PSO Basics: Protecting LTC Safety and Quality Work

Kathryn Wire, JD, MBA
Center for Patient Safety
Long-Term Care and the Law
February 25, 2015

I. Introduction

This paper will describe the basic structure and function of a Patient Safety Organization (PSO), and explore how PSO participation provides enhanced privilege and confidentiality protections for LTC quality and safety information. It will also discuss potential protection for multi-provider safety improvement work in a PSO's confidential environment. NOTE: When this paper refers to "Patients," it will be in reference to a specific term from the statute and regulation that form the basis for PSO's. The law applies to long-term care, but does not use LTC-friendly terminology.

The statute itself is short and the provisions that apply to providers (vs. PSO's) are even shorter. Accordingly, this is a quick summary, and anyone who needs to work with the provisions should read the statute. The final rule and preamble contain a great deal of helpful information, and the cases indicate that the discussion in the Federal Register will be important for the interpretation of this statute.

II. The Statute and Regulation (Referred to together as the Law)

Congress passed the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act, Pub. L 109-41) in response to the Institute of Medicine report To Err is Human, as a federal solution to improve patient safety and minimize errors. The Act amended Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) by inserting a new Part C, sections 921 through 926, which are codified at 42 U.S.C. 299b–21 through 299b–26. The Agency for Healthcare Research and Quality (AHRQ) manages and enforces the PSO process. It is designed to support specific Patient Safety Activities, delineated in the definitions. (42 USC 299b–21):

5) *Patient Safety Activities*.—The term 'patient safety activities' means the following activities:

(A) Efforts to improve patient safety and the quality of health care delivery.

(B) The collection and analysis of patient safety work product.

(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

(D) 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…

(G) The utilization of qualified staff.

(H) 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.

Patient Safety Organizations. The Law enables willing organizations to become certified Patient Safety Organizations, which gather information from healthcare providers and engage with providers in Patient Safety Activities. The basic structure involves providers voluntarily contracting with a PSO and sending it information on adverse events, near misses and safety concerns. The PSO aggregates and analyzes the data it receives and provides feedback to the participants. The PSQIA's Final Rule (42 CFR Part 3) outlines the details for those processes. However, within broad parameters, it leaves the details of PSO participation very flexible.

Patient Safety Evaluation System. The Act describes the concept of a "Patient Safety Evaluation System" (PSES), which collects, manages or analyzes information for reporting to or from a PSO. Provider/participants and PSO's have their own PSES's, and the two can work together.

Patient Safety Work Product. (PSWP) is "data, reports, records, memoranda, analyses (such as root cause analyses, or written or oral statements)." These items must (1) have been assembled or developed for reporting to AND actually reported to the PSO and (2) constitute information which could result in improved healthcare safety, quality or outcomes. In addition, the law also protects any information which identifies

or constitutes the deliberations and analysis of the PSES, as well as information which identifies the fact of reporting via the PSES. The protections for deliberations and analysis are very broad.

Data That Cannot Be PSWP. The Law specifically identifies certain information that cannot be protected PSWP. Generally, it is information that is generated for other operational purposes, such as medical and billing records, or any other information that is developed and/or exists separate from the PSES. Information that must be reported to Federal, State or local agencies is typically non-PSWP. Non-PSWP can be provided to the PSO, but it will not gain protection. The changes implemented as a result of safety analysis cannot be protected, for example new policies or educational content.

Protection of PSWP. PSWP is privileged and therefore not subject to a Federal, State, or local civil, criminal or administrative subpoena or other discovery methods, including administrative disciplinary proceedings against providers. PSWP is also "confidential and shall not be disclosed." The protections continue to apply after a permitted or unpermitted disclosure. Inappropriate disclosure can lead to the imposition of civil money penalties.

Exceptions to Privilege and Confidentiality. The exceptions are contained in both the definition of disclosure and in a separate section on protections in the statute, and in §3.206 of the final rule. These are the highlights:

- Disclosure is the transfer of identifiable PSWP to another person or entity, other than a workforce member of the provider. Workforce includes employees, volunteers, trainees, contractors or others under the direct controls of the provider.
- PSWP can be disclosed in very limited settings involving criminal acts or if all providers named in the materials consent to the disclosure in writing.
- PSWP can be disclosed to those with whom the provider or PSO has contracted to undertake patient safety activities on its behalf. The contractor is bound by the protections.
- Affiliated providers (those with common control by ownership or contract) can share PSWP. The final rule has a specific definition of the term.
- Providers that participate with a PSO can share PSWP with other participating (reporting) providers as part of their patient safety activities, if they follow certain steps for limited de-identification of the data. (42 CFR Part 3 § 3.206(b)(4)(iii)) .
- PSWP may be disclosed as part of reporting to the FDA.
- PSWP may be disclosed to accountants, attorneys and other professionals, though they may not further disclose.

- For facilities that are accredited by an agency like the Joint Commission, selected PSWP may be shared with the agency. This does NOT include state and federal surveyors.

III. The Social Contract

While this paper (and the related presentation) will focus on the protections available under the PSQIA, it is important to remember that the law's primary purpose is the development of data to drive improvements in the safety and quality of care. The Agency for Healthcare Research and Quality (AHRQ) has developed common data formats for the submission of information to PSO's, and all of the background information, including investigation, deliberations and root cause analysis can be submitted (and therefore protected) for adverse events, near misses and safety concerns.

Actual reporting of data is the touchstone for protection. In essence, the protections exist to protect the activity of developing data to report. This is the "social contract" AHRQ seeks to promote and enforce.

IV. The Developing Case Law

Courts in a number of states have reviewed the PSQIA in the context of efforts to protect PSWP from discovery. A separate handout describes the key cases to date, but several general themes have emerged.

- All the courts have recognized the applicability of the PSQIA protections where the provider had a contract with a PSO and a process for developing and reporting data.
- The cases have uniformly acknowledged that the federal law pre-empts less protective state law.
- The litigation challenges have related to the scope of exceptions to the protections, particularly information that has to be reported to state agencies.
- Cases in two states focus on privilege exceptions for information related to state data-gathering and reporting requirements. The do so based on the language in the statute that excludes from PSWP any data developed for purposes other than PSO reporting . These states (Kentucky and Florida) have regulations that require the development of certain reports, though not all the information has to be submitted to the state.
- The PSO community has appealed the cases, Language in the preamble to the final rule contemplates situations in which information might be gathered for PSO reporting, but also might support other mandated reporting activities:

All of this information, collected in one patient safety evaluation system, is protected as patient safety work product unless the provider

determines that certain information must be removed from the patient safety evaluation system for reporting to the state. Once removed from the patient safety evaluation system, this information is no longer patient safety work product.…Providers have the flexibility to protect this information as patient safety work product within their patient safety evaluation system while they consider whether the information is needed to meet external reporting obligations. Federal Register, Part III, Vol. 73, No. 226, at 70742 (Nov. 21, 2008).

V. Implications for Defense Attorneys

Attorneys defending PSO participants need to be aware of the dual potential pitfalls of (1) not raising the PSO protections timely or accurately in responses to discovery, and (2) not protecting PSWP that may come to them. (Attorneys may see PSWP, but can't share it.) The following tips were shared in an E-mail Brief for the Liability and Litigation Practice Group:

- Providers should have policies in place

defining their PSES. The law does not require this, but strongly encourages it. The cases interpreting the law have used compliance with those policies to support a claim of protection. It is harder to protect work that took place within a poorly defined PSES.

- Review the provider's PSES policies, so that discovery responses accurately reflect the structure and workflow. Because providers define their PSES' differently, each client's PSES needs careful review.
- Confirm that the requested material falls within the scope of the client's PSES and PSWP. Both the attorney and client must be clear about the workflow that creates the PSWP. Discuss with the client WHY the information is PSWP and remember that the client representative needs to be able to comfortably testify in defense of the protections. Know what your supporting affidavit will say.
- Some providers contract with a PSO but have never reported to their PSO. Reporting to a PSO is a prerequisite for protections. Confirm that your client has reported or be ready to explain why that requirement wouldn't apply (e.g. technical problems with reporting system, etc.). If they are going to claim they haven't had any adverse events to report, make sure they can defend that position with a straight face.
- Work with clients pro-actively so they can take full advantage of this new protected workspace.

VI. Practical applications and advantages of PSO confidentiality protections for safety/quality work

The protections under the PSQIA are very broad, both in terms of the QA/PI activities that can be protected and the variety of committees and workgroups that can do that protected work. Unlike many state statutes, the protection covers teams that include unlicensed staff or residents or families. It applies to any activities designed to improve safety or quality, not just the review of care provided by individual providers, which is often the case with state protections. State protections do not always cover long-term care, and are much less likely to provide any protection to assisted living providers.

The non-PSQIA federal protection for quality assurance work in skilled nursing facilities is found in 42 USC 1395i-3(b)(1)(B):

A skilled nursing facility must maintain a quality assessment and assurance committee, consisting of the director of nursing services, a physician designated by the facility, and at least 3 other members of the facility's staff, which

(i) meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary and

(ii) develops and implements appropriate plans of action to correct identified quality deficiencies. A State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this subparagraph.

The interpretation of this provision is often left to the states (Bailey v. Manor Care of Mayfield Hts., 2013-Ohio-4927), and at least one court has held that it must interpret the provision as restrictively as possible and that it only protects the records generated by the committee, but nothing submitted to it. *State of Missouri ex rel. Boone Retirement Center Inc. v. Hamilton, 946 S.W.2d 740 (Mo. 1997).*

The PSQIA can protect information submitted to quality and safety committees. It can also protect the work of other teams, such as the Performance Improvement Project teams suggested by CMS to comply with the upcoming Quality Assurance and Performance Improvement regulation.[1]

The CMS document "QAPI at a Glance" provides insight into the broad range of work expected under QAPI that can be protected under a properly constructed PSES:

A QAPI program must be ongoing and comprehensive, dealing with the full range of services offered by the facility, including the full range of departments. When fully implemented, the QAPI program should address all systems of care and management practices, and should always include clinical care, quality of life, and resident choice.

[1] Section 6102(c) of the ACA 6102(c) of the Affordable Care Act of 2010 requires nursing homes to have an acceptable QAPI plan within a year of the promulgation of the QAPI regulation, which was due out two years ago. Hospitals are currently subject to QAPI requirements. Tools describing anticipated QAPI frameworks in skilled nursing facilities are available at http://www.cms.gov/Medicare/Provider-Enrollment-and-Centerification/QAPI/qapitools.html.

Under Boone, information gathered for a traditional QA committee cannot be protected under non-PSQIA provisions. Only the material generated by the committee can be protected. Yet CMS has developed specific expectations about the breadth of information to be gathered in a QAPI program. For example,[2]

- The governing body and/or administration of the nursing home develops a culture that involves leadership seeking input from facility staff, residents, and their families and/or representatives….
- The facility puts in place systems to monitor care and services, drawing data from multiple sources. Feedback systems actively incorporate input from staff, residents, families, and others as appropriate.
- A Performance Improvement Project (PIP) is a concentrated effort on a particular problem in one area of the facility or facility wide; it involves gathering information systematically to clarify issues or problems, and intervening for improvements. The facility conducts PIPs to examine and improve care or services in areas that the facility identifies as needing attention. Areas that need attention will vary depending on the type of facility and the unique scope of services they provide.

If a facility includes those activities inside its PSES, the information gathered and the process for gathering it can be protected.

[2] These examples were excerpted from "QAPI At A Glance," a descriptive booklet prepared by CMS in anticipation of the publication of the QAPI regulation.

VII. The Surveyor Challenge

For unknown reasons, CMS/AHRQ did not include an exception in the law that would allow disclosure of PSWP to surveyors. CMS has promised to try and resolve this issue internally with AHRQ, but providers and the PSO community are still waiting for that solution. Under the present law, providers must choose between having any PSQIA protection for a given type of information and having it available for surveyors. Providers need to carefully select the information that they include in the PSES so that they can demonstrate compliance with CMS and state requirements, yet still protect sensitive quality and safety work product.

Providers have opted, for example, to leave certain basic data points on incident reports (or the whole basic incident report) outside of the PSES, while protecting the investigation or care planning component. Others have opted to leave summary documents, such as a fall log, outside the protected space.

The surveyors will always have access to resident records, policies and staff interviews about the facts of care, as those cannot be protected. They should also have access to policies outlining the safety and quality activities. The goal is to help them identify good targets for their own investigations without exposing all the deliberations and analysis that takes place in the facility.

VIII. Conclusion

Both the PSQIA and the QAPI requirement are new, and in the latter case, still speculative as to form. However, in planning for QAPI compliance, facilities would do well

to include an assessment of the possible PSQIA protections. Counsel also needs to develop a deep understanding of the various protections under state and federal law, as well as their limitations, in order to properly advise nursing facilities about the potential advantages of PSO participation.