

The Patient Safety and Quality Improvement Act of 2005

The Institute of Medicine (IOM) report noted that medical errors are the eighth leading cause of death in the United States with as many as 98,000 people dying per year. Our nation was shocked by this report.

It is worth noting that most patient safety research and innovations come from the hospital setting, however most health care in the United States is provided in the outpatient setting. For every 8 people that are hospitalized, 217 visit a physician's office, and more than half of those visit their primary care provider. Preventing adverse events represents one of the greatest challenges to health care.

The AMA is working diligently to promote a culture of patient safety. For instance, The AMA's Quality of Care Campaign includes several initiatives on behalf of America's patients. The campaign activities fall under four primary categories: Safety, Advocacy, Measurement and Education. The AMA believes that by asking, listening and learning its physician members can play a roll in improving the health of the nation. The AMA has partnered with the Institute for Healthcare Improvement (IHI) to prevent common in-hospital system errors. The AMA lobbied aggressively for federal patient safety legislation that would create a voluntary, confidential error-reporting system. It is their belief this would end the "Blame-and-Shame" era, and that everyone will benefit when errors can be shared in a voluntary and confidential manner.

On July 29, 2005 President Bush signed the Patient Safety and Quality Improvement Act of 2005 (PSQIA), which was designed to create a national patient safety center to address medical errors within the health care system. This legislation is designed to strike the proper balance between maintaining confidentiality and legal protection for medical error reporting while maintaining providers' accountability and patients' rights. The Act will promote cultures of safety across health care settings and will encourage the voluntary reporting of medical errors, serious adverse events and their underlying causes. Previously evaluative information about the underlying causes of adverse events was not always considered confidential or protected from lawsuits, a fact that the IOM blamed for driving errors underground and slowing progress in improving patient safety.

The Secretary of Health and Human Services has been directed to establish a network of databases that will collect the information and disseminate it throughout the country. The PSQIA will establish/approve Patient Safety Organizations (PSOs) to which providers (individuals and entities) can voluntarily report medical errors and patient safety information. These PSOs then aggregate and analyze the information, which is referred to in the Act as "Patient Safety Work Product" or "PSWP", to develop strategies to improve patient safety.

Patient Safety Organizations

A PSO must primarily engage in patient safety activities including: collecting and analyzing PSWP, developing and disseminating information with respect to improving patient safety, utilizing PSWP for the purposes of encouraging a culture of safety and providing feedback and assistance to effectively minimize patient risk.

Patient Safety Work Product

PSWP is defined as any information in written or oral form that may result in improved patient safety, health care quality or health care outcomes and is either:

- gathered by a provider to be reported to a PSO and is actually reported, or
- developed by a PSO for patient safety activities.

PSWP does **not** include:

- individual patient medical records
- billing and discharge information
- other original patient or provider record, or
- information that is collected or maintained separately from a patient safety evaluation process.

Privilege & Confidentiality

Patient Safety Work Product is both confidential and privileged under the Act. With some exceptions, PSWP is not subject to subpoenas, discovery or even court orders in civil, criminal, or administrative proceedings. PSWP may not be used as evidence in any civil, criminal, or administrative proceeding or in any “professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under state law.” PSWP is also confidential in situations other than legal proceedings. Stronger state confidentiality and/or privilege protections are not preempted by the Act.

Implications for Health Care Providers

PSWP does not include information that is collected, maintained or developed separately, or that exists separately, from a patient safety evaluation system. In order to ensure confidentiality and privilege protections apply, a reporting provider must ensure that its patient safety information is handled only within its patient safety evaluation system.

A health care provider reporting patient safety information to a PSO must make certain that its patient safety evaluation system is organized and well defined in order to preserve that protection under the Act.

Voluntary reporting of PSWP by institutions and individuals providing health care suggests that health organizations should carefully consider reviewing and/or structuring their patient safety evaluation system to assure appropriate **coordination and collaboration** between individual providers and associated organizations with respect to medical error reporting. Reporting by individual providers without the knowledge of an associated organization raises concerns that the information may not be privileged and confidential PSWP if it was collected, maintained or developed by the individual **outside** of a patient safety evaluation system.

Despite many outstanding issues about the Act (PSQIA) including the fact that PSOs have not yet been certified, the structure of PSO reporting is not clear and is voluntary, it is **important for providers to act now**. Begin by taking these steps:

- Evaluate existing peer review, quality improvement and risk management systems to determine how to best take advantage of both federal and state protections.
 - Establish and implement a patient evaluation system.
 - Develop a guiding document known as a patient safety plan.
 - Integrate existing/revised/new peer review, quality improvement, patient safety and risk management activities into the plan.
 - Develop a culture of safety and no blame, drive the change. Foster that culture.
 - Identify a structure for reporting and reviewing adverse events, peer review and quality improvement processes and data.
 - Educate and implement new processes once approved.

Call your Risk Management Consultant with questions or for assistance in navigating this process.

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