

Patient Safety and Quality Improvement: A Policy Assessment

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ABSTRACT

Background: The regulation implementing the Patient Safety and Quality Improvement Act of 2005 (PSQIA) was published on November 21, 2008, and became effective on January 19, 2009 (42 C.F.R. Part 3).¹ PSQIA establishes a voluntary reporting system to enhance the data available to assess and resolve patient safety and health care quality issues. To encourage the reporting and analysis of medical errors, PSQIA provides federal privilege and confidentiality protections for patient safety information.

Purpose: Greater reporting and analysis of patient safety events will yield increased data and better understanding of patient safety events. A PSO's workforce must have expertise in analyzing patient safety events, such as the identification, analysis, prevention, and reduction or elimination of the risks and hazards associated with the delivery of patient care.

Implications: This new legislation provides a vehicle to better understand at a macro level how the clinical laboratory threatens patient safety and how that threat can be better controlled. What is imperative is that the clinical laboratory staff be involved in collecting and analyzing data. If they are not, the probability is high that data being reported by the laboratory will be misunderstood at the PSO and laboratories may be cited as a threat to patient safety because of a lack of understanding of laboratory operations.

ABBREVIATIONS: AHRQ – Agency for Healthcare Research and Quality, OCR – Office of Civil Rights, PSO – Patient Safety Organization, PSQIA – Patient Safety and Quality Improvement Act of 2005, PSR – PSR, PSWP – Patient Safety Work Product

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INTRODUCTION

The regulation implementing the Patient Safety and Quality Improvement Act of 2005 (PSQIA) was published on November 21, 2008, and became effective on January 19, 2009 (42 C.F.R. Part 3).¹

PSQIA establishes a voluntary reporting system to enhance the data available to assess and resolve patient safety and health care quality issues. To encourage the reporting and analysis of medical errors, PSQIA provides federal privilege and a confidentiality protection for patient safety information called the patient safety work product and includes information collected and created during the reporting and analysis of patient safety events. PSQIA authorizes HHS to impose civil money penalties for violations of patient safety confidentiality.

The confidentiality provisions of the Act will improve patient safety outcomes by creating an environment where providers may report and examine patient safety events without fear of liability risk. Greater reporting and analysis of patient safety events will yield increased data and better understanding of patient safety events.

The Patient Safety and Quality Improvement Act of 2005

The Patient Safety and Quality Improvement Act of 2005 (PSQIA) amends the Public Health Service Act (42 U.S.C. 299 et. seq.; P.L. 109-41) by inserting sections 921 through 926, 42 U.S.C. 299b-21 through 299b-26.¹

OCR has responsibility for interpretation and implementation of the confidentiality protections and enforcement provisions in section 922. AHRQ has responsibility for the listing of and outreach to patient safety organizations (PSOs) and the creation of a network of patient safety databases in sections 923, 924, and 925.

The PSR

The Patient Safety Rule (PSR) implements select provisions of PSQIA. Subpart C of the PSR establishes the confidentiality provisions and disclosure permissions for the *patient safety work product* and the enforcement procedures for violations of confidentiality pursuant to section 922 of the statute. OCR enforces these confidentiality protections.

AHRQ lists patient safety organizations pursuant to section 924 of PSQIA and has responsibility for common formats and network of patient safety databases pursuant to section 923.² OCR has responsibility for interpreting and implementing the confidentiality protections described in Subpart C and the enforcement provisions described in Subpart D. AHRQ has responsibility for listing and delisting of patient safety organizations (PSOs) described in Subpart B.¹

Defining a PSO

A PSO is an entity or a component organization that is listed by AHRQ based upon a self-attestation by the entity or component organization that it meets certain criteria established in the PSR.

The primary activity of an entity or component organization seeking to be listed as a PSO must be to conduct activities to improve patient safety and health care quality. A PSO's workforce must have expertise in analyzing patient safety events, such as the identification, analysis, prevention, and reduction or elimination of the risks and hazards associated with the delivery of patient care. See 42 CFR 3.102 for the complete list of requirements.

There are eight patient safety activities that are carried out by, or on behalf of a PSO, or a health care provider as described by AHRQ.²

- Efforts to improve patient safety and the quality of health care delivery;
- The collection and analysis of the *patient safety work product* (PSWP);
- The development and dissemination of information regarding patient safety, such as recommendations, protocols, or information regarding best practices;
- The utilization of PSWP for the purposes of encouraging a culture of safety as well as providing feedback and assistance to effectively minimize patient risk;
- The maintenance of procedures to preserve confidentiality with respect to PSWP;
- The provision of appropriate security measures with respect to PSWP;
- 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.

The term "safety" refers to reducing risk from harm and injury, while the term "quality" suggests striving for excellence and value. By addressing common, preventable adverse events, a health care setting can become safer, thereby enhancing the quality of care delivered. PSOs create a secure environment where clinicians and health care organizations can collect, aggregate, and analyze data, thus identifying and reducing the risks and hazards associated with patient care and improving quality.

Common Formats

Common Formats include common definitions and reporting formats used to facilitate the collection and reporting of patient safety events. AHRQ developed Common Formats, Version 1.0, for use by health care providers and PSOs. Common Formats may be viewed at www.psoppc.org. Currently, the Common Formats are limited to patient safety reporting by acute care hospitals. Future versions of the Common Formats will be developed for other settings, such as nursing homes, ambulatory surgery centers, and physician and practitioner offices.

PSO Logo's

PSOs that are currently listed by the HHS Secretary are entitled to display the "Listed PSO" (Figure 1). This logo is intended to identify entities whose PSO certifications have been accepted in accordance with Section 3.104(a).²



Figure 1. Patient Safety Organization Logo

The second logo that may be used is the "AHRQ Common Formats" logo which may be displayed by any organization that is using the Common Formats developed by AHRQ (Figure 2). Such entities do not need to be listed as a PSO by the HHS Secretary to employ the Common Formats and thus display the logo. The Common Formats are available in the public domain to facilitate their widespread adoption and implementation. Entities who display the logo should use the Common Formats as a whole; however, entities that have a limited focus may use the Common Formats that pertain only to that area.



Figure 2. AHRQ Common Formats Logo

Benefits of Working with a PSO

PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events. Communications with PSOs are protected to allay fears of increased risk of

liability because of collection and analysis of patient safety events.

The protections of the PSR enable PSOs that work with multiple providers to routinely aggregate the large number of patient safety events that are needed to understand the underlying causes of patient harm from adverse events and to develop more reliable information on how best to improve patient safety. The uniform Federal protections that apply to a provider's relationship with a PSO are expected to remove significant barriers that can deter the participation of health care providers in patient safety and quality improvement initiatives, such as fear of legal liability or professional sanctions.

Most health care providers strongly believe in active participation in ongoing efforts to improve the safety, quality, and outcomes of the patient care they provide. All too often, however, their participation places them at increased liability because the information that they report or develop could be used against them in litigation or proceedings before professional licensure boards or accreditation agencies. The PSR ensures that health care providers will not face any additional liability as a result of their participation in patient safety activities. The product of their efforts will be subject to uniform federal confidentiality and privilege protections so that health care providers are confident that PSWP may only be disclosed as prescribed in the PSR.

Implementation of the Patient Safety Act

AHRQ is responsible for the provisions dealing with the listing of PSOs such as administering the certification processes for listing; verifying that PSOs meet their obligations under the PSR; working with PSOs to correct any deficiencies in their operations; and, if necessary, revoking the listing of a PSO that remains out of compliance with the requirements.

Congress vested the authority for implementing the Patient Safety Act with AHRQ by incorporating its provisions into AHRQ's authorizing statute. As the lead Federal agency for patient safety research, AHRQ is an appropriate partner for PSOs and health care providers.

The PSR establishes in subpart B the requirements that an entity must meet to seek listing, and remain listed, as a PSO. The PSR authorizes AHRQ to conduct reviews (including announced or unannounced site visits) to assess PSO compliance. To assist PSOs in making the required attestations and preparing for a compliance review, AHRQ developed a *Patient Safety Organizations: A Compliance Self-Assessment Guide* to suggest approaches for thinking systematically about the scope of these requirements and what compliance may mean for an individual PSO.

The Office of Civil Rights (OCR)

OCR is responsible for the investigation and enforcement of the confidentiality provisions of the PSR. OCR will investigate allegations of violations of confidentiality through a complaint-driven system. To the extent practicable, OCR will seek cooperation in obtaining compliance with the confidentiality provisions, including providing technical assistance. When OCR is unable to achieve an informal resolution of an indicated violation through voluntary compliance, the HHS Secretary has the discretion to impose a civil money penalty (CMP) of up to \$10,000 against any PSO, provider, or responsible person for each knowing and reckless disclosure that is in violation of the confidentiality provisions.

Becoming a PSO

The PSR permits many types of entities—either an entire organization or a component of an organization, a public or private entity, a for-profit or not-for-profit entity—to seek listing as a PSO. Both the *mission* and the *primary activity* of the entity (or component) must be to conduct activities to improve patient safety and the quality of health care.

The PSR requires an entity to certify that it meets 15 distinct statutory requirements; a component of another organization must attest that it meets another three statutory requirements; and each entity or component organization must comply with several additional regulatory requirements.

Every entity seeking to be a PSO must certify to AHRQ that it has policies and procedures in place to perform the eight patient safety activities specified in the PSR. In

addition, an entity must also, upon listing, certify that it will comply with the following seven additional criteria specified in the PSR:

- The mission and primary activity of the entity are to conduct activities that improve patient safety and the quality of health care delivery.
- The entity has appropriately qualified staff, including licensed or certified medical professionals.
- The entity, within each 24-month period that begins after the date of the initial listing as a PSO, will establish two bona fide contracts, each of a reasonable period of time, with more than one provider, for the purpose of receiving and reviewing PSWP.
- The entity is not, and is not a component of, a health insurance issuer.
- The entity shall fully disclose:
 - a) any financial reporting or contractual relationship between the entity and any provider that contracts with the entity; and
 - b) if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity.
- To the extent practical and appropriate, the entity collects PSWP from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.
- The entity uses PSWP for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.

The PSR also establishes several additional requirements (see 42 CFR 3.102(a)).

If the entity seeking listing is a component of another organization, the entity must also certify that it is, and will be in compliance with, three additional requirements specified in the PSR:

- The entity maintains PSWP separately from the rest of the organization, and establishes appropriate security measures to maintain the confidentiality of the PSWP.

- The entity does not make an unauthorized disclosure of PSWP to the rest of the organization in breach of confidentiality.
- The mission of the entity does not create a conflict of interest with the rest of the organization.

The Patient Safety Act excludes a health insurance issuer or a component of a health insurance issuer from becoming a PSO. The PSR also excludes the following entities: regulatory agencies; organizations that serve as agents of regulatory agencies (e.g., entities that carry out inspections or audits for a regulatory agency); accreditation and licensure entities; and entities that administer a Federal, State, local, or tribal patient safety reporting system to which health care providers are required to report by law or regulation (see 42 CFR 3.102(a)(2)(ii)).

Entities submitting certifications for initial listing need to attest that they meet the requirement that both their mission and their primary activity are to conduct activities to improve patient safety and the quality of health care delivery (42 CFR 3.102(b)(2)(i)(A) and 42 CFR 3.102(b)(2)(ii)). A multi-purpose entity with a broader scope can create or designate a component that more clearly meets the mission and primary activity criterion. The component of that entity can then seek listing.

There are two requirements relating to PSO staff in the PSR. PSOs must have policies and procedures in place to conduct each patient safety activity, for which PSOs are required to use qualified staff (42 CFR 3.102(b)(1)(i)). Second, PSOs must have an appropriately qualified workforce, including licensed or certified medical professionals (42 CFR 3.102(b)(2)(i)(B)). AHRQ has interpreted this language to mean that each PSO has a qualified staff with relevant medical experience available. The language does not require every member of a PSO's workforce to have this expertise, but at least one individual must have medical credentials and experience. Such a workforce can include individuals who serve on a volunteer basis, as well as those who are paid as employees or serve under contract. It is desirable that the medical experience reflects the type of patient safety events reported to and

analyzed by the PSO. For example, a PSO that receives patient safety event information related to the delivery of hospital care would want to have a physician as part of their workforce; a PSO that primarily deals in adverse drug events would likely benefit from having a pharmacist as a member of their workforce. The overarching requirement is that the qualified staff works under the direct supervision of the PSO.

Applying to Become a PSO

AHRQ has prepared a *PSO Certification for Initial Listing* form that an entity must use to certify that it meets the requirements to become listed as a PSO. To access this form go to: <http://www.pso.ahrq.gov/listing/psoforms.htm>. There is no deadline for applying to be listed as a PSO. Applications for PSO status will be accepted at any time and will be reviewed as expeditiously as possible. A PSO is listed for a period of 3 years. To renew its listing for an additional 3 years, the PSO will be required to complete and submit a *PSO Certification for Continued Listing* form before the expiration of its period of listing. The PSO must certify that it is performing, and will continue to perform each of the patient safety activities and that it is complying with, and will continue to comply with, the other requirements of the PSR. The PSO's 3-year period of listing will automatically expire at midnight of the last day of the PSO's listing period if AHRQ has not received and approved the PSO's continued listing form.

Protecting Data

If a PSO's listing is revoked for cause, health care providers may continue to submit data to the delisted PSO for 30 calendar days, beginning on the date and time that the PSO is delisted and ending 30 days thereafter. Data submitted during this 30 day period are treated as PSWP and are subject to the confidentiality and privilege protections of the Patient Safety Act. For example, if a PSO is delisted for cause at midnight on March 1, a health care provider can continue to submit data to the delisted PSO until midnight on March 31 and the data will be protected. Data submitted to the former PSO after midnight on March 31 would not be protected. All PSWP submitted to a former PSO in accordance with provisions of the Patient Safety Act and PSR remains protected after the PSO ceases operations.

The Patient Safety Work Product

PSWP is the information protected by the privilege and confidentiality protections of the Patient Safety Act and PSR. PSWP may identify the providers involved in a patient safety event and/or a provider employee that reported the information about the patient safety event. PSWP may also include patient information that is protected health information as defined by the Health Insurance Portability and Accountability Act (HIPAA).

The Patient Safety Act and Rule make PSWP privileged and confidential. Subject to certain specific exceptions, PSWP may not be used in criminal, civil, administrative, or disciplinary proceedings. PSWP may only be disclosed pursuant to an applicable disclosure exception (see 42 CFR 3.206). A patient's original medical record, billing and discharge information, and any other original patient or provider records cannot become PSWP. Copies of selected parts of original provider records may become PSWP.

The PSR permits a health care provider, such as a hospital, to work with more than one PSO. Any information that is eligible to become PSWP reported to a PSO by a health care provider is protected. The definition of PSWP (42 CFR 3.20) provides important detail on what information is eligible for protection and when those protections apply.

The Patient Safety Act authorizes AHRQ to facilitate the development of a network of patient safety databases (NPSD), to which PSOs, health care providers, or others can voluntarily contribute nonidentifiable PSWP. The Patient Safety Act directs AHRQ to incorporate the nonidentifiable trend data from NPSD in its annual *National Health Care Quality Report (NHQR)*. The NHQR is available in hard copy and electronically on the AHRQ Web site at <http://www.ahrq.gov/qual/qdr07.htm>. The NPSD is currently under development. It is anticipated that the NPSD will be ready to receive nonidentifiable information in 2010. In order to submit information to the NPSD, PSOs will need to use AHRQ's Common Formats (<http://www.pso.ahrq.gov/formats/commonfmt.htm>).

By enabling PSOs to aggregate PSWP on their own and to contribute nonidentifiable PSWP to the NPSD, the stage has been set for breakthroughs in our understanding of how best to improve patient safety. The NPSD will facilitate the aggregation of sufficient volumes of patient safety event data to identify more rapidly the underlying patterns and causes of risks and hazards associated with the delivery of health care services. By contributing nonidentifiable PSWP to the NPSD, PSOs can accelerate the pace at which the NPSD can advance our knowledge and provide an important adjunct to a PSO's own analyses.

PSWP must be nonidentified before it is submitted to the NPSD. Nonidentification requires that the information identifying individual and institutional providers, patients, and provider employees reporting patient safety events be removed from the PSWP.

The Patient Safety Act makes PSWP privileged and confidential. The Patient Safety Act and the PSR generally bar the use of PSWP in criminal, civil, administrative, or disciplinary proceedings except where specifically permitted. Strong privacy and confidentiality protections are intended to encourage greater participation by providers in the examination of patient safety events. By establishing strong protections, providers may engage in more detailed discussions about the causes of adverse events without the fear of liability from information and analyses generated from those discussions. Greater participation by health care providers will ultimately result in more opportunities to identify and address the causes of adverse events, thereby improving patient safety overall.

Issues for the Clinical Laboratory

Unlike other health care disciplines the clinical laboratory by its nature is different in defining patient safety issues. For example, administering a wrong medication, the incorrect dosage or at the scheduled time is an event that is easily understood and documented. On the other hand the laboratory may identify patient safety issues at different points in the laboratory process. To complicate the issue, some laboratories may define an event as a patient safety issue while others do not. Some examples may illuminate the point.

A glucose value is being reported by the laboratory. The true value is 498 however, the CLS enters a value of 98. The error is caught by the supervisor before the report leaves the lab. Some labs consider this a medical error that potentially threatens patient safety. Others do not because it did not leave the laboratory. Expanding on the same example, if the report leaves the lab and the CLS has to call the physician/nurse to amend the report but no action to the patient has been taken by the physician/nurse, some labs would consider this a threat to patient safety and others would not. Some labs consider all amended reports as medical errors and threats to patient safety. Now consider a blood culture. At three days, a "no growth" report is issued however, at two weeks an amended report is issued reporting a growth of yeast. Applying the rule that all amended reports are threats to patient safety is clearly not appropriate in this case.

It is clinical laboratory nuances like these that pose challenges to PSO's and clinical laboratories. Two large challenges to PRO's are that there is no uniform taxonomy of medical errors in the laboratory so reporting will be inconsistent yielding data that lacks validity. The second challenge is that PSO's need CLS staff members that understand and are attuned to clinical laboratory nuances.

Implications

Improving patient safety is an initiative that the clinical laboratory supports and has long been working on improving. This new legislation provides a vehicle to better understand at a macro level how and when the clinical laboratory threatens patient safety and how that threat can be better controlled. What is imperative is that the clinical laboratory staff be involved in collecting and analyzing data. If they are not, the probability is high that data being reported by the laboratory will be misunderstood at the PRO and laboratories may be cited as a threat to patient safety because of a lack of understanding of laboratory operations. The other equally disturbing possibility is that opportunities to improve patient safety on the part of the laboratory will be missed.

Educated clinical laboratory scientists who can tease out patient safety issues related to the laboratory and those related to other healthcare professions must be involved in PRO's.

REFERENCES

1. 42 U.S.C. 299 et. seq.; P.L. 109-41 and available at <http://vlex.com/vid/regulations-c>. Accessed October 24, 2009.
2. AHRQ. Available at <http://www.pso.ahrq.gov/index.html>. Assessed October 24, 2009.

2011 Annual Meeting Abstract Deadline

The deadline for abstracts for oral or poster presentations of research or case studies at the 2011 ASCLS Annual Meeting is April 1, 2011. Submission instructions and the proposal form may be found at www.ascls.org/conferences. The completed proposal form and abstract must be submitted electronically by the deadline.

The 2011 Annual Meeting will be held July 26-30 in Atlanta, GA. Additional meeting information will be available at the ASCLS Conferences webpage.