



Compliance TODAY

February 2017

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

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Chief Compliance Officer

Millennium Health

San Diego, CA

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Using PSO protections to enhance the effectiveness of clinical registries

- » Using a Patient Safety Organization (PSO) with a clinical registry can be a powerful tool to improve outcomes.
- » A PSO clinical registry breaks down the barriers providers face in sharing confidential information.
- » The protections afforded by the Patient Safety and Quality Improvement Act (the Patient Safety Act) were designed to empower providers to develop a registry of Patient Safety Work Product (PSWP).
- » Registry PSOs are granted immunity from lawsuit for PSWP.
- » Comparative hospital performance data can be shared with the registry member community.

Peggy Binzer (pbinzer@allianceforqualityimprovement.org) is Executive Director Alliance for Quality Improvement and Patient Safety (AQIPS) in Alexandria, VA and **Kristen Lilly** (Klilly@pyapc.com) is Consulting Manager with PYA in Atlanta.

Many organizations interested in increasing the usefulness of clinical registries to measure and improve patient health outcomes have established Patient Safety Organizations (PSOs). A PSO is an organization whose primary mission is to conduct activities aimed at improving patient safety and the quality of healthcare delivery. A clinical registry that is a PSO can significantly impact safety and quality. A clinical registry provides the data to understand and learn from variations in treatment and outcomes; to examine care patterns, including appropriateness of care; to assess effectiveness; to identify excellence; to monitor safety and harm; and to measure quality of care.¹

Registries are an important source of information regarding healthcare patterns, decision-making, and delivery, as well as the subsequent association of these factors with

patient outcomes. Registries have the potential to produce large databases of quality information. Analysis of such data can provide valuable insight into the safety and/or effectiveness of an intervention or the efficiency, timeliness, and quality of a healthcare system.

Without protections, providers may be reticent to fully participate in a registry, because registries are vulnerable to the use of performance data and feedback in legal proceedings. The Patient Safety and Quality Improvement Act (PSQIA or the Patient Safety Act),² which establishes PSOs, is the single comprehensive federal law providing protections for: (1) registry data from disclosure; (2) providers and patients; and (3) analytics and comparative outcomes. Therefore, participating in a clinical registry that is a PSO provides assurances to empower providers to report more robust information, including peer-protected information, to the registry.



Binzer



Lilly

The Patient Safety Act was designed “to accelerate the development of new, voluntary provider-driven opportunities for improvement” and to “set the stage for breakthroughs in our understanding of how best to improve patient safety.”³ The Patient Safety Act contemplates the discussion and sharing of quality and performance information that has never been previously collected, analyzed, and shared because of the concern that it may not be kept confidential. Thus, the Patient Safety Act helps to eliminate at least one critical barrier to the development of effective clinical registries—fear of disclosure. The Patient Safety Act provides federal protections for clinical registry data, analysis, quality reports and benchmarking, and other performance tools that contain information that could otherwise not be protected under existing state peer review privilege, because it is shared among registry participants to improve care by participating providers.

The Patient Safety Act was designed with clinical registries in mind. Congress recognized that state peer protections were being eroded⁴ and federal healthcare programs were growing. In response, Congress developed a comprehensive federal protection from legal discovery or use by government agencies for compliance purposes to permit providers to share and learn from information that would not otherwise be developed.

Three protections under the Patient Safety Act

The Patient Safety Act provides three separate protections for both identifiable and non-identifiable “patient safety work product” (PSWP) and special protections for information developed or analyzed in the PSO. First, the information is protected by a privilege. The privilege runs with the PSWP and cannot be intentionally or unintentionally waived by any provider. This permits registries to share confidential quality information among

hospitals, medical groups, and other providers across state lines to raise the quality of care delivery among all providers. Privilege provides a shield for all licensed providers, which in turn enables those providers who may not have typically conducted quality improvement processes (due to a lack of state peer protections or privileges for such quality improvement practices) to participate in clinical registries.

The Patient Safety Act privilege is stronger than any state peer privilege or attorney-client privilege, preempts state tort laws, and crosses state lines. The Patient Safety Act provides:

- (a) ...Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be privileged and shall not be (1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;
- (2) Subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil, criminal, or administrative disciplinary proceeding against a provider;
- (3) Subject to disclosure pursuant to section 552 of Title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;
- (4) Admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or

(5) Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.⁵

The second protection is the statutory confidentiality provision, which provides privacy rights for providers and patients. According to the Patient Safety Act: “Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be confidential and shall not be disclosed.”⁶

The confidentiality protections are intended to empower providers to submit information to a PSO and feel secure that their professional reputations will not be harmed.

Although PSOs are not a government program, the Office for Civil Rights (OCR), the agency that enforces both the Patient Safety Act rules and the Health Insurance Portability and Accountability Act (HIPAA), protects the privacy of PSWP and the identity of providers and patients. OCR can investigate and fine a responsible person for impermissible disclosures and also can fine additional persons for secondary disclosures under the confidentiality provisions.

PSOs are subject to HIPAA; a PSO is a business associate and its activities are healthcare operations. However, as a PSO, patient safety activities are considered quality improvement activities and not research, thus PSOs are not subject to the regulations for the protection of human subjects, including the Common Rule and informed consent. Congress intended for PSOs to share their learnings and best practices throughout the healthcare continuum, including publishing in peer-reviewed journals.

Finally, the PSO has immunity for privileged and confidential PSWP it collects or develops. Importantly, under the PSO pathway, Congress placed a limitation on actions

against a PSO. A PSO cannot be compelled to disclose information it collected or developed, whether or not such information is privileged PSWP, unless the plaintiff can show that such information is identified, is not PSWP, and is not reasonably available from another source.⁷ This shifts the burden of proof to the party who wants information from a PSO to make the required showing before any information can be obtained from the PSO. The special protection makes PSWP developed and analyzed by the PSO “self-enforcing,” meaning that the privilege for PSWP cannot be challenged in court and is not therefore subject to judicial interpretation.

This added protection prevents fishing expeditions in a rich database of confidential quality information and analysis that is collected and aggregated for the purpose of learning for the benefit of patients. It also protects the feedback and benchmarking reports from PSOs to providers, which may include information related to measured processes of care (e.g., whether specific care was delivered to appropriate patients at the appropriate time) and those that measure outcomes of care (e.g., outcomes related to a specific procedure).

Congress did not mean to prevent plaintiffs from redressing harm, but intended that the PSO reporting system be used to permit healthcare providers to create a learning system for the benefit of patient care. Congress stated in the legislative history that:

...protecting data in a reporting system ... does not mean that the plaintiff in a lawsuit could not try to obtain such information through other avenues if it is important in securing redress for harm; it just means that the plaintiff would not be assisted by the presence of a reporting system designed specifically for other purposes beneficial to society.⁸

Information becomes protected using one of three pathways

Congress did not limit the Patient Safety Act protections to the collection and analysis of reports to reduce medical errors. Instead, Congress provided wide latitude for what can become PSWP, that is, any identifiable or non-identifiable data, reports, records, memoranda, analysis (such as root cause analysis), deliberations, or written or oral statements:

1. “Assembled or developed by a provider for reporting to a PSO and are reported to a PSO” (i.e., the reporting pathway); or
2. “Developed by a Patient Safety Organization for the conduct of patient safety activities” (i.e., the PSO pathway)⁹ that could improve patient safety, quality of care, and patient outcomes; or
3. Information that identifies or constitutes the analysis or deliberations in the Patient Safety Evaluation System (PSES), which is the analysis and deliberations pathway (A&D pathway).¹⁰

Patient safety activities include “efforts to improve patient safety and the quality of healthcare delivery.” The PSES is for use by the provider to participate in the process of collecting, reporting, managing, and analyzing PSWP reported to or developed by the PSO, including feedback and other patient safety activities pursuant to the Patient Safety Act. The PSES exists anywhere the provider conducts patient safety activities and extends to anywhere within the provider where the use of PSWP may result in the reduction of risk of harm to patients and quality improvement. Any analysis performed in the PSES is PSWP.

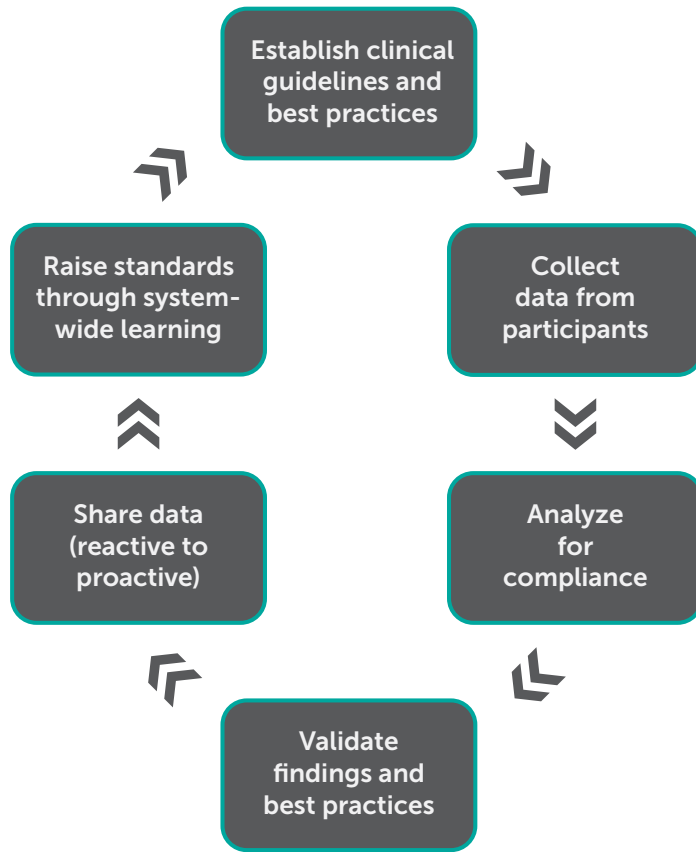
The reporting pathway is for any data, reports, records, memoranda, analysis, or written or oral statements which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO. The

reporting pathway is not self-enforcing and cannot protect information that is required to be reported under a federal program, such as measures of clinical processes, or original records, such as medical records. However, “additional information” such as contributing factors concerning why a measure of clinical process was not met can be protected PSWP. This PSWP can be used by the PSO to update the clinical guidelines or to issue best practices to ensure that other providers do not fail to meet a clinical process measure for the same reason.

Most clinical registries are designed using the PSO pathway. The PSO pathway enables the PSO to collect information from original patient records and additional information, such as results from a root cause analysis (RCA) disclosed by the provider using the A&D pathway or conducted by the PSO itself in its own investigation and data collection activities. The PSO pathway is self-effectuating and the only limitation associated with this pathway is that its PSWP is developed for patient safety activities and could be used to improve patient safety, quality of care, or healthcare outcomes.

Under the A&D pathway, which applies to both the PSO and the provider, any analysis or deliberations (including RCA and feedback) that occur within the provider’s PSES is PSWP. Like the PSO pathway, PSWP developed under the A&D pathway is also self-effectuating. This means that the reason the PSWP was developed is not open to judicial interpretation, because there is no purpose limitation for this pathway. The test is simply whether the analysis or deliberations occurred within the PSES. In addition, specific information collected for the analysis, even if it is not by definition PSWP (e.g., information drawn from original patient medical records) is PSWP if it could reveal the analysis performed in the PSES. This protects the provider from having

Figure 1: PSO Registry System of Outcome Improvement




to turnover a road map of their analysis to trial lawyers.

Unlike the PSO pathway, though, the provider has the burden of proving that information within the PSES is PSWP and thus privileged. To meet this burden, providers document the activities that occur in the PSES in policies and procedures. PSWP developed in the PSES is disclosed to the PSO through a disclosure permission; that is an exclusion to the confidentiality protection for the specific disclosure to the PSO. The information remains PSWP in the PSO and can be used for further analysis or shared with all providers.

The extraordinary benefits gained from participating in PSO clinical registry are that the PSO can share analysis and learnings with all of the providers contributing to that registry and participants can share amongst each other, neither of which could happen under state peer review protections or under

attorney-client privilege. The sharing of the results of a PSO's analysis permits all providers to learn from best practices and transform healthcare delivery by focusing on continuous quality improvement with an aim for prospective risk anticipation and mitigation. Similarly, recommendations and best practices developed by a PSO can be shared with the healthcare community to improve patient care, improve performance, enhance efficiency, and reduce healthcare costs (See Figure 1).

Conclusion

PSOs are the only program that permits healthcare providers to investigate how they are providing patient care and how they can do a better job without fear of litigation or harm to professional reputation. PSO clinical registries can and do assist healthcare professionals in figuring out how to continually improve healthcare delivery in a safety culture that reinforces professionalism and learning to the benefit of patients. With the confidence provided by the Patient Safety Act, transparency through the registry is intended to raise the level of care by all providers and make patient care more reliable across the entire health system. 

1. Gliklich R, Dreyer N, Leavy M, eds.: *Registries for Evaluating Patient Outcomes: A User's Guide*. Third edition. Two volumes. Available at <http://bit.ly/2irxnKB> and <http://bit.ly/2if4tgV>
2. 42 USC 299b-1 et seq. Title IX of the Public Health Service Act.
3. Patient Safety and Quality Improvement, Proposed Rule, 73 Fed. Reg. 8112, 8113 (February 12, 2008).
4. *Idem*.
5. 42 USC 299b-22(a)
6. 42 U.S.C. 299b-22(b).
7. 42 U.S.C. 299b-22(d)(4)(A)(i). Available at <http://bit.ly/2i8CH7X>
8. Senate Report 108-196 – Patient Safety and Quality Improvement Act of 2003. Available at <http://bit.ly/2i8xywu>
9. 42 U.S.C. 299b-21 (5)(A).
10. 42 U.S.C. 299b-21(7)(i)(I), (II) and (ii).