Patient Safety Organizations: Protecting Collaborative Safety and Quality Work

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Introduction

Post-Acute and Long Term Care Services (PALS) clients face a brave new world. Skilled nursing organizations and home health providers are encountering increasing demand for transparency about the quality and safety of their care. Reimbursement will soon depend on compliance with quality measures and producing good outcomes. Hospital partners in bundled and accountable care arrangements will seek post-acute providers who can help them succeed in this new environment.

Providers can, however, obtain support in this new environment from an often-overlooked federal law that can help them address all of these concerns—the Patient Safety and Quality Improvement Act (PSQIA).[1] They can collaborate regionally and nationally while protecting their safety and quality work from disclosure in civil or criminal venues and most regulatory investigations. Attorneys for PALS providers should be aware of the PSQIA's potential for their clients.

The Legal Framework

Congress passed the PSQIA in response to the Institute of Medicine report, *To Err is Human*,[2] as a federal solution to improve patient safety and minimize errors. The PSQIA amended Title IX of the Public Health Service Act[3] by inserting a new Part C, Sections 921–926.[4] The Agency for Healthcare Research and Quality (AHRQ) manages and enforces the Patient Safety Organization (PSO) process, which consists of specific Patient Safety Activities, delineated in the definitions as follows:

> 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.[5]

PSOs

The PSQIA enables organizations to become certified PSOs, which gather information from health care providers and engage with providers in Patient Safety Activities.[6] Providers voluntarily contract with a PSO and send 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 outlines the details for those processes.[7] Within broad parameters, however, it leaves the details of PSO participation flexible.

Patient Safety Evaluation System

The PSQIA relies on the concept of a Patient Safety Evaluation System (PSES), which collects, manages, or analyzes information for reporting to or from a PSO.[8] Provider/participants and PSOs all have their own PSESs, and the two can work together.[9]

Patient Safety Work Product

Patient Safety Work Product (PSWP) is "data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements."[10] These items must: (1) have been assembled or developed for reporting to *and* actually reported to the PSO; and (2) constitute information that could result in improved health care safety, quality, or outcomes.[11] The PSQIA affords protection to PSWP, as further described below.[12] In addition (and at least as important), the PSQIA also protects any information that identifies or constitutes the deliberations and analysis of the PSES, as well as information that identifies the fact of reporting via the PSES.[13] The protections for deliberations and analysis are broad.

Data That Cannot Be PSWP

The PSQIA specifically identifies certain information that cannot be protected PSWP. Generally, information that is generated for other operational purposes, such as medical and billing records, or any other information that is developed or exists separately from the PSES, falls outside the protections.[14] Information that must be reported to federal, state, or local agencies is typically non-PSWP.[15] Non-PSWP can be provided to the PSO, but it will not gain protection.[16] 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.[17] PSWP also is "confidential and shall not be disclosed."[18] The protections continue to apply after a permitted or unpermitted disclosure.[19] Inappropriate disclosure can lead to the imposition of civil monetary penalties.[20]

Exceptions to Confidentiality

There are certain exceptions to the prohibition on disclosure of PSWP. The exceptions are contained in both the definition of disclosure and in a separate section on protections in the statute, and in Section 3.206 of the final rule.[21] 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 control of the provider.[22]
- PSWP can be disclosed in limited settings involving criminal acts or if all providers named in the materials consent to the disclosure in writing.[23]
- 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.[24]
- Affiliated providers (those with common control by ownership or contract) can share PSWP. The final rule has a specific definition of the term.[25]
- 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.[26]
- PSWP may be disclosed as part of reporting to the U.S. Food and Drug Administration.[27]
- PSWP may be disclosed to accountants, attorneys, and other professionals, though they may not further disclose.[28]
- For facilities that are accredited by an agency like The Joint Commission, selected PSWP may be shared with the agency.[29] This does *not* include state and federal surveyors.

The Social Contract

While providers value the PSQIA's protections, it is important to remember that the law was passed to develop data that would improve the safety and quality of care. AHRQ has developed common data formats for the submission of information to PSOs, 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 shelter activities related to the development of data to report. This is the "social contract" that AHRQ seeks to promote and enforce.

Implications for PALS 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 may not share it.)[30] The following tips will help:

- Providers should have policies in place defining their PSES. The PSQIA does not require this but strongly encourages it. The cases interpreting the PSQIA have used compliance with those policies to support a claim of protection.[31] 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 PSESs 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 the protections of the PSQIA to attach.[32] Confirm that your client has reported or be ready to explain why that requirement would not apply (e.g. technical problems with the reporting system, etc.) If they are going to claim they have not had any adverse events to report, make sure they can defend that position with a straight face.
- Work with clients proactively so they can take full advantage of this new protected workspace. Some PSOs will help set up structures and processes for their participants. Attorneys who are involved in those initial processes will have a better understanding of their clients' programs if they have to defend the protections.

PSOs and Collaborative Care Arrangements

Evidence abounds that PALS providers will need to develop new muscles in the evolving world of referral, reimbursement, and regulation. Medicare (and private payment sources are never far behind) is introducing accountable care organizations, bundled payments, and quality measures that affect payment rates for PALS providers. All of these focus

attention on the smooth and effective movement of patients through a system that provides quality care. A breakdown at any point in the continuum can affect the well-being of all the providers in the chain.

Unfortunately, current state and federal protections for safety and quality improvement work are spotty, and they almost never provide an umbrella of protection for work among providers unless they are under common ownership and control. Even then, protection is incomplete and inconsistent from state to state. Participation with a PSO can offer various providers a protected venue to work through common issues, including:

- A way to systematically identify emerging vulnerabilities and near misses that have the potential to create risk across the integrated clinical environment;
- A means of analyzing and understanding medical errors in a protected environment to improve patient safety in all segments of the collaborative structure;
- A forum for learning about potential problem issues and best practices to support patient safety and quality improvement efforts among all the providers;
- A way to identify if and how errors that occur in one segment of the system can affect the occurrence of errors in other parts of the system; and
- A means to understand how activities in one segment of the clinically integrated system can serve to prevent, mitigate, or exacerbate errors and adverse outcomes in other parts of the system.

The PSQIA: Comparison to Current Federal Protection

The protections under the PSQIA are broad, both in terms of the quality assurance and performance improvement (QAPI) 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/patients or families.[33] It applies to any activities designed to improve safety or quality. 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 provides that:

> 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.[34]

The interpretation of this provision is often left to the states,[35] 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.[36] The PSQIA can protect information submitted to quality and safety committees. It also can protect the work of other teams, such as the Performance Improvement Project teams suggested by the Centers for Medicare & Medicaid Services (CMS) to comply with the upcoming QAPI regulation.[37] 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.[38] As care increasingly involves coordination with other providers, this process also will include them if the skilled nursing facility expects to improve outcomes. The document describes QAPI expectations broadly:

> 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.[39]

Under *State of Missouri ex rel. Boone Retirement Center Inc. v. Hamilton*, information gathered for a traditional QAPI committee cannot be protected under non-PSQIA provisions.[40] 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. Consider how these QAPI-required tasks, excerpted from *QAPI at a Glance*, would look in a collaborative care environment, and whether they can be protected under non-PSQIA provisions:

> 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.[41]

If a facility includes those activities inside its PSES, the information gathered and the process for gathering it can be protected. If all the providers in a collaborative/shared risk arrangement participate with a PSO, the work can be structured to protect deliberations and analysis about safety for patients throughout the continuum.

The Surveyor Challenge

For unknown reasons, CMS and its sister agency AHRQ did not include an exception in the PSQIA that would allow disclosure of PSWP to surveyors. CMS has promised to try to 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 and deliberative component. Others have opted to leave summary documents, such as a fall log, outside the protected space.

The surveyors always will have access to resident records, policies, and staff interviews about the facts of care, as those cannot be protected.[42] They should also have access to policies outlining the safety and quality activities. When working with them to meet their needs without emasculating PSQIA protections, facilities need to be able to share data that helps the surveyors identify good targets for their own investigations without exposing all the deliberations and analysis that takes place in the facility.

Conclusion

Counsel needs to develop a deep understanding of the various new structures under the PSQIA that both challenge and create opportunity for their clients. Understanding the protections under state and federal law, as well as their limitations, will help attorneys properly advise nursing facilities about the potential advantages of PSO participation and the best way to protect the various types of work they do.

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1 Patient Safety and Quality Improvement Act of 2005, Pub. L No. 109-41, 119 Stat.424.
2 Institute of Medicine, To Err Is Human: Building a Better Health System (Linda T. Kohn et al. eds.,2000), *available at* www.nap.edu/openbook.php?isbn=0309068371.
3 Public Health Service Act, 42 U.S.C. §§ 299–299c7 (2010).
4 Codified at 42 U.S.C. §§ 299b-21 to -26.
5 *Id.* at § 299b-21(5).
6 *Id.* at § 299b-24.
7 42 C.F.R. §§ 3.10–.552 (2015).
8 42 U.S.C. § 299b-21(6) (2010); 42 C.F.R. § 3.20 (2015).
9 *Id.*
10 42 U.S.C. § 299b-21(7)(A) (2010); 42 C.F.R. § 3.20 (2015).
11 *Id.*
12 *See infra* notes 16–18 and accompanying text.
13 42 U.S.C. § 299b-21(7)(A) (2010); 42 C.F.R. § 3.20 (2015).
14 42 U.S.C. § 299b-21(7)(B) (2010); 42 C.F.R. § 3.20 (2015).
15 *Id.*
16 *Id.*
17 42 U.S.C. § 299b-22 (2010); 42 C.F.R. § 3.204–.206, -.402–404 (2015).
18 42 U.S.C. § 299b-22(b) (2010); 42 C.F.R. § 3.206(a) (2015).
19 42 U.S.C. § 299b-22 (2010); 42 C.F.R. § 3.204–.206, -.402–404 (2015).
20 *Id.*
21 42 U.S.C. § 299b-22(c) (2010); 42 C.F.R. § 3.20, .206(b) (2015).
22 *Id.*
23 *Id.*
24 *Id.*
25 *Id.*
26 42 C.F.R. § 3.206(b)(4)(iv) (2015).
27 42 U.S.C. § 299b-22(c) (2010); 42 C.F.R. § 3.20, .206(b) (2015).
28 *Id.*
29 *Id.*
30 42 C.F.R. § 3.206(b)(9) (2015).
31 *Dep't of Financial & Prof'l Regulation v. Walgreen Co.*, 2012 Ill. App. 2d 110452 (Ill. App. Ct. 2012); *Petraskiewchz v. Laser Spine Inst.*, Case No. 13-CA-14394 (Fla. Cir. Ct. 2015).
32 42 U.S.C. § 299b-21(7)(A) (2010); 42 C.F.R. § 3.20 (2015).
33 *See generally* 42 C.F.R. § 3.20 (2015) (protecting all work within a PSES and not specifying or limiting what individuals can be included).
34 42 U.S.C. § 1395i-3(b)(1)(B) (2013).
35 *Bailey v. Manor Care of Mayfield Hts.*, 2013-Ohio-4927, 4 N.E.3d 1071 (Ohio Ct. App. 2013).
36 *State of Missouri ex rel. Boone Retirement Ctr. Inc. v. Hamilton*, 946 S.W.2d 740 (Mo. 1997).
37 Section 6102(c) of the Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 199, 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 currently are subject to QAPI requirements. Tools describing anticipated QAPI frameworks in skilled nursing facilities are *available at* www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/qapitools.html.
38 Centers for Medicare and Medicaid Services, QAPI at a Glance: A Step by Step Guide to Implementing Quality Assurance and Performance Improvement (QAPI) in Your Nursing Home, www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/QAPIAtaGlance.pdf (a descriptive booklet prepared by CMS in anticipation of the publication of the QAPI regulation).
39 *Id.* at 8.
40 *State of Missouri ex rel. Boone Retirement Ctr. Inc. v. Hamilton*, 946 S.W.2d 740 (Mo. 1997).
41 *See* QAPI at a Glance, *supra* note 37.
42 42 U.S.C. § 299b-21(7)(B) (2010); 42 C.F.R. § 3.20 (2015).

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Post-Acute Care Provider Antidiscrimination Obligations

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Title III of the Americans with Disabilities Act (ADA)[1] and Section 504 of the Rehabilitation Act of 1973[2] are federal antidiscrimination laws applicable to post-acute care providers (e.g. skilled nursing facilities (SNFs) and assisted living communities (ALCs)). These federal civil rights laws help protect individuals from unfair treatment or discrimination because of race, color, national origin, disability, age, gender, and religion. This article examines how these laws apply to residents with disabilities, with an emphasis on HIV related-cases, enforcement actions by governmental administrative agencies, and how voluntary resolution agreements are being utilized.

Title III of the ADA

The ADA has had an interesting evolution. Historically, private businesses were not considered "places of public accommodation."[3] As such, they did not have a legal duty to undertake care or to refrain from discriminatory practices when selecting customers.[4] This concept, however, was eliminated through legislation, coupled with Title VI of the Civil Rights Act of 1964, implementing a nondiscrimination principle in the case of health care services furnished by private providers receiving federal funds.[5]

Title III of the ADA applies to "places of public accommodation."[6] One particular category applicable to post-acute care facilities are "places of public lodging" and "social service center establishments."[7] The ADA provides comprehensive civil rights protections for "individuals with disabilities."[8] An individual with a disability is a person who:

- Has a physical or mental impairment that substantially limits one or more major life activities;
- Has a record of such an impairment; or
- Is regarded as having such an impairment.[9]

Impairments recognized by the U.S. Department of Justice (DOJ) include any physical or mental impairment, such as but not limited to:

> contagious and noncontagious diseases and conditions [such] as orthopedic, visual, speech, and hearing impairments; cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis,