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**PHYSICIANS AND PATIENT SAFETY  
ORGANIZATIONS: FURTHERING CLINICAL  
INTEGRATION**

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**Physicians and Patient Safety Organizations: Furthering Clinical Integration**  
**By Alice G. Gosfield, Esq.**

*Diligence, the necessity of giving sufficient attention to detail to avoid error and prevail against obstacles... Diligence is both central to performance and fiendishly hard...Ingenuity...demands more than anything a willingness to recognize failure, to not paper over the cracks and to change."*  
--Atul Gawande, "better"<sup>1</sup>.

The new market imperative is for health care providers to produce more valuable health care with improved quality at lower cost. The fact that Americans are subjected to overuse of health care services-- receiving more services than are necessary -- has been a high profile concern in the public and private sectors for a long time.<sup>2</sup> This phenomenon has contributed significantly to the increase in insurance premiums which employers decry and economists bemoan as a threat to the vitality of the American economy.

The enactment of the Affordable Care Act has only highlighted these problems with the adoption of value-based payment modifiers for both hospitals and physicians in Medicare, increased transparency of measured performance, bundled payment demonstrations, and innovative delivery vehicles like Accountable Care Organizations in the Medicare Shared Savings program. Many of the same innovations are emerging in the commercial sector as well. Through these diverse initiatives and changed incentives, it is expected that providers will change the way they deliver care.

To truly change care delivery, though, providers must first develop data about what they are currently doing to analyze what should be changed. Then they must continuously improve. Among the many ways to improve quality and increase value is to focus on eliminating potentially avoidable complications of care and improving patient safety, which remains little changed since the publication of the Institute of Medicine's seminal work, "To Err Is Human."<sup>3</sup> To survive, let alone succeed, in the coming environment will require both diligence and ingenuity with the leadership of physicians.

Some of what has likely impeded much progress on these fronts might well be provider anxiety regarding potential malpractice and other liabilities stemming from change. "If

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<sup>1</sup> Holt and Company, New York 2007, pp 8-9

<sup>2</sup> Chassin, "Improving The Quality of Health Care: What's Taking So Long?" Health Affairs (Nov 2013) pp. 1761-1765; Korenstein, et al, "Overuse of health care services in the United States: an understudied problem" Arch Int Med 2012 JN 23: 172(2): 171-8; Chassin, Galvin et al, "The Urgent Need to Improve Health Care Quality," 280 JAMA 1000 (Sept 16, 1998). For a survey of some of the findings of the last forty years on these themes see, Gosfield, "Contracting For Quality: Then, Now and P4P," HEALTH LAW HANDBOOK (2004 ed), WestGroup, a Thomson company, pp. 103-121

<sup>3</sup> Chassin, "Improving The Quality of Health Care: What's Taking So Long?", Health Affairs (Nov 2013) pp. 1761-1765; Gluck, "Patient safety: some progress and many challenges", Obstet Gynecol (Nov 2012) pp 1149-59; Grady, "Study Finds No Progress in Safety at Hospitals", NYTimes (Nov 25, 2010) p.A1

we develop information about what we need to improve, it will be used against us” would be the fear. Still, physicians have long been found to overestimate their risk of being sued in malpractice for not doing something for a patient.<sup>4</sup> This defensive medicine has been discussed in the health care cost debates, but it pales in its impact on high health care costs (2.4% of health care expenditures overall)<sup>5</sup> when viewed against the expenses associated with potentially avoidable complications, patient safety failures, and overuse. In addition, as we learned in the early 1970s when most state peer review protection acts were adopted during a then very challenging malpractice insurance market<sup>6</sup>, physicians were also fearful of engaging in good peer review out of concerns that they could be sued by their aggrieved, reviewed colleagues, mostly in hospital credentialing and privileging activities. So, many state legislatures enacted laws which would protect participants in legitimate peer review activities by making their considerations confidential and providing them with immunity from suit if they acted in good faith. Later, similar federal immunity for privileging and credentialing were enacted in the Health Care Quality Improvement Act of 1996.<sup>7</sup>

In the late 1990s, there was considerable attention devoted to whether health plans should be held liable for the malpractice of their contracted providers. Enterprise liability was bandied about as an answer to concerns about medical management programs imposed by health plans on providers through contract, which activities might end up harming individuals.<sup>8</sup> At the same time, the ever present call for tort reform emanated from the house of medicine. In 2000, I wrote an article which argued that while tort reform might be appropriate for certain providers, tort reform was not necessarily appropriate for all providers. Rather, I posited that if providers engaged in three activities -- (1) they participated in a closed clearinghouse of reported errors to which access was only available to providers who also reported to the clearinghouse; (2) they had an infrastructure determined by a third party to generally drive toward continuously improved quality-- a form of accreditation; and (3) they participated in public reporting of their performance -- then they should be able to opt out into an alternative system for tort compensation, like worker's compensation or no fault.<sup>9</sup>

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<sup>4</sup> Carrier, Reschovsky, Katz and Mello, "High Physician Concern About Malpractice Risk Predicts More Aggressive Diagnostic Testing in Office-Based Practice," Health Affairs (Aug 2013) pp 1383-1391

<sup>5</sup> Mello, Chandra, Gawande and Studdert, "National Costs Of the Medical Liability System," Health Affairs (Sept 2010), pp. 1569-1577

<sup>6</sup> See, Rodriguez, "Peer Review Protection Revisited: The Challenge of Transparency with Improvement," HEALTH LAW HANDBOOK (2003 Ed) WestGroup, A Thomson Publication, pp 219-255

<sup>7</sup> 42 USCA § 11101

<sup>8</sup> Sage, "Enterprise Liability and The Emerging Managed Care System," 60 Law and Contemporary Problems 159 (1997)

<sup>9</sup> Gosfield, "Liability for Quality: A Modest Proposal", Manged Care and Cancer (Jan/Feb 2000) pp. 11-12 <http://www.gosfield.com/PDF/Liabilty%20for%20Quality.A%20Proposal.pdf>

Five years later, by 2005 there was still relatively little progress made in significant improvements in quality and safety (or tort reform). That year Congress passed the Patient Safety and Quality Improvement Act (PSQIA).<sup>10</sup> It would provide sweeping protections for data collected and analyzed to improve patient safety and health care quality, when it was reported to a patient safety organization (PSO). The data would not be discoverable or admissible in court, or anywhere else, subject to very limited exceptions. Although the law was considered self-executing by many, unfortunately, it was virtually impossible to take advantage of its protections for some time since it was three years before final regulations were published governing how the protections would be made available, and who qualified as a PSO. PSOs were expected to analyze data submitted to them and report back to participating providers to help them make care safer and better.

Now, more than five more years later, in addition to their original purposes, PSOs may well serve to bolster the new initiatives to alter the health care landscape in previously unanticipated ways. If providers undertake the challenge of change diligently and with ingenuity, they will, without question, uncover patterns of existing substandard performance which will have to be improved to achieve the value proposition at the core of better health care delivery. Continuous improvement holds the same risks. Providers will want to know that by studying and acting on such information they are not increasing their liability exposure by doing this hard, important work. This chapter presents what PSOs do, explores the extent of their protections of data to inform changed care delivery, reviews caselaw, and considers their use -- particularly by physicians seeking to clinically integrate to improve their care, even in their own practices. In very few states do physician groups outside of a formal hospital based or medical society based peer review program obtain the protections of the peer review statutes.

#### \_\_\_\_.1 PSOs and PSEs.

As of November 2013, there were 76 patient safety organizations (PSOs) listed by the Agency for Healthcare Research & Quality (AHRQ).<sup>11</sup> Some have a specific focus, as around anesthesia practices, radiology, emergency medicine, or pediatrics. Some are sponsored by state hospital associations, like New Jersey, Tennessee, and Nebraska. Others are separate components of provider organizations, like Fresenius Medical Care PSO, Piedmont Clinic, Inc., and Ascension Health Patient Safety Organization. The American College of Physicians has a component PSO. All can serve any provider anywhere in the country. A provider can choose any PSOs to report to and AHRQ offers tips to providers choosing a PSO.<sup>12</sup> In addition, a provider may have contracts with more

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<sup>10</sup> 42 USCA § 299b-21 et seq.

<sup>11</sup> [www.pso.ahrq.gov/listing/psolist.htm](http://www.pso.ahrq.gov/listing/psolist.htm). Another 51 PSOs have been “delisted” by AHRQ for not meeting the requirements to qualify as a PSO.

<sup>12</sup> [www.pso.ahrq.gov/psos/pschoice.htm](http://www.pso.ahrq.gov/psos/pschoice.htm)

than one PSO.<sup>13</sup> Listed PSOs use common formats established by AHRQ for reporting so that information can be maintained in protected databases, and analyzed so participating providers can learn from what is reported.

There is no requirement that a PSO maintain or analyze reported data, but whatever is reported to it must be safeguarded as confidential and not disclosed, except in analyses to reporting providers. PSOs are private organizations that enter into private relationships with providers. They are not funded by the government; and they adopt their own mechanisms of analysis and reporting. However, to provide the requisite protection of information that is the primary purpose of PSOs, they must meet certain standards,<sup>14</sup> which are beyond the scope of this chapter, but at a minimum require that at least two separate providers have contracted with them to report information; and a single health system with 20 hospitals would count as one contract and not twenty.<sup>15</sup>

The most powerful aspect of the PSO relationship is the incredibly broad privilege and confidentiality protections that are provided for patient safety work product (PSWP).

“Notwithstanding any other provision of Federal, State, local, or Tribal law, patient safety work product is privileged and shall not be: (1) subject to Federal, State, local, or Tribal civil, criminal, or administrative subpoena or order, including in a disciplinary proceeding against the provider; (2) subject to discovery in connection with a Federal, State, local, or Tribal civil, criminal, or administrative proceeding, including a disciplinary proceeding against the provider; (3) subject to disclosure under the Freedom of Information Act or similar Federal, State, local, or Tribal law; (4) admitted as evidence in any Federal, State, local, or Tribal governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against the provider; or (5) admitted in a professional disciplinary proceeding of a professional disciplinary body established as specifically authorized under State law.”<sup>16</sup>

The regulators stated they expected that the enforcement of this privilege would be by tribunals, agencies, or professional disciplinary bodies before which the information is sought and before whom the proceedings take place (which we will see below has happened). This is in contrast with the confidentiality provisions which prohibit the disclosure of patient safety work product and are enforced by the Office of Civil Rights of HHS. To make these overarching protections work, several definitions are critical.

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<sup>13</sup> 73 Federal Register 70779, November 21, 2008.

<sup>14</sup> 42 C.F.R. § 3.102.

<sup>15</sup> 73 Federal Register 70753, November 21, 2008.

<sup>16</sup> 42 U.S.C. § 299b-22

The prohibitions regarding disclosure are also broad. “Disclosure” means the release of, transfer of, provision of access to, or divulging in any other manner of, patient safety work product by an entity or natural person holding the patient safety work product to another legally separate entity or natural person, other than a workforce member of, or a physician holding privileges with, the entity holding the patient safety work product. The definition of the “patient safety work product,” which is protected, is information that is

“assembled or developed by a provider for the purpose of reporting to a PSO and is reported to a PSO. Second, patient safety work product is information developed by a PSO for the conduct of patient safety activities. Third, patient safety work product is information that constitutes the deliberations or analysis of, or identifies the fact of reporting pursuant to, a patient safety evaluation system.”<sup>17</sup>

The proposed regulations would not have protected data until it was submitted to a PSO. The final rule provides protection once it is documented that the information was collected for reporting to a PSO.<sup>18</sup> Once data is created in a patient safety evaluation system (PSES) even before it is submitted to a PSO, the confidentiality strictures are triggered. Once submitted, even if a provider wanted to release the information at a later date, it could not do so unless all providers identified in the data authorized its disclosure.<sup>19</sup> Before submission, a provider can remove data from its own PSES.

Patient safety work product does not include a patient’s original medical record, billing and discharge information, or any other original patient or provider record. The regulators have also distinguished between external reporting obligations, which continue and cannot be satisfied with patient safety work product. These include state incident reporting requirements, adverse drug event information reporting to the Food and Drug Administration, certification or licensing records for compliance with health oversight agency requirements, reporting to the National Practitioner Databank of Physician Disciplinary Actions, or complying with required disclosures by particular providers or suppliers pursuant to Medicare’s Conditions of Participation or Conditions of Coverage.<sup>20</sup> The rules also include the statutory provision that prohibits construing anything in the act from limiting (1) the discovery of or admissibility of information that is not patient safety work product in a criminal, civil, or administrative proceeding; (2) the reporting of information that is not patient safety work product to a Federal, State, or local governmental agency for public health surveillance, investigation or other public health purposes or health oversight purposes; or (3) a provider’s recordkeeping obligation with

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<sup>17</sup> 73 Federal Register 70739, November 21, 2008.

<sup>18</sup> 73 Federal Register 70741, November 21, 2008.

<sup>19</sup> 42 C.F.R. § 3.206(a)(3)

<sup>20</sup> 73 Federal Register 70740, November 21, 2008.

respect to information that is not patient safety work product under Federal, State, or local law.<sup>21</sup>

Disclosure of PSWP is permitted in criminal proceedings, but only after the court makes an in camera determination that the PSWP contains evidence of a criminal act, the PSWP is material to the proceeding and the PSWP is not reasonably available from any other source.<sup>22</sup> PSWP can be disclosed for specified research activities, to the FDA, and to law enforcement.<sup>23</sup> PSWP with specified identifiers removed may be disclosed to another PSO or provider or by a provider on a voluntary basis to an accrediting body.<sup>24</sup> The recipients may not further disclose the PSWP.

In order to invoke the protections, the data which is assembled or developed by a provider must be created within a “patient safety evaluation system” (PSES), which means the collection, management, or analysis of information for reporting to or by the PSO. It is not even required that the existence of the patient safety evaluation system be documented “because it exists whenever a provider engages in patient safety activities for the purpose of reporting to a PSO or a PSO engaged in these activities with respect to information for patient safety purposes.”<sup>25</sup> A patient safety evaluation system is unique and specific to a provider.

The breadth of the activities included as “patient safety activities” is extraordinary. The statute specifically establishes that it includes “any efforts to improve patient safety and the quality of health care delivery.”<sup>26</sup> That is virtually unlimited. As examples, the statute lists the following as “patient safety activities”: the collection and analysis of patient safety work product; the development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices; 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 risks; the maintenance of procedures to preserve confidentiality with respect to patient safety work product; the provision of appropriate security measures with respect to patient safety work product; the utilization of qualified staff and activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants that have patient safety evaluation systems.

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<sup>21</sup> 73 Federal Register 70742, November 21, 2008.

<sup>22</sup> 42 C.F.R. § 3.206(b)(1)

<sup>23</sup> 42 C.F.R. § 3.206(b)(6), (7) and (10)

<sup>24</sup> 42 C.F.R. § 3.206(b)(3)(iv) and (8)

<sup>25</sup> 73 Federal Register 70738, November 21, 2008.

<sup>26</sup> Emphasis added. 42 U.S.C. § 299b-21.

In its FAQs with regard to PSOs, AHRQ has outlined its perspective on why the terms “safety” and “quality” are used.

“The term “safety” refers to reducing risk from harm and injury, while the term “quality” suggests driving for excellence and value. By addressing common, preventable adverse events, a health care setting can become safer, thereby enhancing the quality of care delivery. PSOs create a secure environment where clinicians in health care organizations can collect, aggregate, and analyze data, thus identifying and reducing the risks and hazards associated with patient care and improving quality.”<sup>27</sup>

## \_\_2 Practicalities.

Besides PSOs themselves, the individuals and entities that can claim the protection of the PSO system are “providers,” “licensed or otherwise authorized under State law to provide health care services,”<sup>28</sup> which includes clinicians of all types, as well as facilities of many types, including hospitals, home health agencies, laboratories, or health centers. The definition goes on to extend the eligibility of the system to agents of tribal governments that deliver health care, organizations engaged as contractors by such governments to deliver health care, and individual health care practitioners employed by them, or a parent organization of one of the entities in the definition of providers.<sup>29</sup>

Interestingly, with regulations published in 2008, organizations such as Physician-Hospital Organizations (PHOs) or Individual Practice Associations (IPAs) are not addressed. Accountable Care Organizations (ACOs) were barely thought of, then. Nor do such networks meet the definition of a “provider” because typically they are not licensed or authorized under state law to deliver health care, which is a fundamental requirement, under the regulations, of being a provider. Presumably a health plan or HMO is not a provider either.<sup>30</sup> The disclosure of data between a provider and the PSO is protected. Similarly, a provider or PSO may disclose patient safety work product for patient safety activities to an entity with which it has contracted to undertake patient safety activities on its behalf. Additionally, disclosure of patient safety work product for patient safety activities may be made by a provider to an “affiliated provider.” Although there is no formal definition of an “affiliated provider,” “if all identified providers are in agreement regarding the need to share identifiable safety work product, each provider may authorize and thereby permit a disclosure.”<sup>31</sup> One would argue that the providers who are in an

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<sup>27</sup> <http://www.pso.ahrq.gov/psos/fastfacts.htm>

<sup>28</sup> 42 C.F.R. § 3.20

<sup>29</sup> 42 C.F.R. § 3.101.

<sup>30</sup> Although as we will see in section 3, Kaiser has invoked the protections of the law unsuccessfully, but the court did not address this issue.

<sup>31</sup> 72 Federal Register 70737, November 21, 2008.

ACO, an IPA, or a PHO would be affiliated with each other, and could share patient safety work product to conduct patient safety activities within the organization, especially if the PSES exists in that entity and not in its constituent participants. Arguably, these entities could also be considered contractors to the participants for patient safety activities and therefore disclosing to them and through them to the PSO would be permitted.<sup>32</sup>

The patient safety evaluation system, which collects the data to be reported to the PSO, is generally established on the basis of a written policy within the organization. The PSES is described as

“a protected space or system that is separate, distinct, and resides alongside, but does not replace, other information collection 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 the health care system.”<sup>33</sup>

The regulators have recommended that providers and PSOs consider documenting how information enters the patient safety evaluation system; what processes, activities, physical space, and equipment comprise or are used by the patient safety evaluation system; which personnel or categories of personnel need access to patient safety work product; the category of patient safety work product to which access is needed, and any applicable conditions; as well as what procedures the PSES uses to report information to a PSO or disseminate information outside of the PSES.<sup>34</sup> Although it is not mandated that the PSES itself be documented, the government asserts that “Documentation may provide substantial proof to support claims of privilege and confidentiality and will give notice to, will limit access to, will create awareness among employees of, the privileged and confidential nature of the information within a PSES, which may prevent unintended or impermissible disclosures.”<sup>35</sup> In the hospital setting, many of the operational governance committees which deal with quality and patient safety issues may well be included as part of the system, including operating room committees, medication safety committees, morbidity and mortality review committees, as well as specified committees of the medical staff.

In addition to adopting its own patient safety evaluation system, the provider seeking the protections of confidentiality and privilege has to have a contract with the PSO, which becomes a business associate of the provider. The patient safety activities of the provider and the PSO are considered part of the operations of the provider for HIPAA purposes.

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<sup>32</sup> 42 C.F.R. § 3.206(b)(4)(ii).

<sup>33</sup> Zimmer and Rebold, "The Physician Practice: Strategies for Reducing Risk and Improving Patient Safety", ECRI Institute, [https://www.ecri.org/EmailResources/PSRQ/Physician\\_Practice\\_Webinar.pdf](https://www.ecri.org/EmailResources/PSRQ/Physician_Practice_Webinar.pdf).

<sup>34</sup> 73 Federal Register 70738, November 21, 2008.

<sup>35</sup> Id.

One of the choices that has to be made is whether the provider will actively report collected information to the PSO or will engage in a “functional reporting system” that allows the PSO to access the data within the PSES without the need for the provider to physically transmit information to the PSO. The regulators specifically chose to allow great flexibility in this approach, which is not even addressed in the regulations but is discussed in the preface.<sup>36</sup>

### \_\_\_.3 Caselaw

There is some small body of caselaw relevant to the practicalities of the implementation of the protections available under the PSQIA. In *Shlagel v. Kaiser Foundation Health Plan*,<sup>37</sup> the Kaiser Health Plan was sued by a patient who was enrolled in the Kaiser Health Plan Kidney Transplant program, which was operational from June 2004 to May 2006, when it was closed. A range of state and federal organizations investigated, and the California Department of Managed Health Care fined Kaiser \$5 million for numerous violations of state law. The agency issued a report that made reference to documents generated by two Kaiser peer review committees, the Quality Utilization and Oversight Committee and the Quality Health Improvement Committee. The Center for Medicare and Medicaid Services (CMS) had cited Kaiser for violating 15 federal regulations governing the conduct of transplant centers. The plaintiff, suing in state court for breach of the duty of good faith and fair dealing, breach of contract, negligence, fraud, negligent misrepresentation, and intentional and negligent infliction of emotional distress, sought documents relating to the overall operation of Kaiser’s transplant program, including documents relating to any investigation and audits of the transplant center by Kaiser, the Department of Managed Health Care, CMS, and the United Network for Organ Sharing. The defendants asserted both a privilege under the California Evidence Code and that Congress created a broad peer review privilege when it enacted the PSQIA.

The court characterized the protections of the law as “a narrow peer review privilege for work product prepared by a patient safety organization or prepared for, and reported to, a patient safety organization.”<sup>38</sup> The court went on to say,

“It is apparent that the unique and narrow privilege created by the Patient Safety Act was not intended to apply to the materials requested by Plaintiff in discovery. There is no indication that the investigations conducted by Kaiser, UNOS, CMS, and DMHC were prepared for and reported to a patient safety organization. Rather, each of those investigations results from Kaiser’s decision to shut down its kidney transplant program. None of these entities themselves is a patient safety organization. Additionally, there is no indication that the “mission and

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<sup>36</sup> 73 Federal Register 70740-1, November 21, 2008.

<sup>37</sup> See CV 070520 MCE KJM (October 14, 2008).

<sup>38</sup> Id. at p 4.

primary activity” of any of the relevant entities concerns the goal of patient safety as defined by this statute.”<sup>39</sup>

The case stands for the proposition that to claim the privilege provided by the act, documents must reflect that they were created in the context of the PSES and were reported to a PSO. It also raises the implication that entities which would seek to function as contractors to providers for patient safety activities—IPAs, PHOs, ACOs—should adopt as one of their core missions the improvement of quality and safety.

In *KD ex rel. Dieffenbach, a minor, vs. United States of America*,<sup>40</sup> the court took a different view of the implications of the PSQIA. Here, the plaintiff was enrolled in a clinical trial at the National Institutes of Health and was harmed by his enrollment in the study at the National Heart, Lung & Blood Institute. Under the federal rules governing how the NIH operates, safety monitoring is required, and may be conducted by NIH staff or by a separate Data Safety Monitoring Board composed of clinical trial experts, biostatisticians, physicians, and others knowledgeable about the disease or treatment under study. The court observed that a privilege for medical peer review materials has not been recognized in the Second Circuit. “Despite this substantial authority, this court recognizes a qualified privilege for confidential evaluative materials produced by the NIH review process involved here based on the public policy evident in Maryland privilege law, the intent of Congress in passing the Patient Safety Quality Improvement Act of 2005, and the particular circumstances of this case.” Interestingly, the court distinguished between the Health Care Quality Improvement Act of 1986,<sup>41</sup> about which many courts have concluded that federal policy is hostile to a medical peer review privilege. Citing from *Nilvar v. Mercy Health System-Western Ohio*,<sup>42</sup> the court said 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.”<sup>43</sup> Going further, the court said that the HCQIA is no longer Congress’ final word on the issue of medical peer review, characterizing the PSQIA protections as “a more general approval of the medical peer review process and more sweeping evidentiary protections for material used therein.”<sup>44</sup> The court noted the Institute of Medicine Report “To Err Is Human” as the instigation for the PSQIA reflected in the fact that the PSQIA was designed to encourage a culture of safety by “providing for broad confidentiality and legal protections of information collected and reported voluntarily for the purposes of improving quality of medical care and patient safety.”<sup>45</sup> The court reviewed the NIH’s review process and

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<sup>39</sup> Id. at p 5.

<sup>40</sup> 715 F. Supp. 2d 587, (2010).

<sup>41</sup> 42 U.S.C. § 11101 at sec.

<sup>42</sup> 210 FRD 597, 602 (S.D. Ohio 2002).

<sup>43</sup> *KD v. USA* at p 9.

<sup>44</sup> Id. at p 9.

<sup>45</sup> Id. at p 10.

concluded that it “collects the same kind of safety data as enumerated in the PSQIA, within the same organizational structure, to accomplish the same goal (i.e. ensuring participant safety and effectiveness of care). The court is confident that protecting otherwise confidential and evaluative materials resulting from this process would not substantially offend the federal policy announced in the PSQIA.”<sup>46</sup> The court then further clarified that the privilege it was recognizing applied only to materials prepared with the expectation they would be kept confidential and not, in fact, disclosed. Therefore, records and materials for meetings and reviews held open to the public or which were later made publicly available were not protected under the court’s order.

In a third case upholding the broad privilege, the plaintiff was the Department of Financial and Professional Regulation in the State of Illinois, which was seeking to discipline some pharmacists who were employed by Walgreen. The Illinois Appellate Court upheld the dismissal of the agency’s petition to enforce administrative subpoenas served on Walgreen.<sup>47</sup> The three subpoenas requested “all incident reports of medication error” involving three named pharmacists. Walgreen asserted that whatever reports they had qualified for the privilege as patient safety work product. Walgreen had a policy that when a medication error occurs, its pharmacists are required to complete a report to its own “STARS” system (Strategic Tracking and Analytical Reporting System). This system, it asserted, was used to generate confidential and privileged quality improvement reports, known as STARS reports. Most significantly, each STARS report is transmitted to the Patient Safety Research Foundation, Inc., which is a federally certified patient safety organization. Witnesses testified that Walgreen had no other incident reports collected within the corporation. The state agency tried to produce evidence of other kinds of reports that were in the form of performance evaluations of pharmacists that had been made available in other cases, but the court focused on the subpoenas requesting “incident reports” for which there were no other reports that would be responsive.

Based on the limited caselaw to date, for protection to prevail, the obvious documentation of data as reviewed, evaluated, and considered part of a PSES as “Patient Safety Work Product” would seem a best practice.<sup>48</sup> Actually reporting to a PSO is also required.

#### 4.4 Physicians and Safety

By far the vast majority of information reported to PSOs is about hospital performance. Although reporting to a PSO is otherwise voluntary, the Affordable Care Act requires that hospitals with a high readmission rate and those of more than 50 beds who seek to

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<sup>46</sup> Id. at p 11.

<sup>47</sup> *Department of Financial and Professional Regulation v. Walgreen*, 2012 IL APP. (2d) 110452 (May 29, 2012).

<sup>48</sup> There is another case pending before the Kentucky Supreme Court, *Tibbs v. Bunnell*, No. 2012-CA-00916-OA (Aug. 16, 2012) in which the lower appellate court denied protection to hospital incident reports applying an old common law state standard. It appears to fly in the face of the broad preemption in the law.

provide care for a qualified health plan through the exchanges under health reform, report to a PSO.<sup>49</sup> Adverse events, sentinel events, never events, near misses, hospital acquired conditions, quality indicators, such as rates of infection, readmission, morbidity, and mortality, and root cause analyses are examples of safety issues that are suggested by various commentators for reporting. Risk management reports including incident reports, interview notes, and a variety of committee reports including safety, quality, medication, blood transfusions and the like have also been frequently identified as potential sources of data to maintain in a PSES and report to a PSO. AHRQ's common formats as of November 2013 addressed only hospitals and skilled nursing facilities. Most of the literature around PSOs is hospital-centric.

Yet the physician practice is increasingly recognized as a source of patient safety concerns. In prioritizing information which might be reported to a PSO, topics which implicate potential liability and discovery in litigation would be high on the list. In 2008, a review of the top ten risk management issues for medical office practices in California focused on a range of patient safety problems. Patient termination, missed appointments and test result follow-up were the first three cited.<sup>50</sup> Medication management, appropriate scope of practice of non-physicians and dealing with disruptive patients made the list.

In 2009, researchers found that in one of out of 14 tests performed on patients in a primary care outpatient setting, abnormal results were not communicated to the patient. Given the critical importance of diagnostic testing to make sure patients are getting the right care, communicating results would seem essential. Of the more than 5,400 medical records reviewed, failure rates varied widely among practices from 0%-26%. Most practices did not have explicit rules for notifying patients of results “and many used the dangerous practice of telling patients that no news is good news.”<sup>51</sup>

Much more is known about patient safety in the inpatient environment. As an example, from 2006 to 2011, the number of studies of patient safety funded by the Agency for Health Care Research and Quality on inpatient care has been almost tenfold that of outpatient studies.<sup>52</sup> In another study in 2011, the focus was on paid malpractice claims involving outpatient care where the most common types of adverse events in the outpatient setting were classified as diagnostic, treatment, and surgical. The researchers there noted as well the longstanding fact that most medical errors never become the

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<sup>49</sup> §399KK; § 1131(h)(1)(A)

<sup>50</sup> 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](http://www.thedoctors.com/KnowledgeCenter/PatientSafety/articles/CON_ID_001896)

<sup>51</sup> Casalino et al “Frequency of Failure to Inform Patients of Clinically Significant Outpatient Test Results,” 169 ARCH. Intern. Med. pp1123-1129; at p. 1127 (June 22, 2009).

<sup>52</sup> Bishop, Ryan and Casalino. “Paid Malpractice Claims for Adverse Events in Inpatient and Outpatient Settings,” 305 JAMA, pp. 2427-2431 (June 15, 2011).

subject of malpractice cases, so the volume of patient safety issues in outpatient care is considerably higher. In their commentary, the researchers suggest that more attention should be paid to adverse events related to diagnostic errors. In addition, improving patient safety, they believe, will likely be more difficult in the outpatient setting because of the diversity in those delivery environments.

ECRI Institute, which itself operates one of the first ten listed PSOs, and also serves as the back office for many others, has long been involved in patient safety assessments. In their guidance to physician practices, they emphasize several areas of attention to reduce liability risks.<sup>53</sup> Access to the practice, waiting times, and missed appointments are sources of dissatisfaction and potential opportunities for missed diagnoses. Communication with patients with particular attention to language and literacy barriers are cited as significant risk areas. Patient education regarding medication safety, particularly when patients are taking more than five drugs, can be important. Communication among providers, with particular attention to verbal or telephone orders, medical abbreviations, timely and accurate communication of test results, and standardized handoff communication were noted as well.

In recognition of the relative dearth of focus on physician practice as a source of patient adverse events, a number of tool kits and assessment tools have been made available. AHRQ itself has developed a toolkit for improving office testing processes, stemming from the fact that about 40% of patient encounters in primary care offices involve some form of medical test and are a significant source of error and patient harm.<sup>54</sup> The American College of Obstetrics and Gynecology has developed the SCOPE program (safety certification in outpatient practice excellence for women's health) which is designed to give office based practices the ability to improve their safety with standardized safety practices and techniques.<sup>55</sup>

The Medical Group Management Association (MGMA) with the Health Research and Educational Trust and the Institute for Safe Medication Practices has developed a Physician Practice Patient Safety Assessment Tool<sup>56</sup> which seeks to have practices submit their information for aggregation and analysis. Because the Institute for Safe Medication Practices is itself a PSO, if the practices develop their information within a PSES, the data would be protected if reported to the Institute or another PSO. The topics addressed in the assessment include medication practices, handoffs and transitions,

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<sup>53</sup> Zimmer and Rebold, "The Physician Practice: Strategies for Reducing Risk and Improving Patient Safety", ECRI Institute, [https://www.ecri.org/EmailResources/PSRQ/Physician\\_Practice\\_Webinar.pdf](https://www.ecri.org/EmailResources/PSRQ/Physician_Practice_Webinar.pdf). I would like to thank Ronni Solomon, Executive Vice President and General Counsel of ECRI Institute, for her time and insights in discussing my ideas around PSOs and physicians.

<sup>54</sup> <http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/ambulatory-care/office-testing-toolkit/>; <http://go.usa.gov/WZXH>

<sup>55</sup> <http://www.scopeforwomenshealth.org>

<sup>56</sup> <http://www.mgma.com/pppsa/>

surgery/anesthesia and sedation/invasive procedures, personnel qualifications and competency, practice management and culture in support of a culture of safety, and patient education and communication.

To provide guidance to physician practices in focusing on patient safety, the same groups that published the practice self-assessment developed resources called “Pathways to Patient Safety” which have three substantive modules of guidance. All provide links to other relevant resources. The first is oriented around working as a team within the practice, providing guidance with respect to improving communication technique and involving patients. There is a patient safety officer position description and examples of agendas for meetings within the group to address patient safety concerns. The second module, “Assessing Where You Stand,” goes beyond the self-assessment tool by providing elements of an effective practice culture as well as a process to enable a practice to plan and achieve improvements in patient safety. They offer examples of plans and goal documents and suggest projects, staff responsibilities, and directions. In addition, this module provides still additional tools, including a “Team Performance Observation Tool,” a framework for root cause analysis and action plan, a health literacy assessment tool to support better communication with patients, plus a Tracking Audit for Medication Safety tool, as well as A Laboratory Test Management Audit tool. Finally, the third module, “Creating Medication Safety,” focuses on medication reconciliation, and high alert medications. All are available at the Physician Practice Patient Safety Assessment website.<sup>57</sup> While all of the documents were created prior to the publication of the Patient Safety Organization regulations, they form the core of a physician-based patient safety evaluation system that could be linked to the PSO system.

#### 5.5 Clinical Integration and The PSES

Against the background of the considerable work which will be necessary to make outpatient physician care safer, the new values in the market mandate that physicians engage in real efforts at clinical integration, which for these purposes is defined as: “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.”<sup>58</sup> Bundled payment models and virtually all ACOs will require new approaches to care delivery to realize the effect of their financial incentives.<sup>59</sup> Because you cannot improve what you do not measure, across a broad array of behaviors, physicians will want to develop assessments of their current circumstances to determine what to change. The Physician Practice Patient Safety Self-Assessment was

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<sup>57</sup> [www.mgma.com/ppsa/](http://www.mgma.com/ppsa/)

<sup>58</sup> Gosfield and Reinertsen, *Achieving Clinical Integration with Highly Engaged Physicians*, (Nov. 2010) <http://uft-a.com/PDF/ACI-fnl-11-29.pdf>

<sup>59</sup> Gosfield, "Bundled Payments Require New Approaches to Clinical Integration", *Improving Incentives*, Vol 1, No, 4 (January 2102) <http://www.hci3.org/content/improving-incentives-newsletter-bundled-payments-require-new-approaches-clinical-integration>

specifically designed to be reported to a PSO. But there are other issues which could produce data that the physicians collecting it would not want to be public or discoverable.

In the Clinical Integration Self-Assessment Tool v 2.0<sup>60</sup>-- which can be used by physician groups, physicians employed by hospitals, the organized medical staff and facility-focused ACOs -- and the network version<sup>61</sup> for otherwise independent physicians to come together in a network for clinical integration, some of these types of data are implied. Some will be instigated by financial issues, because in making value a value of the organization, difficult financial choices will have to be made. When your business model turns far more on value driven payments (e.g. bundled payment, case rates, episode rates, gainsharing), it will be essential to track contemporaneous information regarding the extent of utilization of resources, which data must be made available to the participants for them to be conscious of their utilization patterns. Whether this information is made available by a plan or is generated within the physician group or network, it will not be protected if it is not developed within a PSES and reported to a PSO. If physicians within a group or network are compensated variably depending on their quality scores or performance<sup>62</sup> so as to more strongly incentivize change, that data might also be produced within a PSES to protect it. Imagine a plaintiff's attorney seeking to argue that his client was harmed because the group chose to pay physicians to not deliver a service and the attorney introduced in court the performance scores which generated the compensation.

Standardization is a strong theme of clinical integration. The use of clinical practice guidelines, pathways and protocols to standardize processes of care requires the selection of the pathways to follow, the measuring of performance in accordance with those pathways, analysis of the performance and change to improve further. The PSES is the perfect context within which to perform these critical functions which surely cry out for protection. When physicians share data about from whom they take referrals and to whom they give them, and make judgments about who they want their collaborating providers to be, how that selection is made and the judgments as to who is better can be highly sensitive and would be protected if made within the context of the PSES. Here the risks are not just with plaintiffs' attorneys, but practitioners about whom judgments have been made which affect their referrals and business. Still further, active engagement with those preferred referral sources and referred to providers through sharing data, guidelines, and agreements on the right clinical moment for referral would have no protection under law unless conducted within a PSES. For these purposes the entity conducting the analysis, whether a single group or a network, would have to be a contractor to the outside providers for purposes of conducting the PSES within which these engagements would occur.

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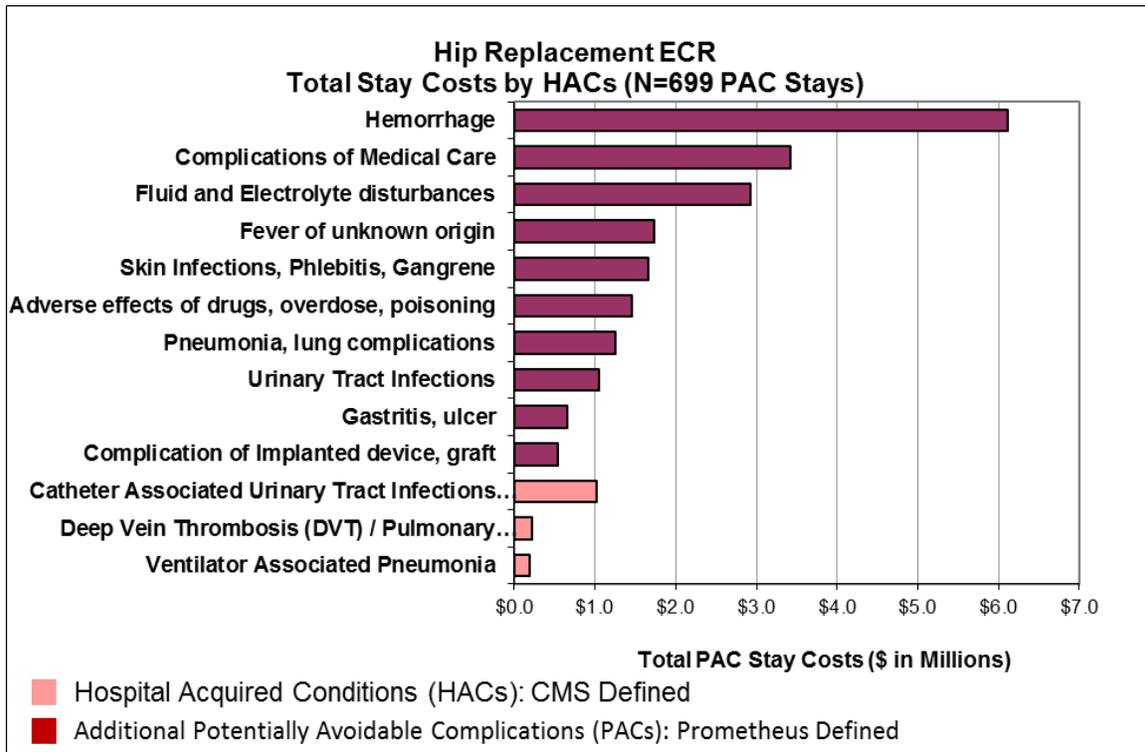
<sup>60</sup> Gosfield and Reinertsen, (2011) <http://www.uft-a.com/CISAT.pdf>

<sup>61</sup> Gosfield, [http://www.uft-a.com/PDF/CISAT\\_IPA\\_V.2.1.pdf](http://www.uft-a.com/PDF/CISAT_IPA_V.2.1.pdf)

<sup>62</sup> Gosfield, "Bolstering Change: Physician Compensation for Quality and Value", HEALTH LAW HANDBOOK (2012 Ed.) WestGroup, a Thomson Company, pp.59-85

In the PROMETHEUS Payment® model,<sup>63</sup> one of the most critical outputs of initial implementation is the identification of Potentially Avoidable Complications (PACs). These are not “never events,”<sup>64</sup> but as can be seen in the figure below represent far more types of less than optimal care than Medicare’s Hospital Acquired Conditions (HACs). These data come from an actual claims database of a large national commercial insurer.

### HACs vs. PACs (Hip Replacement)<sup>65</sup>



This information is vital to improve care and focus the attention of the providers participating in the program on action which will change those results, thereby permitting them to benefit financially, while improving clinical quality and safety. Unless this data is created as part of a PSES of the participants, it is utterly unprotected. In each implementation, the data comes from the health plan’s claims database and is specific to that plan. A health plan, though, is not a provider under the PSQIA definitions and may not itself be a PSO.<sup>66</sup> But the focus on PACs is precisely what a PSES of the participating

<sup>63</sup> [www.hci3.org](http://www.hci3.org)

<sup>64</sup> Smith, “Never Say Never (Events),” HEALTH LAW HANDBOOK (2009 ed.), WestGroup, a Thomson Company, pp 583-607.

<sup>65</sup> Obtained from Francois de Brantes, Executive Director, the Health Care Incentives Improvement Institute, Inc.

<sup>66</sup> 42 C.F.R. § 3.102(a)(2)(i)

providers ought to be doing, so if the PAC data flows into the providers as part of their PSES for reporting to a PSO, one would expect it to be protected.

There will undoubtedly be more ways in which using a PSES and reporting to a PSO might be deployed to further both the strategic and tactical goals of clinical integration, but thinking broadly and with forethought will be important. Once the data is submitted to the PSO, neither it nor any PSO analysis may be disclosed. Without careful attention to management of data, too much reporting could thwart the benefits of clinical integration. For example, imagine a multi-specialty group which works hard on making change. Through its patient safety activities and reporting to a PSO, the PSO generates a report that validates their success. They could not provide that report to a payor in negotiations for better rates. Rather, they would have to generate new data outside of their PSES if they wanted to use it in negotiations.

Some physicians might look at the use of a PSES to conduct these types of activities and consider it an unduly burdensome additional layer of administrative tasks when they are already overburdened by health plan demands, hospital demands, shrinking reimbursement, and the need to function more efficiently. But the work of clinical integration requires diligence and ingenuity and, if effective, will demand elucidation of subpar issues to be improved. As we have learned from caselaw, if the data is developed within a PSES for reporting to a PSO and is documented to have been so, it will be protected. If a PSO actually analyzes the data and compares it to other performers on the same issues, this will bolster the clinical integration of the reporting physicians by providing access to the expertise of the PSO as well as potentially the experience of clinicians far beyond the reporting group. The real value of many physicians reporting to a PSO is that the more who do it, the richer the analysis can be. Finding a compatible PSO and working out what types of reports are sought would help those physicians who are intrigued by the opportunity to learn from others on similar issues.

One might argue that the focus here on protecting data flies in the face of increasing transparency throughout health care. Hospitals post their quality scores on their websites. CMS publishes the effects of the value based purchasing modifier on hospitals.<sup>67</sup> As a result of a court order in 2013 lifting a prohibition which had been in place since 1979,<sup>68</sup> CMS is preparing to reveal the amount of Medicare payments<sup>69</sup> they make to individual physicians and has sought comments on how best to do that. The CMS' "Compare" websites offer quality data regarding hospitals<sup>70</sup>, physicians<sup>71</sup>, nursing homes<sup>72</sup>, home

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<sup>67</sup> Rau, "Medicare Discloses Hospitals' Bonuses, Penalties Based On Quality," *Kaiser Health News* (Dec 20, 2012) <http://www.kaiserhealthnews.org/stories/2012/december/21/medicare-hospitals-value-based-purchasing.aspx>

<sup>68</sup> Florida Medical Ass'n, Inc. v. Department of Health, Educ., & Welfare, 2013 WL 2382270 (M.D.Fla. May 31, 2013).

<sup>69</sup> <http://downloads.cms.gov/files/Request-for-Public-Comment-rePhysician-Data-8-6-2013.pdf>

<sup>70</sup> <http://www.medicare.gov/hospitalcompare/search.html>

health agencies<sup>73</sup> and dialysis facilities.<sup>74</sup> Going back to my 2000 tort reform proposal, today there is an even higher need for good performance information about quality and value about physicians and other providers. In today's world with high deductible health plans, patients bear the burden, both financial and clinical, of choosing among providers in their health plan networks. While government and commercial healthcare report cards are variable in terms of their utility, reliability and depth, if providers are given the protections of the PSQIA to improve safety and quality of care, they also have a moral obligation to facilitate published information about their performance. The best way to do that would not be in self serving press releases, but to a trusted third party which utilizes credible measures that fix accountability for care at the locus of control.<sup>75</sup>

While for hospitals, the Leapfrog Group<sup>76</sup> and the Joint Commission<sup>77</sup> do this, for physicians the options are fewer. NCQA publishes lists of recognized physicians in patient centered medical homes and more.<sup>78</sup> But despite the proliferation of report cards which rate physicians, there are many questions about their reliability and comparability.<sup>79</sup> It is time for physicians to step up, call for and support better, more robust public reporting about their performance.

## \_\_\_6 Conclusion

There is no question that for physicians to succeed in the new environment they will have to improve the safety, quality and value of the services they deliver. To do that will require them to engage in intense self-inquiry -- with diligence and ingenuity -- for which the law now offers protections. To clinically integrate in meaningful ways will change much of what they do, for the better. For those who have been fearful of how their inquiries might be used against them, those fears should be abated. But more importantly

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<sup>71</sup> <http://www.medicare.gov/physiciancompare/>

<sup>72</sup> <http://www.medicare.gov/nursinghomecompare/search.html>

<sup>73</sup> <http://www.medicare.gov/homehealthcompare/search.html>

<sup>74</sup> <http://www.medicare.gov/DialysisFacilityCompare/search.html>

<sup>75</sup> This is one of the five precepts of the unified field theory applied website that I have offered since 2003 with James L Reinertsen, MD. (www.uft-a.com). The others, which come from our paper "Doing Well By Doing Good" ([http://www.uft-a.com/PDF/uft-a\\_White\\_Paper\\_060103.PDF](http://www.uft-a.com/PDF/uft-a_White_Paper_060103.PDF)) are (1) standardize to the science as much as possible; (2) simplify the system and processes to give time back, particularly to physicians; (3) make administrative processes as clinically relevant as possible, beginning with a clinically relevant payment model; and (4) engage the patient around the science and the processes of care.

<sup>76</sup> [www.leapfroggroup.com](http://www.leapfroggroup.com)

<sup>77</sup> [www.jointcommission.org/annualreports.aspx](http://www.jointcommission.org/annualreports.aspx)

<sup>78</sup> <http://recognition.ncqa.org>

<sup>79</sup> Sinaiko, Eastman and Rosenthal, "How Report Cards on Physicians, Physician Groups and Hospitals Can Have Greater Impact on Consumer Choices," Health Affairs pp 602-611 (2012).

if physicians become more proactive and ask compatible PSOs for assistance in doing this work, small physician entities may be able to benefit from larger volumes of information informing the PSOs which inform the reporting physicians. There are some points where creativity will be necessary in structuring provider-PSO arrangements involving new types of networks, but this is a significant opportunity physicians should enthusiastically embrace.