



April 7, 2006

Carolyn M. Clancy, MD  
Director  
Agency for Healthcare Research and Quality  
540 Gaither Road  
Rockville, Maryland 20850

RE: AHRQ Patient Safety Organization Public Meetings

Dear Dr. Clancy:

## **I. Introduction**

The American Academy of Orthopaedic Surgeons, representing over 19,000 board certified orthopaedic surgeons, is pleased to express our support for the Agency for Healthcare Research and Quality's (AHRQ) efforts to implement the Patient Safety and Quality Improvement Act of 2005 (Act). The AAOS has a vested interest in the development of patient safety organizations (PSO). The creation of PSOs, if properly developed, has the potential to provide a safe harbor for patient safety and quality improvement programs and of particular interest to us is its value in creating a national joint replacement registry. We have previously sought AHRQ's expertise and guidance to identify and address critical issues involved with establishing a national joint registry and view these meetings as an occasion to continue our relationship.

The mission of the AAOS national joint registry initiative is to foster a national center for data collection and research on total hip and knee replacements with far-reaching benefits to society including, but not limited to:

- Reduced morbidity and mortality;
- Improved patient safety;
- Enhanced quality of care and medical decision-making;
- More appropriate resource utilization; and
- Advances in orthopaedic science and bioengineering research.

Previously, the collection of data that would enable the realization of this mission would potentially expose the AAOS, its members, and their patients to possible security and confidentiality breaches as well as unnecessary liability risks. These impediments have hampered the establishment of a national joint registry. With legislation in place that provides for the formation of PSOs, a means to achieving the goals of the registry is within reach.

AAOS surgeons and staff members attended each of the 3 meetings held by AHRQ officials regarding the construction of PSO regulations. To assist in your analysis, we have organized our comments by the topics covered at each of those meetings.

## II. COMMENTS

### A. Provider-PSO Relationships, Contracts, Disclosures

***Applicability of PSO Regulations.*** After the March 8, 2006 meeting, we have a growing concern that many stakeholders view PSOs only as adverse event reporting mechanisms. While we are confident that AHRQ officials recognize the broader value of PSOs, we urge you to write consistent, yet flexible regulations that apply to both traditional patient safety and adverse event reporting activities as well as longer-term quality improvement activities. It is the clear intent of the law that PSOs be created to serve these varied functions, and the regulations should reflect that intent.

During the meeting, AHRQ officials asked specifically about the range of patient safety activities that the providers and our potential PSO would provide. The AAOS joint replacement registry project currently plans for three levels of data collection. In discussions about PSOs, AAOS requests that AHRQ address Level 2 data when designing the PSO regulatory scheme:

- Level 1 is the core of the registry, capturing patient, surgeon, hospital, and device specific information- including laterality.
- Level 2 data expands into co-morbidities and complications. The information from Level 2 collection lends itself to current Centers for Medicare and Medicaid Services (CMS) initiatives, including those involving “pay-for-performance.” We are interested in assurances that Level 2 data collection would be considered Patient Safety Work Product (PSWP) and thus protected under the Act. In addition, for the purposes of partnering with CMS, AHRQ, and other government entities (given that public entities can receive a designation as a PSO), it would be helpful to know whether there will be a prospective review of many government initiatives to ascertain whether they qualify as patient safety activities under the Act.
- Level 3 data is comprised of long-term outcomes measures, patient functionality, and device performance.

***Contracting Provisions.*** We hope AHRQ will address the issue of contracting with physicians and hospitals who provide data to PSOs for patient safety and quality improvement activities. While we are proponents of confidentiality and security protections, the cost and resource burdens associated with the execution of individual business arrangement agreements have often proven to be prohibitive. Given the potential public benefits associated with PSO activities, we ask that AHRQ consider provisions that mitigate some of those contracting burdens.

***Data Standards.*** Section 923(b) authorizes (but does not mandate) the Secretary to determine common formatting for data among the patient safety databases, including a “standardized computer interface.” While we think that this is an incredibly important component, the strength in setting data and software formats will be in its universality. For this reason, we encourage AHRQ to suggest that the Secretary take on this endeavor under the auspices of the American Health Information Community (AHIC), or at the very least, conduct this activity in cooperation and consultation with the AHIC and the Office of the National Coordinator for Health Information Technology (ONC).

## **B. Operation of a Component PSO**

We understand the risk that AHRQ is attempting to address with its focus on component PSOs as created by provider organizations. However, we urge you to construct the regulations pertaining to component PSOs in a manner that is not unduly restrictive to non-provider organization component PSOs.

***PSO-Provider Conflict of Interest Risks.*** AHRQ’s concern regarding conflicts of interest between providers and the PSOs to which providers report (regardless of whether the entity is a component PSO) is appropriate. This is an important safeguard for maintaining the integrity of PSO activities. We ask that any conflict of interest provisions, however, focus on disclosure of possible conflicts rather than prohibitions of any particular relationships. Transparency of those relationships will avoid conflicts and highlight any areas that warrant further investigation during the certification process. In addition, because of the variations in form and function that PSOs are likely to take, AHRQ should only promulgate more restrictive regulations upon collection of actual data on how PSOs operate so as to not prematurely preclude legitimate activities and relationships.

There are many possible configurations of component PSOs. The regulations should be broad enough to accommodate diverse organizations and specific enough to insure the integrity of the organization and the protection of the information. The following items are examples of the assurances we would plan to provide in our disclosures:

- Separate oversight boards for PSO and parent organization;
- Formal data request procedures for release of any PSWP;
- External auditing of PSO policies and procedures to ensure compliance; and
- Separate staff and restricted access to databases and reporting functions.

In addition, these provisions would be clearly articulated in the PSOs policies and procedures.

### C. Security and Confidentiality

The PSO functions of security and confidentiality are the most important functions articulated in the Act. While it is incumbent upon the PSOs to develop strong contracts with the providers with whom they create a relationship, we would also hope that AHRQ would write regulations that will give providers reasonable assurance that there will not be unforeseen intervening events that make the patient safety work product discoverable.

***Protected Providers.*** Section 921(2)(A) defines “identifiable patient safety work product” as patient safety work product that is

. . . presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product.

Section 922(c)(1)(C) allows the disclosure of that identifiable patient safety work product if it is “authorized by each provider identified in such work product.”

We ask that AHRQ further explore the authorization required in section 922(c)1(C). We envision a situation in which the PSO contracts with a facility provider (as defined in section 921(8)(A)(i)), but some of the valuable PSWP that would be reported back to the contracted provider would identify physicians or individual providers (as defined in section 921(8)(A)(ii)). While we understand that authorization by “each provider identified” is required under the law, we ask that AHRQ explore mechanisms under which the individual non-contracting providers would be able to provide the disclosure authorization to the contracting facility provider. As the patient safety organization concept develops, the value of the PSO will be its ability to capture a broad, if not complete, series of clinically significant events. The ability to report data to those facility providers that contract with PSOs will be hampered if the PSO is responsible for maintaining separate authorizations for all of the individual providers with whom the facility provider works. In the interest of accomplishing the goals for which the Act was designed, we ask that the regulations maintain a manageable mechanism for collecting and maintaining these authorizations while still upholding the Act’s authorization requirements.

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### III. CONCLUSION

The AAOS encourages AHRQ to expedite the creation and implementation of PSO regulations. We thank you for the opportunity to participate in this important work, and are available to assist you throughout the process. We look forward to submitting more detailed comments upon the release of the notice of proposed rulemaking. For further information please contact Bob Jasak in our Washington office at [jasak@aaos.org](mailto:jasak@aaos.org) or 202.546.4430.

Sincerely,



Richard F. Kyle, MD

President

American Association of Orthopaedic Surgeons



David G. Lewallen, MD

Chair

American Joint Replacement Registry Board