

► March 2009

► PSOs Bring New Opportunities for Learning and Safety Improvement

NEW FEDERAL PATIENT SAFETY INITIATIVE LAUNCHED FOR PROVIDERS

On January 19, 2009, one of the most groundbreaking federal initiatives in patient safety went into effect. The final rule implementing the Patient Safety and Quality Improvement Act of 2005 (PSQIA) lays the groundwork for the first-ever national system for providers to voluntarily report medical errors, near misses, and other patient safety events to designated organizations while having assurance that the information will be protected from legal discovery and kept confidential.

The rule seeks to accomplish two important goals for the healthcare sector:

1. It allows providers to seek expert help in understanding patient safety events and preventing their recurrence in a protected legal environment.
2. It allows the organizations that collect the data—called Patient Safety Organizations (PSOs)—to aggregate and analyze it and share findings and lessons learned. By collecting data from many providers, PSOs can spot problems and trends that an individual provider, with its limited pool of data, may be unable to detect.

This advisory briefly describes some of the provisions of the new reporting program for patient safety by reviewing some basic concepts: PSOs and component PSOs, confidentiality and privilege protections, patient safety work product, and patient safety evaluation systems. It also describes best practices for working with a PSO.

Understanding the Basics

The law broadly defines the types of providers that can benefit from PSO analysis and feedback. Such providers

include any entity licensed or authorized by state law to provide healthcare services, such as hospitals, physicians, nursing homes, and home health agencies. Other providers that can benefit include a parent organization of a provider, such as the parent of a multihospital system or corporation that operates several hospitals and other healthcare facilities.

While providers are under no mandate to comply with the law, many already see the benefits of participating in a system that provides analysis and feedback regarding patient safety matters in a protected legal environment. For a provider to be able to apply the federal privilege and confidentiality protections granted by PSQIA to its patient safety events, data, and reports—referred to in the law as patient safety work product—it must create a patient safety evaluation system, through which the organization collects patient safety work product with the intent of providing it to one or more PSOs for analysis and feedback. Because the information must be provided to a PSO, the provider must have a relationship with a PSO in order for the protections to apply; the provider cannot simply collect patient safety work product within a patient safety evaluation system and expect the protections to apply without ultimately submitting the information to a PSO. That said, the patient safety work product can be protected back to the time of collection; providers do not have to report immediately to a PSO to ensure protection.

PSOs are certified by the U.S. Department of Health and Human Services' (HHS) Agency for Healthcare Research and Quality (AHRQ) as eligible to receive a provider's patient safety work product, analyze the information, and provide feedback based on the findings to assist the provider in improving patient safety. To become listed as a PSO, an organization must attest

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that it meets 15 requirements for certification—8 patient safety activities and 7 operational activities. To continue its listing, the PSO must repeat the process every three years thereafter. First and foremost, the PSO's mission and primary activity must be to improve patient safety and the quality of healthcare delivery.

As of February 2009, AHRQ had already listed nearly 50 PSOs, including ECRI Institute PSO (see "Learn More about ECRI Institute PSO" for more information). These PSOs represent a variety of organizations. For example, included on AHRQ's list are PSOs established by professional organizations, health systems, state and metropolitan hospital associations, consulting firms, information technology firms, and organizations with a role in patient safety. Even a hospital can establish its own PSO, although the law specifies that a PSO must have at least two contracts in place with providers in order to operate as a PSO. AHRQ provides information about each PSO on its Web site at <http://www.pso.ahrq.gov>.

The process to become a PSO is fairly straightforward, and because there is no federal funding for this initiative, HHS emphasizes that the marketplace—namely, the providers contracting with PSOs—will be responsible for evaluating PSOs' services and their effectiveness in fulfilling their mission. However, HHS will oversee PSOs' compliance with PSQIA and could take action to have a PSO's listing revoked if the PSO allows "knowing or reckless" disclosures of a provider's confidential patient safety work product or otherwise fails to comply with the law.

Getting Started with a PSO

What do providers need to do to prepare to work with a PSO?

1. Designate someone within the organization to be responsible for understanding PSQIA and the regulations implementing the law. This individual should also understand how the federal law interacts with state laws such as those offering peer-review protections and those addressing mandatory or voluntary reporting of medical errors or adverse events and near misses. In many organizations, this will be a patient safety officer or risk manager.
2. Establish and document policies and procedures relating to the organization's patient safety evaluation system. This system provides a protected environment for candid consideration and analysis of quality and safety information. The law has no

Learn More about ECRI Institute PSO

ECRI Institute PSO was listed as a Patient Safety Organization (PSO) by the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) on November 5, 2008, making it among the first federally designated PSOs. ECRI Institute PSO is a component of ECRI Institute; its mission is "to achieve the highest levels of safety and quality in healthcare by collecting and analyzing patient safety information and sharing lessons learned and best practices."

ECRI Institute PSO services are based on applied research, interactive tools, a learning network, and a reporting platform powered by rL Solutions. To enable healthcare providers to learn from near misses and adverse events, and to improve patient care, ECRI Institute PSO provides event report collection and analysis; culture-of-safety recommendations; best-practices libraries, advisories, and publications; continuing medical education; ready-to-use toolkits; and more.

Visit <http://pso.ecri.org> to learn more about ECRI Institute PSO services and access additional educational resources, including the following:

- Free audio conference recording: Patient Safety Organization Final Regulations: Issues for PSOs and Hospitals
- Free audio conference recording: Patient Safety Organization (PSO) Regulations: What Healthcare Providers Need to Know
- Special Advisory: Patient Safety Organization Proposed Rule Lays Groundwork for Patient Safety Improvements

specific requirements regarding how a patient safety evaluation system should be established, but providers will likely need to document the following:

- Processes, activities, the physical space, computer systems, and equipment that compose the patient safety evaluation system
- Procedures for entering data and information into the patient safety evaluation system
- Personnel who have access to the patient safety evaluation system and how they carry out their duties and the system's operations
- Conditions for accessing patient safety work product that is part of the patient safety evaluation system
- Procedures for reporting information to the PSO and receiving feedback from the PSO

- ▶ Use of standardized formats for reporting information to the PSO to promote better aggregation of data from various providers
- ▶ Procedures for disseminating information outside the patient safety evaluation system

Examples of components of a patient safety evaluation system include the provider's processes for reporting adverse events, as well as activities related to adverse event investigations, patient safety committees, and root-cause analyses. If patient safety work product is sought in a legal proceeding, documentation related to the patient safety evaluation system will support the provider's defense argument that the data and information that is part of the system is privileged and confidential.

3. Define and document what constitutes patient safety work product. Patient safety work product can include data, reports, records, memoranda, analyses (e.g., root-cause analyses), and written and oral statements—all of which can be used and analyzed to improve patient safety, healthcare quality, and healthcare outcomes. Excluded from patient safety work product are original patient or provider records, such as a patient's original medical record, and billing and discharge information. By carefully documenting what patient safety work product is part of their patient safety evaluation systems, providers can ensure that the legal protections afforded by PSQIA extend to all appropriate information. Providers and PSOs are not specifically required to label the information as patient safety work product; nevertheless, providers should, to the extent feasible and appropriate, conspicuously label such information as a safeguard to prevent inappropriate disclosures.
4. Determine what best practices the organization expects from a PSO, and start to evaluate the suitability of organizations to meet the provider's needs. Examine the PSO's skill sets. Ask for a list of the PSO's references, and contact the PSO's clients. Will the PSO meet contract terms that are important to the provider? What is the PSO's experience in analyzing patient safety events? Further details to assist providers in evaluating PSOs are included with these materials.
5. Promote a culture that encourages widespread internal reporting of adverse events, errors, and near misses. Provide education to the appropriate individuals within the workforce about the PSO

initiative, and give staff an opportunity to ask questions. Explain the PSO's role: to learn from errors and mistakes and to help providers learn from one another in order to improve patient safety. Review the process for managing patient safety work product within the patient safety evaluation system.

Explain how the organization will benefit from the new arrangement. Ensure that staff understand their responsibilities regarding privacy, confidentiality, and security. By educating the appropriate individuals about the new system for analyzing patient safety events and other related matters, providers can ensure that procedures to prevent inappropriate disclosure of patient safety work product are followed.

Once a program is established, continue to monitor the processes that the organization has put in place. And most importantly of all, use the information obtained from the PSO to improve the organization's approach to patient safety and healthcare quality.

BEST PRACTICES FOR WORKING WITH PATIENT SAFETY ORGANIZATIONS

Establishing a patient safety evaluation system that effectively manages the flow of patient safety work product is essential for organizations to fully enjoy the legal protections provided by PSQIA. Healthcare organizations should examine whether their existing systems for reporting, collecting, and analyzing patient safety information ought to serve as a basis for a patient safety evaluation system for reporting to a PSO. Although neither PSQIA nor its regulations require that providers formally define or identify their patient safety evaluation systems, HHS urges providers to do so, noting in the preamble to the implementing regulations that formal identification or designation of a patient safety evaluation system can provide structure to the system's functions and can support providers against legal challenges to privilege and confidentiality.

The regulations allow maximum flexibility for provider patient safety evaluation systems so that providers can establish systems best suited to their specific needs and healthcare settings. A single hospital, for example, might establish a patient safety evaluation system within a particular office, such as the risk management department. An incident reporting system can be designated to serve as one part of a facility's patient safety evaluation system. A multihospital organization

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might designate a single patient safety evaluation system for all its hospitals and the parent organization. Alternatively, affiliated providers may choose to share patient safety work product with each other based on what HHS calls “commonality of ownership.”

ECRI Institute has identified the following best practices for risk managers to consider when reviewing their organization’s existing programs and preparing to implement a patient safety evaluation system for reporting to a PSO.

Designate a “point person” to oversee the patient safety evaluation system. This individual should understand PSQIA, the implementing regulations, the health information privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), state law protections relating to legal privilege, and relevant state reporting mandates. He or she should also be familiar with the organization’s existing patient safety reporting and data collection systems and peer-review and credentialing system. Legal counsel, patient safety officers, and risk managers are among those who may fill this role.

Develop an organizational policy that formally identifies and defines the scope and function of the patient safety evaluation system.

Because PSQIA provides broad legal protections that may not be available under state law, organizations must carefully consider what categories of patient safety information are appropriate for the organization to collect and analyze for reporting to a PSO and what patient safety information should remain outside the patient safety evaluation system. Information that must be reported to states under mandatory reporting laws, to the U.S. Food and Drug Administration or the National Practitioner Data Bank, or to other federal agencies under other mandates (e.g., the Medicare Conditions of Participation) does not gain PSQIA’s protection from disclosure by virtue of being reported to a patient safety evaluation system. However, reporting this category of data to the patient safety evaluation system allows for more inclusive and accurate data analysis. Also consider the scope of state law protections when determining whether internal deliberation and analysis directly related to events subject to state-specific mandatory reporting should be entered into the patient safety evaluation system in order to gain federal legal protections.

Limitations on the use of patient safety work product—for example, limitations that affect whether facilities may want to include peer-review or quality

improvement information in the patient safety evaluation system—should also be considered. Once peer-review analyses are entered into the patient safety evaluation system, the organization may not use the analyses to defend itself in legal proceedings challenging an adverse peer-review determination unless it obtains authorization from all identified physicians, all or some of whom may have competing interests—a hurdle that will likely be difficult to overcome. The question of whether to include elements such as the organization’s credentialing and peer-review activities and medical staff peer-review and quality improvement activities within the patient safety evaluation system, or to maintain these functions separately, raises complex issues that merit substantial consideration.

Centralize the flow of patient safety information for reporting to a PSO. Best practices include the following:

- ▶ Identify and assess all current systems for reporting and collecting patient safety information within the organization.
- ▶ Modify as necessary reporting policies and procedures for existing reporting and collection systems that will be included in the patient safety evaluation system.
- ▶ Determine whether the organization will actively send patient safety data to a PSO or whether a “functional reporting system” that allows a PSO to access the data within the patient safety evaluation system will be established.
- ▶ Develop a flowchart that illustrates how information enters the patient safety evaluation system.

Develop policies for identifying and documenting patient safety work product in the patient safety evaluation system. HHS recommends that providers document the patient safety evaluation system to support the identification and protection of patient safety work product in the event of a legal challenge to privilege or confidentiality.

Key actions include the following:

- ▶ Identify processes and activities that make up the patient safety evaluation system.
- ▶ Identify what data, reports, records, memoranda, deliberations, analyses (e.g., root-cause analyses), statements (written and oral statements and transcripts of oral statements), and other information collected, maintained, developed, or assembled by the organization are to be entered into the facility’s patient safety evaluation system for reporting to a

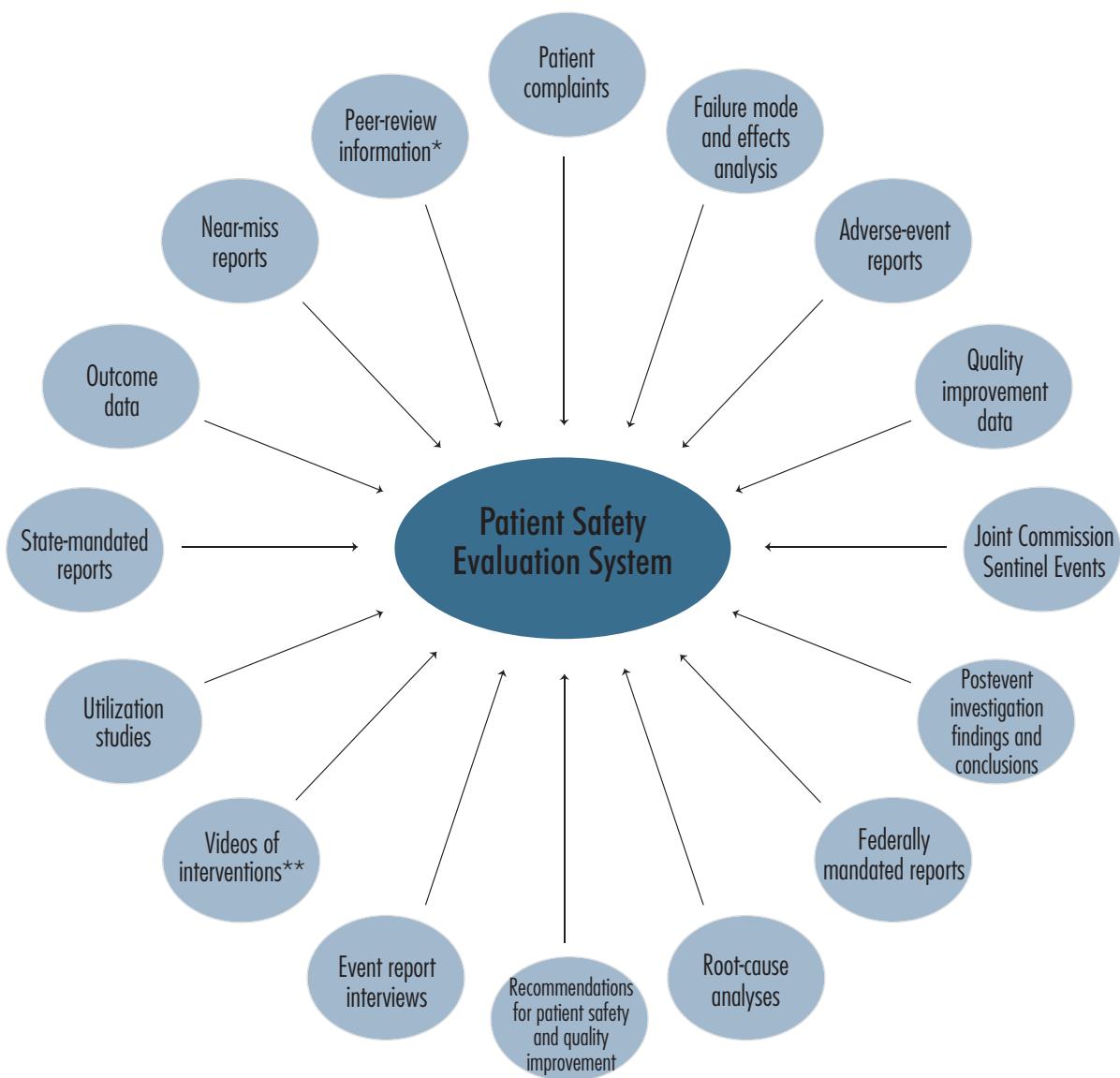
PSO. An incident report that is prepared for reporting to a PSO, for example, would be part of the patient safety evaluation system upon the report's completion. See "Figure. Information Reportable to Patient Safety Evaluation Systems" for examples of the types of data that may be submitted to a PSO.

- Determine whether information that is intended to be reported to the patient safety evaluation system should be labeled or otherwise bear designation as patient safety work product to reduce the risk of

inadvertent or inappropriate disclosure. Use of a legend—for example, "CONFIDENTIAL PATIENT SAFETY WORK PRODUCT. Protected under the Patient Safety and Quality Improvement Act. Do not disclose unless authorized by [Insert name of governing document, office, or body]."—might be considered.

- Designate which data that will be reported to the patient safety evaluation system for analysis does not constitute patient safety work product (e.g., state-mandated and federally mandated reports). While

Figure. Information Reportable to Patient Safety Evaluation Systems



* Consider the scope and implications of state law privileges when deciding whether to report peer-review information.

** Report only if facility policy does not consider the videos to be part of the medical record.

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such information may be reported to a PSO for data analysis, the information does not become patient safety work product by virtue of being reported to a PSO; consequently, such information would not be designated or labeled as patient safety work product.

- Identify information that should not be reported to the patient safety evaluation system because it is not considered patient safety work product under PSQIA, such as the following:
 - The patient's medical record
 - Billing information
 - Discharge information
 - Original patient information (e.g., a patient's living will)
 - Original provider information (e.g., patient intake forms)
 - Information that the organization has otherwise determined must be collected, maintained, or developed separately from or exist separately from the patient safety evaluation system
- Identify procedures used by the patient safety evaluation system to report to a PSO.
- Authorize specific individuals or job functions to enter information into the patient safety evaluation system.
- Authorize specific individuals or job functions to remove information that has been reported to the patient safety evaluation system if the information has been determined to be irrelevant to improving patient safety.
- Identify individuals and job functions that require access to the patient safety evaluation system, the conditions in which such access is appropriate, and the category of patient safety work product that may be accessed.
- Document how information enters the patient safety evaluation system, including the date of entry (consider using a flowchart to document the flow of information).
- Identify the physical space or equipment used by the patient safety evaluation system.
- Develop and document criteria for identifying and removing from the patient safety evaluation system information that has not been reported to a PSO; the act and date of removal should be documented.

- Identify procedures used within the patient safety evaluation system to disseminate patient safety information outside the evaluation system—to attorneys or accountants, for example.
- Develop a procedure for identifying and documenting the receipt of feedback from PSOs.

Develop and implement a program for educating and training the workforce.

A person who discloses identifiable patient safety work product in a knowing or reckless violation of the confidentiality provisions of PSQIA is subject to civil monetary penalties for each act that constitutes a violation. Principals, such as employers, are liable under ordinary principles of agency law for a civil monetary penalty imposed on their employees or agents. Providers should do the following to mitigate unauthorized, impermissible, and inappropriate disclosures:

- Develop and implement a training program for individuals who are authorized to enter information into, access information in, or remove information from the patient safety evaluation system. Retrain these individuals periodically.
- Ensure that the human resources department's policy prohibits the organization from taking adverse employment action against an individual who directly reports information to a PSO in good faith.

Develop and document a contractual relationship with a PSO. PSQIA does not specify the type of arrangement that a provider should establish with a PSO. A best practice is for providers to enter into a written agreement with a PSO that defines the arrangements for reporting patient safety work product to the PSO and accepting feedback from the PSO after it has reviewed and analyzed reported information. The written agreement should also specify confidentiality requirements, which must meet and may exceed what is required by HIPAA. For the purposes of PSQIA, PSOs are treated as business associates of providers.

- Ensure that a written contract that addresses all relevant expectations of the parties is executed between the provider and the PSO that is to receive patient safety work product and information.
- Ensure that a business associate agreement that complies with HIPAA's health information privacy and security requirements is executed between the reporting provider and the PSO that is to receive patient safety work product and that PSO contractors are contractually bound to comply with the same requirements.