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The keys to more effective internal investigations

an interview with Marita Janiga

Executive Director of Investigations
National Compliance, Ethics & Integrity Office
Kaiser Permanente

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by Peggy Binzer, JD and Terri Karsten, JD

The Patient Safety Evaluation System: Building an even safer healthcare system

» Discover the benefits of an effective Patient Safety Evaluation System (PSES).
» Learn how to meet the requirements of section 1311(h) of the Affordable Care Act.
» Create a learning system to prevent the same mistakes from being repeated by other healthcare professionals.
» Learn to use a PSES with integrated care models and new quality performance data tools.
» Use a PSES to create high-reliability in healthcare.

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The Patient Protection and Affordable Care Act (ACA), signed into law in March 2010, has increased attention on quality, efficiency, and value in healthcare delivery. The Centers for Medicare & Medicaid Services' (CMS's) recent final rule implementing section 1311(h) of the ACA requires, among other proposed options, that hospitals with more than 50 beds contracting with a qualified health plan must have a Patient Safety Evaluation System (PSES) by 2017 in order to qualify as a provider for health plans participating in a health insurance exchange.[1] The PSES was established by The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act),[2] in response to the Institute of Medicine report, *To Err is Human*,[3] which ignited widespread discussion about how to prevent medical errors from occurring.

By providing privilege and confidentiality protections for providers who work with federally listed Patient Safety Organizations (PSOs), the Patient Safety Act has become the cornerstone of the federal effort to reduce preventable injuries and deaths in the United States' healthcare system. In passing the legislation, Congress intended to improve the quality of patient care by creating a "culture of safety" through a non-punitive, confidential, voluntary reporting system, and to ensure accountability by raising standards for continuous improvements in healthcare.[4] Creating a PSES provides a great opportunity for hospitals, because it is the only program that permits healthcare providers to evaluate patient care throughout the healthcare continuum without fear of litigation or harm to professional reputation.


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Many healthcare providers and organizations practice in silos, without meaningful connections and information exchange with other healthcare entities to develop peer benchmarking and best practices. The Patient Safety Act breaks the silos and provides necessary confidentiality and privilege protections that permit the sharing of quality data and lessons

learned, which may not otherwise be developed to positively influence the behavior and decisions of the providers for the benefit of patients. The PSES can be used as a tool to help maximize integration and patient care. This article is designed to provide insight into how a provider and PSO use a PSES to improve the quality of care in every healthcare organization across the nation, including new models of care delivery and new performance tools.

Maximizing the quality of patient care

A PSES under the Patient Safety Act is the process a hospital uses to collect, analyze, manage, and maintain information for reporting to or by a PSO.[5] The PSES allows providers to methodically evaluate systems and processes to determine what actually caused the systems to fail and prevent the reoccurrence of the failure without fear of discovery of the information and liability in criminal, civil, administrative, or disciplinary proceedings or harm to professional reputation. The confidentiality protections are intended to encourage greater participation of providers to investigate how they are providing patient care and how they can do a better job without fear of litigation or harm to professional reputation. Many quality programs look only at the what, whereas a PSO can help healthcare professionals figure out the how, in a safety culture that reinforces professionalism and learning, to the benefit of patients. Greater participation of providers throughout the healthcare continuum will allow providers to identify, address, and prevent adverse events from recurrence, thereby improving patient safety overall. The PSES also permits the further sharing of quality information among all the facilities within a health system or with unaffiliated providers who are also members of the PSO. The protections encourage candid dialog among all providers, which permits the exposure of underlying causes that may not be evident in an incident report or are sometimes missed in a root-cause analysis that focuses on one facility rather than the entire system.

The Patient Safety Act was intended to overcome the fear of analyzing incidents and sharing learnings caused by the erosion of state peer review laws, and instead create a national system of sharing and learning with the goal of improving the quality and safety of patient care among all licensed providers and across the continuum of care through a safety culture. The protections also encourage the creation of a learning system for medical providers to report errors and "near-misses" to a PSO, allowing such reports and learnings to be shared among healthcare entities under the protections of the PSES. The goal is to prevent the same medical error from occurring over and over again in organizations across the nation.

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The provider community that works with PSOs focuses on providing consistency in quality and implementing innovative patient safety programs, including care coordination and evaluating systems gaps throughout the continuum of care (e.g., EMS, primary care, ambulatory care, pharmacy, inpatient care, rehabilitation, post-acute care, long-term care, and home healthcare). It follows that the creation of a learning environment is critical to fostering the development and continual

quality improvement of evidenced-based clinical guidelines and high reliability in the quality of patient care.[6]

Through a uniform and national privilege and statutory confidentiality protections, innovative programs (e.g., safe tables and peer review in primary care), developed by healthcare providers and PSOs, can promote transformational change in the quality of healthcare provided to patients.

Integrated care models and new quality/performance data tools

Most state peer review statutes did not contemplate new healthcare models, such as clinically integrated networks, that evaluate a physician's performance by assessing clinical quality and value. Such models necessarily require the sharing of clinical quality documents, such as physician scorecards, outside of the four walls of the provider's facility. State legislatures also did not foresee big data drawn from many providers or health systems to develop dashboards, benchmarking, and predictive statistical analysis. This data is used to drive performance improvement across the healthcare continuum.

In contrast, the Patient Safety Act was designed "to accelerate the development of new, voluntary provider-driven opportunities for improvement" and to "set the stage for breakthroughs in our understanding of how best to improve patient safety."[7] With few limitations, the Patient Safety Act provides protections for new types of clinical quality reports that contain information that could not be produced under the state peer privilege, such as sharing peer data across medical groups for use as benchmarks or in physician scorecards. Thus, the Patient Safety Act contemplates the collection, discussion, and sharing of information that has never been collected or shared because of the concern that it may not be kept confidential. The Patient Safety Act ultimately eliminates this key barrier to clinical integration.

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Privileged patient safety work product

The term "patient safety work product" (PSWP) is broadly defined in the Patient Safety Act and means any data, reports, records, memoranda, analyses (e.g., root-cause analyses), or written or oral statements which could result in improved patient safety, healthcare quality, or healthcare outcomes.[8] The privilege for PSWP applies to information, such as primary healthcare information, to the extent that it was collected for the purpose of reporting to a PSO and reported to a PSO.[9] Information developed by the PSO or analysis or deliberations that occur in the PSES is also PSWP. However, original records (e.g., an x-ray, lab results, or a medical record) are not PSWP. Therefore, the facts of medical errors cannot be hidden in a PSES, because the error must be documented in the medical record. Additionally, information required to be reported under federal, state and local laws also cannot be PSWP.

Congress developed a carefully constructed balance between confidential provider self-driven quality improvement and accountability through regulatory agencies, and the tort system. Congress excluded from the privilege original patient provider records, such as medical and discharge records necessary for regulatory oversight and for plaintiffs to seek

redress for injuries. Thus, the Patient Safety Act does not prevent medical error information from being collected from original records by CMS, state agency surveyors, or plaintiff counsel for use in malpractice lawsuits. However, the Patient Safety Act prevents a plaintiff from being enriched by collecting information from the provider's PSES or the PSO that would not otherwise have been created by healthcare providers but for the promise of the Patient Safety Act's privilege and confidentiality protections.

Conclusion

The Patient Safety Act includes privilege and confidentiality provisions to facilitate building a culture of safety and high reliability in which all licensed healthcare providers are able to openly discuss in a protected manner patient safety hazards, risks, and quality gaps. Providers can learn from the analysis, and share the information with other providers to prevent recurrence. The Affordable Care Act further promotes new care models for clinical integration and patient safety evaluation systems to be developed to improve the quality of patient care. As healthcare shifts to a more performance-based system focused on delivering value, entities across the continuum of care (including EMS, primary care, ambulatory care, pharmacy, inpatient, rehabilitation, post-acute care, long-term care, and home healthcare) will need to embrace the opportunities provided by the legislation and build an effective PSES.

1. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017, 81 Fed. Reg. 12204 (March 8, 2016).
2. The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. § 229b-21, et seq.
3. The Institute of Medicine: Report: *To Err is Human: Building a Safer Health System*, November 1999.
4. H.R. Rep. No. 109-197, at 9.
5. 42 U.S.C. § 299b-21(6).
6. H.R. Rep. 109-197, at 9; S. Rep. No. 108-196, at 3.
7. Patient Safety and Quality Improvement, Proposed Rule, 73 Fed. Reg. 8112, 8113 (February 12, 2008).
8. 42 U.S.C. § 299b-21(7).
9. 42 U.S.C. §§ 299b-21(5)(B).