

The Patient Safety and Quality Improvement Act of 2005 – The Federal Law and its Implications for Missouri

by Rebecca G. Miller, MHA, CPHQ, CHE and Jennifer L. Druckman, JD, MHA, RHIA

With widespread reporting to a patient safety hub, Missouri providers can learn about what errors are occurring, why they occurred and how to prevent them from occurring in the future.



Rebecca G. Miller, MHA, CPHQ, CHE, is Executive Director for the Missouri Center for Patient Safety. Jennifer L. Druckman, JD, MHA, RHIA is an Associate for Greensfelder, Hemker & Gale, P.C. Health Care Practice Group.

Abstract

The Patient Safety and Quality Improvement Act of 2005 establishes a network of federally certified Patient Safety Organizations (PSO). PSOs will establish voluntary, confidential data systems and forums for providers to learn and improve patient safety. The Act provides protections, not available in Missouri, from discovery of data reported to a PSO. Providers should begin assessing patient safety activities and benefits of PSO participation. The Missouri Center for Patient Safety plans to become a statewide PSO.

Institute of Medicine Report

In 1999, the Institute of Medicine (IOM) issued its first report on medical errors, noting that as many as 98,000 people may die each year of medical errors, many caused by faulty systems, processes, or conditions that lead people to make mistakes or fail to prevent them.¹ Since the IOM report, health care providers and Congress searched for a solution to encourage providers to report and share patient safety data so that others can learn from the errors to avoid repeating them. Congress reviewed the non-punitive models in place in other industries, such as the Aviation

Safety Reporting System, which, through its data collection and analysis, was able to significantly improve aviation safety. Congress determined that in order to encourage reporting of patient safety data in the health care industry, providers had to be assured that the report would be received in a blame-free environment and that the provider would not be subjected to additional legal liability.

Patient Safety Quality and Improvement Act

Although the IOM report recommended a mandatory error reporting system, Congress' solution to the problem, the Patient Safety and Quality Improvement Act of 2005, creates a voluntary and confidential reporting system for patient safety data.² The goal of the Act is to establish patient safety organizations to collect, analyze, and make recommendations regarding reducing medical errors while providing protection from discovery of the data collected by the PSOs. As noted by Senator James Jeffords of Vermont, the Act does not (1) change any existing remedies available to injured patients or limit a patient's access to their medical record; (2) "shield" or put patient information that is otherwise available beyond the reach of authorities for the purpose of disciplinary, civil, or criminal proceedings; (3) change current

regulatory processes; or (4) create mandatory, punitive reporting systems.³

Typically, patient safety data is collected in several ways, such as during (1) performance and quality improvement activities; (2) an investigation related to an adverse patient event; or (3) a peer review investigation. In Missouri, there is no protection for patient safety data gathered during performance and quality improvement activities. If an attorney or the insurer directs the investigation into the adverse event, the patient safety data may be protected from discovery under the attorney-client or insurer-insured privilege. If a properly constituted peer review committee undertakes an investigation of the providers involved in the event, the patient safety data may be protected from discovery under the peer review privilege.

Missouri's peer review privilege prohibits discovery of the deliberations, findings, reports, and minutes of peer review committees. A peer review committee is "a committee of health care professionals with the responsibility to evaluate, maintain, or monitor the quality and utilization of health care services or to exercise any combination of such responsibilities."⁴ In contrast to the peer review privilege, the Act allows any individual or entity authorized by state law to provide health care services, including individual providers such as physicians, to participate with a PSO and obtain the benefits of the Act. The Act is less restrictive than the peer review privilege in that the Act permits individual providers to submit data to the PSO rather than requiring the formation of a peer review committee.

Patient Safety Work Product

Prior to the passage of the Act, the privileges available to protect patient safety data from discovery in a typical medical malpractice case were largely a function of state law. Rather than replacing the attorney-client, insurer-insured, or peer review privileges, the Act offers an

additional federal method to protect certain patient safety data and information from discovery. In the event a particular state offers greater protection for its patient safety work product (PSWP) the Act does not preempt the state's law. Missouri has no such law.

The Act defines PSWP as 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 PSO and are reported to a PSO and which could result in improved patient safety, health care quality, or health care outcomes. PSWP also includes data, "which identify, constitute the deliberations or analysis of, or identify the fact of reporting pursuant to a patient safety evaluation system." A "patient safety evaluation system" is a system that collects, manages, or analyzes data and information for reporting to or by a PSO. A patient safety evaluation system includes provider-level activity that is coordinated with and reported to a PSO and can encompass a large percentage of the work performed by a provider for patient safety purposes.

PSWP does not include a patient's medical record, billing and discharge information, or any other original patient or provider record. The key to this portion of the Act is that the PSWP must be collected for the purpose of reporting to a PSO, that the PSWP must actually be reported to the PSO, and that the PSWP is part of a patient safety evaluation system. For example, if a provider collects the patient safety data and performs a root cause analysis to determine the reason for the error, but does not report the data to the PSO, the information may be discoverable unless otherwise protected by another state law privilege. In addition, providers that participate in quality and performance improvement activities may not submit all of their data to a PSO merely for the purpose of obtaining the PSWP privilege.

Requirements for a PSO

There are certain requirements for an organization to qualify as a PSO, including that the PSO works with more than one provider, is not an insurance company, has appropriately qualified staff, and has as its mission and primary activity the performance of activities to improve patient safety and the quality of health care delivery. The PSO must also meet federal criteria yet to be established by the Secretary of the Department of Health and Human Services. PSOs are designed to encourage a culture of safety and preserve the confidentiality and security of the data and information it obtains.

The Act also calls for the establishment of a national network of patient safety databases that provide an interactive evidence-based management resource for providers, PSOs, and other entities. The network of databases will have the capacity to accept, aggregate across a network, and analyze nonidentifiable PSWP to facilitate and enhance individual provider learning as well as regional and national research and learning to improve patient safety.

The data standard format, or taxonomy, that will be used to classify the data is to be determined by the Secretary of the Department of Health and Human Services, which has delegated the task to the Agency for Healthcare Research and Quality (AHRQ).⁵ Research into the standard taxonomy is ongoing. Because the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has been receiving patient safety data in the context of sentinel event reporting for several years, the JCAHO is working closely with the AHRQ and in collaboration with the National Quality Forum or "NQF" to develop the standard taxonomy. Many states with mandatory medical error reporting require reporting of the NQF's 27 "never events" or a subset of these events. The NQF never events are obvious medical errors that should never occur in any health care setting, such as surgery performed on the wrong patient or an infant discharged to the wrong person.⁶

Such nationally defined data sets may be part of the data and information to be collected by PSOs.

PSWP is not subject to discovery or disclosure in (1) civil, criminal, or administrative proceedings; (2) Freedom of Information Act requests; or (3)



professional disciplinary proceedings by a professional disciplinary body, such as a state licensing board. However, PSWP may be disclosed under the following circumstances: (1) in a criminal proceeding, subject to certain limitations; (2) in an action by an employee who suffers retaliation for reporting PSWP; (3) when the providers authorize the disclosure; (4) to the Food and Drug Administration or "FDA" or the Department of Health and Human Services; or (5) certain other disclosures. If the PSWP is disclosed according to a permissible exception, the disclosure is not treated as a waiver of the privilege. For example, if the PSWP is disclosed to the FDA upon the FDA's request, the PSWP is still privileged and may not be disclosed in a medical malpractice case.

There are penalties for persons who knowingly or recklessly disclose patient safety data in violation of the Act. Each violation could subject the person to a \$10,000.00 civil penalty. For the purposes of compliance with the Health Insurance Portability and Accountability Act of 1996 or "HIPAA", PSOs are considered business associates of the providers and the patient safety activities of the PSOs are considered part of the provider's health care operations.

In summary, while the Act provides protection for specific patient safety information, the Act does not fill in the existing gaps in Missouri state law in order to offer protection to all activities related to patient safety and quality and performance improvement that providers may have

preferred to fully encourage patient safety learning and improvements. However, there is much interest and learning to be gained by collecting data from root cause analyses,

in-depth assessments into why an error occurred, and data on near misses. Regardless of the type of data and information to be reported to PSOs, the learning from the data will surely enhance research and lead to patient safety improvements as a result of the ability to perform broader studies on the impact of medical technologies and therapies, networking and sharing of error data and clinical collaborations. PSOs will also expand opportunities to develop and share technical assistance on patient safety related issues to improve the safety of patient care provided across the nation. Health care consumers will also benefit from the work of the PSO network, not only from the safer health care provided as a result of the learning and improvement, but also from the consumer-focused resources and information that will likely result from the PSO's work.

Participation in a PSO

In states, such as Missouri, with no mandatory adverse event reporting law where participation with a PSO is truly voluntary, the real incentive for participation is not only to obtain the protections for patient safety data and information, but to allow for participation in a network to share and learn from

others, participation in an evidenced-based learning environment, and to be part of the movement to improve patient safety nationwide. While there is value in the work currently being done by individual providers and health systems, increased reporting and sharing of events and lessons learned on a broader scale and involving more providers will allow more opportunities for analysis, aggregation and reporting of the data to identify commonality among types of errors, reasons for errors and how to prevent them – all without the fear of retribution for reporting and discovery of the information in a lawsuit. The Act, in particular, provides enhanced protections for health care providers that are outside of the hospital setting for patient safety data and information. With implementation of the Act and development of PSOs, licensed providers and health care professionals will have a safe forum to report, share and learn from not only actual medical errors, but potentially from near misses - errors that could have occurred but didn't because they were caught before they affected a patient, occur in greater numbers than actual errors and can provide a wealth of information for analysis and learning.

Patient Safety Center

The Missouri Center for Patient Safety, established in 2005, is preparing to become a certified PSO to offer protections and enhance statewide sharing and learning to improve patient safety in Missouri. The Center was established in response to the recommendation of the Governor's Commission on Patient Safety or "Commission" to establish a private Center to serve as a statewide resource on patient safety that could work with all health care providers and other stakeholders in patient safety, including serving as a PSO upon passage of federal legislation.⁷ Through the vision of the Commission and initial funding from the Missouri Hospital Association, the Missouri State Medical Association and

Primaris, the Center is now implementing its strategic initiatives to establish a PSO, provide education and training on patient safety, serve as a resource and facilitate special statewide patient safety initiatives. The Center has already established a Web site that contains provider and consumer resources on patient safety topics, developed consumer medication safety resources, surveyed Missouri's hospitals and home health providers on patient safety related work and held a statewide conference on establishing a culture for patient safety.

In anticipation of becoming a certified PSO once regulations are finalized, the Center has assessed adverse events and near miss reporting activity occurring in other states, data platform options for statewide error reporting, and how Missouri providers currently report patient safety events. With widespread reporting to a statewide PSO, Missouri providers can learn about what errors are occurring in Missouri, why the errors occurred and how to prevent them from occurring in the future. Statewide patient safety centers in as many as 27 other states, including centers in Maryland, Pennsylvania and Minnesota that are winners of the national John M. Eisenberg Patient Safety and Quality Award as awarded by the NQF and the JCAHO, have worked at a statewide level to lead efforts that have resulted in measurable improvements in patient safety cultures, clinical processes, health care outcomes and health care costs in their respective states. Such improvements have resulted from the collection of data and information about medical errors and near misses, issuing of safety alerts, providing training and education on high priority patient safety topics and facilitating statewide clinical collaboratives. Such statewide models can be replicated and enhanced in Missouri to achieve the same or better results to make Missouri a safer state.

The Center will most certainly not be the only PSO option for Missouri

providers; however, regardless of whether a provider decides to participate with a PSO and regardless of which PSO the provider selects, consideration should be given to the following:

- ◆ The risk of discoverability of quality and patient safety work if not participating with a PSO;
- ◆ Opportunities to share and learn from other providers to improve patient safety;
- ◆ Governance of the PSO and its credibility and reliability to report and facilitate initiatives;
- ◆ Ability of the PSO to provide a breadth and range of data and information geographically and across provider groups;
- ◆ Ability of the PSO to collaborate with other PSOs; and
- ◆ Ability of the PSO to streamline data collection and reporting with current reporting systems.

While the Act is a good first step towards promoting patient safety, providers are unable to benefit from its protections until the first PSOs are certified by AHRQ. The next step in the Act's implementation is the publication of rules and regulations, which will provide detailed information about how providers may take advantage of the additional protection and learning opportunities provided by the Act. Both the AHRQ and the Office of Civil Rights or "OCR" are working together to adopt the rules and regulations. As the agency responsible for investigating violations of HIPAA, the OCR's contribution will be enforcing the Act's privilege and confidentiality protection. Officials with both agencies have informally stated that they are diligently working on the regulations with the hope of publishing proposed regulations by the end of 2006.

While waiting for the rules and regulations and subsequent certification of the first PSOs, providers should begin reviewing their current structure for quality, risk management, customer service, claims management and peer review as well as reviewing current

policies and procedures regarding the investigation and review of quality improvement, peer review, and patient safety data, including how such work is documented and maintained. In addition, providers may consider developing a list of the data they currently collect and the entities to which they report the data. Depending on the content of the final rules and regulations, providers may want to work with legal counsel to examine their processes to determine if reporting information to the PSO will offer greater protection from discovery. Regardless of the current structure or how robust or formal such programs are currently, the Act and its regulations are an opportunity for providers to assess their current programs and position themselves to participate with a PSO to gain from the protections and tremendous learning that is available under the new federal law. Even if providers decline to participate in the reporting of patient safety data at this time, hopefully all providers and patients will benefit from the lessons learned by the PSOs as the result of receiving patient safety reports and other activities that will be undertaken by the national network of PSOs, including the Missouri Center for Patient Safety.

References

1. Institute of Medicine, *To Err is Human* (November 1999), available at: <http://www.nap.edu/books/0309068371/html/>.
2. The Act may be found at 42 U.S.C.S. § 299b-21 et seq. (2006).
3. 148 Congressional Record S5043-01 (June 5, 2002).
4. Mo. Rev. Stat. § 537.035 (2006).
5. Further information regarding the AHRQ's patient safety activities may be found at: <http://psnet.ahrq.gov/index.aspx>.
6. National Quality Forum, *Serious Reportable Events, A Consensus Report* (March 2002).
7. Missouri Commission on Patient Safety, *Report Presented to Governor Bob Holden* (July 2004).

