American Hospital Association

# Quality Advisory

**October 29, 2008**

# Long-anticipated Patient Safety Organization Program Begins

## AT A GLANCE

***The Issue:***

The *Patient Safety and Quality Improvement Act of 2005* (Patient Safety Act) authorized the creation of Patient Safety Organizations (PSOs) to improve patient safety through the collection and analysis of health care provider data. Recently, the Agency for Healthcare Research and Quality (AHRQ) published interim guidance on how organizations can apply to become PSOs and how the information hospitals submit to these organizations will be protected as privileged and confidential.

***Our Take:***

The PSO program is voluntary and provides a unique opportunity for hospitals to engage in patient safety improvement activities. Because they can aggregate similar data from many organizations, PSOs may be able to identify underlying patterns and develop tools to mitigate the risks of adverse events. The AHA encourages all hospitals to consider participating with a PSO.

This advisory provides background information on the PSO program and an overview of how organizations can apply to become PSOs.

***What You Can Do:***

- ✓ Share this advisory with your senior managers, quality improvement team and risk managers.
- ✓ Consider whether your organization will contract with a PSO for patient safety activities and when you would be ready to do so.
- ✓ Visit AHRQ's PSO Web site at www.pso.ahrq.gov for more background on the PSO program and an up-to-date list of PSOs as they become certified.

***Further Questions:***

Contact Nancy Foster, vice president for quality and patient safety policy, at (202) 626-2337 or nfoster@aha.org, or Beth Feldpush, senior associate director of policy, at (202) 626-2963 or bfeldpush@aha.org.

*AHA's Quality Advisories are produced whenever there are significant developments that affect the job you do in your community. A five-page, in-depth examination of this issue follows.*

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## BACKGROUND

In 1999, the Institute of Medicine (IOM) issued *To Err is Human: Building a Safer Health System*, a landmark report that highlighted critical areas of research and activities needed to improve the safety and quality of health care delivery. One critical component of the report addressed the reporting and analysis of data on adverse events. Although many states have encouraged health care providers to report patient safety events and many individual hospitals have taken such steps, several barriers have impeded the systematic collection of robust patient safety data until now.

Physicians and other clinicians have been reluctant to share information on patient safety events outside their organizations' peer review process for fear of legal liability, professional sanctions or harm to their reputations. State-based legal protections for such health care quality improvement activities, collectively known as "peer review protections," are varied and limited in scope. Current patient safety event reports are not standardized to allow data to be aggregated and shared across different institutions. Thus, it has been difficult to identify and mitigate underlying patterns of causation.

The IOM report spotlighted the serious need to capture data that would help reduce harm to patients. Strong and persistent urging from the AHA and other health care provider organizations encouraged Congress to pass the *Patient Safety and Quality Improvement Act of 2005* (Patient Safety Act) to encourage the expansion of voluntary, provider-driven initiatives to improve the safety of health care, to promote more rapid learning about the underlying causes of risks and harms in the delivery of health care, and to share those findings widely, thus speeding the pace of improvement.

The Patient Safety Act authorized the creation of Patient Safety Organizations (PSOs) to improve safety through the collection and analysis of data on adverse events. PSOs are specifically organized to improve the safety and quality of health care delivery. Through the confidentiality protections embedded in the Patient Safety Act, PSOs will provide a secure environment where clinicians and

hospitals can collect, aggregate and analyze data that enable the identification and reduction of risks and hazards.

The Department of Health and Human Services' (HHS) Agency for Healthcare Research and Quality (AHRQ) is in the process of developing a final rule to implement the Patient Safety Act and formalize a mechanism for organizations to apply to become PSOs. Due to strong interest within the health care community, AHRQ decided to issue interim guidance to begin the process of certifying PSOs and allow hospitals and other providers to work with them before the final rule is published. The final rule is expected to be released before the end of 2008.

This advisory is intended to provide you and your staff with an overview of the interim guidance; specifically, how organizations can become PSOs and the criteria that PSOs must fulfill. This information will assist you as you consider your organization's participation in the program.

## ***FREQUENTLY ASKED QUESTIONS***

***What types of organizations can become PSOs?***

Organizations eligible to become PSOs include public or private entities, for-profit or not-for-profit entities, provider entities such as hospital systems, and other entities that establish special components to serve as PSOs. However, the Patient Safety Act imposes two criteria for entities seeking certification as a PSO. First, the mission and primary activity of the entity must be to conduct activities to improve patient safety and the quality of health care delivery. Second, a health insurance issuer or a component of a health insurance issuer may not become a PSO. A parent organization may create or designate a separate component that meets the mission and primary activity criteria of the Patient Safety Act; that component can then seek to become a PSO.

***What are the requirements to become a PSO?***

To become a PSO, an organization must ensure that it can fulfill 15 requirements outlined in the Patient Safety Act. Requirements include ensuring that the PSO has policies and procedures in place to collect and analyze patient safety data and develop and disseminate information that can improve patient safety. In addition, the organization must assure that staff involved in PSO activities are appropriately qualified. PSOs that are components of larger organizations must certify that they meet three additional requirements designed to ensure that PSO activities will be kept separate from the rest of the organization's activities and that there is no conflict of interest between the PSO activities and the parent organization's mission.

If a PSO has other business relationships with any hospital with which it has a PSO contract, these additional relationships must be fully disclosed. In addition, within the first 24 months following its listing as a PSO, the organization must

submit a certification that it has entered into at least two contracts to provide PSO services.

***How can an entity apply to become a PSO?***
An organization seeking to become a PSO must submit an application form to AHRQ stating that it fulfills the 15 requirements outlined in the Patient Safety Act and the additional three criteria for PSOs that are components of larger organizations, if applicable. The application form is available at www.pso.ahrq.gov. The Secretary of HHS will notify applicants in writing of the outcome of their applications.

***When can I begin submitting data to a PSO?***
Once a PSO is certified by the Secretary, a provider can enter into a contract with the PSO, submit information to the PSO and voluntarily seek the PSO's analysis of patient safety events. A list of certified PSOs will be posted on AHRQ's Web site (www.pso.ahrq.gov).

***For how long is a PSO's certification valid?***
PSOs are certified for a three-year period. At the end of that period, the PSO must formally seek continued certification.

***How are the data that my organization submits to a PSO protected?***
To encourage providers to submit information to a PSO, the Patient Safety Act established privilege and confidentiality protections to protect information collected by hospitals for sharing with PSOs for analysis, analyses performed by the hospitals and/or the PSOs, and information shared between the PSOs and the hospitals they serve. The privilege and confidentiality protections are applicable nationwide and generally protect PSO information from disclosure in connection with federal, state, local or tribal civil, criminal or administrative proceedings. In the case of a knowing or reckless violation of the confidentiality provisions, the Secretary of HHS may impose a civil monetary penalty of up to $10,000.

In addition, the Patient Safety Act prohibits certain actions by accrediting organizations. Accrediting organizations may not take an accrediting action against a hospital based on its good faith participation in the collection, development or reporting of patient safety information. Also, an accrediting organization may not require a hospital to reveal its communications with a PSO.

***How will the PSO aggregate my data with data from other organizations?***
To facilitate the collection and reporting of common patient safety information, AHRQ has released a set of common formats that health care professionals can use to collect and track data. These formats may be used by providers and PSOs to report a range of patient safety concerns, capturing both structured and narrative information. The common formats include descriptions of patient safety events and unsafe conditions to be reported, examples of patient safety

population reports, definitions of data elements to be collected for events and other information for providers. The common formats are available at www.pso.ahrq.gov.

***Could the information my organization submits to a PSO violate the Health Insurance Portability and Accountability Act of 1996 (HIPAA)?***

No. Although hospitals participating in PSO reporting are covered entities under HIPAA, the Patient Safety Act explicitly addressed privacy concerns about the types of information that may be shared with a PSO. The Patient Safety Act stated that PSOs are considered to be "business associates" and patient safety activities are deemed to be "health care operations" under HIPAA, thereby allowing hospitals to share patient-specific information with PSOs. HIPAA would not prevent hospitals from sharing individually identifiable health information regarding their patients with a PSO for patient safety activity purposes, and it would not require the hospital to obtain the patient's authorization to do so.

***When will AHRQ issue the PSO final rule and how will it differ from the interim guidance?***

The interim guidance will remain effective until AHRQ issues a final rule, expected before the end of 2008. It is expected that the basic principles of operation established in the interim guidance will remain intact in the final rule. Any patient safety information collected and reported during the interim period will remain privileged and confidential even after the publication of the final rule.

***How can I stay informed as organizations become certified as PSOs?***

A list of certified PSOs will be posted on the AHRQ PSO Web site (www.pso.ahrq.gov). On the Web site, you also can sign up for PSO e-mail updates from AHRQ.

## NEXT STEPS

The PSO program has the potential to improve patient safety by enabling hospitals to share information and have their data aggregated in a systematic way. PSOs will share the results of their analyses with the hospitals that contract with them to spread good ideas for patient safety practices and tools that can mitigate the risk of patient safety events. Thus, the AHA is encouraging all hospitals to consider partnering with a PSO.

There are several steps you can take now as you consider becoming or working with a PSO:

- Share this advisory with your senior managers, quality improvement team and risk managers and your board of trustees, if appropriate.

- Identify a leader within your organization who can evaluate the PSO program more closely for your hospital.

- Visit the AHRQ's PSO Web site (www.pso.ahrq.gov) for more information and an up-to-date listing of certified PSOs.

- From the PSO Web site, sign up to receive PSO-related e-mails from AHRQ.

- Look for more information from the AHA as PSOs become certified and begin operations.

***Further Questions:***

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