

Patient Safety Organizations and Transparency:

Working Together to Improve Patient Safety



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SUMMARY

The Institute of Medicine's (IOM) landmark report, *To Err is Human*,¹ estimated that 98,000 deaths occur annually due to medical errors in the United States. This report generated a renewed national interest in adverse events in health care. Transparency, the free, uninhibited sharing of information, is fundamental to reversing this trend and achieving meaningful health care quality and patient safety improvements.² Yet, factors such as fear of litigation or adverse professional consequences, embarrassment, misinterpretation of what constitutes harm, disbelief that reporting will lead to improvement, and time required to report hinder transparency efforts.³ Recognizing that medical errors are usually the result of system errors rather than individual carelessness, public reporting of quality data, root cause analyses, mortality morbidity review processes, and Patient Safety Organizations (PSOs) have emerged as mechanisms to support information sharing and replace the culture of blaming health care professionals with an organizational culture of safety.⁴

In response to the IOM report and concern about growing malpractice costs, a sixteen member Missouri Commission on Patient Safety was appointed in 2003 to study the issue and recommend actions to improve patient safety and prevent medical errors in Missouri.⁵ The Commission determined that patient safety activities were fragmented, conducted in isolation, and could not provide an accurate picture of adverse events in the state. Given the lack of a focal point to coordinate patient safety work, the Commission recommended the creation of a private Missouri Center for Patient Safety (the Center) to provide leadership for patient safety improvements including serving as a federally designated Patient Safety Organization (PSO), should proposed federal legislation to establish PSOs be signed into law.⁶ This action positioned Missouri at the forefront of the patient safety movement in developing a coordinated system to perform patient safety activities and disseminate learnings. The Center opened in 2005, and in 2008 became one of the first ten entities in the country to meet requirements for federal listing as a PSO.

This paper provides a brief overview of the legal protections available to health care providers that participate in a PSO, discusses the PSO framework as it relates to transparency efforts, and describes how the PSO protections can work synergistically with other reporting mechanisms, including transparency efforts, to achieve safety and quality improvements.



1 Kohn, LT, Corrigan, JM, & Donaldson, MS (eds.) *To Err is Human: Building a Safer Health System*. (Washington, DC: National Academies Press, 2000).

2 Leape, L, Berwick, D, Clancy, C, et al. *Transforming Healthcare: A Safety Imperative*. *Quality and Safety in Health Care*, 18, 424-428.

3 Leape, LL. (2002). Reporting of adverse events. *NEJM*, 347, 1633-1639. See also Stewart, RM, Cornielle, MG, & Johnston, J, et al. (2006). Transparent and open discussion of errors does not increase malpractice risk in trauma patients. *Annals of Surgery*, 243(5), 645-651; and Levinson, DR. (2012). Hospital incident reporting systems do not capture most patient harm, OIE-06-09-00091. USDHHS: Washington, DC.

4 Alper, EJ, & Wachter, RM. (2011). Commentary: Medical Malpractice and Patient Safety: Tear Down that Wall! *Academic Medicine*, 86(3), 282-284.

5 Missouri Commission on Patient Safety. (July, 2004). *Missouri Commission on Patient Safety Report. Executive Summary, i*.

6 *Id.* at 8.

Putting the PSO Protections into Perspective

The Patient Safety and Quality Improvement Act of 2005 (the “Act”)⁷ and its implementing regulations (“Final Rule”)⁸ established the framework for creation of PSOs. The PSO is an entity where health care providers may voluntarily report information regarding adverse events, medical errors, near misses, and other patient safety activities, on a privileged and confidential basis in order to learn from such events to improve health care quality and safety.⁹ In order to trigger the statutory privilege and confidentiality protections, health care providers and PSOs must define, manage, and maintain patient safety related information according to specific statutory and regulatory requirements. Information that qualifies as Patient Safety Work Product (“PSWP”), with limited exceptions, is not subject to subpoena, discovery or admission into evidence in federal, state or local civil, criminal, or administrative proceedings, including disciplinary proceedings against a Provider.

While health care providers generally accept the need for review of adverse events, the peer review process allows for only closed discussion between legislatively defined professionals, excluding many professionals that should be involved in evaluation of adverse events, and focuses only on individual professional’s performance, in lieu of evaluation and correction of system flaws.¹⁰ Internal transparency achieved through broader provider¹¹ patient safety and quality efforts promotes trust, collaboration, and credibility within an organization. External transparency, achieved through sharing data related to patient safety events with the larger community, further advances patient safety efforts by leveraging a wide range of patient safety information to inform generalizable system improvements.¹²

The legal protections afforded to appropriately defined PSWP are intended to support external transparency by

creating a blame free environment where medical errors and near misses can be constructively discussed in order to drive quality and safety improvements. The protections are not intended to limit public reporting or disclosure of pertinent patient safety events to patients or families. Rather, the statute supports external transparency by providing PSO participants with a pathway to meet reporting and disclosure policies, while maintaining a safe environment in which to better identify error causes and prevention strategies.¹³

Putting Transparency into Perspective

Although quantifiable quality and safety reports are important tools in motivating providers to improve quality of care and supporting patients in making health care decisions, they do not provide the complete story as to why errors occur or how to prevent the next event.^{14,15} The inconsistencies in the scope and measurement of collected data, as well as variations in the availability, credibility, applicability, and

functionality of current reporting mechanisms, limit both the provider’s and consumer’s ability to use safety and quality reports in a meaningful way. For example, CMS Hospital Compare data is available in all geographic areas, but it is limited to specific conditions, and has been found to have only a minimal impact on patient mortality or shifting patients toward higher quality hospitals.¹⁶ Measurement criteria applied to claims data varies by payer and results are usually only

available to members of the particular payer group. Consumers often disregard disease specific clinical quality indicators if they do not have the condition referenced. Quality of care reports for physicians tend to provide physician group level data targeting primary care providers, not specialists.¹⁷

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7 42 USC §§ 299b et seq (2005).

8 42 CFR, Part 3 (2008).

9 42 CFR, Part 3 (2008).

10 RsMO § 537.035 (2005).

11 The Act and Final Rule define a “Provider” as an “individual or entity licensed or otherwise authorized under State law to provide health care services. See 42 CFR § 3.20 (2008).

12 See Stewart et al, supra note3.

13 42 USC §299b-21(7)(b)(iii), and 42 USC §299b-22(c)(d)(2008).

14 Christianson, JB, Volmar, KM, Alexander, J, & Scanlon, DP. (2010). A report card on provider report cards: Current status of the health care transparency movement. *Journal of General Internal Medicine*, 25(11), 1235-41.

15 See Leape, et al., supra note 2.

16 Ryan, AM, Nalamothu, BK, & Dimick, JB. (2012). Medicare’s public reporting initiative on hospital quality had modest or no impact on morality from three key conditions. *Health Affairs*, 31(3), 585-592.

17 See Christianson, et al., supra note 14.

Under some reporting schemes, process of care measures allow for discretionary exclusions based on the medical team's decisions to deviate from a recommended treatment. As a result, metrics comparing quality across institutions do not reflect the care provided to large groups of patients whose inclusion or discretionary exclusion is invisible to the public.¹⁸ Variations in interpretation of surveillance definitions and discrepancies in surveillance practices further complicate inter-institutional comparisons of publicly reported data.¹⁹ Additionally, evidence

highest risk patients.²¹ Reports that present cost data alongside easy to interpret quality data can improve the likelihood that consumers will choose the higher-value health care option.²²

This considerable variation across measures, reports, formats and availability poses a serious challenge to achieving the goals of driving provider improvement through competition and consumer choice through information. While public reporting and the tying of financial incentives to patient safety and quality

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suggests that measurable hospital characteristics, such as proportion of Medicaid patients or nurse-census ratios may be influenced by underlying factors that are not well understood by the public. For instance, one large study of Medicare fee-for-service patient outcomes found that hospitals that disproportionately care for African-American patients had higher rates of potential safety events regardless of patient ethnicity, even when adjusted for baseline differences in proportion of Medicaid patients and nurse-patient ratios.²⁰

Finally, consumer interpretation of public and private patient safety reports can be limited by misinterpretation of risk-adjusted data and influenced by reporting format. In one study of the effectiveness of four different data display formats, respondents with lower educational levels were less likely to interpret the tables correctly. Here, poorly constructed displays led to misinterpretation of available information, with potential unintended adverse consequences. One display method led participants to more often choose the surgeon with the lowest risk population who had the highest risk-adjusted mortality over one with the lowest risk-adjusted mortality who cared for the

metrics are powerful motivators for improvement, gaps in the information can unfairly penalize providers and discourage patient access to appropriate care without conveying useful information for improvement and informed decision-making. However, the protected space of the PSO allows for blame free deliberations and analyses that reveal the underlying contributors to the patient safety event. Combining the publicly reported data related to isolated and provider specific metrics with PSO learning creates the potential for even greater systemic improvements. The aggregated PSO reports can also help to inform consumers' understanding of the myriad of report cards currently available from both public and private sources.

Creating Synergy between Transparency and PSO Protections

In order to achieve significant safety and quality improvements, information must be readily shared among caregivers, with patients, and between organizations. The hierarchical nature of health care and a punitive culture pose significant barriers to obtaining such data. Reporting of patient safety events within a PSO environment provides a mechanism for robust learning from patient safety data while maintaining legal privilege and confidentiality protections for providers, yet allowing consumers legal recourse for obvious provider negligence. However, the statutory and regulatory requirements related to identifying, maintaining and reporting PSWP for PSO purposes creates some tension with transparency

18 Bernheim, SM, Wang, Y, & Bradley, EH, et al. (2010). Who is missing from the measures? Trends in the proportion and treatment of patients potentially excluded from publicly reported quality measures. *American Heart Journal*, 106, 943-950.

19 Lin, MY, Hota, B, & Khan, YM, et al. (2010). Quality of traditional surveillance for public reporting of nosocomial bloodstream infection rates. *JAMA*, 304(18), 2035-2041.

20 Ly, DP, Lopez, L, Isaac, T & Jha, AK. (2010). How do black-serving hospitals perform on patient safety indicators? Implications for national public reporting and pay-for-performance. *Medical Care*, 48(12), 1133-1137.

21 Donelan, K, Rogers, R, & Eisenhauer, A. (2011). Consumer comprehension of surgeon performance data for coronary bypass procedures. *Annals of Thoracic Surgery*, 91, 1400-1406.

22 Hibbard, JH, Greene, J, Sofaer, S, Firminger, K, & Hirsch, J. (2012). An experiment shows that a well-designed report on costs and quality can help consumers choose high-value health care. *Health Affairs*, 31(3), 560-568.

efforts seeking to identify and compare specific health care providers.

In addition to broad legal protections, identifiable PSWP is confidential and cannot be disclosed, except in very specific circumstances. Identifiable PSWP is that information which allows for identification of any providers that are the subject of the work product, or who have participated in or are responsible for activities that are part of the work product.²³ However, nonidentifiable PSWP, that which is anonymized as to provider, deidentified as to protected health information, and contextually deidentified so that the provider, patient or reporter cannot be identified, may be disclosed.²⁴ This means that, while PSOs and their participants are prohibited from disclosing identifiable PSWP, the PSO may issue aggregated reports.

The PSO legal protections do not attach simply because information is designated as PSWP or reported to a PSO. Only that information which meets the statutory and regulatory standards for PSWP can obtain the PSO protections. Further, the confidentiality and privilege protections do not limit the provider's mandatory recordkeeping and reporting obligations.²⁵ As a result, providers who participate in a PSO are motivated to carefully consider how information regarding patient safety and quality is identified and used within their respective setting.

To make information more meaningful to providers and consumers, PSO activities can supplement publicly reported data with additional layers of information from multiple sources. Publicly reported data linked to a specific provider is generally quantifiable. The PSO aggregated reports supplement the publicly reported data with learning distilled from a number of similar incidents and across a number of providers. Further, PSO data collection is based on the Agency for Healthcare Research and Quality (AHRQ) Common Data Format event reporting tools, recommended by the Office of the Inspector General as one mechanism for standardizing and improving incident reporting by hospitals.²⁶ The synergistic effect of pairing quantifiable reported data with PSO learning sets the stage for changing clinical practice through robust collection and analysis of data, dissemination of best

practice recommendations, and development of process knowledge to support implementation of evidence-based recommendations in practice.²⁷ The “seven pillars” transparency model²⁸, highlighted in attachment A, is gaining attention as one model that illustrates the synergy between transparency and PSO reporting.

Conclusion

To a health care provider, one adverse event is cause for introspection and investigation in order to prevent a future similar occurrence. One adverse event is enough to incite action, not waiting until data is collected over time or determined to be statistically significant. Understanding factors that contribute to a near miss and access to information about rare events that other providers experience can help providers decrease the risk of harm to their patients and community. To inform health care decisions, providers and patients need timely, consistent, meaningful, evidence-based information that tells the story behind the numbers. The disclosure process, whether it consists of internal responses to patients harmed by patient safety incidents or publicly reported data, requires careful analysis that leads to fact-based conclusions. This can only be

accomplished through robust reporting and the opportunity to analyze available data in a blame free environment that allows for sharing of health care system vulnerabilities. Rather than limiting transparency in reporting safety and quality

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information, PSO participation provides a platform to analyze both publicly and confidentially reported data to determine the underlying causes of patient safety events and inform meaningful action. The aggregated learnings, based on data provided by a broad range of PSO participants, results in a greater array of improvement recommendations than one provider alone can accomplish when analyzing an isolated event. Finally, only through a PSO and its support of a

23 42 USC § 299b-22; 42 CFR § 3.20.

24 42 CFR § 3.206(5).

25 42 USC § 299b-21(7)(B)(3).

26 See Levinson, *supra* note 3.

27 Saint, S, Olmstead, RN, & Fakh, MG, et al. (2009). Translating health care associated urinary tract infection prevention research into practice via the bladder bundle. *Joint Commission Journal of Quality and Patient Safety*, 35(9), 449-455.

28 McDonald, TB, Helmchen, LA, & Smith, K. (2010). Responding to patient safety incidents: the “seven pillars”. *Quality and Safety in Health Care*, 19:e11. Doi:10.1136qshc.2008.031633. Available at: <http://qualitysafety.bmj.com/content/19/6/1.31.full.pdf> (Accessed Sept. 20, 2011).

culture promoting broad-based reporting of errors and health system vulnerabilities, do health care providers and the public have the greatest opportunity to learn, understand, and take decisive action to prevent medical errors and patient harm. Wouldn't it be better if we knew the risk of medical errors occurring and took timely action to prevent the error, rather than collecting statistics on the number of errors over time with no

identification of the cause of the error, and sharing of learning and prevention strategies across providers and to the public? Learning, sharing and prevention – that is the work of Patient Safety Organizations – working in synergy with transparency efforts.

ATTACHMENT A: Application of the “Seven Pillars” Transparency Model to PSO Participation

The University Of Illinois Medical Center at Chicago’s (UIMCC) “seven pillars” process for disclosure of patient safety events to patients who have been harmed is gaining traction as a model for transparency.²⁹ This model has the potential for application within the PSO framework both within the provider setting and at the PSO level. The following table proposes application of the “seven pillars” model in creating synergy among protected and publicly reported patient safety activities.³⁰

“Seven Pillars” concept ³¹	Health Care Provider	PSO	Outcome
Reporting	Provider defines internal reporting streams per policy: <ul style="list-style-type: none"> Identifies which information is defined and maintained as PSWP (receives PSO related protections). Identifies which information does not meet definition of PSWP, or is needed for other reporting purposes.³² Complies with regulatory or public reporting requirements per policy or regulation. 	<ul style="list-style-type: none"> Information identified as PSWP is reported to PSO. A “copy” of non-PSWP may be submitted to the PSO for data collection purposes. All information submitted to the PSO is deemed to be PSWP in the PSO’s hands and may not be disclosed by the PSO.³³ 	<ul style="list-style-type: none"> Act of internal reporting triggers internal patient safety, quality and other investigative activities. Event-specific information reported to the PSO is added to reports of similar medical errors, near misses and unsafe conditions from other providers and included in aggregated analysis to inform system improvements. Act of reporting to the PSO allows for protected analyses of provider level data and aggregation of data to inform the larger community.
Investigation	<ul style="list-style-type: none"> Provider defines, per policy, internal investigation activities and processes. Investigation that occurs within the provider PSES³⁴ is considered PSWP and falls within the PSQIA confidentiality and privilege protections. This includes information collected outside of the PSES as PSWP, as well as deliberations and analyses that occur within the PSES.³⁵ 	<ul style="list-style-type: none"> PSWP collected within the PSES, and deliberations and analyses occurring within the PSES during the investigation, is reported to the PSO as PSWP. “Copies” of information that does not meet the PSWP requirements or that which is defined by the provider as non-PSWP collected during the investigation may be submitted to the PSO for patient safety purposes. 	<ul style="list-style-type: none"> Conduct of investigation within or outside of the PSES is determined on a case by case basis by the provider. Internal investigation strategy is designed to meet the needs of the patient, provider, and purpose of the investigative activity. Information gathered during the investigation, whether PSWP or non-PSWP, when submitted to the PSO is

29 See McDonald, et al., supra note 26.

30 The “Seven Pillars” concept provides one model for transparency processes. This Addendum is intended to provide an example only of how transparency concepts can work synergistically with PSO concepts. The use of this model in this addendum does not imply Missouri Center for Patient endorsement of this or any transparency model.

31 Id.

32 42 USC §299b-21(7)(2009); 42 CFR §3.20 & §3.206. See also 73 Fed. Reg. 70741-70742.

33 42 Fed. Reg. 70743.

34 PSES refers to the Patient Safety Evaluation System. The PSES is the mechanism by which a provider or PSO may collect, maintain analyze and communicate information for reporting to or by a PSO. The PSES is defined by the provider. 42 USC 299b-21(6); 42 CFR §3.20.

35 42 USC 299b-22; 73 Fed. Reg. 70741; 42 CFR §3.20.

	<ul style="list-style-type: none"> Investigations may take place for varying purposes, such as within a Peer Review committee; for risk management, claims or other such committees; or for human resource purposes. 	<ul style="list-style-type: none"> All information submitted to the PSO is deemed to be PSWP in the PSO’s hands and may not be disclosed by the PSO.³³ 	<p>available for aggregated analyses and reporting to inform the broader community regarding risk factors and potential solutions to patient safety events.</p>
Communication/ Disclosure	<ul style="list-style-type: none"> Process for disclosure to patients is defined per provider policy. Case facts available from non-PSWP sources, including the patient’s medical record, billing and discharge information, or other original patient or provider records may be disclosed. Information about action taken to address the issue and preventive measures may be shared. Deliberations and analyses occurring within the PSES may not be disclosed. Disclosure of defined PSWP is limited.³⁶ 	<ul style="list-style-type: none"> All information submitted to the PSO is deemed to be PSWP in the PSO’s hands and may not be disclosed by the PSO.³³ Items defined within the statute or by the providers as non-PSWP, which may include disclosure provided to the patient, can be submitted to the PSO as a “copy” to inform patient safety activities. PSO recommendations are PSWP, therefore are privileged and confidential. The recommendations can only be disclosed through applicable disclosure permission.³⁷ Actions taken to make improvements based on PSO recommendations are not PSWP and may be disclosed.³⁸ 	<ul style="list-style-type: none"> PSWP may only be disclosed through applicable disclosure permission, as defined in the Act and Final Rule. Individuals receiving PSWP may not further disclose the information. It is important that providers maintain policies that clearly define PSWP and its use within the context of patient and family communications.³⁹
Apology/ Remediation	<ul style="list-style-type: none"> Processes guiding apology and remediation are defined per provider policy. Provider makes internal decisions related to apology and remediation on a case-by-case basis. 	<ul style="list-style-type: none"> Documentation and information about the apology may be provided to the PSO, most likely as a “copy” since the information involved the disclosure process with the patient/family; therefore, cannot be protected as PSWP. 	<ul style="list-style-type: none"> Remediation activities may be performed as part of claims, risk or quality processes within the organization per policy, and may or may not be defined as PSWP as determined by the facility. PSO learnings from information reported pertaining to remediation activities and data collected from multiple participants inform PSO recommendations.
System Improvement	<ul style="list-style-type: none"> Internal investigation findings identify and guide system improvements. 	<ul style="list-style-type: none"> PSO reporting informs learning about actions that can lead to improvement 	<ul style="list-style-type: none"> Knowledge is gained from a broad range of providers about types of events,

³⁶ *Id.*

³⁷ 73 Fed. Reg. 70779.

³⁸ *Id.*

³⁹ 42 USC §299b-22(c)(1)(C); 42 CFR §.

		<p>and prevention of medical errors across numerous providers.</p> <ul style="list-style-type: none"> • Reporting rare, serious events to a PSO allows for analysis and learning across numerous providers not otherwise possible for such rarely occurring events within one or few facilities. • The provider may choose to implement any or all PSO recommendations. PSO recommendations are not mandatory, nor are they to be considered standard of care.³⁷ 	<p>system vulnerabilities, common causes, and prevention strategies.</p> <ul style="list-style-type: none"> • Exponential improvements are possible as a result of broad-based learning across numerous providers working within the full continuum of care. These learnings inform safety priorities, system improvement needs, and prevention strategies. • PSO learnings are broadly published to facilitate further system improvements.
Data Tracking/ Evaluation	<ul style="list-style-type: none"> • Data collected during the investigation is used for internal quality assurance, risk management, research, outreach and dissemination to appropriate parties per provider policy. 	<ul style="list-style-type: none"> • The PSO aggregates and analyzes submitted data and information. • Both PSWP and “copies” of non-PSWP reported as a result of data tracking and evaluation are treated as PSWP in the hands of the PSO. 	<ul style="list-style-type: none"> • Both PSWP and “copies” of non-PSWP submitted to the PSO are aggregated and analyzed to inform broader patient safety activities across providers. • Providers use their specific data/evaluation for internal purposes.
Education/ Training	<ul style="list-style-type: none"> • Provider establishes continuing education requirements and activities related to patient safety activities. 	<p>Required PSO patient safety activities include:</p> <ul style="list-style-type: none"> • Dissemination of information with respect to improving patient safety. This may include recommendations, protocols, and best practices. • Aggregated learnings from PSWP are used to encourage a culture of safety and provide feedback and assistance to reduce the risk of patient harm. 	<ul style="list-style-type: none"> • The PSO is prohibited from disseminating provider specific PSWP, including provider specific learning and recommendations. • Aggregated, non-identifiable PSWP may be disseminated in order to share learning and safety improvement strategies with providers and consumers.⁴⁰

⁴⁰ USC §299b-22.