

## ► New Federal Patient Safety Initiative Launched for Providers

One of the most groundbreaking federal initiatives in patient safety went into effect earlier this year. 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. It was effective January 19, 2009.

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 hospital, with its limited pool of data, may be unable to detect.

This overview 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. Additional materials introduce providers to definitions of key terms discussed in PSQIA and its implementing regulations, answer some of the most commonly asked questions about the voluntary reporting program, and suggest best practices for organizations to prepare to work with PSOs.

### 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. Care must be taken to ensure that the patient safety evaluation system is developed within the context of the provider's state laws for legal privilege and peer review as well as the new federal law. To receive federal protections, 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. The provider must have a relationship with a PSO for the protections to apply. 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.

## 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." As a component PSO, ECRI Institute PSO leverages ECRI Institute's 40 years of experience operating healthcare problem reporting systems and safety initiatives while meeting the security and confidentiality requirements for component organizations.

ECRI Institute PSO services are based on applied research, interactive tools, a learning network, and a reporting platform powered by rL Solutions. All providers can participate at no cost in ECRI Institute PSO's data collection and reporting system.

ECRI Institute PSO's membership program enables healthcare providers to learn from near misses and adverse events and to improve patient care by providing event report collection and analysis; culture-of-safety recommendations; best-practice 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 (PSO) Final Regulations: Issues for PSOs and Hospitals
- Free audio conference recording: PSO Regulations: What Healthcare Providers Need to Know

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, the organization must attest 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 April 2009, AHRQ had listed nearly 60 PSOs. 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. ECRI Institute's component PSO, ECRI Institute PSO, was among the first federally designated PSOs. For more information, see "Learn More about ECRI Institute 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. Some PSOs will be established as component PSOs of a parent organization, which can include accrediting organizations and state regulatory agencies. Providers will want to obtain basic facts about PSOs to select the organizations that best meet their needs.

Even a hospital can establish its own PSO; however, because the law specifies that a PSO's mission and primary activity must be to improve patient safety and the quality of healthcare delivery, hospitals and other providers, which conduct multiple activities, will likely choose to establish component PSOs with missions specifically to conduct their PSO activities.

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.

Given that there is no federal funding for PSOs, PSOs will likely charge a fee for the services they provide to hospitals and other healthcare providers.

## Getting Started with PSOs

What do providers need to do to prepare to work with PSOs?

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. For many providers, 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 system should be developed in consideration of state laws regarding peer review and legal privilege. The federal law has no 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 organization'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. For example, the following legend might be used: "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]."

4. Determine what best practices the organization expects from a PSO, and start to evaluate organizations best suited 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 in the attached 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 new 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 provider's process for managing patient safety work product within the patient safety evaluation system. Explain how the hospital 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.



## COMMONLY USED DEFINITIONS

The Patient Safety and Quality Improvement Act of 2005 (PSQIA) and the regulations that implement the law introduce new terms and concepts to the healthcare sector. Understanding these terms and their definitions is critical to ensuring that providers and patient safety organizations (PSOs) correctly follow the processes outlined in the new law. The following are definitions of some of the most commonly used terms in PSQIA and its related regulations.

**Affiliated provider.** A legally separate provider that is the parent organization of a provider. The affiliated provider is under common ownership, management, or control with the provider or is owned, managed, or controlled by the provider. The final regulation implementing PSQIA allows disclosures of identifiable, nonanonymous patient safety work product among affiliated providers.

**Common formats.** The U.S. Department of Health and Human Services' (HHS) Agency for Healthcare Research and Quality (AHRQ) has issued common definitions and reporting formats to allow PSOs to collect information from providers and standardize how patient safety events are represented. AHRQ expects PSOs to indicate their intent to adopt the common formats at initial listing and to certify that they are using the common formats when their listing is renewed.

Common formats apply to the following types of patient safety concerns:

- ▶ Incidents that reached the patient—whether or not harm occurred
- ▶ Near misses, or events that that did not reach the patient
- ▶ Unsafe conditions, or circumstances that increase the probability of a patient safety event

The initial release of the common formats also provides for reporting of specific information on nine types of events, including falls, healthcare-associated infections, medication events, pressure ulcers, and surgical events. PSO use of common formats ensures that PSOs will be able to compare similar events reported by similar providers and that data can be aggregated (with identifiers removed) to allow analysis of patient safety trends.

AHRQ has issued a paper version of its common formats for hospital reporting (available online at <https://www.psoppc.org/web/patientsafety/paperforms>)

and expects to update the formats based on feedback. The agency will then provide technical specifications for electronic use of the common formats. Once the common formats are in a more final stage, AHRQ will update them annually. In the future, AHRQ intends to develop common formats for other settings, such as long-term care organizations and ambulatory settings.

**Component organization.** This definition establishes the types of organizations that can operate component PSOs. A component organization is a unit or division of a legal entity. The entity can be a corporation, a partnership, or a federal, state, local, or tribal agency or organization. A component organization can also be an organization that is owned, managed, or controlled by one or more legally separate parent organizations. The defining feature of a component organization is management or control by others. For example, a component PSO could be a unit or division of a professional society that controls or manages the PSO. A component PSO can contract with its parent organization; for example, a component PSO established by a multifacility system can have a contract with the system.

The definition of a component organization is broad enough to apply to entities created by corporate organizations and other legal entities. Additionally, a component organization can be created by public agencies such as the U.S. Department of Defense, the U.S. Department of Veterans Affairs, the Indian Health Service, and other state, local, and tribal organizations that manage or deliver healthcare services. An accrediting organization is also permitted to establish a component PSO provided that all requirements for ensuring that a firewall exists between the parent organization and the component PSO are met.

**Disclosure.** Disclosure is specifically defined in the regulations implementing PSQIA, although the definition used in the rule may differ from many providers' typical use of the word "disclosure." Disclosure, as defined by PSQIA, refers to the release of, transfer of, provision of access to, or divulgence of patient safety work product, in any manner, by an entity or person maintaining that patient safety work product to another legally separate entity or person. Impermissible disclosures—such as PSO divulgence of a provider's patient safety work product to another provider not entitled to the information—could result in revocation of the PSO's listing and financial penalties. The regulation outlines limited instances in which disclosures are permissible, such as disclosure to the U.S. Food and Drug Administration

or to law enforcement when the event prompting the disclosure is the reason for law enforcement activity. Nothing prohibits the use or sharing of patient safety work product within a single legal entity. For example, a hospital can allow physicians on its staff to discuss patient safety work product for internal purposes, such as morbidity and mortality rounds. This distinction between *disclosure* and *use* is more specifically addressed in the Health Insurance Portability and Accountability Act of 1996.

PSQIA's definition of the word "disclosure" is unlike the definition of "disclosure" typically used by providers. Most providers understand "disclosure" to mean a factual, but compassionate, recounting of a patient safety event with the patient involved—and, possibly, family members. This understanding of "disclosure" is not affected by the regulations implementing PSQIA.

**Excluded entity.** PSQIA prohibits certain types of organizations from becoming listed as a PSO. Two groups are excluded: entities in the first group, health insurers, are barred from becoming a PSO or a component PSO; entities in the second group, while barred from creating a PSO, may create a component PSO through a parent organization provided that they meet very strict requirements regarding separation of staff and data. The second group includes any entity that accredits or licenses healthcare providers or is an agent of an entity that oversees or enforces statutory or regulatory requirements governing the delivery of healthcare services.

**Functional reporting.** A provider and a PSO can design a flexible reporting mechanism that allows the PSO to access the provider's patient safety work product so that the arrangement is mutually useful and results in a suitable reporting relationship. Such functional reporting enables the PSO, as defined by a contract or agreement between the PSO and provider, to access specific information in the patient safety evaluation system for processing and analysis. This can be done without requiring the provider to physically transmit the information to the PSO. The arrangement should establish the mechanism for control of the information reported or the information to which the PSO has access and the scope of the PSO's authority to use the information.

**Network of patient safety databases.** PSQIA authorizes the creation of a network of patient safety databases to receive nonidentifiable data regarding patient safety events from PSOs and to perform analysis on the aggregated data. The goal is to create a learning system to develop

quality improvement strategies for PSOs and health-care providers. The PSO Privacy Protection Center, an organization funded by AHRQ to support the implementation of PSQIA, will assist PSOs in submitting the data to the network.

**Parent organization.** This term defines the types of organizations that can establish a component PSO. A parent organization owns a controlling or majority interest in the component PSO, can manage or control the component, and has the authority to review and overrule the component's decisions. The ownership of a component PSO can be shared with other organizations, as in a joint venture; however, each of the parent organizations must disclose contact information (the parent organization's name, address, phone number, and Web site address) when the component PSO seeks listing from AHRQ.

**Patient safety activities.** To become certified as a PSO, an organization must perform eight patient safety activities on behalf of a PSO or a provider. The obligations for conducting patient safety activities rest with PSOs, not providers. The eight activities, as listed in the final rule implementing PSQIA, are as follows:

1. Engage in efforts to improve patient safety and the quality of healthcare delivery.
2. Collect and analyze patient safety work product.
3. Develop and disseminate information—such as recommendations, protocols, and suggested best practices—to improve patient safety.
4. Use patient safety work product to encourage a culture of safety, and provide feedback and assistance to minimize patient risk.
5. Maintain procedures to preserve the confidentiality of patient safety work product.
6. Implement appropriate security measures to protect patient safety work product.
7. Use qualified staff (the workforce can include employees, contractors, and others, whether or not they are paid by the PSO).
8. Operate a patient safety evaluation system, and provide feedback to participants within the patient safety evaluation system.

**Patient safety evaluation system.** A patient safety evaluation system is the mechanism for collecting, managing, and analyzing information for reporting to or by a PSO. The system provides a protected environment for candid consideration and analysis of quality and safety information and is flexible and scalable to meet the needs

of the specific hospital. For a multiprovider entity, the final rule permits the establishment of a single patient safety evaluation system or the sharing of patient safety work product among affiliated providers. Regardless of the scope or design of the system, hospitals must continue to fulfill mandatory reporting obligations, such as reporting of patient safety events to state reporting programs. Such information is not considered patient safety work product even though it may be collected by the patient safety evaluation system. A provider may not maintain its patient safety evaluation system within a PSO.

**Patient safety organization (PSO).** A PSO can be a public or private entity. Its mission and primary activity must be to improve patient safety and the quality of healthcare delivery. To become certified as a PSO, the organization must attest that it meets 15 requirements for certification—8 patient safety activities and 7 operational activities. To continue its listing, a PSO must repeat the process every three years thereafter. A PSO must have at least two written contracts with different providers in effect at some point during a 24-month reporting period. AHRQ is responsible for listing PSOs and overseeing their compliance with statutory and regulatory requirements.

**Patient safety work product.** Patient safety work product maintained by the provider and the PSO is subject to federal statutory legal privilege and confidentiality. Information becomes patient safety work product in any of three ways: (1) it is assembled or developed by a provider within a patient safety evaluation system for the purpose of reporting to a PSO and is reported to the PSO, (2) the information is developed by the PSO for the conduct of patient safety work activities, or (3) the information constitutes deliberations or analysis conducted within the scope of the patient safety evaluation system. Federal protections of patient safety work product begin at the time of collection within the patient safety evaluation system for reporting to the PSO. AHRQ stated in the preamble to the final regulations that this period of collection may extend as far back as to passage of PSQIA in July 2005.

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. Certain protections may still apply even though the original record is not patient safety work product. For example, a patient's medical record is considered confidential although it may not be protected from legal discovery. Patient safety work product does not include information that is collected, maintained, or developed separately from, or exists separately from, a patient safety evaluation system. Also, facts about corrective measures that a provider adopts to improve patient safety based on feedback from a PSO are not considered patient safety work product.

**Provider.** Providers, as defined by PSQIA and its implementing regulations, are eligible to work with PSOs or component PSOs by submitting patient safety work product for analysis by the PSO and receiving feedback to improve patient safety—all within an environment offering privilege and confidentiality protections. HHS defines a provider as (1) an entity or individual licensed or authorized by state law to provide healthcare services; (2) an agency, organization, or individual within a federal, state, local, or tribal government that delivers healthcare services or an organization or individual engaged as a contractor to one of these governments to deliver healthcare; or (3) a parent organization (as previously defined) of a provider or a federal, state, local, or tribal government unit providing healthcare services.

HHS's final rule implementing PSQIA offers an extensive list of examples of providers but notes that the list is not exhaustive. Providers can be not-for-profit or for-profit entities. In its preamble to the final rule, HHS clarifies that a medical product vendor, pharmaceutical company, medical device company, or health insurer cannot be considered a provider.



## FREQUENTLY ASKED QUESTIONS ABOUT PSQIA

These frequently asked questions (FAQs) attempt to answer many of the questions that providers are asking about the Patient Safety and Quality Improvement Act of 2005 (PSQIA) and the final rule implementing the law. Some of the answers are gleaned from the federal government's commentary in the preamble to the final rule, published in the November 21, 2008, *Federal Register*. While the preamble may express the government's intent and can be used to interpret the rule, the regulation and statute are the guiding documents for all activities conducted under PSQIA.

The following common abbreviations are used throughout these FAQs on the federal government's new initiative in patient safety:

- ▶ AHRQ—Agency for Healthcare Research and Quality
- ▶ FDA—U.S. Food and Drug Administration
- ▶ HHS—U.S. Department of Health and Human Services
- ▶ HIPAA—Health Insurance Portability and Accountability Act of 1996
- ▶ OCR—Office for Civil Rights
- ▶ PSO—Patient safety organization
- ▶ PSQIA—Patient Safety and Quality Improvement Act of 2005

▷ *Providers are eligible to receive federal protections for patient safety work product collected within a patient safety evaluation system for submission to PSOs.*

### 1. What Organizations Are Eligible to Work with PSOs?

Providers, as defined by HHS's final rule implementing PSQIA, are eligible to receive federal confidentiality and privilege protections for patient safety work product collected for submission to PSOs. HHS broadly defines "provider" as an individual or entity licensed or authorized under state law to provide healthcare services. Examples of entities that are considered providers include hospitals, nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, hospice programs, renal dialysis facilities, ambulatory surgical centers, pharmacies, physician and healthcare practitioner offices (including group practices), long-term care facilities (including state-licensed or -authorized assisted-living residential care facilities that provide healthcare services and other community-based care providers), behavior health residential treatment facilities, clinical laboratories, and health centers.

Examples of individuals who are considered providers include physicians, physician assistants, registered nurses, nurse-practitioners, clinical nurse specialists, certified registered nurse-anesthetists, certified nurse-midwives, psychologists, certified social workers, registered dietitians and nutrition professionals, physical and occupational therapists, pharmacists, and other individual healthcare practitioners.

### 2. What Organizations Are Eligible to Become PSOs?

A PSO can be a public or private entity. Its mission and *primary activity* must be to improve patient safety and the quality of healthcare delivery. To become listed as a PSO by AHRQ, an agency within HHS, the organization must attest that it meets 15 requirements for certification—8 patient safety activities and 7 operational activities. The types of organizations that may become PSOs are wide-ranging. For example, state and metropolitan hospital associations have formed component organizations that serve as PSOs for their member hospitals. Other PSOs have been established by health systems, consulting firms, and professional organizations. Nonprofit organizations focused on patient safety have also established PSOs. For instance, ECRI Institute has formed a component organization, ECRI Institute PSO, that is listed by AHRQ.

Some organizations interested in becoming a PSO may have difficulty demonstrating that their primary activity is to improve patient safety. Hospitals, for example, may engage in other activities that are equally important, such as supporting provider education. These organizations can create a component organization, define the component's primary activity as improving patient safety and healthcare quality, and seek PSO listing for the component.

### 3. What Entities Are Excluded from Becoming a PSO?

The regulations implementing PSQIA specify organizations that are excluded from becoming PSOs. For example, a health insurer, as defined by the regulations, is excluded from operating a PSO.

Additionally, any entity that accredits, licenses, or regulates healthcare providers is barred from becoming a PSO. This exclusion extends to any entity that operates

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a mandatory patient safety reporting system to which healthcare providers report. These entities, however, may establish component organizations in order to operate a PSO. For example, a Quality Improvement Organization may not become a PSO because it serves as an agent of the federal Medicare program, a regulatory program, and some state regulatory bodies. The Quality Improvement Organization could create a component organization that would be eligible to seek listing as a PSO. The regulations create safeguards that allow component PSOs to establish firewalls with their parent organizations so that patient safety work product is not shared with the parent organization.

### 4. What Are the Benefits of Working with PSOs?

PSOs will work with their providers to provide feedback and analysis about the patient safety work product submitted by the provider. The feedback will help providers identify strategies to improve patient safety and healthcare quality.

Another benefit of working with PSOs is tracking patient safety trends from multiple

providers. PSOs will be able to aggregate patient safety data—with all identifying information removed—and spot trends that an individual provider, with its limited pool of data, may not detect. By collecting data in a standardized format, PSOs will be able to aggregate data in order to reduce adverse events and improve healthcare quality.

Importantly, by working with PSOs, providers receive privilege and confidentiality protections for patient safety work product managed within a patient safety evaluation system. Providers can work with their PSOs to improve patient safety without fearing that the information submitted could be used in a malpractice case. Specifically, the final rule states that patient safety work product is privileged from the following:

- ▶ A federal, state, local, or tribal subpoena or order, whether civil, criminal, or administrative, including those related to disciplinary proceedings against a provider
- ▶ Discovery in connection with a civil, criminal, or administrative proceeding, including disciplinary proceedings against a provider (although the rule contains a separate provision granting a court

permission to use confidential information for a criminal proceeding)

- ▶ Disclosure under the federal Freedom of Information Act
- ▶ Admission into evidence during a civil, criminal, or administrative adjudicatory proceeding, including any proceeding against a provider
- ▶ Use in a professional disciplinary proceeding

There are some exceptions to the privilege protections, such as when each of the identified providers authorizes the disclosure or when HHS requires the information in order to investigate compliance with PSQIA. Also, HHS notes in the preamble to the final rule that facts regarding any corrective actions implemented by the provider as a result of feedback from the PSO are not considered patient safety work product and, therefore, could be used in a legal proceeding, depending on the facts and circumstances and applicable rules of evidence.

▷ *PSOs will work with their providers to provide feedback and analysis about the patient safety work product submitted by the provider.*

It is up to the courts and disciplinary bodies to apply the privilege protections; this is not something HHS has the authority to interpret and enforce. Therefore,

providers should document what constitutes patient safety work product and other aspects of complying with PSQIA, as discussed in FAQ 20.

HHS, through OCR, enforces other protections to keep patient safety work product confidential—another incentive for providers to work with PSOs. Except in the case of certain disclosures permitted under PSQIA, patient safety work product is confidential and must not be disclosed by anyone holding the information.

The privilege and confidentiality protections remain in place even if patient safety work product is impermissibly disclosed. In other words, if a PSO impermissibly discloses a hospital's root-cause analysis of a wrong-site surgery to another hospital, the hospital can still claim the privilege and confidentiality protections attached to the root-cause analysis—assuming it was properly collected within the hospital's patient safety evaluation system.

### 5. Will My Organization Violate HIPAA by Providing Protected Health Information to a PSO?

No. PSQIA establishes that PSOs are business associates, as defined by HIPAA, of the providers they serve.

This ensures that in giving patient safety work product with protected health information to the PSO, the hospital does not violate HIPAA.

A PSO will execute a business associate agreement with its participating provider. The business associate agreement will ensure that the provider does not violate HIPAA by giving patient safety work product with protected health information to the PSO.

HHS's OCR, which enforces the privacy provisions of HIPAA, will closely follow the enforcement measures outlined in HIPAA to investigate written complaints of confidentiality breaches related to PSQIA and, if noncompliance is found, attempt to resolve the matter through informal means before turning to enforcement measures, such as levying financial penalties. A confidentiality breach will not be treated as violating both PSQIA and HIPAA unless the breach is a civil violation under one law and a criminal violation under the other.

## 6. Should a Provider Establish Its Own PSO?

Not necessarily. Providers receive the federal confidentiality and privilege protections for their patient safety work product whether they create their own PSO or contract with an independent PSO. Some providers may choose not to bear the financial and operational responsibilities of operating a PSO. Providers that are evaluating whether to establish a PSO must consider the requirement that the mission and primary activity of a PSO be to improve patient safety and the quality of healthcare delivery; since improving patient safety is not the sole activity of hospitals and other providers, providers may want to consider establishing a component PSO if they wish to create their own PSO. Component PSOs must adhere to additional requirements that create a firewall between the component PSO and its parent organization (see FAQ 29).

Another consideration is whether a provider's PSO will benefit from the sharing of aggregated patient safety data. A PSO that has contracts with multiple providers can aggregate the patient safety data and share lessons learned from the aggregated data. A single provider should consider whether this benefit will be available if the provider creates its own PSO to analyze its data.

## 7. How Is an Organization "Certified" to Operate as a PSO?

Organizations seeking to be listed as PSOs by AHRQ complete a straightforward application process certifying that they meet specific criteria. AHRQ purposefully

chose a streamlined process for PSO listing because the initiative is voluntary and unfunded. AHRQ reviews the application and, if the certification criteria are met, grants the organization PSO status for up to three years.

AHRQ provides basic information about every listed PSO on its Web site at <http://www.pso.ahrq.gov/listing/psolist.htm>. Information provided includes address and contact information, information on the PSO's compliance with the minimum contract requirement, and whether the PSO is a component PSO. If the organization is a component PSO, AHRQ will provide required disclosure statements from the component PSO regarding its relationship with its parent organization.

Providers will need to "dig deeper" in selecting a PSO by asking PSOs under consideration to give specific information about their operations, such as the skills and experience of their professional staff, and evidence of relevant accomplishments (see FAQ 13 for more information on selecting a PSO).

## 8. How Many PSOs Will AHRQ Certify?

There is no limit to the number of PSOs that AHRQ will certify. As of April 2009, nearly 60 PSOs were listed. In its regulatory-impact analysis accompanying the proposed rule, HHS estimated that as many as 50 to 100 organizations will be certified as PSOs by January 2012—three years after regulations implementing PSQIA became effective.

## 9. When Must My Organization Have Arrangements in Place with a PSO?

The federal government's framework for provider reporting to PSOs is a voluntary system. Providers are not obligated to establish a relationship with a PSO, although the arrangement offers many benefits, as described in FAQ 4. Nevertheless, as discussed in the preamble to the final rule implementing PSQIA, the regulations do not preclude organizations such as multihospital systems from requiring their provider members to report to a designated PSO.

HHS does not specify the type of arrangement that a provider should establish with a PSO, although a good practice is for providers to enter into a contract with a PSO defining the arrangements for accepting patient safety work product and providing feedback based on the PSO's review of the information, as well as other matters (see FAQ 12).

## 10. Can My Organization Contract with More than One PSO?

There is no limit to the number of PSOs a provider can work with. Some providers may choose to have arrangements with one PSO. Others may have different arrangements with a variety of PSOs, depending on the services offered by each PSO. For example, some PSOs may analyze data for a specific specialty, such as cardiology or orthopedics. It is possible that a provider with a significant presence in both specialties will choose to work with PSOs providing service-specific analysis. A provider can even allow its PSO to disclose patient safety work product to another PSO. If so, all identified providers must authorize the disclosure or the information can be provided in a de-identified manner.

Clinicians working at a hospital may choose to report patient safety work product related to their activities to, for example, PSOs representing their specialties. The law prohibits providers—the hospital, in this situation—from taking disciplinary action against an individual who reports information directly to a PSO.

## 11. How Are PSOs Funded?

There is no federal funding to implement PSQIA. PSOs are likely to fund their activities by charging a provider for reviewing, analyzing, and providing feedback regarding the provider's patient safety work product.

## 12. Is There a Federal Form That My Organization Must Complete to Sign Up with a PSO?

No. HHS gives providers discretion in how they execute their relationships with PSOs. Although contracts are not required, HHS expects providers to have written contracts in place with their PSOs but leaves the terms of these relationships up to the PSO and provider. Throughout the preamble to the final rule, HHS notes that some matters are open to negotiation with PSOs. For example, providers can impose more stringent confidentiality policies and procedures on the PSO during their contract negotiations, although HHS will not enforce these private agreements. Also, a provider can require that in the event its PSO ceases operations, the PSO dispose of the provider's patient safety work product sooner than the statutorily mandated 90 days after the PSO loses its listing.

## 13. How Does My Organization Select a PSO?

AHRQ has purposefully established a framework that puts the onus on providers to carefully weigh the

qualifications of PSOs under consideration. AHRQ certifies that listed PSOs meet the required criteria for becoming a PSO, but many of the details—such as the qualifications of staff and processes for analyzing providers' patient safety work product—are left to the provider to investigate. A provider might start its search by reviewing the list of PSOs on AHRQ's Web site at <http://www.pso.ahrq.gov/listing/psolist.htm>.

AHRQ will indicate whether the PSO is a component of a parent organization. If so, consider the parent organization. Would the parent organization present any potential conflicts in the event that the provider would choose to work with the component PSO?

Examine the PSO's skill sets. Do the PSO's skills complement your organization's needs? For example, a PSO that is dedicated to reviewing surgical safety events may not meet the needs of a provider looking for feedback on a full range of patient safety data and information.

Ask for a list of the PSO's references, and contact the PSO's clients to assess their satisfaction with the PSO's activities and performance. Ask whether the PSO is regarded as credible and trustworthy.

Other questions to consider when selecting a PSO include the following:

- How long has the PSO been certified by AHRQ?
- Has HHS ever issued any deficiency notices regarding the PSO's activities? Has the PSO ever lost its listing or been denied listing by AHRQ?
- Does the PSO understand the intent and purpose of PSQIA?
- What is the PSO's mission? Does the mission statement conform to the requirement that the PSO's mission and primary activity be to improve patient safety and the quality of healthcare delivery?
- Does the PSO understand the provider environment and the implications that its various patient safety recommendations have for providers?
- How is providers' patient safety work product reported to the PSO?
- Is the process for data submission convenient and straightforward for providers?
- Does the PSO offer opportunities for providers to review and discuss data submitted to the PSO and to ask questions about feedback given to providers?

- ▶ What is the PSO's experience in analyzing patient safety events?
- ▶ What approaches does the PSO use for its analysis?
- ▶ What policies and procedures are in place to protect the confidentiality of identifiable information in the patient safety work product?
- ▶ What measures are in place to ensure the security of patient safety work product? If a component PSO stores patient safety work product on information systems that store other data, how does the PSO ensure that patient safety work product is distinguishable from other data?
- ▶ Does the PSO intend to aggregate de-identified data to share with other PSOs? Will providers have access to it?
- ▶ Has the PSO been sanctioned for violations of the confidentiality provisions of PSQIA or the privacy provisions of HIPAA?

#### 14. How Does My Organization Find out the Names of Other Organizations Contracting with the PSO That My Organization Intends to Use?

Ask the PSO for this information. A PSO is generally not required to reveal the names of its clients. Still, most PSOs will want to provide a reference list of clients for prospective clients to contact to inquire about their satisfaction with the PSO's work.

Also, a PSO is required to disclose certain relationships with its contracting providers. Specifically, if the PSO has any relationships with the provider beyond activities under PSQIA—contractual, financial, or reporting—it must disclose those relationships and briefly describe measures to ensure that the PSO can fairly and accurately perform its patient safety activities for the provider. PSOs' disclosure statements are publicly available.

#### 15. What Criteria Must a PSO Meet to Become Listed by AHRQ?

A PSO must certify that it adheres to 15 requirements—8 involving patient safety activities and 7 involving its operations. The eight patient safety activities are listed in the section "Commonly Used Definitions," under the definition for patient safety activities. The seven operational activities are as follows:

1. Ensure that the mission and primary activity of the PSO is to conduct activities to improve patient safety and the quality of care.

2. Use appropriately qualified staff, including licensed or certified medical professionals.
3. Within the 24-month period after initial listing as a PSO, and within each sequential 24-month period thereafter, have at least two contracts with different providers for a reasonable period of time to receive and review patient safety work product.
4. Demonstrate that the PSO is not a health insurer or a component of a health insurer.
5. Make required disclosures to HHS, such as the number of contracts with providers and any relationships with contracting providers that extend beyond the activities of PSQIA.
6. Collect patient safety work product in a standardized manner to permit valid comparisons of similar cases among similar providers.
7. Use patient safety work product to provide direct feedback and assistance to providers to minimize patient risk.

A component PSO must also certify that it meets three other requirements demonstrating that there is a firewall between the component PSO and the parent organization. These three requirements are described in FAQ 29.

#### 16. What Is the Government's Rationale for Requiring a PSO to Have in Place Two Contracts with Providers?

The requirement to have two contracts with different providers ensures that the PSO has a baseline of ongoing activities in place. Since there is no federal funding for PSO activities, contracts will be a PSO's primary source of funding. Providers will want to identify the minimum amount of ongoing business and data they expect a PSO to have in place to ensure its ability to fund and sustain its operations. Failure to comply with the two-contract requirement can result in loss of the organization's listing as a PSO.

HHS's contract requirement for PSOs considers the number of contracts in place, not the number of providers associated with each contract. For example, a PSO that has one contract with a 50-hospital system and another contract with a single practitioner satisfies the two-contract requirement. A single contract with multiple providers is counted as one contract. However, if the PSO has separate contracts with different providers within the same system, each contract is counted separately.

## 17. Does AHRQ or Another Government Agency Oversee the Quality of PSO Services?

No. Although AHRQ assesses PSO compliance with PSQIA, the agency does not oversee the quality of services that PSOs provide. Advocating a market-place approach to PSOs, AHRQ says providers are the ultimate arbiters of the quality of PSOs' services. Providers, therefore, must judge the value of the service they receive from a PSO and, if they are satisfied, will continue to work with the PSO. Providers that are dissatisfied with a particular PSO will likely "shop" for another PSO that offers better services; a PSO that fails to renew its business with providers is unlikely to survive.

AHRQ provides basic information about each listed PSO—such as its location, whether it is a component PSO, and whether it complies with the two-contract requirement—but does not release PSO-specific performance information.

## 18. How Can My Organization Be Assured That the PSO It Works with Is Complying with PSQIA?

To assess compliance, AHRQ performs random site visits for about 5% to 10% of all PSOs each year. During these visits, the agency will ask, for example, that the PSO demonstrate that it has performed all eight patient safety activities as required by the final regulation.

Rather than adopt a punitive approach, HHS will work with a PSO to correct its deficiencies. Such deficiencies can include not fulfilling the requirements that it certified it met when seeking listing as a PSO, failing to adhere to the requirement to have two contracts in place, failing to perform patient safety activities "fairly and accurately" because of its relationship with other contracting providers, and failing to fulfill the requirements of PSQIA. However, if a PSO fails to work with HHS to correct its deficiencies, the department will require the PSO to correct its deficiencies. If HHS's mandatory approach fails, it will begin a process to revoke the PSO's listing. Also, HHS can fine a PSO for "knowing or reckless" breaches of confidential patient safety work product. While HHS will not publicize information about a PSO's deficiencies, a provider considering establishing a contract with a PSO can ask the PSO about any previous deficiencies identified by HHS.

HHS will follow an expedited process to revoke the PSO's certification if any of the three following circumstances exists:

1. The PSO is or is about to become an entity excluded from listing as a PSO; for example, the PSO is about to become a component of a health insurer.

2. The parent organization of the PSO is an excluded entity, such as an accrediting organization, and cannot be listed as a PSO but uses its authority over providers to require them to use the services of its component PSO.
3. Failure to act promptly would lead to serious adverse consequences; for example, a PSO is reckless in its protection of the identity of individuals named in patient safety work product or engages in fraudulent or illegal conduct.

Each time a PSO seeks a new listing or relisting, AHRQ reviews any previous findings regarding the PSO or its senior managers and officials. AHRQ will consider any current activities or history reflecting noncompliance. The federal government may seek additional information from the PSO to increase its confidence that despite the entity's history or the history of its senior managers and officials, the entity can be relied upon to comply with its statutory and regulatory obligations.

## 19. How Does My Organization Establish a Patient Safety Evaluation System?

The regulation purposely avoids outlining requirements for a patient safety evaluation system, giving providers and PSOs flexibility in establishing systems best suited to their specific needs and settings. Nevertheless, providers must consider the patient safety evaluation system in the context of their state peer-review laws and legal privilege protections. The patient safety evaluation system should not jeopardize any existing state protections.

Providers may rely on programs already in place when developing their patient safety evaluation system. For example, some providers may find that their existing event reporting programs can serve as the basis for a patient safety reporting system. How a patient safety evaluation system operates depends on its functions and the provider's tolerance regarding access to sensitive information within the system. A single hospital might establish a patient safety evaluation system within a particular office, such as the risk management department. A multihospital system could designate a single patient safety evaluation system for all its hospitals and the parent organization to use.

A provider might consider designating secure physical and electronic space for the patient safety evaluation system. And although there is no requirement to document policies and procedures related to the patient

safety evaluation system, providers and PSOs should establish best practices for documenting 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 ensure better aggregation of data from various providers
- ▶ Procedures for disseminating information outside the patient safety evaluation system

Documentation of the patient safety evaluation system will support claims that the data and information that is part of the system is privileged and confidential. Also, if the provider documents what data and information is part of the patient safety evaluation system, employees of the provider will be less likely to make unintended or impermissible disclosures.

## 20. 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. The information is collected by the provider within a patient safety evaluation system for reporting to a PSO. It is subject to federal statutory legal privilege and confidentiality protections.

Information can be considered patient safety work product if it is collected for the purpose of reporting to a PSO; the period of collection may extend as far back as to passage of PSQIA on July 29, 2005. Excluded from patient safety work product are original patient and provider records, such as a patient's original medical record, and billing and discharge information. While a medical record is not considered patient safety work product, analysis of information in the medical record is protected. Thus, if the medical record indicates that a patient received an incorrect dose of medication,

this information is not protected by legal privilege. The organization's root-cause analysis of the event, however, is considered patient safety work product if it is developed for reporting to the patient safety evaluation system. Patient safety work product does not include information that is collected, maintained, or developed separately from, or that exists separately from, a patient safety evaluation system.

## 21. What Steps Should My Organization Take to Optimize Protection of Patient Safety Work Product?

By carefully documenting what patient safety work product is part of their patient safety evaluation systems, providers can ensure that the protections extend to all appropriate information. The protections begin at the time of collection by the provider. If, upon analysis, the provider determines that data collected within the patient safety evaluation system does not constitute patient safety work product (e.g., because it is needed to fulfill external reporting obligations), the provider can remove the information from the system if it has not yet been reported to the PSO. Once removed from the patient safety evaluation system, the information is no longer patient safety work product, although information that is not patient safety work product can still be submitted to a PSO.

Although providers and PSOs are not specifically required to label the information as patient safety work product, providers should consider labeling as a recommended practice to prevent inappropriate disclosures. While labeling patient safety work product as such is a good practice, there is no guarantee that a court will accept the label if it is subject to a legal challenge. If the provider chooses to label its patient safety work product, it could also require the PSO to follow a similar approach with patient safety work product that the provider gives to the PSO for analysis. Of course, if the information is removed from the patient safety evaluation system, the label designating it as patient safety work product should also be removed.

## 22. Must All My Organization's Confidential Deliberations Be Conducted within the Patient Safety Evaluation System?

Not necessarily. Providers need to define what works best for them. For example, even though PSQIA permits an organization's credentialing and disciplinary proceedings to occur within the patient safety evaluation system, the hospital must consider the ramifications of this approach. Should a credentialing or disciplinary decision be challenged, a hospital would not be

able to use its deliberations in court to defend its actions—unless all identified providers agree to the disclosure—if the information is protected within the patient safety evaluation system. Significantly, HHS notes that providers within a single legal entity—such as physicians participating in morbidity and mortality rounds at a hospital—are free to discuss and share patient safety work product in identifiable and non-anonymous form for educational, academic, or other professional purposes. These discussions do not risk the divulgence of confidential information under PSQIA because they are not intended for an external entity. Additionally, if affiliated providers choose to share identifiable and nonanonymous patient safety work product among the various affiliates and the parent organization, such activities do not risk violation of the confidentiality provisions of PSQIA.

In general, as noted in the preamble to the final rule, the regulation avoids specifying internal uses of patient safety work product, stating that “sufficient incentives exist” for providers to “prudently manage the internal sharing of sensitive patient safety work product.”

### **23. Should My Organization’s Peer-Review Activities Be Conducted within the Patient Safety Evaluation System?**

As discussed in FAQ 19, a provider must establish its patient safety evaluation system in a manner that best suits the organization. A hospital could choose to organize its peer-review activities within a patient safety evaluation system and submit its findings to the PSO as patient safety work product. The PSO can provide feedback on the findings, which the hospital may, in turn, share with the peer-review committee or other committees as it sees fit. However, because PSO feedback is patient safety work product, the hospital cannot use the PSO feedback to defend a disciplinary action it takes against a provider should the hospital’s actions be challenged in court. Impermissible release of patient safety work product is treated as a breach of confidentiality and can be sanctioned by OCR.

### **24. My Organization Plans to Submit Adverse Events and Our Analysis of Them to Our Patient Safety Evaluation System for Further Review by the PSO. Can the Organization Still Disclose the Event to the Patient and the Patient’s Family?**

PSQIA does not prohibit disclosure of an adverse event to the patient and the patient’s family. Indeed,

with the increasing emphasis on patient-centered care and a culture of safety in healthcare, effective communication among caregivers and patients, including communication of unanticipated outcomes and medical errors, should become part of a healthcare organization’s values and culture. Typically, organizations’ disclosure policies should ensure that within 24 hours of recognition that an unanticipated outcome has occurred, appropriate staff meet with the patient and family and inform them that an unanticipated outcome has occurred, that actions are being taken to minimize the consequences of the event, and that a comprehensive investigation will be conducted to determine more specific information. The disclosure discussion should provide objective facts about the event in a caring and compassionate manner. For example, it is appropriate to let a patient know that a medication error has occurred. However, any staff comments about the possible cause of the error should be reported to the patient safety evaluation system and PSO. Similarly, the organization can provide the patient and family with facts about the findings of an investigation and the measures that have been adopted to prevent recurrence of the event; any deliberations and analysis that were part of the investigation should be reported to the patient safety evaluation system for submission to the PSO.

### **25. My Organization Already Reports Adverse Events and Near Misses to a State-Mandated Reporting Program. Are There Any Prohibitions on Reporting the Same Data to a PSO?**

No, there are no restrictions on reporting the same data to a PSO, although the mandatory reporting requirements must still be satisfied. Indeed, AHRQ encourages organizations to report the data submitted to the state to the PSO as well so that the information is included in any aggregate analysis. If such information is not submitted to the PSO, significant data about adverse events would be missing from the aggregate analysis. It is best to consider the data that is reported to the PSO as a virtual “copy” of the original data reported to a state-mandated reporting program. Any original patient safety data that providers report to external mandatory reporting programs is not patient safety work product and, therefore, does not have the privilege and confidentiality protections of patient safety work product that is part of the patient safety evaluation system. The “copy” of the data that is submitted to the PSO does retain the protections because it is considered patient

safety work product. Consequently, PSOs cannot release the data in response to discovery requests. In other words, PSQIA does not shield providers from their mandated reporting obligations and does not provide that information with legal protections. However, copies of the mandatory reports in the possession of a PSO are patient safety work product. Such information could include data reported to a state-mandated reporting program, adverse drug event information reported to the U.S. Food and Drug Administration, certification and licensing records maintained for compliance with health agency requirements, physician disciplinary actions reported to the National Practitioner Data Bank, and reporting required by the Medicare program (e.g., restraint-related deaths).

Nevertheless, to ensure aggregation of all its patient safety data, a provider may want to record all patient safety events within its patient safety evaluation system as long as it has a mechanism to designate data that does and does not constitute patient safety work product.

Any additional analysis of the data conducted by the provider, such as a root-cause analysis of the event, can be submitted to the patient safety evaluation system as patient safety work product and thus obtain legal protection, regardless of whether the original data met the criteria for patient safety work product.

## **26. Employees and Clinicians within My Organization Are Concerned That the PSO Findings and Feedback Will Be Used to Reprimand Individuals Who Make Mistakes. Is That Permissible?**

Not at all. The intent of PSQIA is to foster an environment that supports efforts to improve patient safety. The identity of individual providers is protected and cannot be disclosed outside the hospital's patient safety evaluation system or the patient safety evaluation system of the PSO used by the hospital. The efforts of PSOs are intended to be nonpunitive.

## **27. My Organization Would Like to Use Some Information Classified as Patient Safety Work Product as Evidence in a Malpractice Case. Is This a Permissible Disclosure under PSQIA?**

Yes, but with caveats. Each provider identified in the patient safety work product intended to be used as evidence must authorize and permit the disclosure.

## **28. My Organization Operates a Captive Professional Liability Insurer. Can the Captive Insurer Become a PSO?**

Yes. In its preamble to the final rule, HHS discusses this particular issue, noting that excluding health insurance issuers from becoming PSOs may have created some ambiguity with regard to professional liability insurance companies, including captive insurers owned by a provider. A captive insurer could create a component organization to serve as a PSO; the primary activity of the component PSO must be to improve patient safety.

In addition to professional liability insurers and reinsurers, risk management service companies may become component PSOs.

## **29. What Is a Component PSO?**

Accrediting organizations and state regulatory agencies—such as those that operate mandatory event reporting programs—are prohibited from becoming PSOs; however, these organizations may establish component PSOs that are owned or managed by the organization. A component organization is a unit or division of a legal entity. The entity can be a corporation, a partnership, or a federal, state, local, or tribal agency or organization.

A component PSO must disclose its parent organization so that providers have information about the parent organization of the component PSO under consideration. The rule requires the component PSO to describe on its Web site the activities of its parent organization that exclude the parent organization from becoming a PSO. This information is also available from AHRQ. Providers can use the information about the parent organization to determine whether there are any barriers to contracting with the component PSO.

Other protections must be put in place to ensure that the component PSO operates separately from the parent organization. In addition to meeting the 15 general PSO certification requirements, a component PSO must certify that it meets 3 other requirements to demonstrate that there is a firewall between the component PSO and the parent organization. The three requirements are as follows:

1. Separate patient safety work product from the rest of the parent organization. Although HHS modified its proposal for component PSOs to maintain separate computer systems from their parent organization, the rule prohibits the parent organization and individuals in the parent organization from

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having unauthorized access to patient safety work product. The component PSO must still establish appropriate security measures to maintain the confidentiality of patient safety work product.

2. Require that members of the component PSO workforce and contractors not make unauthorized disclosures of patient safety work product to the parent organization.
3. Ensure that the mission of the component PSO does not create a conflict of interest with the parent organization.

The component PSO and parent organization must be cautious about sharing personnel and protecting against inappropriate disclosures. For example, the final rule prohibits the parent organization from having unauthorized access to patient safety work product. In its preamble to the final rule, HHS notes that staff of the parent organization should not analyze patient safety work product for the component PSO if this “confounds” the statutory intent for a firewall between the component PSO and the parent organization. There are carefully delineated situations in which staff from the parent organization can assist the component PSO in patient safety activities, such as when the staff’s responsibilities do not involve activities that are the basis for the parent organization’s exclusion as a PSO. If the parent organization’s sole activity is the basis for the exclusion, it should never use its staff to assist the component PSO with the PSO’s patient safety activities. Instead, the component PSO could contract with external individuals and organizations for expertise.

The rule does allow a component PSO to enter into some types of limited collaboration with an excluded entity. For example, the PSO could share its findings with the excluded entity—provided that the data can be permissibly disclosed and all identifying information is removed. Additionally, providers may voluntarily disclose patient safety work product to their accrediting organizations—provided that all identified individuals agree to the disclosure or that identifying information is removed. This provision addresses the need for accredited providers to report sentinel events—such as a fatal medication error or retention of a foreign object after surgery—to the Joint Commission. HHS notes that providers can obtain their staff’s authorization for the disclosure by conditioning employment or privileges on an agreement to the disclosure of patient safety work product to accrediting bodies.

### **30. How Can My Organization Be Assured That the Information Submitted to a Component PSO of an Accrediting Agency or State Regulator Will Not Be Provided to the Parent Organization?**

Except under circumstances outlined in the rule implementing PSQIA—for example, a provider agrees to voluntary disclosure of patient safety work product to an accrediting agency—a PSO is prohibited from disclosing patient safety work product with identifiable information to an entity or individual outside the PSO, such as an accrediting agency or state regulator. Since the primary activity of a PSO is to improve patient safety, a component PSO may not create conflicts of interest by sharing identifiable patient safety work product with a parent organization that could use the information for accrediting or regulatory purposes. Failure to adhere to these prohibitions can result in sanctions and even loss of listing as a PSO.

Additionally, a component PSO of an accrediting organization cannot require its providers to report patient safety work product to the parent organization; indeed, HHS will take action to revoke the listing of a PSO that attempts to do so. Likewise, a parent organization such as an accrediting agency cannot use its authority over providers to require them to use the services of the component PSO. Such action would prompt HHS to conduct an expedited process to revoke the PSO’s listing.

### **31. What Protections Are in Place to Ensure That Information Reported to a PSO Remains Privileged and Confidential?**

PSOs must ensure that patient safety work product is provided only to those entitled to review it, such as employees and contractors of the PSO who will analyze the data. The federal government will investigate confidentiality breaches and has the authority to impose a civil monetary penalty of up to \$10,000 for each “knowing or reckless” confidentiality violation. A PSO could be levied penalties for multiple violations, each up to \$10,000. Violations may also be sanctioned as criminal acts.

PSOs must inform a provider if any of its submitted patient safety work product is inappropriately disclosed or security is breached.

### 32. Will the Feedback My Organization Receives from a PSO Establish a Standard of Care for My Organization?

The establishment of a legal standard of care falls under the jurisdiction of courts and professional organizations' issuing standards and guidelines. The preamble to the final regulation implementing PSQIA states that it is "highly unlikely" that the PSO's feedback will establish a standard of care given that the feedback is provided within a legal environment with confidentiality and privilege protections.

### 33. Is a PSO Obligated to Analyze and Provide Feedback on All the Patient Safety Work Product It Receives from a Provider?

No. A PSO is not required to analyze *all* information received from providers; however, one of the patient safety activities a PSO is generally required to engage in is to provide feedback.

### 34. The Law Allows for Certain Disclosures of Confidential Information. What Are These Exceptions?

Although patient safety work product is generally given federal privilege and confidentiality protections, PSQIA provides exceptions allowing the disclosure of this information. Nevertheless, the recipient of the information must adhere to the same confidentiality provisions as the original recipient of the patient safety work product. Situations in which disclosure is allowed are as follows:

- ▶ Disclosure of patient safety work product for use in criminal proceedings after a court screens the material and determines that the material contains evidence of a criminal act, is relevant to the case, and is "not reasonably available from any other source."
- ▶ Disclosure of patient safety work product to provide "equitable relief" to an employee who reported information in "good faith"—much like a whistleblower—directly to a PSO or to a provider for intended disclosure to a PSO but was subject to an adverse employment action because of the report. A protective order is required to protect the confidentiality of the patient safety work product during a court or administrative proceeding.
- ▶ Disclosure of patient safety work product if authorized by each provider identified in the work product. The disclosing entity must retain a record of the authorization for six years.
- ▶ Disclosure between a provider and a PSO, disclosure to a contractor of a PSO or provider when either entity has engaged the contractor to undertake patient safety activities on its behalf, disclosure among affiliated providers, or disclosure (1) by a PSO to another PSO or to another provider that has reported to the PSO or (2) by a provider to another provider—as long as direct identifiers of any providers and affiliated organizations, practice partners, employees, and others are removed.
- ▶ Disclosure of patient safety work product if information about particular providers or particular reporters as well as patients is nonidentifiable.
- ▶ Disclosure to individuals conducting research that is authorized, funded, certified, or otherwise sanctioned by the HHS secretary.
- ▶ Disclosure by a provider to FDA concerning an FDA-regulated product or activity or disclosure to FDA by another entity or contractor (on behalf of FDA or the entity) involving required reporting about the quality, safety, or effectiveness of an FDA-regulated product or activity.
- ▶ Voluntary disclosure of a provider's patient safety work product to the organization accrediting the provider. Any provider identified in the patient safety work product must agree to the disclosure; otherwise, identifiers must be removed. The accrediting body may not further disclose the patient safety work product, and it cannot require the provider to reveal its communications with any PSO. The contractor may not further disclose the patient safety work product.
- ▶ Disclosure to the provider's or PSO's lawyer, accountant, or other professional in the course of business operations.
- ▶ Disclosure of an event that constitutes a crime or that the disclosing person "reasonably believes" constitutes a crime to law enforcement authorities—provided the disclosing person believes that the information is necessary for criminal law enforcement. Law enforcement personnel who receive the patient safety work product are barred from further disclosing the patient safety work product except to other law enforcement authorities who may need it for law enforcement activities related to the event prompting the disclosure.
- ▶ Disclosure to the secretary of HHS so that the secretary can conduct compliance reviews and investigations

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of a PSO's adherence to PSQIA and its confidentiality measures and to HIPAA privacy provisions.

As long as no information is disclosed for the purposes of assessing the quality of care or actions or failures of an identifiable provider, the rule also creates a narrow "safe harbor" for inadvertent mistakes in disclosing patient safety work product so that legal protections are not lost. This safe harbor applies only to providers and their responsible parties, such as employees—not to PSOs.

### 35. How Is Confidential Data De-Identified for Sharing?

Information that would have permitted identification of a provider, a reporter, or the subject (e.g., a patient) of individually identifiable health information is removed from nonidentifiable patient safety work product. De-identification of patient safety work product is conducted by PSOs for aggregate analysis of the data. De-identification of data can be accomplished in one of two ways: (1) use of statistical and scientific methods to ensure that the information is not individually identifiable or (2) removal of specified categories of direct identifiers. The removal of individually identifiable information is consistent with the HIPAA privacy rule.

### 36. What Happens if the PSO My Organization Selected Goes out of Business or Ceases Operations?

PSOs are listed for a period of three years. HHS requires a PSO to seek relisting no later than 75 days before the expiration of its three-year listing. This ensures that providers are aware in advance of a PSO's intent to "go out of business" and gives providers time to confirm the PSO's plans to cease operations and to identify an alternative PSO to analyze their patient safety work product.

Additionally, HHS will send a PSO a notice of "imminent expiration" at least 60 days before its certificate expires. AHRQ will post the notice on its Web site so that providers are made aware of the situation and can consider whether to identify alternative PSOs to review their patient safety work product. Providers can subscribe to AHRQ's Listserv for PSO activities to receive electronic notice when new information is posted on AHRQ's PSO Web site. The sign-up information is available online at <http://www.pso.ahrq.gov/contact/alertsubscr.htm>. Providers will also be able to sign up on AHRQ's Web site to receive individual e-mails if a provider's PSO has its listing revoked.

If a PSO decides to voluntarily relinquish its certification, it must follow procedures to notify providers that submit patient safety work product to it and explain how its patient safety work product will be disposed of.

If HHS decides to revoke a PSO's certificate—after giving the PSO an opportunity to make its case—the PSO must "take all reasonable action" to notify each provider whose patient safety work product it collected or analyzed of its status and inform the provider how its patient safety work product and any data submitted during the 30 days after loss of the PSO's listing will be disposed of. In their contracts with PSOs, providers can impose more stringent provisions for the disposition of patient safety work product.

### 37. What Happens to the Patient Safety Work Product My Organization Has Provided to the PSO if the PSO Goes out of Business or Ceases Operations?

If a PSO loses its listing, it must dispose of all patient safety work product with identifiable and nonidentifiable information within 90 days. The provisions for loss of PSO listing give providers some leeway if they continue to report patient safety work product to a PSO after it has lost its listing. The regulation says that data submitted as patient safety work product continues to receive confidentiality and privilege protections during the 30 days after loss of a PSO's listing. The PSO must dispose of the data.

The PSO has three options:

1. Transfer the patient safety work product or data, with the provider's approval, to a PSO that will receive the information.
2. Return the patient safety work product and data to the source from which it was submitted.
3. If returning the patient safety work product or data to its source is not feasible, destroy the information.

If a PSO voluntarily decides to cease operations and relinquish its PSO listing, providers will receive notice from the PSO of its intent and instructions to stop reporting patient safety work product to the PSO as soon as possible. In consultation with the providers that submit patient safety work product to the PSO, the PSO will establish a plan for disposing of the data, using any of the three options for disposing of patient safety work product and data.

PSOs that allow their certifications to lapse automatically lose their listing as a PSO and must take the

necessary steps to notify their providers and dispose of patient safety work product. In their contracts with PSOs, providers may impose requirements for notification and disposition of patient safety work product that are stricter than PSQIA's requirements.

### **38. Where Can My Organization Obtain More Information about PSQIA?**

The best resources for understanding PSQIA are as follows:

- ▶ The text of PSQIA, available online at <http://www.pso.ahrq.gov/statute/p1109-41.htm>
- ▶ The November 21, 2008, final rule implementing PSQIA, which was published in the *Federal Register* and is available online at <http://edocket.access.gpo.gov/2008/pdf/E8-27475.pdf>
- ▶ The AHRQ Web site on PSOs, available at <http://www.pso.ahrq.gov/index.html>
- ▶ The ECRI Institute PSO Web site, which is available at <http://www.ecri.org/pso> or <http://pso.ecri.org> and provides advisories, answers to FAQs, and recordings of audio conferences about PSOs
- ▶ The Web site of the PSO Privacy Protection Center, available at <http://www.psoppc.org>



## **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 health-care 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 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

▷ *Establishing a patient safety evaluation system that manages the flow of patient safety work product is essential for organizations to fully enjoy the legal protections provided by PSQIA.*

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question of whether to include elements such as the organization's credentialing, 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 such information may be reported to a PSO for data analysis, the information does not become patient safety work product by virtue of being reporting 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.

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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- ▶ 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.

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- 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.