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PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2003

NOVEMBER 17, 2003.—Ordered to be printed

Mr. GREGG, from the Committee on Health, Education, Labor, and Pensions, submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany S. 720]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 720) to amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

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I. Purpose and Need for Legislation

As many as 98,000 Americans die each year from preventable medical errors, according to the Institute of Medicine in its 1999 report To Err Is Human: Building a Safer Health System. This IOM report recognizes that health care professionals are human, humans are prone to error and most human errors are triggered by system failures. The report emphasizes the need to make system improvements and advises that health care information reporting systems must develop and implement processes through which medical error information can be identified, analyzed and utilized to prevent further medical errors. In addition, the report highlights that society's long-standing reliance on the threat of malpractice litigation discourages health care professionals and organizations from disclosing, sharing, and discussing information about medical errors. As a result, medical errors too often do not get identified and the same systems-oriented errors recur. The availability of civil remedies for patients who have been injured by negligence is important to redress patients' injuries. To reduce errors and improve patient safety the IOM recommended, among other things, that "Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality." The IOM acknowledged that a critical component of a comprehensive strategy to improve patient safety is to create an environment that encourages organizations to identify errors, evaluate causes and design systems to prevent future errors from occurring.

Reporting and analyzing errors is one component of the comprehensive strategy recommended by the IOM to reduce errors and improve patient safety and health care quality. In To Err is Human and subsequent reports, the IOM recommends a tiered approach to improve the quality of care: federal protections for a voluntary error reporting system (which is the focus of this bill); a narrowly focused mandatory reporting system to collect standardized information by State governments about adverse events that result in death or serious harm (about 20 States have implemented mandatory reporting statutes for certain serious events); increased investment in information technology; establishing a national focus to create leadership and enhance the knowledge base about safety; raising standards and expectations for improvements in safety; and creating safety systems inside health care organizations through the implementation of safe practices at the delivery level. Enactment of S. 720 is a significant step in an ongoing effort to improve the quality of care provided to all Americans. The committee notes that HHS has undertaken a number of programs to address medical errors and improve quality.

The committee has held five hearings concerning medical error and patient safety since the release of To Err is Human in 1999. In the course of this examination, the committee found that efforts to improve patient safety could best be strengthened by creating a learning environment characterized by supportive, voluntary data gathering systems. Testimony received during the committee's examination of this issue complements the body of research calling

for the creation of a "safe harbor" for the reporting of medical error information; that is, a means of reporting and analyzing information insulated from the risk of incurring additional liability and that absent a new reporting system would not otherwise exist.

This committee finds that S. 720, the "Patient Safety and Quality Improvement Act of 2003" will promote a learning environment that is needed to move beyond the existing culture of blame and punishment that suppresses information about health care errors to a "culture of safety" that focuses on information sharing, improved patient safety and quality and the prevention of future medical errors. The committee believes that it is important to shift the current focus from culpability to a new paradigm of error reduction and quality improvement. A new system and process—separate from but parallel to complementary laws and regulations designed to ensure accountability—is required to encourage the reporting of errors and to create an environment in which errors become opportunities for learning and improvement. This system and process would be separate from, and parallel to, complementary State, Federal, and local laws and regulations designed to ensure accountability; these State, Federal, and local reporting systems are independent of the system contemplated by this bill. The Department of Veterans Affairs and the Federal Aviation Administration, among others, have demonstrated that establishing a confidential error reporting system encourages reporting and results in substantial advances in safety. The Veterans' Health Administration has not only instituted a program for voluntary error reporting, but has also instituted a comprehensive program to improve the quality of care provided at VHA facilities. Integral to this program is the pervasive use of information technology in clinical practice. Physicians at VHA facilities can access patient records electronically and can enter orders for tests or procedures via an integrated computer system that provides alerts if an intended order is contraindicated for a particular patient. Moreover, the VHA electronic record system can issue reminders for specific procedures or screening tests to be performed, so that needed preventive care is not inadvertently omitted. It is far from certain that voluntary reporting alone would have been sufficient to cause the dramatic improvement in health care quality seen at VHA facilities in recent years.

An indispensable element of the reporting system used by the FAA is the collection and analysis of errors reports at a central site. If problems that could endanger passenger safety are found in any aspect of the federal aviation system, FAA issues directives to rectify those problems. Compliance with directives from the FAA is mandatory. The Aviation Safety Reporting System (ASRS) receives about 30,000 reports annually and has an operating budget of approximately $2 million. While S. 720 adopts a similar voluntary and confidential approach to improving patient safety, the committee believes that collecting potentially a million error reports a year at a central location would be impractical and prohibitively expensive. Not only would the sheer number of reports be overwhelming, but also the necessary expertise that would be necessary to properly analyze reports would be prohibitive. A preferred approach is to allow PSO's to report aggregated, nonidentifiable information to national databases specifically established to collect and disseminate information on improving patient safety.

The committee finds that the entire health care delivery system can benefit from a systems analysis of near misses and errors that have resulted in adverse events for systems improvement and corrective actions.

The purpose of this legislation is to encourage a "culture of safety" and quality in the U.S. health care system by providing for broad confidentiality and legal protections of information collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety. These protections will facilitate an environment in which health care professionals and organizations report and evaluate health care errors and share their experiences with others in order to prevent similar occurrences. This legislation is needed to address what may be as many as 98,000 preventable deaths per year associated with medical errors and the estimated $29 billion in national costs associated with such preventable errors.

This bill accomplishes these purposes by establishing and defining a specific class of information known as "patient safety data" and according this new class of data legal protections designed to promote its collection, reporting and analysis. Patient safety data is not subject to a Federal, State, or local civil, criminal, or administrative subpoena or subject to discovery in a Federal, State, or local civil, criminal, or administrative proceeding. Further, this bill will not permit patient safety data to be disclosed under the Freedom of Information Act (FOIA); admitted as evidence or disclosed in a Federal, State, or local civil, criminal, or administrative proceeding; or used in a disciplinary proceeding against a provider. The bill also provides broad confidentiality protections, which are necessary to engender the trust and cooperation of the health care providers. Without participation of health care providers the system cannot be effective in collecting information.

During the past decade patient safety has emerged as a major health policy issue. There has been a steadily growing and forceful call for Congress to pass legislation that will facilitate the development of a confidential and nonpunitive system for reporting health care errors so that such errors can be identified and analyzed to improve patient safety by preventing future errors.

Members of this Committee have worked in a bi-partisan fashion to draft Federal legislation that reflects the IOM's recommendation for congressional action to establish a confidential reporting system to encourage a cooperative effort among providers and organizations geared to improving patient safety. This committee has worked diligently and deliberately to ensure that this legislation strikes the appropriate balance between plaintiff rights and creating a new culture in the health care industry that provides incentives to identify and learn from errors.

II. SUMMARY

The general intent of S. 720, "The Patient Safety and Quality Improvement Act of 2003" is to establish a system to encourage voluntary reporting of adverse medical events, medical errors and incidents of "near misses" and to facilitate the development and adoption of interventions and solutions that will improve patient safety and the quality and outcomes of health care. This legislation

amends the Public Health Service Act to establish protections that will foster voluntary reporting.

This legislation will encourage "providers" (e.g., physicians, nurses, hospitals, nursing homes, and other health care providers) to report information on errors, incidents of "near misses" and enhanced health care quality practices to organizations known as Patient Safety Organizations (PSO's). PSO's are organizations that collect and analyze "patient safety data" and provide feedback to providers on strategies to improve patient safety and quality of care, and that have been listed by the Department of Health and Human Services (HHS) as such. HHS maintains a network of databases to provide an interactive evidence-based management resource for providers, PSO's, and the public. Providers, PSO's, and others may voluntarily submit nonidentifiable patient safety data to a database(s) in the network. HHS, PSO's and providers may disseminate information on recommended interventions and best practices to other PSO's, providers and consumers to improve quality of care and enhance patient safety.

The legislation grants an evidentiary privilege for information collected and developed by providers and PSO's through this voluntary reporting system. The privilege encompasses not only the report to the patient safety organization but also all aspects of the analysis of, and subsequent corrective actions related to, adverse events, medical errors, and "near misses" reported as patient safety data. It covers all deliberations, including oral and written communications, and work products that meet the requirements for patient safety data. This legislation also establishes confidentiality protections for this written and oral patient safety data to promote the reporting of medical errors. As a result, health care providers will be able to report and analyze medical errors, without fear that these reports will become public or be used in litigation. This nonpunitive environment will foster the sharing of medical error information that is a significant step in a process to improve the safety, quality, and outcomes of medical care.

It is vital to note that these protections do not extend backward to underlying factual information contained within or referred to in patient safety data reported to a PSO. In other words, the adverse event or the medical error itself is not privileged; it is the analysis of and subsequent corrective actions related to the adverse event or medical errors that are privileged. The underlying information remains unprivileged and available for reporting to authorities under mandatory or voluntary reporting initiatives. In practice, however, information that an adverse event or medical error has occurred is available through other record keeping systems (such as the patient's medical record, nursing notes, billing information, insurance forms). Because such information of adverse events or medical errors is available or can be collected or developed independent of the reporting system contemplated by this legislation, these protections do not preempt current or preclude future Federal, State or local requirements for the reporting or disclosure of information that ensures accountability or furthers informed consumer choice (e.g., hospital-acquired infections, medical errors, adverse or sentinel health care events, and medical outcomes) other than patient safety data. These protections do not provide a basis for providers to refuse to comply with such reporting requirements

simply because they have reported the same or similar information through the reporting system contemplated by this legislation nor do they preclude providers from voluntarily reporting such information pursuant to voluntary reporting initiatives. As long as there is another source of the information reported to the PSO—even if it is the same information as is reported—the protections in this legislation will not operate to prevent its release or disclosure because the information would come from the other sources, not from patient safety data. The legislation does not affect privileges or stronger confidentiality protections available under other law. The rules, for instance, which, in certain circumstances, require the Food and Drug Administration to protect the names of patients, providers, and reporters would, where applicable, continue to be in effect as they are now. This legislation recognizes and preserves the protection of confidential patient information under the Health Insurance Portability and Accountability Act of 1996. It requires HHS to develop or adopt voluntary national standards that promote the integration of health care information technology systems, requires a study to assess the impact of medical technologies on patient safety, and does not preempt other State and Federal peer review laws.

This legislation recognizes that patient safety can best be improved by fostering efforts to identify and fix errors while ensuring that providers remain accountable for malpractice. Such a balance was envisioned in the 1999 Institute of Medicine (IOM) report, To Err is Human: Building a Safer Health System, and has been corroborated as responsive by numerous patient safety experts, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and a broad base of medical and health care organizations. However, it is important to note that numerous analyses indicate that voluntary confidential reporting is but one part of a comprehensive program to improve patient care. While an important component of a program to improve health care quality, voluntary reporting alone will not be sufficient to eliminate the serious problem of medical errors that the Nation faces. This conclusion too is supported by numerous patient safety experts, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and a broad base of medical and health care organizations. The committee notes that HHS has already undertaken a number of programs to address medical errors and improve quality.

III. History of Legislation and Votes in Committee

On March 26, 2003, Senator Jeffords, for himself and Senators Frist, Breaux and Gregg introduced S. 720 to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

On July 23, 2003, the committee held an executive session to consider S. 720. Senator Gregg for himself and Senator Jeffords offered a substitute amendment, as modified, that was considered as original text by the committee. The committee approved S. 720, as amended by unanimous vote.

IV. Explanation of Bill and Committee Views

1. Legal protections for patient safety data encourage reporting.

This legislation provides broad confidentiality protections and legal privileges for patient safety data. The committee finds that broad protections are essential to encourage reporting. Currently, there are few incentives and many barriers for providers to collect and report information regarding patient safety. The primary barrier relates to concerns that information shared to promote patient safety would expose providers to liability. Unless this information can be freely shared, errors will continue to be hidden and errors will be repeated. A more open, nonpunitive learning environment is needed to encourage health care professionals and organizations to identify, analyze, and report errors without facing the threat of litigation and, at the same time, without compromising plaintiffs' legal rights or affecting existing and future public reporting initiatives with respect to the underlying data.

This bill provides confidentiality and legal protections for patient safety data, which are defined as information collected or developed and reported to a patient safety organization within a reasonable period of time. The committee recognizes that the reasonableness of the time to report is contingent upon many factors, including the complexity of the facts and circumstances surrounding the analysis of a medical error. Nonetheless, the committee intends that a reasonable period of time be a period of 2 months or less from the collection or development of the patient safety data. This amount of time will allow providers to investigate and report pertinent information to the patient safety organization. The information qualifies as patient safety data during that period if it is collected or developed for reporting and is reported to the patient safety organization within the required time frame. The definition of patient safety data also includes "any deliberative work or process or oral communications with respect to any patient safety data* * * ." (Section 921(A)(ii)) Patient safety data would not be collected or developed in a vacuum, and accordingly the bill includes reports, records, memoranda analyses, oral and written statements and thought processes (or mental impressions) in the definition of patient safety data. For example, if an error occurs, a health care professional must first, at a minimum, evaluate what occurred so that relevant information is recorded in a manner that promotes analysis. Typically, relevant information would be reported on a "data set" or standard form (or computer form) used for reporting such information to a patient safety organization. It is likely that a standard form would be required by a patient safety organization so that only relevant information is collected. Mere inclusion in such a form is not sufficient to establish privilege under the definition of patient safety data. For example, data on hospital-acquired infections may be required to be reported to a State agency and later released to the public. If such data happens to be reported on a standard form for reporting to a PSO, it would not thereby be exempted from the requirement to be reported to the State agency if that State requires such reporting through a parallel but different process. However, analysis or discussion of the data that constituted patient safety data would be exempted.

In addition to protecting the actual information that is submitted to the patient safety organization, it is essential to extend confidentiality and legal protections to any "deliberative work or process" and "oral or written communications" utilized in generating a re-

port to a patient safety organization. This bill includes such communications within the definition of patient safety data to allow for more accurate information to be transmitted to a patient safety organization. As the Institute of Medicine (IOM) stated in its 1999 report, To Err is Human, "The strongest legal protections would cover the entire chain of custody of the information from its initial generation to its ultimate use."

Patient safety data does not include information that is collected or developed and exists separately. For example, data and information that is contained in medical records, hospital claim or billing forms and facts of an adverse event (including oral and written statements not relating to the collection or development of patient safety data) cannot be shielded by being attached to patient safety data and sent to a patient safety organization. This means that medical information—including medical error information—that is currently available under a reporting requirement or initiative or that is available to a patient will continue to be available under this legislation. The bill also provides that patient safety data may be used in a criminal case if the court in camera finds that it contains evidence of certain intentional criminal acts. The legislation respects the discovery rights of plaintiffs in malpractice cases.

Many States extend privilege and confidentiality protections to analyses of medical errors that take place within the hospital, without restricting the right of a plaintiff to other information, such as the medical record and related information as well as the right to depose all health care personnel involved in a patient's care regarding their knowledge at the time of the alleged malpractice. This bill follows a similar approach for the analysis and reporting of adverse events, medical errors, and "near misses." As the IOM stated in To Err is Human, "protecting data in a reporting system * * * does not mean that the plaintiff in a lawsuit could not try to obtain such information through other avenues if it is important in securing redress for harm; it just means that the plaintiff would not be assisted by the presence of a reporting system designed specifically for other purposes beneficial to society." Importantly, the bill does not alter existing rights or remedies available to injured patients. Laws that provide greater confidentiality or privilege protections are also not affected by this legislation.

2. This legislation will not preempt Federal, State, or local law governing accountability for a health care professional's negligence, malfeasance, or criminal acts, or that requires the collection and reporting of underlying data on health care provider quality of care, other than patient safety data.

In creating a nonpunitive and voluntary system for the reporting and analyses of events that have led or could lead to patient harm, the committee recognizes the importance of separate systems of laws, regulations, accreditation and licensing requirements that have been (or may in the future be) established for the purpose of maintaining accountability in the health care system. This legislation provides legal protections for specified patient safety data. It is separate from and independent of mandatory or voluntary reporting systems that have been or may be established under Federal, State or local law or regulation. Reporting an error or other incident under this new system will not limit or affect the reporting

of information that is now or will in the future be required to be made under existing Federal, State, or local law to non-patient safety organizations. Information that must be reported under Federal, State or local reporting requirements (such as New York's incident reporting statute 10 NYCRR § 405.8)—even when those laws or regulations require the reporting of the same or similar information regarding the type of events also reported through the system contemplated by this legislation—is not within the definition of patient safety data because it is not "collected or developed * * * for reporting to a patient safety organization * * *" (section 921(2)(A)(i)(I)). Conversely, information covered under state reporting laws fall outside the definition of patient safety data because such information is "collected or developed separately from and that exists separately from patient safety data * * *" (section 921(2)(B)).

There are numerous, well-established mechanisms by which individuals and entities in the health care system are held accountable. For example, criminal acts by providers that seriously harm patients must be reported under State laws. Hospitals and medical staffs must report such events to law enforcement authorities and hospital licensing laws generally require the reporting of such events as well as certain other reportable events to licensing boards or accreditation organizations. In addition to standard error event reporting (such as wrong site surgery, error in medication, and transfusion error), many States require reporting of adverse events such as suspected abuse of a patient, rape, infant abduction, unanticipated death not related to natural course of patient's illness, suicide of patient, and events that lead to patient harm. JCAHO's sentinel event policy includes an extensive list of adverse events that must be reported. State peer review statutes encourage health care professionals to evaluate care provided by the members of the medical staff and to take appropriate action. Moreover, medical staff bylaws typically provide for an immediate summary suspension of health care professionals in serious situations or other disciplinary action against health care professionals even when peer review activities are underway. Patient deaths are reportable to a medical examiner, who generally has the discretion to conduct an investigation of deaths. Impaired healthcare workers are reported to a designated professional regulatory agency or rehabilitation program pursuant to State licensing laws. Federal, State, and local agencies may investigate and prosecute individuals under their respective authorities. Many States have laws that require a healthcare worker to report to the authorities cases of suspected neglect or abuse, typically applicable to children and senior citizens. Further, the state and federal civil court systems are available to patients who are injured, or their survivors if the patient dies, due to negligence.

In addition, a number of employer organizations have instituted (or are planning to institute) voluntary reporting initiatives for providers that participate in their networks. The operation of these legal requirements, or these voluntary initiatives, is not preempted by this legislation but may not afford the protections provided by this bill. This legislation conveys legal protection only on those communications that are sent to the PSO, or that the PSO prepares to send to a provider (and related communications and mate-

rials)—not to the underlying information contained within those communications that is obtainable from other records or sources.

This legislation will not allow providers and patient safety organizations to hide information about a crime by reporting and analyzing the case using this system. The confidentiality and legal protections in this bill would in no way limit or affect the availability of any information or evidence that does not meet the statutory definition of patient safety data and is currently available under existing Federal, State, or local law (section 922(j)(2)). Furthermore, this bill specifically allows an exception to the confidentiality and legal protections for patient safety data in a criminal proceeding when a court makes an in camera determination that the data includes evidence of an intentional act to harm a patient (section 922(c)(1)). This bill specifically states that nothing in the bill would prohibit a provider from reporting a crime to law enforcement authorities (section 922(j)(5)).

3. Patient Safety Organizations analyze patient safety data and provide recommendations, best practices and systems improvements to improve patient safety and quality of care.

This legislation requires that information be reported to or developed by a Patient Safety Organization (PSO) to qualify as patient safety data. The primary purpose of a patient safety organization is to continually work to improve the quality and safety of care provided to patients. The breadth of data available to PSO's, that are expected to enter into contracts with multiple providers, will facilitate the identification and analysis of patterns of organization and behavior that can lead to errors. This broader, systemic perspective will provide an important complement to the quality and safety improvement initiatives of many health care providers and facilitate the type of "shared learning" envisioned by the IOM report. PSO's should provide guidance and direct feedback to the provider's analysis of adverse events, medical errors, and "near misses" (or a provider may contract with a PSO to undertake the initial analysis as well), undertake broader statistical pattern analyses drawing upon data from two or more providers, and assist health care professionals and organizations in identifying and/or undertaking quality improvement initiatives to minimize patient risk. A PSO may be a component of a larger organization, as long as the component meets the criteria set forth in the bill.

Reporting an error or other incident under this new system will not limit or affect the reporting and disclosure of information that is not patient safety data and that is required to be made under existing or future Federal, State, or local mandatory public reporting systems, whether or not that organization also operates under this legislation as a patient safety organization. For example, a State health agency or a nongovernmental organization that collects and reports data under State law may continue to report or disclose information required by state law notwithstanding its designation and operation as a patient safety organization under this bill. The organization's collection and development, as a PSO, of patient safety data would not place protections as envisioned by this bill on nonpatient safety data handled by the organization for other purposes. The multiple functions of this organization under both this bill and Federal, State, or local law are to continue independently of each other.

This legislation protects and encourages the sharing and dissemination of information about improving patient safety. It is the intent of this committee that interventions, protocols, information about best practices and systems improvements that are developed through the analysis of patient safety data be shared by providers and PSO's to enable patient safety improvements to occur throughout the health care delivery system. Toward this end, the Agency for Health Research and Quality (AHRQ) will maintain a network of databases of nonidentifiable data to provide an interactive evidence-based patient safety management resource for providers, PSO's, and the public.

To allow the sharing of information to improve patient safety, the bill provides for protected disclosures of information (section 922(d)). For example, the bill permits PSOs to share patient safety data with other PSO's. It also permits providers or PSO's to use or disclose patient safety data in connection with providing treatment, improving patient safety, health care quality, administrative efficiency, or any other customary activity of the provider. Disclosures of information pursuant to this section do not waive the privilege or confidentiality of the patient safety data (section 922(g)) and the patient safety data continues to be privileged and confidential (section 922 (e)).

The bill also permits other disclosures (section 922(c)). For example, patient safety data that does not identify the patient or the provider may be disclosed by a provider or a PSO on a voluntary basis (section 922(c)(3). This is the mechanism in the bill that allows disclosure of information to AHRQ, to nonhealthcare related entities, and to the public. For example, under this section, a PSO could release nonidentifiable information about best practices; aggregate data, such as infection rates; or aggregate trend data, such as a decline in a rate of wrong site surgery. In addition, a provider or PSO could publish case studies, methods used to analyze systems failures or factors that can help improve the quality of care.

The use and disclosure under this section—including disclosure to the FDA (section 922(c)(2)) or to CDC (section 922(c)(4))—removes the privilege and confidentiality protections for the information used or disclosed. However, the balance of the patient safety data, which remains at the provider or PSO, continues to be privileged and confidential (section 922(e)). Moreover, even though disclosure to FDA or CDC would remove the privilege and confidentiality protections created under this law for the data disclosed, other statutes and regulations governing confidential information disclosed to the Government may continue to protect such information from subsequent disclosure by FDA or CDC. In any event, this bill does not require any disclosure to FDA or to CDC (or to any other person). It is important to note that except in the case of patient safety data associated with an intentional criminal act (section 922(c)(1)), a PSO cannot be compelled to release any information, whether it is patient safety data or not, even if it has been voluntarily disclosed to others under sections 922(c)(2)–(4). This allows PSO's to focus their efforts on quality improvement and patient safety.

The bill permits a PSO to make voluntary disclosures on behalf of the provider. A provider may by contract with a PSO determine what disclosures may be made by the PSO. For example, a provider

and PSO could agree by contract to distribute only aggregate non-identifiable patient safety data. The bill does not affect any person's right to contract with respect to these issues.

To enable the Agency for Healthcare Research and Quality (AHRQ) to advance the science of patient safety analysis and reporting and to meet its technical assistance requirements under the bill, providers and patient safety organizations are permitted to disclose patient safety data to grantees or contractors carrying out research, evaluation, or demonstration projects authorized by the Director. The committee intends for such disclosures to be provided only to the components of such entities that are actually carrying out the project in question. Such disclosures do not waive privilege or confidentiality and AHRQ grantees and contractors must observe the strict confidentiality safeguards provided under this title.

4. Patient Safety Organizations are subject to an expedited certification process.

The legislation provides an efficient, minimally burdensome certification process to help expedite implementation of a patient safety system. S. 720 requires an organization to certify that it intends to perform [certification]—or that it performs [recertification]—the activities required of a patient safety organization. The Secretary will list as PSO's those organizations that certify that they meet the required criteria.

The Secretary may examine any organization at any time to see whether it in fact is performing those required activities. The PSO would be subject to Federal law that provides sanctions for false certification. Under the Federal False Claims Act, those operating PSO's would be subject to fines or imprisonment in a federal facility for up to 5 years. The committee believes that this process strikes the proper balance of ensuring that PSO's function as intended under S. 720 while ensuring that the patient safety process is not unduly delayed by requiring that the Secretary review the operations of each entity applying for recognition as a PSO.

5. The system is voluntary and nonpunitive.

As an acknowledgment of the necessity to have a nonpunitive environment, the bill contains "whistle blower" protections for those reporting patient safety data. This bill directly prohibits retaliation against an individual for making a report in good faith to the provider for reporting to the PSO or directly to the PSO, while still allowing employers the opportunity to initiate disciplinary actions for other permissible reasons. With respect to State employers, the privilege shall not attach to the patient safety data unless the employer consents to being subject to the legislation's whistle blower protections. For this voluntary reporting system to achieve its intended goal, its nonpunitive nature must extend not only to health care organizations but also to health care professionals and support staff.

6. The Secretary establishes standards for healthcare data.

The bill seeks to accelerate the pace of progress on healthcare data exchange standards for electronic medical records. Now, many providers are waiting to make significant investments in critical technology. One of the primary difficulties in establishing various information technology systems is the fear that a system will need to be completely replaced within a short period of time because it no longer has the appropriate specifications for interacting with

government or other entities. Therefore, the bill directs the Secretary to develop or adopt voluntary standards to facilitate the development of the basic infrastructure, the National Health Information Infrastructure recommended by the National Committee on Vital and Health Statistics. In fulfilling this requirement, the committee intends for the Secretary to take into account existing standards and the ongoing activities of other-standard-setting bodies both within and outside the Federal Government.

V. Regulatory Impact Statement

The committee has determined that there will be minimal increases in the regulatory burden imposed by this bill. The bill does not mandate any new reporting system but provides protection for data submitted to patient safety organizations (PSO) to prevent medical errors from occurring and improve quality of care for patients. Each PSO will certify to HHS that it performs the functions stated in S. 720 and must recertify every 3 years. The Secretary, on his own initiative, or on complaint, could examine the PSO to determine whether the PSO is in fact performing the required functions. HHS will also maintain a network of databases and provide technical assistance to PSO's to assist them with the certification process and with improving patient safety. Accordingly, the committee has determined that there will be minimal regulatory burden imposed with respect to the certification process.

VI. Application of Law to the Legislative Branch

Section 102(b)(3) of Public Law 104–1, the Congressional Accountability Act (CAA), requires a description of the application of this bill to the legislative branch. S. 720 encourages a culture of safety and quality by providing for the legal protection of voluntarily reported patient safety data. Accordingly, the legislation limits permissible disclosures of patient safety data and provides no special exception for disclosure of identifiable patient safety data to the legislative branch. The legislation requires the Department of Health and Human Services to maintain a list of certified PSO's, which collect patient safety data from providers and provide strategic patient safety feedback to the providers. HHS is also required by the legislation to maintain a network of databases to provide an interactive evidence-based management resource for providers, patient safety organizations and the public; to develop or adopt voluntary national standards that promote the integration of health care information technology systems; and to assess the impact of medical technologies on patient safety. As such, it has no application to the legislative branch.

VII. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, August 15, 2003.

Hon. JUDD GREGG,
Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 720, the Patient Safety and Quality Improvement Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Chris Topoleski and Margaret Nowak.

Sincerely,

DOUGLAS HOLTZ-EAKIN,
Director.

Enclosure.

S. 720—Patient Safety and Quality Improvement Act of 2003

Summary: S. 720 would establish certification procedures for patient safety organizations (PSOs) and require the Secretary of Health and Human Services to maintain a list of certified PSOs, which collect patient safety data voluntarily submitted by health care providers for inclusion in a patient safety network of databases. The bill also would establish privacy protections and impose civil monetary penalties for violations of those protections. The bill would require the Secretary to report to the Congress on effective strategies for reducing medical errors and increasing patient safety.

CBO estimates that implementing S. 720 would cost $4 million in 2004 and $51 million over the 2004–2008 period, assuming the appropriation of the necessary amounts. CBO estimates that receipts from fines for violation of the privacy protections would amount to less than $500,000 a year.

The bill would require the Secretary of Health and Human Services to develop methodologies for the collection of patient safety data and provide technical assistance to PSOs. In addition, the Secretary would develop voluntary national standards that promote the comparability of medical information technology systems.

S. 720 would preempt state laws that govern the disclosure of information provided to patient safety organizations. While that preemption would be intergovernmental mandates as defined in the Unfunded Mandate Reform Act (UMRA), it would impose no requirements on states that would result in additional spending; thus, the threshold as established by UMRA would not be exceeded ($59 million in 2003, adjusted annually for inflation).

The bill would impose a private-sector mandate on health care providers, as defined in UMRA, by not allowing them to use the fact that an employer reported patient safety data in an adverse employment action against the employee. This mandate would not have any direct cost, however, because patient safety data as defined in the bill does not exist under current law.

Estimated cost to the Federal Government: The estimated cost of S. 720 is shown in the following table. The bill could also result in

an increase in revenues from fines, but CBO estimates that any such increase would be less than $500,000 a year. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—				
	2004	2005	2006	2007	2008
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Estimated Authorization Level	12	13	12	13	13
Estimated Outlays	4	9	12	13	13

Basis of estimate

Spending subject to appropriation

S. 720 would expand the current duties of the Agency for Healthcare Research and Quality (AHRQ). Although not specifically named, the AHRQ is the most likely and appropriate agency within the Department of Health and Human Services to carry out the provisions of the bill. The new duties would include providing technical assistance to PSOs that have (or are developing) systems for reporting medical errors. AHRQ also would oversee the certification and listing of PSOs, which collect patient safety data from health care providers. (PSOs are private or public organizations that conduct activities to improve patient safety and the quality of health care delivery.) PSOs would not receive funding under this bill.

In addition, the bill would require AHRQ to maintain a patient safety network of databases to collect, support, and coordinate the analysis of patient safety data that is reported on a voluntary basis. Based on information from AHRQ, CBO expects that these tasks would require increased staff for providing assistance to PSOs, oversight of PSOs, and collection and maintenance of the patient safety database. CBO estimates that the agency would need additional appropriations of $12 million in 2004 and $63 million over the 2004–2008 period to carry out these responsibilities. We estimate that outlays would total $51 million over the 2004–2008 period, assuming the necessary amounts are appropriated. In 2004, we estimate that the agency would spend about $4 million, primarily on maintaining the patient safety database.

The bill would require the Secretary to develop methodologies for collecting data on patient safety. In addition, S. 720 would require the Secretary to develop voluntary, national standards that promote the compatibility of health care information technology systems across all health care settings. CBO estimates that these efforts would cost less than $500,000 a year.

Revenues

Because those prosecuted and convicted for violation of the bill's privacy provisions could be subject to civil monetary penalties, the federal government might collect additional fines if the bill is enacted. Collections of civil fines are recorded in the budget as governmental receipts (i.e., revenues). CBO estimates that any additional receipts would be less than $500,000 a year.

Estimated impact on State, local, and tribal governments: S. 720 would preempt any state freedom of information law or other laws governing civil or administrative procedure that require the disclo-

sure of information provided by a health care provider to a certified patient safety organization. This preemption would be an intergovernmental mandate as defined in UMRA, because it would limit the application of those state laws. CBO estimates that this mandate would impose no requirement on states that would result in additional spending; thus, the threshold as established by UMRA would not be exceeded ($59 million in 2003, adjusted annually for inflation).

Estimated impacted on the private sector: The bill would impose a private-sector mandate on health care providers, as defined in UMRA, by not allowing them to use the fact that an employee reported patient safety data in an adverse employment action against the employee. This mandate would not have any direct cost, however, because patient safety data as defined in the bill does not exist under current law.

Previous CBO estimates: On March 3, 2003, CBO transmitted a cost estimate for H.R. 663, the Patient Safety Quality Improvement Act, as ordered reported by the House Committee on Energy and Commerce on February 12, 2003. CBO estimated that implementing the provisions of that bill would increase discretionary spending by $104 million over five years. The difference in the estimates for S. 720 and H.R. 663 is largely due to the grant program for establishing an electronic prescription program authorized by H.R. 663. In addition, H.R. 663 would require the inclusion of a unique product identifier on packaging of a drug or biological product that is subject to regulation by the FDA. This provision, which would be a private-sector mandate, is not included in S. 720.

On March 5, 2003, CBO transmitted a cost estimate for H.R. 877, the Patient Safety Improvement Act, as ordered reported by the House Committee on Ways and Means on February 27, 2003. CBO estimated that implementing the provisions of that bill would increase direct spending by $59 million and increase discretionary spending by $4 million over five years. The difference in the estimates for S. 720 and H.R. 877 is largely due to the provision in H.R. 877 that would establish the Medical Information Technology Board to provide recommendations regarding medical information technology.

Estimate prepared by: Federal costs: Margaret Nowak and Chris Topoleski; Impact on State, local, and tribal governments: Leo Lex; Impact on the private sector: Dan Wilmoth.

Estimate approved by: Peter H. Fontaine Deputy Assistant Director for Budget Analysis.

VIII. SECTION-BY-SECTION ANALYSIS

The bill amends title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

Sec. 1. Short title

Section 1 entitles the Act the "Patient Safety and Quality Improvement Act of 2003."

Sec. 2. Findings and purpose

Establishes a series of findings, which point to the critical need for confidentiality and legal protections with respect to information

reported for the purposes of quality improvement and patient safety. Specifies that the primary purpose of the bill is to encourage a culture of safety and quality in the health care system by providing for the legal protection of information reported voluntarily for the purposes of quality improvement and patient safety, and ensure accountability by raising standards and expectations for continuous quality improvements in patient safety.

Sec. 3. Amendments to Public Health Service Act

Amends title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) by redesignating part C as part D, redesignating section 921 through 928 as section 931 through 938, and inserting the following sections under new Part C:

Section 921. Definitions.

Section 921(1): Defines the term "non-identifiable" as information presented in a form and manner that prevents identification of a provider, a patient or a reporter of patient safety data.

Section 921(2): Defines "Patient Safety Data" as any data, reports, records, memoranda, analyses (such as root cause analyses), or statements that could result in improved patient safety, quality, or outcomes that are collected or developed by a "provider" for reporting to a PSO and are reported within a reasonable period of time, requested by a PSO, reported to a provider by a PSO, or collected from a provider or PSO or developed by PSO. The definition includes any deliberative work or process or oral communication with respect to patient safety data. Patient safety data does not include information that is collected or developed and exists separately from Patient Safety Data (such as, medical records and copies of "separate" information).

Section 921(3): Defines "Patient Safety Organization" as a public or private organization or component thereof that is listed by the Secretary as a patient safety organization, after the submission of a certification pursuant to section 924 (c). A PSO will (A) conduct, as its primary activity, efforts to improve patient safety and the quality of health care delivery; (B) collection and analysis of "patient safety data" that are submitted by more than one provider; (C) the development and dissemination of information to providers to improve patient safety; (D) utilization of "patient safety data" to encourage a culture of safety and providing direct feedback and assistance to providers to minimize patient risk; (E) maintenance of procedures to preserve confidentiality of patient safety data, and (F) provision of security measures for "patient safety data."

Section 921(4): "Provider" is broadly defined as a person licensed or otherwise authorized under state law to provide health care services. Includes physicians, physician offices, hospitals, nurses, nursing facilities, pharmacists, pharmacies, home health agencies, hospice, ambulatory surgical centers, long term care facilities, clinical laboratories, psychologists, or any other person specified in regulations promulgated by the Secretary.

Section 922. Privilege and Confidentiality Protections.

Section 922(a): Patient Safety Data is privileged and shall not be: subject to a federal, state, or local civil, criminal, or administrative subpoena; subject to discovery in a federal, state, or local civil, criminal, or administrative proceeding; disclosed pursuant to the Freedom of Information Act (FOIA); admitted as evidence or dis-

closed in a federal, state, or local civil, criminal, or administrative proceeding; or utilized in a disciplinary proceeding against a provider.

Section 922(b): Patient safety data shall be confidential and shall not be disclosed, except as set forth in paragraphs (c) and (d).

Section 922(c): The following disclosures and uses are allowed: disclosure of relevant patient safety data by a provider or PSO for use in a criminal proceeding only after a court makes an in camera determination that such data contains evidence of an intentional act to directly harm a patient; voluntary disclosure by provider or PSO to the FDA or a person subject to the FDA's jurisdiction regarding a FDA-regulated product or activity; voluntary disclosures by provider to CDC for public health surveillance, investigation, or other public activities; and voluntary disclosure by provider or PSO of non-identifiable data.

Section 922(d): The following disclosures are also allowed: disclosure by a provider or PSO to carry out the activities of the PSO; use or disclosure by a provider or PSO in connection with providing treatment, improving patient safety, health care quality or administrative efficiency, or other customary activity of the provider or in obtaining payment; disclosure among PSOs; disclosure by provider or PSO to grantees or contractors carrying out patient safety research, evaluation, or demonstration projects authorized by the Director; and disclosure by a provider to an accrediting body that accredits that provider.

Section 922(e): Patient safety data used or disclosed in accordance with section 922(d) shall continue to be privileged and confidential in accordance with sections 922(a) and (b) and shall not be disclosed by an entity that possessed such information before such use or disclosure, or by an entity to which the information was disclosed, unless such additional disclosure is permitted under section 922(d).

Section 922(f): Except as provided in section 922(c), no action may be brought or process served against a patient safety organization to compel disclosure of information collected or developed under this part whether or not such information is patient safety data. An accrediting body may not require a provider to reveal its communications with a PSO.

Section 922(g): Except with respect to the specific patient safety data that is used or disclosed, disclosure under sections 922(c) and 922(d) is not treated as a waiver of any privilege or protection, nor are protections waived when patient safety data is inadvertently disclosed.

Section 922(h): A provider may not take an adverse employment action against an individual based upon the fact that the individual in good faith reported information to the provider with the intention of having the information reported to a PSO or directly to a PSO.

Section 922(i): Civil monetary penalty up to $10,000 may be imposed for a negligent or intentional disclosure of patient safety data. State employers must consent to being subject to such penalties to invoke the privileges provided by this legislation. If the disclosure was in violation of HIPAA, then the HIPAA penalties apply instead of the civil monetary penalty under this Act. A civil action may be brought by any aggrieved individual to enjoin any

act or practice that violates section 922(h) and to obtain other appropriate equitable relief (including reinstatement, back pay, and restoration of benefits) to redress such violation.

Section 922(j): This legislation does not: limit other privileges and confidentiality protections available under federal, state, or local laws that provide greater protection; limit, alter, or affect the requirements of federal, state, or local law pertaining to patient-related data that is not privileged or confidential under this Title; affect the health information privacy provisions under HIPAA; limit the authority of any provider, PSO, or other person to enter into a contract requiring greater confidentiality protections than provided in this Title or delegating authority to make a disclosure or use in accordance with the Title; or prohibit a provider from reporting a crime to law enforcement authorities.

Section 923. Patient Safety Network of Databases.

The Secretary shall maintain a network of databases that provides an interactive evidence-based management resource for providers, PSOs, and others. Providers, PSOs, and others may voluntarily submit non-identifiable patient safety data to a database(s) in the network. The Secretary may also determine common formats for the reporting to the patient safety network of databases of non-identifiable patient safety data, including necessary data elements, common and consistent definitions, and a standardized computer interface for the processing of such data.

Section 924. Patient Safety Organization Certification and Listing.

A PSO must certify to the Secretary that it satisfies the criteria in the definition of PSO. A PSO may receive initial certification without meeting the activity of collecting and analyzing patient safety data submitted by more than one provider, but must file supplemental certification within 2 years that the PSO performs such activity. The Secretary shall notify a PSO if its certification is accepted or will provide the reasons for non-acceptance. The Secretary must compile and maintain a current list of certified PSOs. The Secretary may revoke a PSOs certification after notice and hearing, must publish a notice of revocation in Federal Register, and require the PSO to notify providers of revocation. Certification expires after 3 years and may be renewed. Patient safety data held by a PSO that loses its certification remains privileged and confidential. If the Secretary removes an organization from the PSO listing—due to revocation of certification or because the PSO has ceased operation for any reason—the decertified PSO must transfer patient safety data to another certified PSO, return the data to the provider, or destroy the data if returning the data is not practicable.

Section 925. Technical Assistance.

AHRQ may provide technical assistance to PSOs, including convening meetings to discuss methodology, communication, data collection, or privacy concerns.

Section 926. Promoting the Interoperability of Health Care Information Technology Systems.

Within 3 years, HHS must develop or adopt (and review and periodically update) voluntary national standards that promote the integration of health care information technology systems.

Section 927. Authorization of Appropriations.

Authorizes for appropriations such sums as necessary.

Sec. 4. Studies and reports

Requires the Secretary to contract with a research organization to assess the impact of medical technologies and therapies on patient safety, patient benefit, health care quality, cost of care, and productivity growth. The Secretary must report the results to Congress within 18 months.

IX. ADDITIONAL VIEWS OF SENATORS KENNEDY, DODD AND CLINTON

The signatories of these "Additional Views" fully support the goal of establishing a voluntary national patient safety reporting program with a legal privilege to adhere to any information newly created for that program. Such a program would be the first step in a comprehensive effort to reduce errors and enhance the quality of health care. The signatories believe, however, that enhanced use of information technology should be an integral part of any effort to improve health care quality and reduce errors.

Improved use of information technology (IT) is an integral part of reducing medical errors and improving patient care. Over one million serious medication errors are made in American hospitals every year, resulting in over 7,000 deaths. The economic costs of medication errors are also staggering. Each serious medication error adds $2,000 to the cost of a hospital stay. The total cost of medication errors is over $2 billion annually.

Dramatic decreases in medication errors are seen consistently when computerized systems are installed and used. To cite but a few examples, use of a computerized prescription order entry system was shown to reduce hospital length of stay by 0.89 days per patient and to reduce costs by 12.7%, according to a study by Tierney and colleagues published in the Journal of the American Medical Association.

In a study of a computerized prescription order entry system for patients with infectious disease, Evans and colleagues found that use of the system reduced by 76% prescriptions of drugs to which patients were allergic, reduced excess drug dosages by 78% and reduced adverse reactions by 86%. The same study showed that the system reduced the cost per patient of drugs prescribed by over 75% and reduced hospital costs per patient by 41%.

Computerized records also allow doctors to look at a patient's entire medical records at once—making proper care coordination a real possibility. According to the Institute of Medicine, "Health information is dispersed in a collection of paper records that are poorly organized and often illegible, and frequently cannot be retrieved in a timely fashion, making it nearly impossible to manage many forms of chronic illness that require frequent monitoring and ongoing patient support." IT systems can transform this sorry state of affairs and help patients get the type of coordinated care they need. The Institute of Medicine, in its recent report Leadership by Example, concluded that, "the Federal government should take steps immediately to encourage and facilitate the development of information technology infrastructure that is critical to health care quality and safety enhancement."

IT also enables the provision of health quality information to providers, purchasers, and consumers. Certain model information

technologies, such as the personal health record, which is an electronic medical record that patients can access, append to, and share with their providers, build in the concept of informing consumers to improve health quality and encourage informed patient choice and decisionmaking.

Average IT spending per employee per year among all U.S. industries is nearly $7,000 per year, and the banking sector spends almost $125,000 per employee. Yet health care invests only $3000 per employee per year on IT. Despite evidence that greater investments could yield monetary returns for society at large, as well as individual providers, the health care providers have been slow to adopt.

The signatories of these views strongly believe that the federal government should assist the health care sector in enhancing its use of IT. We believe that IT is inherently a patient safety issue, and therefore that this legislation is an appropriate vehicle for IT provisions. However, we are willing to work with Chairman Gregg and other members of the Committee to ensure that this issue is addressed soon.

TED KENNEDY.
HILLARY RODHAM CLINTON.
CHRISTOPHER J. DODD.

X. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

PART A—ESTABLISHMENT AND GENERAL DUTIES

SEC. 901. MISSION AND DUTIES.

(a) IN GENERAL.—* * *

* * * * * * *

PART B—HEALTH CARE IMPROVEMENT RESEARCH

SEC. 911. HEALTH CARE OUTCOME IMPROVEMENT RESEARCH.

(a) EVIDENCE RATING SYSTEMS.—* * *

* * * * * * *

SEC. 912. PRIVATE-PUBLIC PARTNERSHIPS TO IMPROVE ORGANIZATION AND DELIVERY.

(a) SUPPORT FOR EFFORTS TO DEVELOP INFORMATION ON QUALITY.—

(1) SCIENTIFIC AND TECHNICAL SUPPORT.—* * *

* * * * * * *

(c) REDUCING ERRORS IN MEDICINE.—The Director*, in accordance with part C,* shall conduct and support research and build private-public partnerships to—

PART C—PATIENT SAFETY IMPROVEMENT

SEC. 921. DEFINITIONS.

In this part:

(1) NON-IDENTIFIABLE INFORMATION.—

(A) IN GENERAL.—The term "non-identifiable information" means information that is presented in a form and manner that prevents the identification of a provider, a patient, or a reporter of patient safety data.

(B) IDENTIFIABILITY OF PATIENT.—For purposes of subparagraph (A), the term "presented in a form and manner that prevents the identification of a patient" means, with respect to information that has been subject to rules promulgated pursuant to section 264(c) of Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), that the information has been de-identified so that it is no longer individually identifiable health information as defined in such rules.

(2) PATIENT SAFETY DATA.—

(A) IN GENERAL.—The term "patient safety data" means—

(i) any data, reports, records, memoranda, analyses (such as root cause analyses), or statements that could result in improved patient safety or health care quality or health care outcomes, that are—

(I) collected or developed by a provider for reporting to a patient safety organization, provided that they are reported to the patient safety organization within a reasonable period of time;

(II) requested by a patient safety organization (including the contents of such request);

(III) reported to a provider by a patient safety organization; or

(IV) collected from a provider or patient safety organization or developed by a patient safety organization; or

(ii) any deliberative work or process or oral communications with respect to any patient safety data described in clause (i).

(B) LIMITATION.—The term "patient safety data" shall not include information (including a patient's medical record) that is collected or developed separately from and that exists separately from patient safety data. Such separate information or a copy thereof submitted to a patient safety organization shall not itself be considered as patient safety data.

(3) PATIENT SAFETY ORGANIZATION.—The term "patient safety organization" means a private or public organization or component thereof that performs all of the following activities (which are deemed to be necessary for the proper management and administration of such organization or component thereof), and that is currently listed by the Secretary as a patient safety organization pursuant to section 924(c):

(A) The conduct, as its primary activity, of efforts to improve patient safety and the quality of health care delivery.

(B) The collection and analysis of patient safety data that are submitted by more than one provider.

(C) The development and dissemination of information to providers with respect to improving patient safety, such as

recommendations, protocols, or information regarding best practices.

(D) The utilization of patient safety data for the purposes of encouraging a culture of safety and of providing direct feedback and assistance to providers to effectively minimize patient risk.

(E) The maintenance of a process to preserve confidentiality with respect to the information that is not non-identifiable.

(F) The provision of appropriate security measures with respect to patient safety data.

(G) The submittal to the Secretary of a certification pursuant to section 924.

(4) PROVIDER.—The term "provider" means—

(A) a person licensed or otherwise authorized under State law to provide health care services, including—

(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietition or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

(B) any other person specified in regulations promulgated by the Secretary.

SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTECTIONS.

(a) PRIVILEGE.—Notwithstanding any other provision of Federal, State, or local law, patient safety data shall be privileged and, subject to the provisions of subsection (c), shall not be—

(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena;

(2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding;

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

(4) admitted as evidence or otherwise disclosed in any Federal, State, or local civil, criminal, or administrative proceeding; or

(5) utilized in a disciplinary proceeding against a provider.

(b) CONFIDENTIALITY.—Notwithstanding any other provision of Federal, State, or local law, and subject to the provisions of subsections (c) and (d), patient safety data shall be confidential and shall not be disclosed.

(c) EXCEPTIONS TO PRIVILEGE AND CONFIDENTIALITY.—Nothing in this section shall be construed to prohibit one or more of the following uses or disclosures:

(1) Disclosure by a provider or patient safety organization of relevant patient safety data for use in a criminal proceeding only after a court makes an in camera determination that such patient safety data contains evidence of an intentional act to directly harm the patient.

(2) Voluntary disclosure by a provider or patient safety organization of information to the Food and Drug Administration, or to a person that is subject to the jurisdiction of the Food and Drug Administration, with respect to a Food and Drug Administration-regulated product or activity for which that entity has responsibility, for the purposes of activities related to the quality, safety, or effectiveness of a Food and Drug Administration-regulated product or activity or a Food and Drug Administration proceeding.

(3) Voluntary disclosure of non-identifiable patient safety data by a provider or a provider patient safety organization.

(4) Voluntary disclosure by a provider of patient safety data to the Centers for Disease Control and Prevention for public health surveillance, investigation, or other public health activities.

(d) PROTECTED DISCLOSURE AND USE OF INFORMATION.—Nothing in this section shall be construed to prohibit one or more of the following uses or disclosures:

(1) Disclosure by a provider or patient safety organization of information to which subsections (a) or (b) applies to carry out activities described in paragraph (2) or (3) of section 921.

(2) Use or disclosure by a provider or patient safety organization of patient safety data in connection with providing treatment, improving patient safety, health care quality or administrative efficiency, or any other customary activity of the provider or in obtaining payment.

(3) Disclosure of patient safety data among patient safety organizations.

(4) Disclosure of patient safety data by a provider or patient safety organization to grantees or contractors carrying out patient safety research, evaluation, or demonstration projects authorized by the Director.

(5) Disclosure of patient safety data by a provider to an accrediting body that accredits that provider.

(e) CONTINUED PROTECTION OF INFORMATION.—Patient safety data used or disclosed in accordance with subsection (d) shall continue to be privileged and confidential in accordance with subsections (a) and (b) and shall not be disclosed—

(1) by an entity that possessed such information before such use or disclosure; or

(2) by an entity to which the information was disclosed;

unless such additional disclosure is permitted under subsection (d).

(f) LIMITATION ON ACTIONS.—

(1) PATIENT SAFETY ORGANIZATIONS.—Except as provided in subsection (c), no action may be brought or process served against a patient safety organization to compel disclosure of information collected or developed under this part whether or not such information is patient safety data.

(2) PROVIDERS.—An accrediting body shall not take an accrediting action against a provider based on the good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety data in accordance with this part. An accrediting body may not require a provider to reveal its communications with any patient safety organization established in accordance with this part.

(g) DISCLOSURE OR USE OF INFORMATION.—

(1) IN GENERAL.—Except with respect to the specific patient safety data that is used or disclosed, the disclosure or use of any patient safety data in accordance with subsection (c) or (d) shall not be treated as a waiver of any privilege or protection established under this part.

(2) INADVERTENT DISCLOSURE OR USE.—The inadvertent disclosure or use of patient safety data shall not waive any privilege or protection established under this part with respect to such data.

(h) REPORTER PROTECTION.—

(1) IN GENERAL.—A provider may not take an adverse employment action, as described in paragraph (2), against an individual based upon the fact that the individual in good faith reported information—

(A) to the provider with the intention of having the information reported to a patient safety organization; or

(B) directly to a patient safety organization.

(2) ADVERSE EMPLOYMENT ACTION.—For purposes of this subsection, an "adverse employment action" includes—

(A) loss of employment, the failure to promote an individual, or the failure to provide any other employment-related benefit for which the individual would otherwise be eligible; or

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

(i) ENFORCEMENT.—

(1) PROHIBITION.—Except as provided in subsections (c) and (d) and as otherwise provided for in this section, it shall be unlawful for any person to negligently or intentionally disclose any patient safety data described in subsection (a) and any such person shall, upon adjudication, be assessed in accordance with section 934(d).

(2) RELATION TO HIPAA.—The penalty provided for under paragraph (1) shall not apply if the defendant would otherwise be subject to a penalty under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) or under section 1176 of the Social Security Act (42 U.S.C. 1320d–5) for the same disclosure.

(3) EQUITABLE RELIEF.—Without limiting remedies available to other parties, a civil action may be brought by any aggrieved individual to enjoin any act or practice that violates subsection (h) and to obtain other appropriate equitable relief (including reinstatement, back pay, and restoration of benefits) to redress such violation.

(4) ACTIONS AGAINST STATE EMPLOYEES.—Notwithstanding subsection (a), with respect to a State employer, the privilege described in such subsection shall not apply to such employer unless the employer consents, in advance, to be subject to a civil action under paragraph (3).

(j) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

(1) limit other privileges that are available under Federal, State, or local laws that provide greater confidentiality protections or privileges than the privilege and confidentiality protections provided for in this section;

(2) limit, alter, or affect the requirements of Federal, State, or local law pertaining to patient-related data that is not privileged or confidential under this section;

(3) alter or affect the implementation of any provision of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033), section 1176 of the Social Security Act (42 U.S.C. 1320d–5), or any regulation promulgated under such sections;

(4) limit the authority of any provider, patient safety organization, or other person to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with subsection (c) or (d); and

(5) prohibit a provider from reporting crime to law enforcement authorities.

SEC. 923. PATIENT SAFETY NETWORK OF DATABASES.

(a) IN GENERAL.—The Secretary shall maintain a patient safety network of databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other persons. The network of databases shall have the capacity to accept, aggregate, and analyze nonidentifiable patient safety data voluntarily reported by patient safety organizations, providers, or other persons.

(b) NETWORK OF DATABASE STANDARDS.—The Secretary may determine common formats for the reporting to the patient safety network of databases maintained under subsection (a) of nonidentifiable patient safety data, including necessary data elements, common and consistent definitions, and a standardized computer interface for the processing of such data. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of Part C of title XI of the Social Security Act.

SEC. 924. PATIENT SAFETY ORGANIZATION CERTIFICATION AND LISTING.

(a) CERTIFICATION.—

(1) INITIAL CERTIFICATION.—Except as provided in paragraph (2), an entity that seeks to be a patient safety organization shall submit an initial certification to the Secretary that the entity intends to perform the activities described in subparagraphs (A) through (F) of section 921(3).

(2) DELAYED CERTIFICATION OF COLLECTION FROM MORE THAN ONE PROVIDER.—An entity that seeks to be a patient safety organization may—

(A) submit an initial certification that it intends to perform the activities described in subparagraph (A) through (F) of section 921(3) other than the activities described in subparagraph (B) of such section; and

(B) within 2 years of submitting the initial certification under subparagraph (A), submit a supplemental certification that it performs the activities described in section 921(3)(B).

(3) EXPIRATION AND RENEWAL.—

(A) EXPIRATION.—An initial certification under paragraph (1) or (2)(A) shall expire on the date that is 3 years after it is submitted.

(B) RENEWAL.—

(i) IN GENERAL.—An entity that seeks to remain a patient safety organization after the expiration of an initial certification under paragraph (1) or (2)(A) shall, within the 3-year period described in subparagraph (A), submit a renewal certification to the Secretary that the entity satisfies the criteria described in subparagraphs (A) through (F) of section 921(3).

(ii) TERM OF RENEWAL.—A renewal certification under clause (i) shall expire on the date that is 3 years after that date on which it is submitted, and may be renewed in the same manner as an initial certification.

(b) ACCEPTANCE OF CERTIFICATION.—Upon the submission by an organization of an initial certification pursuant to subsection (a)(1) or (a)(2)(A), a supplemental certification pursuant to subsection (a)(2)(B), or a renewal certification pursuant to subsection (a)(3)(B), the Secretary shall review such certification and—

(1) if such certification meets the requirements of subsection (a)(1) or (a)(2)(A), (a)(2)(B), or (a)(3)(B), as applicable, the Secretary shall notify the organization that such certification is accepted; or

(2) if such certification does not meet such requirements, as applicable, the Secretary shall notify the organization that such certification is not accepted and the reasons therefore.

(c) LISTING.—

(1) IN GENERAL.—Except as otherwise provided in this subsection, the Secretary shall compile and maintain a current listing of patient safety organizations with respect to which the Secretary has accepted a certification pursuant to subsection (b).

(2) REMOVAL FROM LISTING.—The Secretary shall remove from the listing under paragraph (1)—

(A) an entity with respect to which the Secretary has accepted an initial certification pursuant to subsection (a)(2)(A) and which does not submit a supplemental certification pursuant to subsection (a)(2)(B) that is accepted by the Secretary;

(B) an entity whose certification expires and which does not submit a renewal application that is accepted by the Secretary; and

(C) an entity with respect to which the Secretary revokes the Secretary's acceptance of the entity's certification, pursuant to subsection (d).

(d) REVOCATION OF ACCEPTANCE.—

(1) IN GENERAL.—Except as provided in paragraph (2), if the Secretary determines that a patient safety organization does not perform any activity described in subparagraphs (a) through (f) of section 921(3), the Secretary may, after notice and an opportunity for a hearing, revoke the Secretary's acceptance of the certification of such organization.

(2) DELAYED CERTIFICATION OF COLLECTION FROM MORE THAN ONE PROVIDER.—A revocation under paragraph (1) may not be based on a determination that the organization does not perform the activity described in section 921(3)(B) if—

(A) the listing of the organization is based on its submittal of an initial certification under subsection (a)(2)(A);

(B) the organization has not submitted a supplemental certification under subsection (a)(2)(B); and

(C) the 2-year period described in subsection (a)(2)(B) has not expired.

(e) NOTIFICATION OF REVOCATION OR REMOVAL FROM LISTING.—

(1) SUPPLYING CONFIRMATION OF NOTIFICATION TO PROVIDERS.—Within 15 days of a revocation under subsection (d)(1), a patient safety organization shall submit to the Secretary a confirmation that the organization has taken all reasonable actions to notify each provider whose patient safety data is collected or analyzed by the organization of such revocation.

(2) PUBLICATION.—Upon the revocation of an acceptance of an organization's certification under subsection (d)(1), or upon the removal of an organization from the listing under subsection (c)(2), the Secretary shall publish notice of the revocation or removal in the Federal Register.

(f) STATUS OF DATA AFTER REMOVAL FROM LISTING.—

(1) NEW DATA.—With respect to the privilege and confidentiality protections described in section 922, data submitted to an organization within 30 days after the organization is removed from the listing under subsection (c)(2) shall have the same status as data submitted while the organization was still listed.

(2) PROTECTION TO CONTINUE TO APPLY.—If the privilege and confidentiality protections described in section 922 applied to data while an organization was listed, or during the 30-day period described in paragraph (1), such protections shall continue to apply to such data after the organization is removed from the listing under subsection (c)(2).

(g) DISPOSITION OF DATA.—If the Secretary revokes the acceptance of an organization's certification under subsection (d)(1) and removes the organization from the listing as provided for in subsection (c)(2), with respect to the patient safety data that the organization received from providers, the organization shall—

(1) with the approval of the provider and another patient safety organization, transfer such data to such other organization;

(2) return such data to the provider of that patient safety data; or

(3) if returning such data to the provider is not practicable, destroy such data.

SEC. 925. TECHNICAL ASSISTANCE.

The Secretary, acting through the Director, may provide technical assistance to patient safety organizations, including annual meetings for patient safety organizations to discuss methodology, communication, data collection, or privacy concerns.

SEC. 926. PROMOTING THE INTEROPERABILITY OF HEALTH CARE INFORMATION TECHNOLOGY SYSTEMS.

(a) DEVELOPMENT.—Not later than 36 months after the date of enactment of the Patient Safety and Quality Improvement Act of 2003, the Secretary shall develop or adopt voluntary national standards that promote the electronic exchange of health care information.

(b) UPDATES.—The Secretary shall provide for the ongoing review and periodic updating of the standards developed under subsection (a).

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

SEC. 927. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated such sums as may be necessary to carry out this part.

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PART [C] *D*—GENERAL PROVISIONS

SEC. [921] *931.* ADVISORY COUNCIL FOR HEALTHCARE RESEARCH AND QUALITY.

(a) ESTABLISHMENT.—* * *

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SEC. [922] *932.* PEER REVIEW WITH RESPECT TO GRANTS AND CONTRACTS.

(a) REQUIREMENT OF REVIEW.—

(1) IN GENERAL.—* * *

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SEC. [923] *933.* CERTAIN PROVISIONS WITH RESPECT TO DEVELOPMENT, COLLECTION, AND DISSEMINATION OF DATA.

(a) STANDARDS WITH RESPECT TO UTILITY OF DATA.—

(1) IN GENERAL.—* * *

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SEC. [924] *934.* DISSEMINATION OF INFORMATION.

(a) IN GENERAL.—The Director shall—

(1) * * *

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(d) PENALTY.—Any person who violates subsection (c) shall be subject to a civil monetary penalty of not more than $10,000 for each such violation involved. [Such penalty shall be imposed and collected in the same manner as civil money penalties under sub-

section (a) of section 1128A of the Social Security Act are imposed and collected.] *Penalties provided for under this section shall be imposed and collected by the Secretary using the administrative and procedural processes used to impose and collect civil money penalties under section 1128A of the Social Security Act (other than subsections (a) and (b), the second sentence of subsection (f), and subsections (i), (m), and (n)), unless the Secretary determines that a modification of procedures would be more suitable or reasonable to carry out this subsection and provides for such modification by regulation.*

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SEC. [925] *935*. ADDITIONAL PROVISIONS WITH RESPECT TO GRANTS AND CONTRACTS.

(a) FINANCIAL CONFLICTS OF INTEREST.—* * *

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SEC. [926] *936*. CERTAIN ADMINISTRATIVE AUTHORITIES.

(a) DEPUTY DIRECTOR AND OTHER OFFICERS AND EMPLOYEES.—

(1) DEPUTY DIRECTOR.—* * *

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SEC. [927] *937*. FUNDING.

(a) INTENT.—* * *

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SEC. [928] *938*. DEFINITIONS.

In this title:

(1) ADVISORY COUNCIL.—The term "Advisory Council" means the National Advisory Council on Healthcare Research and Quality established under section [921] *931*.

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