAS  
EARL POMEROY, NORTH DAKOTA

ALLISON H. GILES,  
CHIEF OF STAFF

JANICE MAYS,  
MINORITY CHIEF COUNSEL

To: Members, Committee on Ways and Means

Fr: Bill Thomas, Chairman

Re: Health Subcommittee Report

The Subcommittee on Health marked up H.R. 4889, the "Patient Safety Improvement Act of 2002," on September 12, 2002. H.R. 4889 was ordered favorably reported to the Full Committee, as amended, by voice vote.

Pursuant to Committee Rule 11, Subcommittee Chairman Johnson submitted a Subcommittee Report to the Full Committee on Friday, September 13, 2002. Attached is a copy of the Subcommittee Report.

NANCY L. JOHNSON, CONNECTICUT, CHAIRMAN  
SUBCOMMITTEE ON HEALTH

JIM McCRERY, LOUISIANA  
PHILIP M. CRANE, ILLINOIS  
SAM JOHNSON, TEXAS  
DAVE CAMP, MICHIGAN  
JIM RAMSTAD, MINNESOTA  
PHILIP S. ENGLISH, PENNSYLVANIA  
JENNIFER DUNN, WASHINGTON

FORTNEY PETE STARK, CALIFORNIA  
GERALD D. KLECZKA, WISCONSIN  
JOHN LEWIS, GEORGIA  
JIM McDERMOTT, WASHINGTON  
KAREN THURMAN, FLORIDA

EX OFFICIO:  
BILL THOMAS, CALIFORNIA  
CHARLES B. RANGEL, NEW YORK

BILL THOMAS, CALIFORNIA, CHAIRMAN  
COMMITTEE ON WAYS AND MEANS

ALLISON H. GILES, CHIEF OF STAFF  
JOHN E. McMANUS, SUBCOMMITTEE STAFF DIRECTOR

JANICE MAYS, MINORITY CHIEF COUNSEL  
CYBELE BJORKLUND, SUBCOMMITTEE MINORITY

RECEIVED  
COMMITTEE ON  
WAYS AND MEANS  
Congress of the United States  
House of Representatives  
2002 SEP 13 PM 6:14  
*Bill Thomas*

COMMITTEE ON WAYS AND MEANS

WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

September 13, 2002

The Honorable William Thomas  
Chairman, Committee on Ways and Means  
U.S. House of Representatives  
1102 Longworth House Office Building  
Washington, D.C. 20515

Dear Mr. Chairman:

On Thursday, September 12, 2002 the Subcommittee on Health ordered favorably reported to the Full Committee, H.R. 4889, the "Patient Safety Improvement Act of 2002," as amended, by voice vote.

The Subcommittee proposal would reduce health care errors by promoting voluntary and confidential reporting of errors and "close calls" to newly created private Patient Safety Organizations (PSOs) certified by the U.S. Department of Health and Human Services (HHS). The reporting system will be accompanied by an analysis of information in order to discover and remedy the root causes of medical errors.

Transmitted herein, in accordance with Committee Rule 11, is a report containing a comparison with present law and a section-by-section analysis of the proposed changes.

Sincerely,



Nancy L. Johnson  
Chairman

Committee on Ways and Means  
Subcommittee on Health  
Subcommittee Report on H.R. 4889  
The Patient Safety Improvement Act of 2002

A. PURPOSE AND SUMMARY

Purpose

More than 3 years ago, the Institute of Medicine (IOM) reported that preventable medical errors are the eighth leading cause of death in America – ahead of breast cancer, AIDS, and traffic deaths. And yet, no legislation has been approved by any committee or either chamber of Congress to deal with this crisis. Nearly 100,000 patients die in hospitals each year as a result of preventable mistakes. The number of injured is far greater.

A recent report by Auburn University who analyzed data from 36 hospitals and nursing homes in Colorado and Georgia over an 81-day period in 1999, found medication errors in about 20 percent of the doses administered in a "typical" 300-bed facility; researchers considered 7percent of the errors "potentially harmful."

According to the Pittsburgh Regional Healthcare Initiative, medication errors result in \$3,500 to \$4,000 additional costs per incident, an unacceptable financial cost borne by hospitals, individuals, public health programs and Medicare.

The purpose of the bill is to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect health outcomes. Specifically, this act will encourage a culture of safety by providing for the legal protection of information reported voluntarily for the purposes of quality improvement and the reduction of medical errors, and ensuring accountability by raising standards and expectations for continuous quality improvements.

Summary

*Error Reporting Process.* The bill creates a new process to allow confidential reporting of patient safety data from health care providers to Patient Safety Organizations (PSOs). The PSOs analyze reports from providers, provide feedback to providers as to what went wrong, and share non-identifiable information

with other PSOs and to the Center for Quality Improvement and Patient Safety database of medical errors.

*Patient Safety Organizations.* The PSOs must be certified by the Secretary, and are public or private organizations assist health providers in improving patient safety. Specifically, PSOs:

- Collect and analyze voluntary patient safety data reported by more than one provider.
- Develop and disseminate information to providers to end errors and improve best practices.
- Must maintain confidentiality and security of health information.
- Submit non-identifiable information to the errors database.

The PSOs must be managed and operated independently from reporting health providers.

*Privilege and Confidentiality.* The bill provides for confidentiality and peer review protections for patient safety data. The privilege only applies to patient safety data and does not apply to information that is available outside the process, such as records of a patient's medical diagnosis and treatment and other primary health records of a health care provider. This patient safety information is privileged and confidential and, therefore, cannot be subject to civil or administrative subpoena; subject to discovery in connection with a civil, or administrative proceeding; disclosed pursuant to FOIA; or admitted as evidence in any civil or administrative subpoena.

*Center for Quality Improvement and Patient Safety.* The bill provides statutory authority to the existing Center for Quality Improvement and Patient Safety in the Agency for Healthcare Research and Quality. The Center will:

- Certify and recertify PSOs.
- Collect and disseminate information regarding patient safety.
- Establish a Patient Safety Database to collect and support the analysis of non-identifiable data, and make recommendations to improve patient safety.
- Provide technical assistance to states that have or are developing medical errors reporting systems

*Interoperability Standards.* The legislation requires the Secretary to develop to develop voluntary, national standards that promote the interoperability of health care information technology systems across all health care settings.

*Best Practices.* The Secretary should encourage health care providers to adopt appropriate evidence-based methods to improve patient safety. Such standards are not national practice guidelines or a Medicare condition of participation.

*Program Evaluation.* Five years after implementation the U.S. General Accounting Office shall conduct a comprehensive evaluation of the usefulness of the analyses, information and recommendations, effectiveness of the program in reducing medical errors.

*Advisory Board.* The Secretary shall appoint a 17 member Medical Information Technology Advisory Board with expertise in medical information, information technology, health researchers and purchasers. The Board will make recommendations on best current practices in medical information technology and methods of implementing health care information technology interoperability.

### **Subcommittee Action**

On September 12, 2002, the Subcommittee on Health ordered favorably reported to the full Committee H.R. 4889, the “Patient Safety Improvement Act of 2002,” on a voice vote with a quorum present.

In the 106<sup>th</sup> Congress, the Subcommittee held a hearing on the prevalence and nature of medical errors in the health care system on February 10, 2002. During the 107<sup>th</sup> Congress, the Subcommittee held a hearing on March 7, 2002, on improving health quality by reducing the incidence of medical errors. The information gained from that hearing lead to the introduction of H.R. 4889, the “Patient Safety Improvement Act,” to provide incentives to report error information and glean knowledge about medical mistakes and system failures in order to reduce medical errors. On September 10, 2002, the Subcommittee held a legislative hearing on the draft substitute amendment to H.R. 4889.

### **Analysis of Legislation, Justification, and Comparison with Present Law**

#### **Section 1. Short Title; Table of Contents**

*Current Law.* No provision.

*Explanation of Provision.* The legislation would be cited as the Patient Safety Improvement Act of 2002 and would amend Title XI of the Social Security Act by adding Part D — Patient Safety Improvements — with six new sections (Sections 1181–1186). A Medical Information Technology Advisory Board would also be established.

*Effective Date.* Upon enactment.

*Reason for Change:* Not applicable.

## **Section 2. Patient Safety Improvements**

*Current Law.* No statutory provisions. The Institute of Medicine’s (IOM) 1999 report, *To Err is Human*, focused attention on the problem of preventable medical errors and the need for systematic steps to reduce their incidence to enhance patient safety. Among other proposals, IOM recommended that Congress create a Center for Patient Safety within the Agency for Healthcare Research and Quality (then called the Agency for Health Care Policy and Research) to promote knowledge and prevention of medical errors, set national goals for patient safety, fund patient safety research, evaluate methods for identifying and preventing medical errors, disseminate information on effective safety practices, and issue an annual report to the President and Congress on patient safety. The IOM recommended that the Center for Patient Safety encourage the development of voluntary reporting systems and outlined various actions that could be undertaken. Furthermore, IOM recommended that Congress pass legislation to extend peer review protections to data related to patient safety and quality improvement. While existing law often shields data about errors within a given institution, the IOM report noted that this protection may be lost if the information is transmitted elsewhere, even to a voluntary reporting system serving as the backbone of a collaborative effort to reduce medical errors.

*Explanation of Provision.* The provision would establish a new Part D in Title XI of the Social Security Act to encourage a voluntary reporting system for patient safety data.

A new **Section 1181** would be added which would permit a health care provider to voluntarily collect and report patient safety data to a patient safety 5

organization in a way that maintains the information as confidential and privileged. Patient safety organizations would analyze the reported data, develop and report back to providers information to improve patient safety, and submit non-identifiable information to the Center for Quality Improvement and Patient Safety for inclusion in the Patient Safety Database. Patient safety organizations would be permitted to share non-identifiable information, but the disclosure of identifiable information from one such organization to another would require the explicit authorization of the provider who initially reported the information.

In this legislation, a *health care provider* would mean: (1) facilities and their employees that provide services under Medicare Part A; (2) a health care entity or individual (including a physician) who furnishes Medicare Part B services; and (3) an organization offering a Medicare+Choice plan.

*Patient safety data* would mean any data, reports, records, memoranda, analyses, deliberative work, statements, or root cause analyses that are collected or developed to improve patient safety or health care quality. That would include patient safety data collected or developed by a provider to report to a patient safety organization on a timely basis, as well as data collected or developed by a patient safety organization or by the Center for Quality Improvement and Patient Safety, regardless of whether the data are transmitted back to the health care provider that supplied the information originally. Patient safety data would also encompass descriptions of corrective actions taken by providers in response to the provider's reporting of data to a patient safety organization, regardless of whether the organization has provided feedback to the provider.

A *patient safety organization* would mean a private or public organization that conducts activities to improve patient safety and health care quality as certified by the Secretary. Such activities would include: (1) the collection and analysis of patient safety data that are voluntarily reported by more than one provider on a local, state, regional, or national basis; (2) the development and dissemination to providers and other patient safety organizations of information such as recommendations, protocols, and best practice data; and (3) the utilization of patient safety data to assist providers to minimize patient risk. Patient safety organizations would be required to ensure the confidentiality of individually identifiable data, submit information to the Center for Quality Improvement and Patient Safety if applicable in an established format, and maintain appropriate data security measures.

Other requirements would be imposed on patient safety organizations. Such organizations would be required: (1) to be managed, controlled, and operated independently from providers that report data to it; (2) to collect data from providers in a standardized manner to permit comparisons of similar cases across similar providers; and (3) to meet other requirements specified by the Secretary. An entity that no longer qualified as a patient safety organization would be required to destroy its patient safety data, return (if practicable) the data to the reporting providers, or transfer data to another patient safety organization with the approval of the provider and that organization. Patient safety organizations that charge fees for their activities would be required to impose a uniform fee across all types and classes of providers, taking into account the size of the health care provider. A patient safety organization could not use data reported by a provider to take regulatory or enforcement actions it otherwise performs against the provider. The Secretary would be able to give technical assistance to patient safety organizations in providing recommendations and advice to providers on methodology, communication, data collection, security and confidentiality concerns. Nothing in this part would be construed to limit or discourage reporting patient safety data within a health care provider.

A new **Section 1182** would designate patient safety data as privileged and confidential. That designation would apply to information, such as medical records and other primary health care information, that was collected and developed for the purpose of improving patient safety and health care quality, and reported to a patient safety organization. Such privilege would not apply to information merely by reason of its inclusion in reported patient safety data. With some limitations, patient safety data would not be subject to: (1) a civil or administrative subpoena; (2) discovery in connection with a civil or administrative proceeding; (3) disclosure pursuant to a Freedom of Information Act request; or (4) admission as evidence or disclosure in any civil or administrative proceeding.

The privilege established by this section would not apply to: (1) medical records and other information that is not patient safety data; (2) information disclosed by a provider or patient safety organization of data to the Food and Drug Administration (FDA), or to a person subject to FDA jurisdiction, regarding an FDA-regulated product or activity; and (3) disclosures of non-identifiable patient safety data from an patient safety organization to the Patient Safety Database and the further disclosure of such data by the Center for Quality Improvement and Patient Safety. A health care provider would not be permitted to take any adverse employment action against an employee who reported patient safety data to a

patient safety organization. Disclosures in violation of the provisions of this section would be unlawful. Persons found in violation would be subject to the same penalties as those relating to inappropriate disclosures made by peer review organizations under the Medicare program, which provide for fines of up to \$1,000 per disclosure, up to 6 months in prison, or both, and payment of the costs of prosecution.

Nothing in this part would be construed as preempting or otherwise affecting any state mandatory reporting requirements for health care providers.

The privileges established under this section would not preempt Federal or state laws that provide greater peer review or confidentiality protections than those provided by this legislation. The health information privacy provisions in the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and related implementing regulations would not be affected by this legislation. Patient safety organizations would be treated as business associates under HIPAA's privacy rule. Permissible disclosures to FDA under these provisions would not waive any privilege established by this legislation or under State law. Patient safety data of an organization that loses its certification as a patient safety organization would continue to be privileged and confidential until returned to the providers that supplied the data, transferred to another patient safety organization, or otherwise destroyed.

The GAO would be required to conduct a survey of State laws regarding patient safety peer review systems, evidentiary privilege applicable to data developed in such systems, and court interpretations of such laws. The GAO would be required to submit a report on this subject to Congress within 9 months of enactment.

A new **Section 1183** would grant statutory authority for the existing Center for Quality Improvement and Patient Safety within the Agency for Healthcare Research and Quality. The Secretary, through the Center, would be required to: (1) provide for the certification and recertification of patient safety organizations; (2) collect and disseminate information related to patient safety; (3) establish a Patient Safety Database to collect, support and coordinate the analysis of non-identifiable information submitted to the database; and (4) facilitate the development of consensus among providers and interested parties concerning patient safety and related recommendations. The Secretary would be required to consult with and develop appropriate partnerships with health care organizations,

providers, public and private sector entities, patient safety organizations, health care consumers and other relevant experts.

Certification and recertification of patient safety organizations would be made under a process that is approved by the Secretary that is consistent with published criteria. The Secretary would be able to revoke such certification upon a showing of cause, including the inappropriate disclosure of patient safety data. Certification would terminate, subject to recertification, upon 3 years from the date of certification or upon revocation. In carrying out these responsibilities, the Secretary would be required to facilitate the development of patient safety goals, track progress in meeting these goals, ensure that data submitted by a patient safety organization to the Patient Safety Database are comparable and useful for research and analysis, and ensure that research findings and patient safety alerts are presented in clear and consistent formats.

The Secretary, acting through the Center, would: (1) establish a Patient Safety Database to collect voluntarily reported, non-identifiable information concerning patient safety; and (2) establish common formats for reporting data to the Patient Safety Database. The Secretary would also be required to establish criteria to determine the organizations that may voluntarily contribute to, and that data that comprises, the Patient Safety Database, and ensure that the Database is only used by qualified entities. The Secretary would also be permitted to enter into contracts with private and public entities to administer the Database. Non-identifiable information would mean information that is presented in a form that precludes the identification of any provider, patient, or reporter of the information. There would be authorized to be appropriated such sums as may be necessary for each fiscal year to carry out this section.

A new **Section 1184** would require the Secretary within 2 years of enactment to develop (and periodically review and update) voluntary, national standards that promote the interoperability of health care information technology systems across all health care settings. These standards would be developed in consultation with the National Committee for Vital and Health Statistics, and the Medical Information Technology Advisory Board (established under Section 3). The Secretary would be required to disseminate these standards. There would be authorized to be appropriated such sums as may be necessary for each fiscal year to carry out this section.

A new **Section 1185** would require the Secretary to encourage providers to adopt appropriate evidence-based methods to improve patient safety. These methods would not constitute national practice guidelines or conditions of participation in the Medicare program.

A new **Section 1186** would require GAO to conduct a comprehensive evaluation of the implementation of Sections 1181–1185 and report to Congress within 5 years of enactment. Such an evaluation would include: (1) an examination of the patient safety data that were reported by health care providers; (2) the usefulness of the analyses, information, and recommendations provided by the patient safety organizations in response to such reported data; (3) the response of providers to such analysis, information, and recommendations; and (4) the effectiveness of these efforts in reducing medical errors.

*Reason for Change:* Nearly 100,000 patients die in hospitals each year as a result of preventable mistakes. The number of injured is far greater. The Subcommittee believes these provisions, taken together, will reduce preventable medical errors and improve quality. In addition, the Subcommittee believes the development, promulgation and adoption of voluntary interoperability standards by HHS will promote efficiency and quality of health care delivery, while helping to reduce costs.

### **Section 3. Medical Information Technology Advisory Board**

*Current Law.* No provision.

*Explanation of Provision.* Within 3 months of enactment, the Secretary would be required to appoint the Medical Information Technology Advisory Board (MITAB) and designate a chairman. The chairman would be required to be affiliated with an organization having expertise in creating American National Standards Institute (ANSI) standards governing health care information technology and to be a member of the National Committee for Vital and Health Statistics. The MITAB would consist of no more than 17 members that include: (1) experts from the fields of medical information, information technology, medical continuous quality improvement, medical records security and privacy, individual and institutional clinical providers, health researchers, and health care purchasers; (2) one or more staff experts from the Centers for Medicare and Medicaid Services, the Agency for Healthcare Research and Quality, and the Institute of Medicine of the National Academy of Sciences; (3) representatives of private organizations

with expertise in medical informatics; (4) a representative of a teaching hospital; and (5) one or more representatives of the health care information technology industry. Individuals would be appointed for the life of the MITAB, with any vacancy filled in the same manner in which the original appointment was made. The new appointment would be made no later than 30 days after the MITAB is given notice of the vacancy. Such a vacancy would not affect the ability of the remaining members to perform the duties of the MITAB.

The MITAB would meet at the call of its Chairman or a majority of its members. MITAB members would receive no additional pay, allowances, or benefits stemming from their service on the board, but would receive travel expenses and per diem in lieu of subsistence as directed by Sections 5702 and 5703 of Title 5 of the United States Code (USC). The Chairman would appoint an executive director of the MITAB who would be paid at level V of the Executive Schedule. With the approval of the MITAB, the director would be able to appoint appropriate personnel without regard to the provisions of Title 5 USC governing appointments in the competitive services or those relating to job classification and pay rates. The MITAB director would also be able to procure temporary and intermittent services under Section 3109(b) of Title 5 USC. Upon the request of MITAB, the head of any Federal agency would be able to detail, without reimbursement, any personnel of that agency to MITAB. The detail would not interrupt or affect the civil service status of the Federal employee.

MITAB would be able to hold hearings and undertake other activities as necessary to carry out its duties. If requested by MITAB, a Federal agency would be required to provide technical assistance to the MITAB as deemed necessary. At the request of the MITAB chairman, the MITAB would be able to secure directly from any Federal agency information necessary to carry out its duties, if the information may be disclosed under the Freedom of Information Act (Section 552 of Title 5 USC).

MITAB would advise, and make recommendations to, the Secretary regarding medical information technology, including: (1) best practices in medical information technology; (2) methods of implementing health care information technology interoperability standardization, and records security; and (3) a recommendation for a common lexicon for computer technology. MITAB would also be required to make recommendations on methods to promote information exchange to enhance compatibility among information systems in order to: (1) maximize positive outcomes in clinical care by providing decision support for

diagnosis and care, and assisting in the emergency treatment of a patient at a facility with no medical record of the patient; (2) contribute to the development of a patient assessment instrument that minimizes the need for different records when patients move from provider to provider; (3) reduce redundant paperwork; (4) minimize medical errors; and (5) contribute to compatible information technology architecture.

MITAB would be required within 18 months of enactment to submit to Congress and the Secretary an initial report of its deliberations and recommendations. Subsequent annual reports would be due in each of the following 2 years after the initial report is submitted.

MITAB would terminate 30 days after the date of submission of its final report. The provision provides such sums as necessary for the operations of MITAB.

*Effective Date.* Upon enactment.

*Reason for Change:* The Subcommittee believes a new advisory board on medical technology will promote the adoption of better, more efficient and effective systems that will help health care providers reduce errors by making patient information more readily available, and promote quality by providing expert advice to HHS on the adoption of interoperability standards and through promotion of information technology.