Overview of Patient Safety Organizations (PSOs)
June 2009

Background
The Patient Safety and Quality Improvement Act of 2005 was signed into law on July 29, 2005. The purpose of this Act is to create a voluntary reporting system for hospitals and health care providers to report their medical errors with complete confidentiality for the purpose of learning from their mistakes. The law protects “patient safety work products,” which are the reports hospitals make to a certified PSO. After an analysis of the patient safety work product, the PSO is to provide the hospital feedback and help in determining how to prevent similar patient harm in the future. The information reported to PSOs is completely confidential, with very limited exceptions. However, this law does not override other public reporting laws. For example, if a hospital in California is still required to report adverse events to the Department of Public Health pursuant to current law regardless of whether or not that hospital chooses to work with a PSO.

On January 19, 2009, the Patient Safety Rule became effective. The Rule provides a framework for establishing Patient Safety Organizations (PSOs), including entities eligible to become PSOs, disclosure and security requirements, and responsibilities of the Secretary of Health and Human Services, the Agency for Healthcare Research and Quality (AHRQ) and the Office of Civil Rights regarding regulation and enforcement of PSOs.

PSO Roles and Responsibilities
The primary purpose of PSOs is to collect, aggregate, and analyze confidential information reported by health care providers to identify patterns of failures and propose measures to eliminate patient safety risks and hazards. Eligible organizations include public or private entities, profit or not-for-profit entities, provider entities, such as hospital chains, and other entities that establish special components. Health insurance companies and their affiliates are ineligible. The requirements to become a PSO and specifics regarding the certification process are listed in a separate document.

Voluntary Reporting and Confidentiality Protections
This Act is based on the philosophy that patient safety improvement efforts have been hampered by providers’ fears of legal liability, professional sanctions, or injury to their reputations. This is contrary to the prevailing philosophy that transparency regarding health care outcomes is an essential element for improving health care quality and safety. Therefore, the Act establishes a completely secret system that protects information reported to PSOs in the following ways:
1. Provides Federal legal privilege and confidentiality protections to the information reported by providers to a PSO.
2. Limits the use of this information in criminal, civil, and administrative proceedings.
3. Provides monetary penalties for violations of confidentiality or privilege protections.

Data Standardization and Reporting
The Act also seeks to standardize data collection to ensure faster analysis, reporting and the development of recommendations. Data collection and reporting will be standardized in two primary ways:
Development of Common Formats – standard online and printable forms that allow health care providers to collect and submit standardized information regarding patient safety events including:

- Incidents: patient safety events that reached the patient, whether or not there was harm;
- Near misses or close calls: patient safety events that did not reach the patient; and
- Unsafe conditions.

Establishes a Network of Patient Safety Databases (NPSD) - to provide an interactive, evidence-based management resource for health care providers, PSOs, and other entities. AHRQ will use data from the network to analyze national and regional statistics, including trends and patterns, regarding patient safety events. These aggregate general findings will be made public and included in AHRQ's annual National Healthcare Quality Report.

The Patient Safety Organization (PSO) Certification Process

This fact sheet provides a summary of the Patient Safety Organization (PSO) certification process and requirements outlined in the federal Patient Safety and Improvement Act of 2005 and regulations that became effective on January 19, 2009.

Oversight Agencies
The Agency for Healthcare Research and Quality (AHRQ) of the federal Department of Health and Human Services (HHS) is the responsible agency to carry out the Secretary of HHS’s requirements in the law. AHRQ will review PSO applications for initial and continual PSO listing. AHRQ will issue national summary public reports on the numbers and kinds of medical harm being reported to PSOs. The Office of Civil Rights will work with the HHS Secretary on investigations related to breaches in confidentiality.

PSO Eligible Entities
Public or private entities, profit or not-for-profit entities, provider entities (such as hospital chains) and other entities that establish special components are eligible to become a PSO to collect, analyze and develop recommendations regarding patient safety health care events (medical errors). The following entities are ineligible to become a PSO: health insurance companies and their affiliates, an entity that accredits or licenses health care providers, an entity that oversees or enforces statutory or regulatory requirements governing the delivery of health care services or an entity that operates a patient safety reporting system. However, an ineligible entity may seek an exception according to additional requirements (see list below).

PSOs do not receive federal funding for these activities. However, there is collaboration between PSOs and the federal government through the certification, regulation and enforcement of PSOs and their work with providers.

PSO Certification Requirements
The Patient Safety Rule has established the following requirements for PSOs for initial or continual listing online as a PSO:

1) Develop written policies and procedures concerning the following activities:
• Efforts to improve patient safety and the quality of health care delivery;
• Collection and analysis of patient safety work product, which includes data, analysis and reports developed from information about medical errors by health care providers;
• Development and dissemination of information with respect to improving patient safety such as recommendations, protocols, or information regarding best practices;
• Utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to hospitals and other providers to more effectively minimize the risk of future patient harm;
• Procedures to preserve confidentiality with respect to patient safety work product;
• Provide appropriate security measures with respect to patient safety work product;
• Utilization of qualified staff; and
• Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

2) Comply with following additional requirements:
• Ensure the mission and primary activity of PSO will be to conduct activities to improve patient safety and quality of health care delivery.
• Must have qualified workforce, including licensed and certified medical professionals.
• Must maintain 2 contracts with different providers for the purpose of receiving and reviewing patient safety work product (PSOs must have a separate contract with at least 2 providers during a 24 month period to maintain their PSO status).
• Not be a health insurance issuer or a component of one.
• Inform the secretary through AHRQ whether or not the PSO has met the 2 contracts requirement and any relationships the PSO has with providers.
• To the extent practical and appropriate, collect information from providers in a standardized manner to permit valid comparisons among similar providers. If not, provide a clear explanation of why it is not practical or appropriate to do so.
• Utilize patient safety work product to provide direct feedback and assistance to health care providers to effectively minimize patient risk.

Security Requirements
In addition to the requirements above, PSOs must meet the following securing requirements:
1. Security management: Develop written policies and procedures regarding security requirements and training for PSO workforce and contractors on confidentiality and security.
2. Distinguish patient safety work product: Maintain information gathered and analyzed for patient safety work product separate from non-patient safety work product, keep information secure, and follow procedures to sanitize and destroy information.
3. Security control and monitoring: Identify staff authorized to handle information and identify methods to prevent unauthorized use.

Exceptions to ineligibility
If an excluded entity wishes to become a PSO, it must follow additional specified requirements including:
• Provide a statement to AHRQ outlining the role and authority of parent organization.
• Affirm there are no policies or procedures inducing providers to report to the entity or parent organization patient safety work product.
• Prominently post on its website any promotional materials for dissemination to providers, a summary of parent organization’s role, and its authority in relation to the PSO.
• Ensure there is no conflict of interest between the mission of the parent organization and the mission of the PSO.
• Maintain all materials and information related to patient safety work separate from the parent organization.
• Ensure that staff does not disclose any information to the rest of the parent organization and not share staff between the parent organization and the PSO.

Certification Review Process

1. Criteria
The Secretary of HHS (through AHRQ) may consider the following information in making a determination about a PSO’s initial or continual listing: Certification application, prior history with or current non-compliance by entity or PSO or staff, prior actions Secretary has taken against the entity or POS including delisting, relationship of PSO and providers, and any findings from the certification requirements.

2. Notification: AHRQ will notify the entity in writing of its decision and reasons. The Secretary will maintain a list of PSOs on AHRQ’s website for 3 years and meet continued listing requirements for longer listing periods.

3. Correcting Deficiencies: If AHRQ finds deficiencies with the PSO’s compliance with certification requirements, contract requirements or required performance, the Secretary will: 1) send a written notice of preliminary deficiency findings, which will state the actions or inactions that encompass the deficiency, outline the evidence of deficiency, specify the corrective action, and establish a date by which actions must be taken; 2) the PSO must file evidence of action within 14 calendar days of actual or constructive receipt showing evidence of the contrary; 3) the Secretary will review any materials in response to the deficiency notice; and 4) the Secretary may find: a) PSO has corrected the action; b) PSO has acted in good faith to correct action but more time is necessary for the corrective action; c) PSO has not acted reasonably to correct deficiency and the Secretary will propose a revocation and delisting.

Disclosure of Information
In general, the purpose of the Act is to keep the information collected through providers’ voluntary reporting of certain medical errors confidential and privileged to encourage a culture of safety in reporting and promote new solutions for patient safety. The Act outlines exceptions to the confidentiality requirements to the following situations.

Patient safety work product may be used in the following ways:
1. Criminal proceedings after the court has made specific determinations regarding the alleged criminal act, the importance of the patient safety work product to the criminal act, and that the information is not reasonably available from any other source.
2. Disclosure is permitted when information is authorized by the health care provider/hospital.
3. Disclosure is permitted between providers, contracting providers and PSOs authorized to undertake patient safety activities.
   - Certain information must be retracted from the patient safety work product, including names, addresses, and other identifying information.

**Disclosure of Non-identifiable Patient Safety Work Product:**

Non-identifiable patient safety work product, is that information which is not attributed to a particular patient or health care provider/hospital, and may be shared for the following purposes:
1. Research purposes as authorized by the act and by the Secretary.
2. Products concerning the Food and Drug Administration.
3. Voluntary disclosure can be given to an accrediting body as long as identifying information is removed, no actions are taken against the reporting provider, and no communications between provider and PSO are required to be revealed.
5. Law enforcement if there is a reasonable belief that a crime has been committed.

**Enforcement**

The Secretary can request information and conduct announced or unannounced visits to assess or verify PSO compliance with the requirements of the Act.

**Complaint Process**

1. Filing a complaint. A complaint regarding the disclosure of privileged information must be in writing, on paper or electronically.
2. A complaint must include the name of the person alleged to have breached the confidentiality standards and the activities believed to be in violation of the act.
3. The complaint must be filed within 180 days of the act.

**Penalties and Hearings**

The Secretary will work with the Office of Civil Rights to investigate breaches of confidentiality of the patient safety work product. A civil penalty can be levied against an entity, or staff member, found to have released confidential information knowingly or recklessly. Several factors will be considered in determining the amount of the civil penalty including the nature of violation, circumstances of the violation, whether it was intentional, financial condition of the entity, and how the entity has responded to previous complaints. A PSO has the opportunity to request a hearing before the Administrative Law Judge of the HHS.