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Five Reasons Physicians Should Use Patient Safety Organizations

By Alice G. Gosfield

The current environment in health care is pushing all providers to improve their quality performance and demonstrate value. Arguably, physicians are critical actors in conforming with these demands in their ordering practices, and virtually all hospitals and health systems are focused on alignment strategies to bolster these efforts. But there is no question that physicians will have to change their own clinical processes and administrative support for them within their own practices, as well. To determine what needs change, and then to make the change, the fundamental predicate is to examine data with regard to quality and performance. This data, by definition, will reveal suboptimal performance—and it is utterly unprotected from discovery in litigation or publication by those who become aware of it.

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In 2005, the Patient Safety and Quality Improvement Act[1] (PSQIA) was passed by Congress to provide two sweeping protections for patient safety work product (PSWP) that would be reported to and analyzed by Patient Safety Organizations (PSOs)—a privilege and confidentiality. Although many commentators described the law as self-executing, this was wrong, especially since it took the government three years to publish regulations defining how organizations would become ''listed'' as PSOs to which the protections would pertain.[2]

The law offers a broad preemptive privilege to protect PSWP that is produced within a provider's patient safety evaluation system (PSES) and is reported to a PSO. A ''provider'' includes virtually all facilities and all clinicians licensed under state law to deliver health care services. There is no obligation on the PSO to analyze the data reported to it, but it was the intent that PSOs would analyze and report back to providers on what could be learned from the submitted data. Even if no report is made back, the protections apply. Under the privilege, which has extremely limited exceptions, the protected information cannot be introduced in any federal, state, local, or tribal civil, criminal or administrative proceeding, nor is it subject to disclosure under the Freedom of Information Act or similar federal, state local or tribal law, or admissible as evidence in any proceeding.

Data developed within a PSES and reported to a PSO must be held confidential and is not subject to disclosure except within the PSO system in accordance with specified conditions and subject to some extremely limited exceptions. The privilege is enforced by tribunals where it is asserted. The confidentiality provisions are subject to enforcement by the Office of Civil Rights of the Department of Health and Human Services, which also manages enforcement of HIPAA. Compliance with the PSO rules is enforced by the Agency for Health Care Research and Quality (AHRQ).

Virtually everything that has been published about the protections and reporting is focused around hospitals. But physicians also should be paying attention to the opportunities represented by this web of regula-

[1] 42 U.S.C. §§ 299b-21 et seq.

[2] 73 Federal Register 70,731 (Nov. 21, 2008), 42 C.F.R. § 3.10 et seq.

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tions. Here are five reasons physicians should utilize PSOs.

1. There is no protection of data for clinical integration or improved safety without reporting it to a PSO.

Most state peer review protection acts do not protect activities within a private physician practice,[3] and even those that do define peer review in a more narrow frame of reference than activities that give rise to the type of data that will support clinical integration and positioning for the current marketplace. The only other federal law that some might think could provide some protection is the Health Care Quality Improvement Act.[4] In a case in which the U.S. District Court for the District of Delaware refused to provide the protections of the PSQIA to the National Heart, Lung and Blood Institute, for failure to act in conformity with the PSQIA, the court noted that the prevailing analysis of the HCQIA is that ''Congress spoke loudly with its silence in not enacting a broad privilege against discovery of peer review materials.'' [5] The court said that the HCQIA no longer is Congress's final word on the issue of medical peer review, acknowledging that the PSQIA was enacted in the wake of the Institute of Medicine's report, ''To Err Is Human.'' The intent of the law was ''to encourage a culture of safety by providing for broad confidentiality and legal protections and information collected and reported voluntarily for the purposes of improving quality of medical care and patient safety.'' [6]

2. The definitions of ''patient safety work product'' (what is protected) and ''patient safety activities'' (how work product is produced) are extremely broad and flexible.

PSWP is defined as any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of this material) that could improve patient safety, health care quality or health care outcomes. Any such data that identifies or constitutes the deliberations or analysis of, or identifies the fact of reporting pursuant to a PSES are included. PSWP does not include the patient's medical record, billing and discharge information or any other original patient or provider information or information required by law to be reported to other agencies. Other than those items, as long as the data is developed within a PSES for reporting to a PSO, the protections will extend to it.

Patient safety activities are any ''efforts to improve patient safety and the quality of health care delivery.'' [7] That is virtually limitless! However, since the protections extend both to providers who report and to the PSOs themselves, the statute identifies a range of patient safety activities: collection and analysis of PSWP; development and dissemination of information with respect to improving patient safety such as recommendations, protocols or information regarding best practices; utilization of PSWP for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk; maintenance of procedures to preserve confidentiality with respect to PSWP; provision of appropriate security measures with respect to the PSWP; utilization of qualified staff; and activities related to the operation of a PSES and to the provision of feedback to PSES participants.

Under these definitions an enormous amount of the work that physicians will have to do to improve their quality, safety and efficiency will be protected. This will include activities that are far broader than efforts to prevent mishaps that are traditionally viewed as patient safety activities. Consider such matters as selecting clinical practice guidelines, measuring conformity with them and taking action to do better, or developing a physician compensation model that rewards quality and efficiency and then applying it to the members of the group. If not protected, if a patient were harmed and litigation ensued, the incentive to avoid unnecessary services or the results of the internal evaluations would be completely discoverable.

3. Physician groups should be deploying something akin to a PSES in order to improve care, in which case it would be logical to use the services of a PSO.

A PSES is defined as the collection, management or analysis of information for reporting to or by a PSO. It is a provider-specific creation. Accepting the definition of ''clinical integration'' to be ''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,'' [8] physicians who will really engage in this work will have to do so *systematically*. To claim the protections of the law, data must be developed specifically within the identified system and must be reported to a PSO. The law does not require, but best practices would suggest, that physician groups should develop a policy that identifies the processes, activities, physical space and equipment (e.g., storage, electronic directories) that comprise the PSES. Much like privacy and security policies, the PSES policy should identify which categories of personnel need access to PSWP. The policy should identify how reports will be made to a PSO and how PSWP will be managed, marked and isolated from other business records.

There are 76 PSOs ''listed'' by the Agency for Healthcare Research and Quality.[9] Some are components of providers — like Piedmont Healthcare Inc. and Fresenius Medical Care . Some have a specific focus, includ-

[3] *See*, Nagele and Poppitt, ''Is The Peer Review Privilege in Critical Condition?'' (50 state survey of peer review statutes), American Health Lawyers Association Annual Meeting (June 2013).

[4] 42 U.S.C. §§ 11101 et seq.

[5] *KD v. United States*, 715 F. Supp. 2d 587 (D. Del. 2010) (19 HLR 779, 6/3/10). The decision is available at http://op.bna.com/hl.nsf/r?Open=jaqo-85zj5l.

[6] *Id.*

[7] 42 U.S.C. § 299b-21(5)(A).

[8] Gosfield and Reinertsen, ''Achieving Clinical Integration with Highly Engaged Physicians'' (November 2010), http://www.uft-a.com/PDF/ACI-fnl-11-29.pdf.

[9] http://www.pso.ahrq.gov/listing/psolist.htm.

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ing on medication practices, emergency medicine, anesthesia, breast cancer and behavioral health, for example. Some are offshoots of state hospital associations. Others have a broader focus. (The American College of Physicians has a listed PSO.) They are private organizations. They are not funded by the government. They charge variably for their services.

If physician groups appreciate the potential that the PSQIA offers them, they will become a new market for the PSOs, and likely the PSOs' fees to them will be negotiable. PSOs are business associates to the providers who report to them. AHRQ is supposed to develop common formats for reporting to facilitate further reporting to a national clearinghouse of data, but so far they have common formats only for hospitals and skilled nursing facilities. So, physician groups seeking to avail themselves of the law's protections will need to identify a compatible PSO, contract with it and execute a business associate agreement with it.

4. Physicians who are focused on clinical integration should consider practice-based patient safety activities to be part of their systematic approach to change.

There is increasing data that demonstrates that physician practices are a source of patient safety issues. Missed diagnoses; unreported abnormal laboratory studies; medication management, particularly for patients taking more than five drugs; and patient misunderstanding of instructions have all been cited.[10] All of these diminish the value of care, both in terms of increased expense and decreased quality. The Medical Group Management Association, with the Institute for Safe Medication Practices and the Health Research and Education Trust developed a ''Physician Practice Patient Safety Self Assessment Tool'' that focuses on some of these issues.[11] AHRQ has also published a Toolkit for Improving Office Testing Processes because 40% of physician patient encounters entail diagnostic testing.[12] Clinical integration has to focus on eliminating these forms of waste, but this will be new work for most physicians. And so, given the vulnerabilities that creating and disseminating data regarding safety will produce, the PSQIA protections will be especially important.

5. If multiple physician groups report to the same PSO on common topics, this will have the effect of creating a virtual clinically integrated network that will benefit from the protections of the law.

The protections under the law are available to providers, which are facilities or clinicians licensed under state law to deliver health care services. By definition, this excludes most newly forming networks, whether fashioned as accountable care organizations, clinically integrated networks, individual practice associations or physician-hospital organizations. Typically, they are not licensed or formally authorized to deliver health care services. While there are some nuances by which those entities might claim protection as contractors to their participating providers, for physician practices, common reporting can accomplish many of the same goals as forming a corporately organized network. If groups as part of their own PSES use the same guidelines, report their conformity with them and have the PSO analyze the data, the reports back will multiply the effect of the analysis by providing more robust information. The key will be finding a compatible PSO and compatible peers to participate. But for many smaller groups, the dilemma of ''how can we figure out what the data means?'' goes away when the expertise of the PSO is brought to bear.

Conclusion

The PSQIA was enacted eight years ago when the health care world was a different place. Still, the language in the statute and the protections in the regulations may be even more important now than they were then. As physicians are key to much of the change that will unfold, they must step up to accept the responsibility of clinical integration or they suffer financial and other consequences. The PSOs have been relatively quiescent on these issues, but they should be motivated to be responsive to this market. If the ones in existence are not responsive, physicians should organize themselves or their professional organizations to take up this mantle. Important work will depend on it.[13]

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[10] Stillwell, ''The Top 10 Risk Management Issues for Medical Office Practices in California,'' *The Doctors Company* (June 2008), http://www.thedoctors.com/KnowledgeCenter/PatientSafety/articles/CON_ID_001896; Casalino, et al. ''Frequency of Failure to Inform Patients of Clinically Significant Outpatient Test Results,'' 169 *Arch. Intern. Med.*, pp. 1123-1129, at p. 1127 (June 22, 2009); Bishop, Ryan and Casalino, ''Paid Malpractice Claims for Adverse Events in Inpatient and Outpatient Settings,'' 305 *JAMA*, pp. 2427-2431 (June 15, 2011).

[11] http://www.mgma.com/pppsa/.

[12] http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/ambulatory-care/office-testing-toolkit/.

[13] For a deeper consideration of these issues see Gosfield, ''Physicians and Patient Safety Organizations: Furthering Clinical Integration,'' Health Law Handbook (2014 ed.), WestGroup a Thomson Co., prepublication draft available at http://www.gosfield.com/publications.htm.