

Using Patient Safety Organizations to Further Clinical Integration

Alice G. Gosfield, Esq.*

This article addresses why in the current context driving toward improved value, physician groups ought to consider developing a patient safety evaluation system and reporting to a patient safety organization. The fundamental challenge to physicians to succeed in the future is to clinically integrate within their own practices, standardizing to the evidence base, and measuring their performance. In addition, it is increasingly clear that the physician office practice is a source of patient safety issues. The Patient Safety and Quality Improvement Act provides two powerful protections for data that will support and bolster clinical integration and patient safety. The protections and how to deploy them are presented.

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Alice G. Gosfield and Associates, PC;
e-mail: agosfield@gosfield.com.
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AQ1 “[Clinical integration is] physicians working together systematically, with or without other organizations and professionals, to improve their collective ability to deliver high quality, safe, and valued care to their patients and communities.”¹

It is now virtually a truism that we are moving from a volume-driven healthcare system to a value-driven system that will change payment models and demand altered processes in the delivery of care. Arguably, the most significant actors to effect real change are physicians who drive virtually everything that happens in the rest of the healthcare system by virtue of their medical orders.

Relevant and meaningful change can only occur based on measured performance. Regardless of the practice setting—whether employed by a hospital, in a large multispecialty group, or remaining in independent practice—all physicians will have to change some aspects of their behavior. Relevant and meaningful change can only occur based on measured performance. Measured performance produces data about what needs to be improved. By definition then, the collection of these data provides a threshold statement of suboptimal performance.

It is increasingly known that the physician office practice is a fertile source of patient safety issues.^{2,3} Malpractice carriers and patient safety experts report that typical patient safety problems in the office practice include

drug interactions, patient falls, drug mismanagement, misdiagnoses, failure to report test results, and patient misunderstanding of instructions.⁴ By the same token, those physicians who seek to engage in true clinical integration in accordance with the definition noted above, will also want to pay attention to other issues that will improve value, including choosing clinical practice guidelines for standardization, measuring conformity with those guidelines, designing a physician compensation model that is consistent with the desired clinical performance, and tracking data for scoring on that model. (For a deeper consideration of these issues, see Gosfield, “Physicians and Patient Safety Organizations: Furthering Clinical Integration,” *Health Law Handbook*, 2014 ed., WestGroup.) As hospitals and physicians collaborate increasingly under bundled payment models and various network configurations, including accountable care organizations (ACOs), shared information with respect to readmission rates, utilization of resources, rates of potentially avoidable complications, and from whom to take referrals and to whom to give them will be important.

All of the information noted above could be used by adversaries in a variety of ways. Obviously, plaintiffs’ attorneys could use baseline data as an admission against interest of suboptimal performance. As the value proposition lowers the volume of defensive medicine and overuse, information regarding a physician compensation model

to incentivize more efficient behavior could be cast in a nefarious light. Certainly the data for scoring on such a model could prove problematic. None of this qualifies for peer-review protection under state and federal law. What is to be done?

Little known by physicians as relevant to them, in 2005, Congress enacted the Patient Safety and Quality Improvement Act (PSQIA) to broadly protect information that could be used to improve patient safety, healthcare quality, or healthcare outcomes. Virtually all of the literature on the subject to date has been focused around hospitals. In fact, hospitals that seek to be offered in networks on the healthcare exchanges under the healthcare reform legislation must have a contract to report data to patient safety organizations (PSOs), whose authority comes under the PSQIA. Unfortunately, no regulations were published until November 2008. But in examining what will be necessary for physician practices to succeed in the coming environment, the legislation and regulations offer an enormously flexible opportunity for physician practices to protect highly sensitive information they develop in an effort to improve their care.

SOME FUNDAMENTAL CONCEPTS

What is protected in this system of providers reporting to PSOs is “patient safety work product” (PSWP). What qualifies is extraordinarily broad since it includes any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material) that could improve patient safety, healthcare quality, or healthcare outcomes; and which are assembled or developed by a provider for reporting to a PSO and are reported to PSO. The PSWP includes information that is documented as having been developed within a patient safety evaluation system (PSES) for reporting, and it includes the date the information entered the PSES or is data independently developed by a PSO for the conduct of patient safety activities. PSWP identifies or constitutes the deliberations or analysis of or identifies the fact of reporting pursuant to a PSES. On the other hand, it does not include a patient’s medical record, billing and discharge information, or any other original patient or provider information or information that is collected, maintained, or developed separately or exists separately from the PSES.

A “patient safety evaluation system” is loosely defined as the collection, management, or analysis of information for reporting to or by a PSO. It need not take any specific form, although it must be managed as separate and potentially parallel to general business records.

“Patient safety activities” that are protected under the statute include “any efforts to improve patient safety and the quality of healthcare delivery.” That is almost limitless. It applies to patient safety organizations that receive and analyze information as well to providers and contractors to

either one of them. Patient safety activities further include the collection and analysis of PSWP, the development and dissemination of information with respect to improve patient safety, such as recommendations, protocols, or information regarding best practices. It further extends to utilization of PSWP for the purpose of encouraging a culture of safety and providing feedback and assistance to effectively minimize patient risk. Patient safety activities are also the maintenance of procedures to preserve confidentiality with respect to PSWP, as well as the provision of appropriate security measures for PSWP. It includes the utilization of qualified staff and activities related to the operation of a PSES and to the provision of feedback to participants in a PSES.

The entities and individuals that may take advantage of the reporting opportunity are “providers,” which are defined as an individual or entity licensed or otherwise authorized under state law to provide healthcare services. Notably, this does not include ACOs, individual practice associations, physician hospital organizations, or any variety of clinically integrated networks that include otherwise independent practitioners or facilities, because they are typically not licensed to deliver healthcare services. That said, there are ways to structure relationships so that data within these networks can be protected utilizing the opportunity to report to a PSO and obtain analysis from it.

PSOs are not federally funded, and they operate pursuant to private contracts with the providers reporting to them.

The PSO itself is a private entity subject to regulations and administration by the Agency for Healthcare Research and Quality (AHRQ). PSOs are not federally funded, and they operate pursuant to private contracts with the providers reporting to them. The providers pay the PSO to receive and potentially analyze the PSWP they submit. To qualify as a “listed PSO,” an organization must meet standards that are set forth in federal regulation. There are 76 listed PSOs.⁵ Some are focused around specific areas, including medication practices, emergency medicine, anesthesia care, breast cancer, and behavioral health. Some are offshoots of state hospital association as in Nebraska, Maryland, and New Jersey. Some are components of providers, such as Piedmont Health and Fresenius. Others are more general in their activities.

PSOs are expected to analyze data reported to them among providers and report back so that providers can learn from their own and others’ experience. However, there is no obligation for the PSO to analyze and report back. Nevertheless, the protections of the law pertain if

the data are reported to a PSO, even if the PSO does nothing with it.

THE BASIC PROTECTIONS

The law provides two fundamental protections: (1) a privilege that prevents the introduction of PSWP in courts or other tribunals; and (2) a prohibition against disclosure of PSWP, subject to very limited exceptions.

Under the PSQIA, notwithstanding any other provision of federal, state, local, or tribal law, PSWP is privileged and not:

1. Subject to subpoena or order, including in a disciplinary proceeding against a provider;
2. Subject to discovery;
3. Subject to disclosure under the Freedom of Information Act; and
4. Admitted in any federal, state, local, or tribal governmental civil proceeding, criminal proceeding, administrative rule-making proceeding, or administrative adjudicatory proceeding.

PSWP may not be admitted in a professional disciplinary proceeding of a professional disciplinary body established as specifically authorized under state law.

Case law has held that the protection is so broad, that where the seeker of PSWP was itself the government in the person of the Department of Financial and Professional Regulation in the State of Illinois, data which it was seeking to discipline some pharmacists who were employed by Walgreens could not be disclosed since the data had been reported to a PSO. [*Department of Financial and Professional Regulation v. Walgreen*, 2012 II App. (2nd) 110452 (May 29, 2012).] There are very limited exceptions that are similar to the very limited exceptions under the confidentiality provisions. The privilege is enforced by the courts and other tribunals where the data are sought to be introduced. The confidentiality provisions are enforced by the Office for Civil Rights, the HIPAA enforcers.

Subject to very limited exceptions set forth in regulation, PSWP is held confidential and may not be disclosed. “Disclosure” is defined as the release of, transfer, provision of, access to, or divulging in any other manner of PSWP by an entity or natural person holding the PSWP to another legally separate entity or natural person other than a work-force member of or a physician holding privileges with the entity holding the PSWP. The exceptions for disclosure include for equitable relief if there is retaliation against the reporter of the PSWP. PSWP can be disclosed in criminal proceedings where the PSWP contains evidence of a criminal act, is material to the proceeding, and is not reasonably available from any other source.

Interestingly, PSWP may be disclosed pursuant to a “valid” authorization by all identified providers in the PSWP. Validity requires a writing signed by the provider containing

sufficient details to fairly inform the provider of the nature and scope of the disclosure. The authorization must be retained for six years from the date of the last disclosure.

Because the provider and PSO will themselves share information or may share with a contractor of theirs or among affiliated providers, to the extent that the data are shared for patient safety activities among them, this is an exception. Nonidentifiable data in accordance with federal regulations may be disclosed to another PSO or provider. Data may be disclosed for research, to the FDA and entities required to report to the FDA, by a provider voluntarily to an accrediting agency, for business operations to attorneys, accountants or other professionals, and to law enforcement.

CREATING A PSES

In order to obtain the protections of the PSQIA, the data reported to the PSO must have been explicitly created within a PSES. The PSES has been described as “a protected space or system that is separate, distinct, and resides alongside, but does not replace, other information collecting activities mandated by laws, regulations, and accrediting and licensing requirements, as well as voluntary reporting activities that occur for the purpose of maintaining accountability in a health care system.”⁶

PSWP does not become protected unless it is reported to a PSO.

While the regulators have said that as a matter of law, the existence of the PSES need not be documented, best practices would suggest that providers adopt a policy that takes into account such issues as processes, activities, physical space, and equipment that make up the system. The policy should identify the personnel or categories of personnel who need access to PSWP. To the extent possible, it should identify the categories of PSWP to which access is necessary and the conditions of access. It should also address how reports will be made to the PSO. Providers can report to multiple PSOs. AHRQ is to develop common formats for reporting, which it has done for hospitals and nursing facilities, but there are no common formats yet for physicians to report. Still, that should not stand in the way of physicians utilizing PSOs effectively.

PSWP does not become protected unless it is reported to a PSO. This requires a contract between the provider (e.g., a physician group) and the PSO. Typically, the provider pays the PSO for its services. Fees can be variable. Given the relative dearth of physician group-PSO activities, the fees likely are negotiable. The PSO is a business associate of the provider under HIPAA.

PSOs are expected to analyze data submitted by providers and report back to them so they learn from each others’

experiences. If smaller physician entities report to the same PSO on the same issue, they will get the power of the PSO's analysis multiplied beyond their own experience, while their data remain protected. This may prove increasingly important in the near term.

CONCLUSION

All physician practices will have to change some aspect of their clinical processes and supporting administrative processes to improve results. The necessary clinical integration for change will not proceed at all if physicians are fearful of the uses of the data they might collect about themselves. Although improving patient safety in the physician practice ought to be part of these activities, the real work of clinical integration goes far beyond patient safety.

Because you cannot improve what you do not measure, all of the activities of clinical integration driving toward the value proposition turn on the generation and analysis of data. Given the sensitivity of these data,

physician practices should seriously consider developing a PSES to report to a PSO, and should find and contract with a compatible PSO. ■■

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