

Patient Safety Organizations: Navigating the Selection Process

Created under the Patient Safety and Quality Improvement Act of 2005, patient safety organizations (PSOs) are entities that contract with healthcare providers to collect and analyze data on medical errors and system vulnerabilities. The law allows PSOs to function as “safe harbors” for providers, exempting information about adverse events from legal discovery requirements.

With the passage of the Patient Protection and Accountable Care Act of 2010 (PPACA), certain hospitals are now required to participate in a PSO and establish a system to collect, manage and analyze patient safety-related information.¹ A sound PSO partnership can benefit hospitals and their accountable care partners by:

- *Creating a systematic method of identifying current and emerging vulnerabilities across the clinical spectrum.*
- *Providing a means of analyzing medical errors in a legally protected environment, in order to gain insight into causes and implement appropriate preventive measures.*
- *Establishing a forum for learning about patient safety issues and best practices to support safety and quality improvement efforts.²*

However, not all PSOs are created alike, and some make more suitable partners than others. Selecting a PSO that can build upon and sustain an organization’s safety culture requires a thorough due diligence process. This edition of *AlertBulletin®* lists questions to ask of prospective PSO contractors about such essential risk management considerations as certification, range of services, operating procedures and data security, in order to ensure a good fit and a clear mutual understanding.

ELIGIBILITY REQUIREMENTS

- *Is the PSO certified by the U.S. Department of Health and Human Services (HHS) Agency for Healthcare Research and Quality (AHRQ)?*
- *Has the PSO ever received any deficiency notices from HHS regarding its activities, or been omitted from the AHRQ’s central PSO list?*
- *Can the PSO articulate the Patient Safety Rule, and does its mission statement reflect a commitment to the eight core patient safety activities?³*
- *Is the PSO located nearby, if proximity is an important selection criterion?*
- *Is the PSO staffed by licensed and certified professionals, who are qualified to perform all contracted services?*
- *Is the PSO willing to share its job descriptions for all employed and contracted positions, as well as staff educational and experience levels?*
- *Does the PSO contract with consultants to collect or analyze patient safety data, and do the consultants utilize appropriate and effective policies and methods?*
- *Does the PSO have an existing financial, reporting or contractual relationship with the healthcare organization, or with a provider that contracts with the organization, which would necessitate disclosure to the HHS? (For a sample disclosure statement from the AHRQ, see <http://www.pso.ahrq.gov/sites/default/files/disclosfm.pdf>.)*
- *Does the PSO provide services to other, comparable health-care organizations, and are references from these providers readily available?*
- *Is the PSO a component of a parent organization – such as an accrediting or state regulatory agency – whose activities potentially may conflict with the PSO’s “safe harbor” function?*
- *Can the PSO confirm that it is not a health insurance issuer and is not affiliated with one?*

¹ Effective January 1, 2015, hospitals with more than 50 beds must participate in a PSO in order to contract with a qualified health plan that is part of the PPACA’s health insurance marketplace.

² See Kendig, S. and Miller, R. “PSOs: Essential to ACO Success.” Available from the Center for Patient Safety at <http://www.centerforpatientsafety.org/wp-content/uploads/2014/04/WhitePaper-PSOs-and-ACOs.pdf>. In addition, for a list of core patient safety activities, see <https://www.pso.ahrq.gov/faq>, scrolling down to “What Are ‘Patient Safety Activities?’” under PSO General Information.

³ The Patient Safety Rule establishes a framework by which hospitals, doctors and other healthcare providers may voluntarily report information to PSOs on a privileged and confidential basis, for the purpose of aggregating data and analyzing patient safety events. The Patient Safety Rule and related information is available at <http://www.hhs.gov/ocr/privacy/psa/regulation/rule/>.

SCOPE OF SERVICES AND KNOWLEDGE

- *Can the PSO describe the specific methods, tools and approaches it will utilize to compile and analyze clinical data?*
- *Does the PSO provide clear, up-to-date written materials outlining the patient safety and quality improvement activities it offers to healthcare organizations and providers?*
- *Does the PSO provide examples of how it helps foster a culture of safety within partner healthcare organizations?*
- *Can the PSO assist in establishing and maintaining a Patient Safety Evaluation System (PSES), which collects safety-related information within the context of state laws regarding legal privilege and peer review?*
- *Does the PSO educate personnel about how to access the PSES and extract useful information from it for risk management, quality or patient safety purposes?*
- *Does the PSO perform a broad range of analytical functions, including both general review of safety events and category-specific assessment (e.g., medication errors, ambulatory surgery, diagnosis)?*
- *Does the PSO offer value-added services and resources, such as patient training, expert consultation, data analysis, safety alerts and safety culture assessments?*
- *Is the PSO aware of current patient safety trends, and do staff members educate themselves in various ways, including joining professional associations, participating in national conferences and soliciting expert panel input?*

DATA COLLECTION

- *Does the PSO have written procedures for entering data into the PSES, and is it willing to show these procedures to prospective partners?*
- *Does the PSO formally define patient safety work product (PSWP), and does this written definition include clinical data, investigative reports, committee records, memoranda, root-cause analyses, and written and oral statements?*
- *Does the PSO collect and analyze PSWP in a standardized manner, ideally using an AHRQ common format?⁴*
- *Does the PSO's format permit aggregation of data from multiple providers and facilitate comparison of similar cases?*
- *Does the PSO instruct providers on how they should submit requested data (e.g., hard copy, electronic transmission, secure portal system)?*
- *Does the PSO permit examination of its data collection and display capabilities by providing examples of non-identifiable PSWP from other organizations upon request?*

PRIVACY SAFEGUARDS

- *Does the PSO have written PSWP confidentiality policies and procedures, and are these policies available to prospective partners for review?*
- *Does the PSO place limits on PSWP disclosure, and are these limits aligned with the healthcare organization's rules and practices regarding confidentiality?*
- *Does the PSO require personnel with access to PSWP to sign confidentiality agreements, and does this policy cover contractors as well as employees?*
- *Does the PSO educate its own staff and contractors about confidentiality provisions and their responsibility to prevent inappropriate disclosure of PSWP?*
- *Does the PSO have policies regarding data breaches, including written protocols for notifying client organizations?*
- *Has the PSO ever been sanctioned for violating the confidentiality provisions of the Patient Safety and Quality Improvement Act or the privacy provisions of HIPAA?*

REPORTING PARAMETERS

- *Does the PSO explicitly describe the privileges and confidentiality protections accorded to providers who report patient safety-related information?*
- *Does the PSO specify the various types of feedback that it will provide – e.g., useful recommendations, protocols, best practice standards – as well as how and when this feedback will be presented?*
- *Does the PSO encourage providers to review and discuss data and feedback, in order to better understand findings and make constructive changes?*
- *Is the reporting of aggregated information governed by written policies, and does the PSO require prior written authorization from partners before sharing these data with other PSOs, healthcare organizations or the National Patient Safety Database?*
- *Does the PSO grant partner organizations access to aggregate and non-identifiable data for benchmarking purposes?*

⁴ AHRQ common formats and related information can be accessed at <http://www.pso.ahrq.gov/common>.

SECURITY PROVISIONS

- Does the PSO have a data security committee, and has this committee assigned specific roles and responsibilities to designated individuals?
- Does the PSO take appropriate measures to secure the confidentiality of PSWP, including password-protected screens, automatic logoffs, hardware firewalls and network restrictions?
- Does the PSO have a physical security plan to prevent unauthorized access to PSWP storage areas, and does it include such features as locked doors, surveillance cameras, alarms and security cables on computers?
- Is the security plan regularly assessed to ensure continued effectiveness and compliance with contemporary standards?
- Does the PSO conduct security checks of personnel, and does the process include investigation of prospective and new hires, as well as periodic review of employees' level of data access?
- Does the PSO routinely erase the hard drives of all electronic devices taken out of service, including printers and copiers?
- Are security passwords issued to employees with authorized access to a PSES, and are these passwords changed at regular intervals?
- Are server logs continuously monitored to detect unauthorized access attempts?
- Does the PSO carefully distinguish PSWP from other data stored in its information systems?
- Does the PSO encrypt electronic PSWP when it is transmitted for wireless access or for use outside of a healthcare organization's PSES?
- Is there a set time frame for removal of terminated employees and cancellation of their passwords?

PSOs can help hospitals achieve their safety and quality goals by providing a protected method of identifying risk factors, enhancing the benchmarking process and supporting culture change efforts. While relationships between hospitals and PSOs promise to be beneficial for all concerned, including patients, they may affect the claims reporting process. For this reason, administrators are advised to discuss PSO arrangements and related discovery issues with their insurance carrier.

ADDITIONAL RESOURCES FROM AHRQ

- Federally listed PSOs at <https://www.pso.ahrq.gov/listed>.
- PSO general information at <https://www.pso.ahrq.gov/>.
- PSO program resources at <https://www.pso.ahrq.gov/legislation> and http://www.pso.ahrq.gov/legislation/more_resources.
- Patient Safety and Quality Improvement Act of 2005 at <https://www.pso.ahrq.gov/legislation/act>.



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