



**American Hospital
Association**

Legislative Advisory

AHA's Legislative Advisory, a service to members, is produced whenever there is a significant development that affects the job you do in your community

The Patient Safety Act – Signed Into Law

A Message to AHA Members:

On July 29, President Bush signed the Patient Safety and Quality Improvement Act of 2005 into law. The American Hospital Association (AHA) supported the legislation and called the new law a major step toward improving the safety and quality of care that Americans receive.

This legislative safety and quality improvement effort started on the heels of the 1999 release of the Institute of Medicine report, "To Err is Human," which called on Congress to establish a way in which providers could share patient safety related information confidentially to enable broad-based learning. In the 108th Congress, lawmakers came close to passing legislation, but the two differing House and Senate versions were never reconciled. This year, after much negotiation and debate, representatives and senators reached agreement. The law amends the Public Health Service Act and designates certain patient safety work product as privileged and confidential, and provides for voluntary reporting of medical errors to patient safety organizations.

The AHA will continue to work with Department of Health and Human Services (HHS) Secretary Mike Leavitt to implement this voluntary federal effort in a way that does not disrupt current state-level efforts. We'll also work with the hospital field and HHS, specifically the Agency for Healthcare Research and Quality, to develop specifications and clear guidance for data collection and common formats. In the meantime, please share this advisory with your legal counsel, patient safety officer and others who oversee patient safety programs in your facility.

If you have questions about the Patient Safety and Quality Improvement Act, contact the AHA's Curtis Rooney, senior associate director and counsel for federal relations, at (202) 626-2678.

Sincerely,

Rick Pollack
Executive Vice President

August 24, 2005



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On July 29, President Bush signed the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) into law. The American Hospital Association (AHA) supported the legislation and called the new law a major step toward improving the safety and quality of care Americans receive.

Background

This legislative patient safety and quality improvement effort started on the heels of the 1999 release of the Institute of Medicine report, “To Err is Human,” which called on Congress to set up a network of independent patient safety organizations. During the 108th Congress in 2004, lawmakers came close to passing similar legislation, but the two differing House and Senate versions were never reconciled.

Patient Safety Protections and PSOs

The law amends the Public Health Service Act to establish procedures for the voluntary, confidential reporting of medical errors to patient safety organizations (PSOs). A PSO is an organization certified by the Secretary of Health and Human Services (HHS) that seeks to improve patient safety and quality through collecting and analyzing patient safety data. The Secretary also must maintain a network of databases with the capacity to accept, aggregate and analyze non-identifiable patient safety data that has been voluntarily reported. The result should provide an interactive format for providers and PSOs.

After medical errors have been voluntarily and confidentially reported to the PSO, the PSO in turn would submit the data to a national database for analysis and recommendations on ways to improve patient safety and reduce medical errors. The data reported to the PSOs will be shielded from use in liability suits and other litigation. This information cannot be used against a provider by an accrediting agency or other regulator. Under this new law, organizations cannot punish employees based on good-faith reporting of information.

Other Provisions

Additional provisions in the bill include the development or adoption of voluntary national standards that promote the electronic exchange of health care information; contracting with a research organization to study the impact that medical technologies and therapies have on health care; and imposing penalties for disclosing privileged and confidential information.

The law is effective immediately, but HHS still must implement a process to certify PSOs. The AHA will continue to work with HHS, specifically the Agency for Healthcare Research and

Quality, on the implementation of the law. We look forward to gathering input from hospital leaders, particularly in those states where patient safety efforts are well under way.

The attached “Questions and Answers” should assist you as you begin to make changes to comply with this new law.

For more information, contact Curtis Rooney, senior associate director and counsel, federal relations, at (202) 626-2678 or crooney@aha.org.

***Questions and Answers:
The Patient Safety and Quality Improvement Act of 2005***

Q. What is the purpose of the Patient Safety and Quality Improvement Act of 2005?

A. The new law will allow hospitals, physicians and other health care providers to create voluntary reporting systems involving medical errors and "near misses" in a manner that is legally privileged and confidential when reported to patient safety organizations (PSOs). These reports will allow experts to analyze problems, recommend solutions and advance patient safety. These new protections will allow health care providers to voluntarily report medical mistakes without fear of these reports being used against them in litigation.

Q. What types of information does the bill consider "privileged" and "confidential"?

A. In general, the law considers information that a "provider" collects or develops in the course of performing "patient safety activities" to be "patient safety work product" and, if reported to a PSO, "privileged" and "confidential." The law states that any "data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements which are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization are privileged and confidential." These protections also apply to materials developed by a PSO in order to carryout patient safety activities.

The law only protects information collected or developed for patient safety activities, not for other purposes. For example, a patient's medical record, billing and discharge information or any other original patient or provider record are not considered protected.

Q. What are the protections provided?

A. In general, "patient safety work product" is not subject to federal, state or local civil, criminal or administrative subpoena or order; is not subject to discovery in connection with a federal, state or local civil, criminal or administrative proceeding, including a disciplinary proceeding against a provider; and cannot be admitted into evidence against a provider, including in a professional disciplinary proceeding. The law does contain exceptions to this rule. For example, disclosure of relevant patient safety work product for use in a criminal proceeding is allowed but only after a court makes an *in camera* determination that it contains evidence of a criminal act and that the patient safety work product is material to the proceeding and not reasonably available from any other source. Disclosure also is allowed when authorized by each provider identified by the patient safety work product. The law also permits voluntary disclosure of a patient safety incident to the accrediting body that accredits that provider but prohibits the accreditor from requiring that a provider's communication with its PSO be disclosed.

Q. When can a provider start asserting the legal protections?

A. While it is not clear how long it will take for the Administration to implement the PSO certification process, Congress intended that the privilege and confidentiality protections be effective immediately.

Q. What is a “patient safety organization” and who can be one?

A. A PSO can be a private or public entity or a component of such an entity that carries out various activities outlined in the law. The law envisions two kinds of PSOs: an entity that is solely dedicated to conducting activities that improve patient safety and the quality of health care delivery, and one that is a “component” of another organization; it must comply with an additional set of requirements aimed at ensuring that its patient safety work product is kept separate and secure from the larger organization’s activities. The law contains a “primary purpose” test that will help those interested in becoming a PSO decide whether they should apply as an entity whose sole purpose is PSO-type activity or as a component of a larger entity.

To become a PSO the Secretary must certify that the entity meets the requirements under the law. The Secretary is charged with maintaining a list of all certified PSOs.

Q. When can an entity seek PSO certification?

A. Under the law, the Secretary must create a process through which PSOs can be certified. The law does not specify a deadline for the Secretary to issue regulations. The American Hospital Association will work with HHS, specifically the Agency for Healthcare Research and Quality, and others to assist in the implementation of this important law.

Q. How will the law affect state reporting systems or other reporting systems in which hospitals participate?

A. The federal law does not directly affect state or other reporting systems. The law creates a federal, voluntary system of reporting medical errors with protection for patient safety work product when those reports are made to a certified PSO. The law permits any entity or individual licensed as a health care provider under state law to report to a PSO. To the extent a provider wants to continue patient safety activities or reporting under the protections currently afforded by state law, it may do so and the federal law will not have any effect. If, however, a provider finds that the federal privilege and confidentiality protections are greater than under state law, the provider may choose to comply with the federal law and obtain the additional protections. In that case, the entity to which the provider reports will need to be a certified PSO. By participating in the federal system, the federal protections for patient safety work product will apply. However, to the extent some of that information may have greater protection under state law, those state protections will continue to apply. The federal law does not affect “any State law requiring a provider to report information that is not patient safety work product”

Q. What are the penalties for disclosing privileged and confidential information?

A. The bill contains penalties of up to \$10,000 for disclosing confidential information. Penalties apply to providers if the “patient safety work product” is identifiable and the disclosure is done “knowingly” and “recklessly.” This is a relatively high legal standard.

Q. Does the law create a new federal patient safety database?

A. The law creates a framework in which the Secretary can facilitate the creation and maintenance of a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations and other entities. The network of databases will have the capacity to accept, aggregate across the network, and analyze non-identifiable patient safety work product voluntarily reported by PSOs. The results of the analysis of this non-identifiable information will be made available to the public and published annually.

Q. Does the bill mandate data standards for the reporting of patient safety work product?

A. One of the provisions of the law calls for the establishment of a national network of databases so that researchers can analyze de-identified patient safety reports. To facilitate the aggregation of reports across the PSOs into this national network, the Secretary is empowered to specify common formats. It is likely that PSOs will adopt this standard format for reporting by providers into the PSOs database. The law does not specify a timetable for this to be accomplished.

Q. Does the bill contain “whistle blower” protections?

A. The bill contains protections for those who report patient safety information. For example, 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. Such an employment action includes 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 an adverse evaluation or decision made in relation to accreditation, certification, credentialing or licensing of the individual.

Q. When is the bill effective?

A. Although the bill does not contain an explicit effective date, the weight of previous court rulings supports the position that the bill was effective when President Bush signed it on July 29, 2005.