Mr. MCCONNELL. Mr. President, I ask that the live quorum under rule XXII be waived.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. MCCONNELL. Mr. President, I now withdraw the motion to proceed.

The PRESIDING OFFICER. The motion is withdrawn.

**MORNING BUSINESS**

Mr. MCCONNELL. Mr. President, I ask unanimous consent there now be a period for morning business with Senators permitted to speak therein for up to 10 minutes each.

The PRESIDING OFFICER. Without objection, it is so ordered.

**PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005**

Mr. ENZI. Mr. President, as chairman of the Health, Education, Labor, and Pensions Committee, I would like to take the opportunity to comment on a very important piece of legislation the Senate passed this week—a managers' substitute for S. 544, the Patient Safety and Quality Improvement Act of 2005, offered by myself, Senators Jeffords, Gregg, Kennedy, Frist, Murray, and Bingaman.

More than 5 years in the making, this legislation is an important step toward building a culture of safety and quality in our health care system.

The bill reflects a carefully negotiated bipartisan, bicameral agreement between the chairmen and ranking members of the Senate Health, Education, Labor, and Pensions Committee and the House Energy and Commerce Committee. I want to thank my colleagues Senator Kennedy, Chairman Barton, and Representative DINGELL, for their hard work in bringing this agreement to fruition.

Tremendous credit also goes to the HELP Committee's previous Chairman, Senator Jeffords, sponsor of the original legislation upon which this agreement builds.

The Patient Safety and Quality Improvement Act will create a framework through which hospitals, doctors, and other health care providers can work to improve health care quality in a protected legal environment.

More specifically, the bill will extend crucial legal privilege and confidentiality protections to health care providers to allow them to report health care errors and "near misses" to specially designated patient safety organizations. In turn, these patient safety organizations, some of which exist in limited form today, will be able to collect and analyze patient safety data in a confidential manner.

After conducting this analysis, patient safety organizations will report back to providers on trends in health care errors and will offer guidance to them on how to eliminate or minimize these errors. Some of this takes place today, but much more information could be collected if providers felt confident that reporting such errors would not increase the likelihood that they could be sued.

It is not the intent of this legislation to establish a legal shield for information that is already currently collected or maintained separate from the new patient safety process, such as a patient's medical record. That is, information which is currently available to plaintiffs' attorneys or others will remain available today. Rather, what this legislation does is create a new zone of protection to assure that the assembly, deliberation, analysis, and reporting by providers to patient safety organizations of what we are calling "Patient Safety Work Product" will be treated as confidential and will be legally privileged.

Errors in medical treatment take place far too often. Unfortunately, however, providers live in fear of our unpredictable legal system. This fear, in turn, inhibits efforts to thoroughly analyze medical errors and their causes. Without appropriate protections for the collection and analysis of patient safety data, providers are understandably loath to participate in medical error reporting systems.

I am pleased that the negotiated final version of this bill reflects and upholds several of the key priorities of the bill the HELP Committee marked up earlier this year, which was also passed out of the Senate last year.

For example, this agreement makes very clear that, in addition to strong legal privilege provisions, patient safety work product will also be subject to a clear and affirmative duty of confidentiality. That is, not only will patient safety work product be subject to a privilege in legal and related proceedings, but the bill will also impose penalties of up to $10,000 per violation should such patient safety work product be disclosed.

It was a key priority of the Senate bill that such information not only be privileged in a legal proceeding, but also that serious consequences will ensue if patient safety organizations, providers, or anyone else divulges it in ways not permitted under the bill. I am very pleased that the compromise agreement we are passing this week upholds this commitment to an affirmative duty of confidentiality.

Also, we were very strongly that the definition of patient safety work product—that is, exactly what kind of information is to be protected—be drawn broadly enough to assure that providers will feel safe and secure in participating in a patient safety system—and that they not be chilled from participating by fear that their efforts to assemble, analyze, deliberate on, or report patient safety information to patient safety organizations would somehow fall outside of a too-narrow statutory definition of patient safety work product.

With this in mind, we negotiated a definition in the agreement which takes great care to make clear that providers that the assembly of data, its analysis, deliberations about it, and its reporting to a patient safety organization will be firmly protected. We also clarified that information that is collected, maintained, or developed separately from the patient safety system will continue to be treated the same as it is under current law.

Before I close, I want to take just a minute to thank the many Senate staff who worked very hard to bring this legislation to where it is today. Among those who deserve special recognition and thanks are Andrew Patzman and Stephen Northrup of my HELP Committee professional staff, David Bowen of Senator Kennedy's Committee staff, Peggy Binzer with Senator Gregg, Dean Rosen of Senator Frist's Leadership staff, and Sean Donohue with Senator Jeffords. Much credit also goes to the hard work of the staff of the House Energy and Commerce Committee, the expert and very capable legislative staff at the Department of Health and Human Services.

I ask unanimous consent that a section-by-section summary of the legislation be printed in the Record.

There being no objection, the material was ordered to be printed in the Record, as follows:

**SECTION-BY-SECTION SUMMARY**

"PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005"

**MANAGERS SUBSTITUTE AMENDMENT**

(July 2005)

**SECTION 1. SHORT TITLE**

The Patient Safety and Quality Improvement Act of 2005.

**SECTION 2. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT**

Creates a new Part C of Title IX of the Public Health Service Act, Entitled "Patient Safety Improvement".

**SECTION 921. DEFINITIONS**

"Patient Safety Activities" describes activities involving providers and certified patient safety organizations (see Sec. 924, below) which include the following: (1) efforts to improve patient safety and the quality of health care delivery, (2) collection and analysis of patient safety work product, (3) development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practice, (4) utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively manage current risk, and (5) maintenance of procedures to preserve confidentiality with respect to patient safety.
work product, (6) activities related to the operation of a patient safety evaluation system, and to the provision of feedback to participants in a patient safety evaluation system. “Patient Safety Work Product” is the data and other information for which the bill provides legal privilege and confidentiality protection. Patient safety work product includes reports, records, analyses, or work products that are compiled, maintained, or developed in the course of patient safety evaluations or analyses of information for reporting to or by a patient safety organization.

Criteria for certification as a patient safety organization include the following: (1) the mission and primary activity of the entity are the product activities that are to improve patient safety and the quality of health care delivery, (2) the entity has appropriately qualified staff as determined by the Secretary, including medical professionals, (3) the entity receives and reviews patient safety work product from more than one provider, (4) the entity is not a health insurance plan; (5) the Secretary, including medical professionals, (6) activities related to the operation of a network of patient safety data-bases to collect and analyze relevant non-identifiable patient safety information; (7) the patient safety work product to be analyzed includes patient safety events that are to improve patient safety and the quality of health care delivery, and (8) the entity has appropriately qualified staff as determined by the Secretary, including medical professionals.

S8742

PROTECTIONS

Provides that patient safety work product is legally privileged and as such is not subject to (1) Federal, State or local civil, criminal, or administrative proceedings, (2) discovery in connection with a Federal, State or local civil, criminal, or administrative proceeding, (3) disclosure pursuant to the Freedom of Information Act (FOIA), (4) discovery in connection with any Federal, State or local civil, criminal, or administrative proceeding, (5) admitted in a professional disciplinary proceeding, (6) disclosed to an employer for an adverse employment action based on a person’s having made a good faith report of a patient safety organization.

Exceptions to the confidentiality rule but not to the privilege protection include disclosure of patient safety work product to carry out patient safety activities, (1) to avoid a violation of HIPAA confidentiality regulations (regarding the patient’s health insurance portability and accountability act (HIPAA)), (2) to save lives and reduce the tragedy of needless medical errors. This legislation also starts with a simple premise. Let us set up a system that enables and encourages the trust of providers and the patients they serve.

The passage of this legislation represents the successful culmination of efforts, by many of our colleagues, that began with the publication of a small but significant report about medical errors.
that Hippocrates’ maxim to “first, do no harm” is as relevant to the practice of medicine today as it was in 400 B.C.

That IOM report was among the first to galvanize national attention on the issue of patient safety when it reported that medical errors contribute to approximately 100,000 patient deaths a year. This startling and troubling statistic has been verified in subsequent studies and cited in peer reviewed articles in the leading journals of biomedical research, including the Journal of the American Medical Association, the Lancet, and the New England Journal of Medicine.

When I was Chairman of the Senate Committee on Health, Education, Labor, and Pensions in 1999, I undertook several hearings—five in all—to examine this issue and discuss the recommendations of the To Err is Human report. The preponderance of testimony overwhelmingly agreed with several of the original Institute of Medicine recommendations.

Perhaps the most important of these recommendations stresses that improving patient safety requires a learning environment rather than a punitive environment; voluntary data gathering systems required to mandatory systems; and appropriate legal protections—including confidentiality and privilege from discovery—that allow for the review and analysis of medical error information.

In response to this attention to patient safety issues, a myriad of public and private patient safety initiatives have begun. The Department of Health and Human Services has initiated several patient safety projects, including project grants funded by the Agency for Healthcare Research and Quality. AHRQ. The work of the Veterans’ Administration in developing and implementing innovative patient safety systems—especially in the area of medication systems—has drawn national attention from throughout the country. In addition, the Quality Interagency Coordination Taskforce has recommended steps to improve patient safety that can be taken by each Federal agency involved in health care; and agency activities to implement these steps are ongoing. Finally, efforts are well underway to bring the advanced electronic technology of the information age to bear on solving many of the problems associated with medical errors.

Several non-governmental organizations and professional societies have also “stepped up to the plate” on patient safety. The Joint Commission on Accreditation of Healthcare Organizations, the U.S. Pharmacopoeia, the American Medical Association, medical specialty societies and other health care providers including the American Hospital Association and the American Federation of Hospitals have launched innovative efforts dedicated to improving patient safety.

Consumers of healthcare and academia are involved in reducing errors in patient care as well. Examples of these include: “The Leapfrog Group” an initiative driven by organizations that buy health care that are working to initiate breakthrough improvements in the safety, quality and affordability of healthcare; and the Institute for Healthcare Improvement, founded by an original IOM panel member, Dr. Don Berwick, which has provided seminal work advancing the goals of patient safety. All of these efforts deserve our gratitude because without them deaths and injuries due to medical errors would continue to increase.

However, many of the organizations currently collecting patient safety data have expressed the need for legal protections that will allow them to review protected information so that they may collaborate in the development and implementation of patient safety improvement strategies. The work of Lucien Leape, another member of the IOM panel and adjunct professor of health policy at Harvard University, has supported this view.

Dr. Leape has argued persuasively that we, as a society, will continue to have difficulty reducing medical errors and improving patient safety because our current health care system is driven into a “blame and punish approach to errors and a focus on individual culpability” in turn, “the fear of malpractice litigation thus becomes a major barrier to openly discussing and reporting errors.”

To respond to these needs, I and several of our colleagues have for many years introduced legislation that would promote the open discussion of medical errors that is so needed to curb these needless deaths and injuries. Last year, this legislation passed the Senate unanimously, but unfortunately, a conference with our House colleagues never occurred.

This Congress, I reintroduced S. 544, the Patient Safety and Quality Improvement Act, with the bipartisan support of Senators Gregg, Bingaman, Enzi, Frist, and Murray. Our group was soon joined in this effort by Senators Sessions, Landrieu and Collins. Early in this session, the Health, Education, Labor, and Pensions Committee unanimously passed S. 544. To Chairman Enzi’s great credit, he recognized the significance of this legislation early on and, enlisting the support of Senators Sessions and Landrieu, worked his way to resolving differences between S. 544 and language that was being considered by our colleagues in the House of Representatives. Together, these Members worked untiringly to hone and improve this legislation, which resulted in its consideration by, and the unanimous support of, our colleagues last night.

The legislation raises expectations for higher standards for continuous patient safety improvement and it encourages a new and needed culture of patient safety among health care providers and American hospitals. The bill accomplishes these goals by establishing appropriate legal protections for patient safety information voluntarily shared among patient safety organizations and providers. Our legislation reflects the belief that a culture of patient safety can flourish best in an environment where information, data, processes, and recommendations enjoy legal protection and privilege.

Because it appropriately addresses an obvious need and concern, the Patient Safety and Quality Improvement Act has enjoyed widespread endorsement by hospital, patient, doctor, and consumer organizations. This degree of support underscores the broad appeal and essential nature of this proposed legislation.

In the time since the release of To Err is Human, the Congress has been unable to enact sensible legislation to reduce medical errors and increase patient safety. In that time, assuming that the IOM data are accurate, approximately one-half million more individuals have died and countless others have experienced significant injuries through medical errors.

With the leadership of Chairman Enzi and Senator Kennedy we have met to work out differences with our colleagues in the House and it too will soon consider legislation. I am encouraged that we have reconciled disagreements that have previously stopped this legislation from moving forward and I hope the House will act favorably so that this legislation can become law.

We need to apply Hippocrates’ admonition to “first, do no harm” beyond the medical community to the legislative community. We need to pass legislation now that will help the health care community stop the needless injury caused by unintentional medical errors.

Of course, we also live in a complex society—one in which medical errors that may have harmed a patient might also raise the basis for litigation. It is a right under our laws to seek a remedy when harmed, and we need to preserve access to certain information for this redress of grievances.

However, an unfortunate consequence of living in a litigious society is that hospitals and providers often feel that it’s not in their best interests to share information openly and honestly. We know, in fact, that their attorneys and risk managers often advise them not to do so. So, in order for our system to work, it needs to balance these sometimes competing demands.

I believe the Patient Safety and Quality Improvement Act strikes this balance. It calls for the creation of new entities we call Patient Safety Organizations that would collect voluntarily and confidentially reported data in the form of patient safety work products. This bill provides the protections of confidentiality and privilege to that patient safety data—but this bill also sets definite limitations to what can be considered confidential and privileged.

This legislation does nothing to reduce or affect other Federal, State or
We legislate on many issues in the Congress, but it is not often we can say that what we do makes a difference as a matter of life and death. Patient safety, however, is one of those issues. When this legislation is signed into law, everyone that has worked to implement it, in this instance, they have made that difference.

LONG-TERM CARE
Mr. AKAKA. Mr. President, the Department of Veterans Affairs is to be applauded for facilitating a conference on the role of medical foster homes. The conference is titled: “Medical Foster Home: A New Choice for Long-Term Care.” The conference kicks of tomorrow in Little Rock, AR.

I also want to applaud the conference participants for taking time to attend the conference. We truly must be open to new ideas about how VA can care for veterans in long-term care. In my view, medical foster homes are an important part of the equation.

We know that today VA is facing tremendous demand for long-term care. In the years ahead, demand will explode. Yet the President’s budget includes significant cuts to long-term care programs. The goal seems to reduce VA’s workload and shift the burden elsewhere. But where are veterans to go?

Should VA be cutting back at a time when demand is growing? Should those veterans need to be housed in county and state home beds? According to the President’s budget proposal, the answer is yes.

There is another side to this story: there are places on the VA landscape where some truly wonderful things are happening to keep veterans well cared for and in the setting of their choice. Good programs must be fostered.

Indeed, there are VA clinicians who, in grappling with the demand, have not waited but have found some innovative solutions. I am always deeply gratified by the level of dedication and innovation of VA employees, and I salute those who have moved forward.

One such good program is the medical foster home program in Arkansas. In 2002, Tom McClure testified before the Senate VA Committee about the foster home program. I know that all the Members of the Committee were amazed at the success of the program—something the VA has for years faced along the way. Nearly 3 years later, it seems VA is finally ready to advance the concept.

For my part, I recently introduced legislation to develop a medical foster home program on the Island of Oahu in Hawaii. While we may not have a marvelous VA nursing home—the Center on Aging, it only has 60 beds. Unfortunately, community nursing homes have few beds, as well. So, it is absolutely critical that Hawaii veterans be provided with needed long-term care.

More and more veterans are seeking alternatives to nursing homes. They want to remain in the community.

With the right kind of support and care from VA, they are able to do so—even with chronic and debilitating conditions. I do want to say that for many veterans, however, non-institutional options will not work; and because of this Congress is on record stating that VA must have sufficient nursing home capacity.

It is vital that VA’s role as a model for long-term care be recognized and rewarded, because we will have enormous problems with demand for this care in the years ahead. The only entity of any scope, size, or capacity that is dealing with how to meet the needs of an older population is VA. This role of VA must be highlighted and supported.

DEPARTMENT OF HOMELAND SECURITY APPROPRIATIONS ACT

Ms. COLLINS. Mr. President, last week, Senator LIEBERMAN and I offered, and the Senate adopted, Amendment #1142 to H.R. 2360, the Department of Homeland Security Appropriations Act. The amendment, which seeks to improve the process for providing homeland security grants to State and local governments, is nearly identical to S. 21, the Homeland Security Grant Enhancement Act of 2005, a bill which was reported out of the Committee on Homeland Security and Governmental Affairs. S. 21 was placed on the Senate’s legislative calendar on May 4, 2005, and a detailed and comprehensive report from the Committee, Senate Report 109-71, accompanied S. 21 at that time. Because of the near identity of S. 21 and the amendment, this report pertains to Amendment #1142 as well.

Mr. LIEBERMAN. Mr. President, I agree with the Senator from Maine that the Committees are focused on the amendment as well as to S. 21, on which the amendment is almost wholly based. The report provides a useful explanation of, and a broader context to, the amendment, and I recommend that those participating in the conference of the Homeland Security Appropriations bill look to it to elucidate the amendment. Also, to the extent that the language of Amendment #1142 will be enacted, I urge the Department of Homeland Security and others who may be called upon to implement or interpret these provisions to look to the text of the committee report for guidance in that implementation or interpretation.

Ms. COLLINS. Mr. President, I join with the Senator from Connecticut in encouraging those who are conference on this bill and those who will be implementing the amendment if it is enacted to read and rely on the text of Senate Report 109-71.