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Association**

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April 14, 2008

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Director
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RE: (AHRQ; RIN-0991-AA01) Patient Safety and Quality Improvement; Proposed Rule (Vol. 73, No. 29), February 12, 2008

Dear Dr. Clancy:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Agency for Healthcare Research and Quality's (AHRQ) proposed rule to establish a framework by which providers may voluntarily report information to patient safety organizations (PSOs), and to outline the requirements that entities must meet to qualify as a PSO.

The AHA has long supported the establishment of the PSO program and is, in general, pleased with the proposed rule. However, we are concerned about:

- application of the minimum contracting requirement;
- limitations on disclosing patient safety work product to independent contractors; and
- the potential exclusion of self-insured provider organizations as PSOs.

These concerns and some other issues are outlined in greater detail below. Most importantly, we urge the Department of Health and Human Services (HHS) to consider comments expeditiously and to quickly finalize the rule to allow hospitals and other health care providers to begin to work with these organizations to improve the safety of care for all Americans.



APPLICATION OF THE MINIMUM CONTRACTING REQUIREMENT

AHRQ's decision to define a parent organization that has a controlling interest in one or more hospitals or other health care provider entities as a "provider" is worrisome. This could have negative implications because organizations are required to enter into bona fide contracts with two different providers to be certified and listed as a PSO. This would mean that a PSO entering into one contract with a multi-hospital health care system would not meet the rule's minimum contracting requirement. The PSO instead would be required to enter into multiple agreements with the system's individual hospitals in order to meet this minimum contracting requirement. This is an inefficient and redundant contracting process for health care systems, which frequently negotiate and manage contracting only on a system-wide basis. **The final rule should recognize and accept system-wide contracts that cover multiple hospitals within the same health care system as sufficient for meeting the minimum contracting requirement.**

DISCLOSURE TO INDEPENDENT CONTRACTORS

AHRQ defines "patient safety work product" as any data, reports, analysis or other records developed by a provider or PSO to conduct patient safety activities that could improve patient safety or quality of care. AHRQ defines the "disclosure" of patient safety work product as occurring when that information is shared with another entity or person. AHRQ does not propose to regulate the use, transfer or sharing of patient safety work product internal to a legal entity, such as a provider or PSO. Moreover, AHRQ believes that to regulate uses of patient safety work product within providers and PSOs would be intrusive, especially given that patient safety activities are meant to be voluntary. AHRQ presumes that there are sufficient incentives in place for providers and PSOs to prudently manage the uses of such sensitive information. **We agree that the regulation generally should not dictate specific uses of patient safety work product internal to a legal entity.**

However, the proposed rule makes a distinction between a contractor that is under the direct control of an entity and an independent contractor. In the case of the independent contractor, the release, transfer, provision of access to or divulging in any other manner of patient safety work product would be a disclosure. Under the rule, a provider or PSO would be permitted only to disclose patient safety work product to an independent contractor engaged specifically to undertake patient safety activities on its behalf. Interpreted literally, this would mean that a hospital would not be able to disclose patient safety work product to any contractor assisting the hospital in activities other than patient safety activities, even when access to such information is necessary for accomplishing the contractor's work. For example, this limitation might prevent the hospital from sharing relevant recommendations about patient room cleanliness derived from patient safety activities with a housekeeping contractor who is directly responsible for maintaining such cleanliness. **We recommend that the rule be modified to clarify that a provider may share patient safety work product with its independent contractors when such information is relevant to the contractor's ability to perform its contractual duties.**

SELF-INSURED ORGANIZATIONS

Subpart B describes the requirements of PSOs, including the exclusion of certain organizations. We ask AHRQ to provide clarification regarding the exclusion prohibiting health insurance issuers or their components from becoming PSOs. As written, the regulation does not specify whether self-insured organizations, which issue insurance to their own employees and their dependants, fall into the excluded category. Several large hospital systems have indicated an interest in becoming PSOs. As large organizations, they may be self-insured and, therefore, may be excluded under the current language in the regulation. **We do not believe it was AHRQ's intent to exclude self-insured organizations from becoming PSOs and strongly urge AHRQ to clarify this in the final rule.**

ADDITIONAL COMMENTS

Subpart A – Definitions

AHRQ proposes to define a subsidiary corporation as a “component” of its corporate parent. A subsidiary typically would not be considered a component of the parent organization because it generally is separate organizationally and operationally. But rather than opting to rely on a structural legal model of corporations, AHRQ opts for a more relational or behavioral model in classifying a subsidiary of an organization. AHRQ notes that such a model would be consistent with current legal trends and the specific objectives of the regulation's proposed certification requirements, namely keeping patient safety work product confidential and separate from the parent organization of a component PSO. AHRQ also notes that neither the statute nor the proposed regulation imposes any legal responsibilities, obligations or liability on the organization(s) of which a component PSO is a part. Therefore, we agree it is appropriate to consider a subsidiary of an organization a “component” of that organization.

We agree that the documentation of “patient safety evaluation systems” should be encouraged. This documentation can provide protections to both the PSO and its reporting entities, as it provides explicit boundaries about what information within the system is patient safety work product, and therefore protected. We would expect that providers would choose to enter into an agreement with a PSO with a well-documented and defined patient safety evaluation system. Still, we believe documentation of the patient safety evaluation system should not be required under the regulation. Patient safety evaluation systems will evolve as PSOs and providers gain experience with the program. These regulations should not stifle innovation or the natural evolution of the process by which providers and PSOs share information.

“Functional” reporting as defined in the rule is a practical approach to reducing the burden on providers to actively transmit all patient safety work product to a PSO. Under the definition, a provider could place information into a database shared by the provider and PSO, and the PSO could access the information as needed. **This is a sensible approach. The mechanics of any functional reporting should be defined in the contracts between a provider and a PSO; no further regulatory parameters are necessary.** Any information exchanged between a provider and a PSO should be allowed to flow through functional reporting as it is defined in the contract between the two entities.

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As soon as a provider begins to assemble information with the intent of reporting it to a PSO, that information should be protected. Thus, we encourage AHRQ to change the wording of the current language in Subpart A, §3.20 to reflect this protection. We agree with AHRQ that the date of passage of the *Patient Safety and Quality Improvement Act of 2005* (Patient Safety Act) on July 29, 2005 is a logical date to establish the earliest point in time in which a provider may collect information to be reported to a PSO.

Subpart B – PSO Requirements and Agency Procedure

AHRQ proposes to clarify in the final rule how a PSO can fulfill the statutory requirement of having contracts with providers “for a reasonable period of time.” AHRQ “intends to create certainty” for contracting providers and PSOs as to whether the contracting duration requirement has been met. This requirement would apply only to the two required contracts, and a PSO would be permitted to enter into additional contracts without regard to the standards set for the two required contracts.

We urge AHRQ to adopt both time- and task-based standards for compliance with this statutory contracting requirement. Both types of contracting standards are legitimate and appropriate bases for establishing contracts “for a reasonable period of time,” as the statute requires. Moreover, the use of multiple contracting approaches permits providers and PSOs to enter into relationships that meet their specific objectives and goals related to quality improvement. However, the standards that the final regulation establishes for each approach should not be overly prescriptive in order to remain consistent with the voluntary program the statute established.

AHRQ does not propose to require reporting of impermissible disclosures of patient safety work product that do not contain protected health information that is otherwise regulated by the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) medical privacy rule. AHRQ specifically notes that such reporting requirements could be voluntarily agreed to by contract between providers and their PSOs. We agree that such reporting is likely to be part of the specific contract between a provider and its PSO and that, as a result, the regulation does not need to require such a reporting arrangement. **However, the regulation could, and should, encourage providers and PSOs to consider whether such reporting arrangements are appropriate for their particular relationship.** The provider-PSO relationship is specifically a HIPAA business associate relationship and must be structured in accordance with all of the required provisions of a HIPAA-compliant business associate agreement. Thus, providers are likely to incorporate into their service agreements with PSOs provisions related to the use and disclosure of patient safety work product that parallel those for protected health information, including reporting of improper disclosures.

We encourage AHRQ to develop a public Web site that can provide information to PSOs and providers. The Web site should include information on each PSO to assist providers when seeking out a PSO. Such information should include the PSO’s contact information, the effective date of the PSO’s listing, any disclosure statements filed by the PSO, whether the PSO has certified that it has met the two-contract requirement and any other information that may be

of assistance to providers or PSOs. The Web site also should indicate if the PSO's three-year listing period is about to expire and whether the PSO has sought continued listing.

The rule states that if the HHS Secretary determines that an organization has not fulfilled the PSO requirements, providers have 30 days from the date of delisting during which they can still submit data to the PSO and have that data remain protected as a patient safety work product. This 30-day period allows for some continuity in a provider's patient safety activities while that provider seeks out a relationship with another PSO. In contrast, under the rule, if a PSO voluntarily resigns its status, there is no 30-day window within which providers can continue to submit data. **AHRQ should make the process consistent for providers, regardless of whether their PSO voluntarily ceased operations or was forced to stop.** Thus, we urge the agency to include a requirement that when a PSO voluntarily ceases operation, providers may submit data within 30 days of that date and continue to have that data protected as patient safety work product.

We agree with AHRQ's decision that, should a PSO voluntarily cease operations, it cannot take advantage of the processes and appeals that would apply when a deficiency is identified.

Subpart C – Confidentiality and Privilege Protections of Patient Safety Work Product

The proposed rule permits disclosure of patient safety work product between certain entities, thereby excluding these disclosures from the rule's confidentiality requirements. This includes the disclosure of patient safety work product between a provider and a PSO, a contractor of a provider and a PSO, a PSO and another PSO, and a provider and another provider. The entities listed in the rule reflect all appropriate entities that should be included in the exemptions from the confidentiality requirements; no additional entities are necessary. **However, AHRQ should monitor the disclosure of patient safety work product as providers and PSOs begin to engage in patient safety activities.** If, in the future, it appears that there should be other entities included under this exception, AHRQ should propose these additional exceptions through the rulemaking process, allowing for public comments on the proposed additions.

As currently written, the rule also appears to encompass the appropriate business operations exceptions from confidentiality. If AHRQ plans to make any changes to the exceptions in the future, it would be prudent to do so through the rulemaking process, which allows for public input and feedback. **In the meantime, AHRQ could provide guidance to the field as to what situations may appropriately fall under the business operations exceptions to help illustrate acceptable circumstances.** For example, an exception for reporting patient safety event information to a federal, state or local government agency to comply with external reporting requirements would ensure that providers may fully meet their reporting obligations without requiring duplicative data collection and administrative processes. Such an exception would not undermine the confidentiality protections.

The proposed rule also permits the use of patient safety work product in a legal proceeding about an adverse employment action taken against any individual who, in good faith, reports information to the provider for subsequent reporting to a PSO or to a PSO directly. To protect the patient safety work product as much as possible in these circumstances, **the rule should**

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require that the reporter obtain a proper protective order in order to use the information in the legal proceeding.

The Patient Safety Act explicitly includes patient safety activities performed by, or on behalf of, a covered provider as part of health care operations under HIPAA, thereby making it a permissible disclosure. The Patient Safety Act also specifically designates a PSO as a HIPAA business associate of a covered provider. Even without these explicit statutory pronouncements, HIPAA's regulatory definitions of "health care operations" and "business associate" would unambiguously encompass patient safety activities and PSOs. **We recommend HHS also alter the HIPAA medical privacy rule's definitions to include a specific reference to "patient safety activities," and "patient safety organizations."** The inclusion of specific references in the HIPAA rule would create consistent and mutually reinforcing legal frameworks. For similar reasons, HIPAA's provision permitting the disclosure of protected health information for health care operations should be modified to conform to the patient safety work product disclosures for patient safety activities.

Subpart D – Enforcement Program

AHRQ proposes to apply the HIPAA enforcement framework for violations of the confidentiality requirements of the Patient Safety Act. In general, the final HIPAA enforcement rule provides an appropriate framework. When an entity self-reports that there has been an impermissible disclosure of patient safety work product, the fact that the entity voluntarily reported the error should be taken into consideration in assessing the monetary penalty.

In general, the rule's limitations on the disclosure and redisclosure of patient safety work product provide greater assurances that information will be available and used only for the purposes for which it is intended. The AHA believes that this general approach will not interfere with the appropriate exchange of patient safety work product between and among providers and PSOs. However, we urge AHRQ to monitor the impact of the rule to ensure that it does not improperly impede the appropriate sharing of patient safety work product between and among providers and PSOs nor inhibit the evolution of patient safety activities.

We thank AHRQ for the opportunity to comment on this proposed rule. Should you have any questions, please contact me or Nancy Foster, vice president for quality and patient safety, at (202) 626-2337 or nfoster@aha.org.

Sincerely,

Rick Pollack
Executive Vice President