

Patient Safety Organizations: Champions for Quality



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Hospitals, Providers, Clinicians, and Compliance Officers Have a New Means of Improving Quality and Compliance

The Patient Safety and Quality Improvement Act of 2005 (PSQIA) (PubLNo 109-41) included development of patient safety organizations (PSOs) as a means of allowing health care organizations, physicians, clinicians, quality managers, and compliance managers to share quality and incident data to improve the quality of care provided to patients.¹ The goals of PSOs include reducing the frequency of incidents that result in adverse patient outcomes and improving patient safety and the quality of care.² On November 21, 2008, the Patient Safety and Quality Improvement Final Rule authorizing the creation of PSOs and invoking unique protections for the information shared with PSOs was published in the *Federal Register*.³

In this article, we interview physician, compliance officer, and quality leader Rory Jaffe, MD, MBA, to learn more about PSOs and how they work to improve quality and compliance. Dr. Jaffe is the executive director of the California Hospital Patient Safety Organization (CHPSO), the second registered PSO established in the United States. He has a distinguished career as a physician, quality officer, and compliance officer and is the immediate past president of the Health Care Compliance Association (HCCA). He also established the first-ever national Compliance and Quality Conference that is now in its third year.

PROMOTING A SAFETY CULTURE; PROTECTING INCIDENT AND PATIENT SAFETY DATA: KEYS TO IMPROVING QUALITY

In the PSQIA, federal legislation recognized the need for health care providers, clinicians, hospitals, and health care organizations of all types to share data on

incidents and quality improvement without fear of disclosure. The PSQIA includes formidable protections against discovery, subpoena, and disclosure of information shared with PSOs for the purposes of improving patient safety.⁴

Are PSOs important to compliance officers? According to Dr. Jaffe, "Compliance officers have to be aware of PSOs and understand the privilege protections provided information shared with the PSO. The strong federal protections established in PSQIA apply to patient safety work product (PSWP). Specifically, PSWP is defined as "...any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements which are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system."⁵

PSQIA goes on to specify, however, that medical records, billing and discharge information, or other original patient records are not considered PSWP.⁶ Also, from a systems standpoint, ultimately the culture of safety and the culture of compliance are very similar. Measuring these cultures requires asking the workforce many of the same questions, such as: Are you aware of problems? Are you comfortable discussing them without fear of reprisal? Is appropriate action taken when problems are identified?⁷ Compliance officers should collaborate with those working on patient safety to develop an organization with these four cultures of safety and compliance:

- Just culture: Errors and unsafe/improper acts will not be punished if the error was unintentional; however, those who act recklessly or take deliberate and unjustifiable risks will still be subject to disciplinary action.

- Reporting culture: People have confidence to report safety/compliance concerns without fear of blame. Confidentiality will be maintained, and the information they submit will be acted upon.
- Informed culture: The organization collects and analyzes relevant data and actively disseminates safety/compliance information.
- Learning culture: The organization is able to learn from its mistakes and make changes.

PATIENT SAFETY WORK PRODUCT PROTECTIONS

Protection of PSWP is a foundation of the effectiveness of PSOs. Organizations should carefully review the Act, the final rule, and consult with their PSO of choice (as well as competent legal counsel, if necessary) to consider protections and establish proper reporting systems. In addition to reading provisions of the Act, readers are directed to the final rule, specifically the section "When is information protected,"⁸ for a detailed discussion of what information is, and what information may not be, protected.

Once PSWP enters the PSO system, it is protected from disclosure by layers of regulations, including Health Insurance Portability and Accountability Act (HIPAA), PSQIA, and civil monetary penalty protections. These protections are noted to extend broadly to:

...patient, provider, and reporter identifying information...that is collected, created, or used for patient safety activities and imposes civil monetary penalties (CMPs) for impermissible disclosures of this information...⁹

CHPSO addresses the issues of discoverability of information and liability for that information at www.chpso.org:

Until passage of the Patient Safety and Quality Improvement Act of

2005 (PSQIA), we did not have the appropriate tools to address systems issues and disseminate information learned from safety events. Quality improvement activities tended to be regulated by state laws, which generally addressed peer review of the qualifications and skills of individual practitioners. Systems review, and the types of activities that benefit systems learning, were not protected by the state laws. The lack of protection inhibited reporting and learning from these failures.

Systems failures, unlike individual failures, are often best addressed by sharing the experience with others (e.g., other hospitals). The PSQIA recognizes this, and created PSOs as a method of sharing and analyzing information within a sphere of confidentiality for both patient and provider, and privilege from discovery.¹⁰

“Compliance officers and legal counsel need to study the confidentiality and privilege rules that are part of PSQIA,” says Dr. Jaffe. “It is important to ensure the right kind of data is protected as patient safety work product. It is important to know that releasing information containing provider identification under PSWP protections requires consent of all health care providers who are affected.

“The strong protection for PSWP means that for the first time we can talk about and share information across our health system without fear of discovery. We can talk about problems. We can write emails about concerns. We can hold meetings and openly discuss issues and needs, and all of these actions are protected as long as the PSWP privilege is properly invoked,” he adds.

PSOs also allow health care providers and organizations to aggregate data from a large number of sources to better analyze issues that may affect patient safety. Prior to the PSQIA, safety concerns seldom were

analyzed across a variety of health care providers and institutions, due in large part to fears of discovery. The PSO will be able to produce detailed analysis of patient injury events and incidents, depending on the quality and quantity of data collected by health care organizations that become its members.¹¹

The significance of this ability to share data is immediately clear: Health care facilities and providers will now be able, through PSOs, to develop and obtain national benchmarks for safety and quality improvement. Aggregated data also will allow an understanding of the systems issues behind the event — a perspective that frequently requires comparison of experiences among many providers.

They can use these comparisons to evaluate their own experiences and improve processes. Instead of working to improve safety in isolation, health care providers can share information that can provide means for a unified approach to improvements. Forward-thinking organizations can use data from the risk experiences of other organizations to design new approaches and identify concerns that have not yet resulted in injuries in their own facilities.

Establishment of these unique federal protections gives health care organizations and providers a unique new ability to share data, develop information on patient safety and injury events, and develop solutions to common problems. The potential impact on improving quality of care and reducing patient injuries is huge. The PSO is a huge leap forward in the ability of health care organizations to improve quality. To serve effectively, PSOs now need patient safety data from health care providers.

SETTING UP INTERNAL SYSTEMS FOR PSWP

A large part of preparing to effectively utilize membership in a PSO involves setting up internal policy and procedure that will organize a patient safety evaluation system (PSES). The PSES is a process of including information in a protected investiga-

tion process and establishing patient safety work product protections.

“The workflow process may include instruments that collect incident or event data, communications between investigating staff, memos, medical staff reports, even email messages between involved staff members,” says Dr. Jaffe. “It is important to fully understand the internal PSES described in detail in PSQIA and the final rule.”

He also notes that once information enters the PSES, it may be extracted from the system only before submission to the PSO. “Let’s say a medical staff recognizes that a series of patient injury events reveals a need to report a provider. Information can be extracted from the PSES and used to make a report to the Board of Medical Examiners, for example. And, of course, mandatory state reports must still be made, even though data may also be in the PSES. If the information in the PSES has already been reported to a PSO, the provider may have to independently recreate the report. Therefore, timing of PSO submission and coordination with reporting requirements is important.”

CHOOSING A PSO

CHPSO was the second PSO in the country registered with the Department of Health and Human Services (HHS) and the Agency for Healthcare Quality and Research (AHRQ). It is one of only 59 PSOs listed by AHRQ as of the time this article was written. Only PSOs listed with HHS and AHRQ and displayed on the AHRQ Web site are qualified to receive and use provider information on patient safety events or incidents.¹² A list of the 59 approved PSOs (as of the time of this article) can be seen on the HHS/AHRQ PSO Internet site.¹³ “PSOs are governed by a bazillion regulations,” says Dr. Jaffe. A review of the PSO application for listing with HHS reveals a small part of the difficulty involved in establishing a PSO. The application form requires extensive and detailed information.¹⁴ In addition, PSOs must follow a specific scope of

required work. The patient safety activities required under 42 USC include:

- efforts to improve patient safety and the quality of health care delivery;
- the collection and analysis of patient safety work product;
- the development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
- the utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
- the maintenance of procedures to preserve confidentiality with respect to patient safety work product;
- the provision of appropriate security measures with respect to patient safety work product;
- the utilization of qualified staff; and
- activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.¹⁵

Understanding the extent of regulations governing PSOs can alert health care providers and compliance officers that PSOs are a protected and structured environment for sharing patient safety data and using that data to improve outcomes. Federal support for PSOs is strong from regulatory agencies and even lawmakers. “PSQIA passed with a unanimous Senate vote and had only three no-votes in the House,” notes Dr. Jaffe.

So how do you choose the right PSO? Dr. Jaffe notes that there are no prohibitions against joining multiple PSOs that serve different needs. He notes that most organizations will choose a primary PSO — typically one that focuses on a type of provider (*e.g.*, hospitals). They also may select a geographically localized organization that will allow all providers in an area to share experiences and information across the entire continuum of care. “It makes sense for organizations to join a PSO operating in their geographic

area,” he says. “Providers need to be able to talk to one another.” He notes that PSOs may be provider or medical service specific and may be centered in unique areas like metropolitan centers or rural settings.

CHPSO is an example of a hospital-focused regional model. CHPSO is focused on California hospitals and improving outcomes in that state. Like many other statewide PSOs, it will focus on patient safety initiatives, laws, and regulations that are specific to its geographic region. A benefit of this approach is that it may allow a PSO to share information with a group of hospitals in a way that allows all facilities and health care providers in that network to address safety concerns and improve simultaneously.

PSOs also can work collaboratively across state lines, however. For example, on February 19, 2009, CHPSO was selected as one of the state hospital associations and PSOs to participate in a demonstration project that will study how to reduce central catheter line associated bloodstream infections in hospital intensive care units (ICUs). According to the press release from AHRQ, hospital associations in 10 states were selected to participate in the project. “States are California, Colorado, Florida, Massachusetts, Nebraska, North Carolina, Ohio, Pennsylvania, Texas, and Washington. In addition, the California Hospital Patient Safety Organization, the North Carolina Center for Hospital Quality and Patient Safety, and the Ohio Patient Safety Institute will participate in the project...”¹⁶

Ultimately, AHRQ plans to aggregate de-identified data from many PSOs into a national patient safety database. The deidentification will be performed by the PSO Privacy Protection Center.

PSO Cost

“The PSO will be a small organization in most cases,” says Dr. Jaffe. “Cost of joining should not be excessive.” PSOs also provide a significant economy of scale: not only leveraging the PSO employees’ skills among

many providers but also allowing the providers themselves to share talents and insights of each others’ workforce.

A review of a variety of PSO Internet sites reveals that many offer packages of services, all of which are voluntary. Some offer very specific services, such as the ability to provide information or intervention in a specific patient safety event or incident. These enhanced services may include root cause analysis, continuing medical education (CME) related to improving specific instances of performance, or other programs. The cost of joining a PSO should be well outweighed by the benefits of being able to share information with peers in a protected manner and develop better patient safety systems.

PSOs AND THE FUTURE OF HEALTH CARE

“Health care has become more effective but at the same time has become more complex and dangerous. The establishment of PSOs is all about redesigning health care delivery systems,” Dr. Jaffe concluded during our interview for this article. “PSOs should help us figure out how to deal with human fallibility...including issues like workload and information overload. The practice of medicine must change. To be safer we need to redesign our delivery systems to accommodate human fallibility. This will require a number of new practices, such as establishing reproducible procedures in medicine — like the extensive checklists that helped make the aviation industry one of the safest means of travel in the world.”

Endnotes:

1. The Patient Safety Act (PubLNo 109-41), 42 U.S.C. §299(b)(21)-(29).
2. HHS, Agency for Healthcare Research and Quality (AHRQ), Patient Safety Organization Information, available at www.pso.ahrq.gov/psos/overview.htm. Accessed May 6, 2009.
3. Final rule, 73 FR 70732, Nov. 21, 2008.
4. AHRQ, Legislation and Regulations, available at www.pso.ahrq.gov/regulations/regulations.htm. Accessed May 6, 2009.
5. *Supra* n.1 at (b)(21)(2)-(7).

6. *Id.*
7. Interview with Rory Jaffe, MD, MBA, May 13, 2009. To learn more about CHPSO and PSOs, visit www.chpso.org.
8. AHRQ, When is Information Protected, available at www.pso.ahrq.gov/regulations/2008-27475_pi-1.pdf. Accessed May 14, 2009.
9. HHS, Office for Civil Rights, Delegation of Authority, available at www.hhs.gov/ocr/privacy/psa/understanding/delegationofauthority.html. Accessed May 6, 2009.
10. California Hospital Patient Safety Organization (CHPSO), *What is CHPSO?*, available at www.chpso.org. Accessed May 6, 2009.
11. AHRQ, Patient Safety Organization Information, available at www.pso.ahrq.gov/psos/overview.htm. Accessed May 6, 2009.
12. AHRQ, Alphabetical Directory of Listed Patient Safety Organizations, available at www.pso.ahrq.gov/listing/alphalist.htm. Accessed May 6, 2009.
13. AHRQ, PSO List, available at www.pso.ahrq.gov/listing/psolist.htm. Accessed May 12, 2009.
14. AHRQ, PSO Registration Form, available at www.pso.ahrq.gov/listing/certfm.pdf. Accessed May 12, 2009.
15. *Supra* n.1 at (b)(21).
16. AHRQ, Press Release, *10 State Project to Study Methods to Reduce Central Line-Associated Bloodstream Infections in Hospital ICU's*, available at www.ahrq.gov/news/press/pr2009/clabsipr.htm. Accessed May 6, 2009.

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