

The Patient Safety and Quality Improvement Act of 2005 *Public Law 109-41*

BACKGROUND AND OVERVIEW

On July 29, 2005, in response to the 1999 “To Err Is Human” report of the Institute of Medicine calling for Congress to establish a network of independent patient safety organizations, President Bush signed the Patient Safety and Quality Improvement Act of 2005 into law. This action followed several years of draft legislation that was previously extensively debated but didn’t reach a compromise in the House and Senate until 2005. The law amends the Public Health Service Act to establish procedures for voluntary, confidential reporting of medical errors to designated patient safety organizations (PSO) and provides protection and confidentiality for entities and individuals reporting such errors.

Draft regulations defining implementation of the law were published in the February 12, 2008 *Federal Register*, followed by release of Common Data Formats as a guideline for PSO reporting and Interim Guidance to allow for PSO certification by the Agency for Healthcare Research and Quality. Final regulations were published November 21, 2008.

KEY PROVISIONS OF THE ACT

Establishes Patient Safety Organizations

- Public or private entities or components of such with the exception of a health insurance issuer, a unit or division or entity owned, managed or controlled by such, and entities that accredit or license health care providers, oversee or enforce statute or regulation or acts as an agent of such or operates a federal, state, local or tribal patient safety reporting system to which providers are required to report.
- Must meet criteria established by the government and be listed by the Secretary of Health and Human Services.
- Shall undertake efforts to improve patient safety and quality of health care delivery.
- To develop and implement processes for voluntary and confidential reporting of adverse events and for providing feedback to participants.
- To participate in a national network of patient safety databases to be established by HHS.
- To work with providers to identify and analyze threats to patient safety and other quality of care problems.

PSOs must have policies and procedures in place addressing the following:

- Efforts to improve patient safety and the quality of health care delivery
- Collection and analysis of patient safety work product
- Development and dissemination of information to improve patient safety
- Use of patient safety work product to encourage a culture of safety and provide feedback and assistance to minimize patient risk
- Procedures to preserve confidentiality and security of patient safety work product
- Use of qualified staff
- Activities related to operation of a patient safety evaluation system and to provide feedback to participants in the system

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PSOs are to recertify every three years and comply with the following:

- Be performing patient safety activities as defined for initial certification
- Maintain a mission and primary activity of conducting activities to improve patient safety and quality of health care delivery
- Have appropriately qualified staff (directly or through contract)
- Within 24 months of initial listing have contracts with more than one provider to receive and review patient safety work product
- Not be a component of an insurance issuer or other excluded entity
- Fully disclose financial, reporting or contractual relationships and, if applicable, that the entity is not managed, controlled and operated independently from any provider that contracts with the entity
- Collect work product from providers in a standardized manner to permit comparisons
- Use patient safety work product to provide feedback and assist providers in minimizing patient risk

Patient Safety Data Protections

- Defines patient safety work product protected by the law (data, reports, records, memoranda, analyses, written or oral statements reported to or developed by a PSO for the purpose of improving safety, quality or outcomes with defined exceptions)
- Provides confidentiality to the entities and individuals that report to the PSO in good faith
- Provides protection from discovery of work product in legal proceedings with defined exceptions
- Provides protection from use of work product against a provider by any accrediting agency or regulator
- Provides protection to employees from adverse employment actions as a result of reporting information to a PSO

Other Provisions

- Development of national standards for electronic exchange of health care information
- Contracting by the federal government with a research organization to study the impact of medical technologies and therapies on health care
- Imposes monetary penalties for violations of confidentiality protections
- HHS is to maintain a network of patient safety databases to collect and analyze data to identify trends, develop common formats to ensure aggregation of data meets reporting requirements and may provide technical assistance to PSOs

MISSOURI CENTER FOR PATIENT SAFETY

- Founded by the Missouri Hospital Association, Missouri State Medical Association and Primaris in response to the recommendation of the Missouri Commission on Patient Safety to serve as a Patient Safety Organization.
- Certified as one of the first ten PSOs in the nation effective November 5, 2008 to provide legal protections and processes for reporting, learning and sharing to improve the safety of care provided.

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