American Health Information Management Association®

April 14, 2008

Center for Quality Improvement and Patient Safety
Attn: Patient Safety Act NPRM Comments
AHRQ
540 Gaither Rd.
Rockville, MD 20850

The American Health Information Management Association (AHIMA) welcomes the opportunity to comment on the Patient Safety and Quality Improvement Notice of Proposed Rulemaking regarding the framework for Patient Safety Organizations (PSO) as published in the February 12, 2008 *Federal Register*.

AHIMA is a not-for-profit professional association representing more than 51,000 health information management (HIM) professionals who work throughout the healthcare industry. AHIMA's HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by collecting, managing, analyzing, reporting, and utilizing data which is vital for patient care, while making it accessible to healthcare providers and other appropriate users of health information.

AHIMA and its members participate in a variety of projects with other industry groups and federal agencies related to the use of healthcare data for the purpose of including direct care, quality measurement, reimbursement, public health, patient safety, biosurveillance, and research. HIM professionals also assume the role of information stewards and are concerned for the confidentiality and security of information as it is aggregated, stored, and utilized.

General Comments

AHIMA commends the Center for Quality Improvement and Patient Safety and the Office for Civil Rights for carefully gathering and assessing input from industry stakeholders during the development of the final rule for the PSO framework. Our comments focus on those areas of particular interest to our members. We believe the proposed rule provides a good foundation; however, we have outlined below recommendations for consideration as the Agency for Healthcare Research and Quality (AHRQ) continues to develop the final rule for a sound patient safety program.

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The proposed rule indicates reporting to a designated PSO is voluntary. However, healthcare provides report information related to healthcare treatment, disease, quality, and so forth to a variety of government and private parties. Information data definitions and data sets included in the multitude of reporting requirements are currently not harmonized and AHIMA is concerned an additional reporting program that is similar, may have its own rules and guidelines for reporting. This will continue to increase the reporting burden for providers who are currently struggling to meet the existing demands for data and raises the question of data integrity. AHIMA recommends AHRQ evaluate current reporting initiatives to determine opportunities for harmonizing and leveraging existing reporting initiatives to maximize infrastructures and business processes.

With this same concern for integrity, it will be essential to provide clear direction to both PSOs and healthcare providers regarding changes and updates to patient safety reporting requirements. For instance, AHIMA members have raised concerns regarding the data collected for patient safety initiatives might also be the same data collected for quality measurement however, with slight modifications. AHIMA recommends AHRQ add clarification to the final rule describing how updates to data collection and reporting requirements will be facilitated as well as methods for communicating data collection guidelines to ensure consistent reporting. For further information on AHIMA's recommendations for heath data stewardship, please refer to the response submitted to AHRQ Request for Information as published in the June 4, 2007 *Federal Register.* http://www.ahima.org/dc/documents/MicrosoftWord-AHIMANHDSERFIresponse-final_2007-08-03_.pdf

II. Overview of Proposed Rule (73FR8114)

The proposed rule indicates PSOs will be required to enter into a HIPAA[1] Business Associate (BA) agreement with providers that are covered entities under HIPAA. The BA agreement will offer privacy and security protection; however, this does not allow the same stringent protections and guidance for providers that are not HIPAA-covered entities, leaving the situation open to interpretation and ambiguity. AHIMA recommends the rule be modified to require contractual obligations for and between the healthcare provider and the PSO when the healthcare provider is not a HIPAA covered entity. By implementing this infrastructure, it will establish an approach which is uniform and consistent across all healthcare providers and PSOs.

The overview and description of the rule raise numerous discussions regarding a contract between the healthcare provider and the PSO, often suggesting there is or is not a need for a contract beyond the BA. AHIMA believes given the extent of legal and other process questions raised in the proposed rule that a contract (beyond the BA) or memorandum of agreement (MOU) be required in all cases except when the PSO is a component organization within the specific healthcare provider. We recognize not all contracts need to cover all the aspects raised in the rule, however we do believe providers and PSOs should ensure all requirements raised in the proposed rule are covered in an agreement to exchange or share data. AHIMA recommends AHRQ require a contract between the PSO and provider.

[1] Health Insurance Portability and Accountability Act

A. Subpart A – General Provision

Proposed § 3.20 Definitions: Documentation (73FR8120)

AHIMA supports AHRQ's comments regarding the need for strong process documentation and a description of the systems that support the patient safety evaluation system. Given the nature of the patient safety evaluation system, maintaining sound documentation which articulates the process for entering data into the system, data aggregation and use, data access, and transmitting data between the provider and PSO serves to protect all parties including patients. If an organization is not a covered entity under HIPAA, the organization is not required to follow the documentation recommendations as described in this proposed rule. AHIMA urges AHRQ to add clarification in the final rule regarding the need for more stringent documentation requirements; furthermore, AHIMA recommends documentation requirements similar to those highlighted in this section also be referenced and required in any contract or MOU between a healthcare provider and a PSO.

Proposed § 3.20 Definitions: Information assembled or developed and reported by providers (73FR8121)

AHIMA appreciates AHRQ's interest in improving efficiencies by allowing the PSO access to a shared database for reporting purposes; however, we believe establishing this system may ultimately prove problematic given professional and public concerns for privacy. We therefore do not support this proposed configuration. AHIMA does support the proposed method of transmitting the data in a manner where there is no uncertainty the PSO has received the data and there will be a log or audit trail of the actual process of transmitted data. If a patient safety database is set up for PSO access ("reporting") issues may arise as to whether the data was officially "reported" as well as the timing for data available for reporting, and potential data integrity issues.

An alternative to the PSO accessible database might be for a separate healthcare provider database for PSO work products that can only be accessed by designated healthcare provider personnel and whose only purpose is patient safety reporting. Such a database should then provide the same protections as provided for all patient safety work products. Currently, most organizations maintain data in both an electronic and paper-based media. Once the healthcare industry becomes fully electronic, the alternatives raised by this section may need to be readdressed.

Proposed § 3.20 Definitions: Information assembled or developed and reported by providers (73FR8121)

AHIMA agrees with AHRQ's consideration there should be protection of the data under the PSO constructs, and it should be protected even when not reported, despite the consideration it is under other protections as described in the proposed rule on page 73 FR8122. AHIMA recommends protection of the information should begin immediately at the point in time when the data is being prepared for reporting purposes to the PSO.

Proposed § 3.102(b)(2) Required Certification Regarding Seven PSO Criteria: Collecting data in a standardized manner and the process for developing and maintaining common data formats (73FR8129)

AHIMA commends AHRQ for requiring PSOs to collect patient safety work products in a standardized manner, allowing for comparison among similar providers. We recommend AHRQ require patient safety data elements be harmonized with other data reporting requirements and formats (when possible) to facilitate collection of data once for multiple reporting purposes. In this regard the final rule should require adherence to applicable national standards for patient safety reporting when such standards exist. Similarly, when classification codes are used, they should adhere to the standards and guidelines in existence, and not be modified by the PSO for local purposes.

Proposed § 3.106 (b) Security Framework (73FR8134)

AHIMA commends AHRQ for establishing proposed security measures for PSOs; however, we strongly recommend AHRQ change the framework from being based upon the National Institute of Standards and Technology (NIST) standards for security to that of the HIPAA Security Regulation. NIST provides standards by which federal agencies must follow, and while we do not take issue with NIST standards, most healthcare providers are not designated federal agencies nor are they most likely familiar with the NIST standards. By imposing the NIST standards as part of the PSO final rule, providers will be required to abide by additional security rule(s) and concerns regarding how NIST rules intercept with HIPAA Security standards will arise.

To maintain consistency and reduce confusion within the healthcare security environment, AHIMA strongly recommends HIPAA security standards be used within the patient safety security framework. If the final rule issues the requirement to comply with NIST security standards, AHIMA recommends AHRQ provide guidance and an appropriate amount of time to implement such a framework.

Proposed § 3.106(b)(1) Security Management (73FR8134)

In this Security Management section, AHRQ proposes the requirement for PSOs to document their security requirements for patient safety work products. In the spirit of “security” AHIMA finds this requirement to be inconsistent with the previous section (73FR8120) where AHRQ “encourages” providers and PSOs to “consider” documenting certain aspects of the system (for example, personnel with access to the PSO evaluation system and what processes, activities, physical space and equipment comprise and use the system). The concepts described in the two sections of the proposed rule are contradictory, thus setting up an environment for confusion and error. AHIMA strongly recommends AHRQ clarify the security concepts and management approach to ensure consistency, reduce confusion, and eliminate potential errors in the process.

Proposed § 3.10(b)(3) Disposition of Patient Safety Work Product and Data (73FR8137)

AHIMA recommends AHRQ consider using the standards as developed by HIPAA for the disposition of data and patient safety work products. For example, it is unclear in the proposed rule on the destruction of data when it is necessary to destroy patient safety data following revocation or delisting of a PSO. HIPAA Privacy provides clear guidance on the destruction of data. To ensure consistency and reduce confusion for the users of the patient safety system, AHIMA recommends adoption of current HIPAA practice to reduce burden and confusion for the users of the system.

Subpart B - PSO Requirements and Agency Procedures

§ 3.102 Process and requirements for initial and continued listing of PSOs (2) Restrictions on certain entities (73FR8173)

The proposed rule indicates organizations such as payers, accreditation, and licensure entities may not seek listing as a PSO, with the exception of component organizations of some of these entities. The purpose of preventing the parent organization from seeking listing as a PSO is to foster an environment or a culture of safety so the reporting providers can feel confident the information is used for learning and improvement, not retribution. AHRQ assumes adequate safeguards are in place to prevent inappropriate sharing of the data, and the marketplace will determine whether a component PSO has acceptable or unacceptable ties to an entity with regulatory authority. AHIMA has received concerns from the provider community there are not enough stringent requirements in place to prevent inappropriate relationships or potential data sharing practices. AHIMA urges AHRQ to revisit this concept and provide for more rigorous disclosure requirements and guidelines regarding the separation of a PSO from parent organizations in the restricted class that would impose the enforcement of fines or other penalty when violations occur.

Long Term Considerations

Given that PSOs are collecting and aggregating patient safety data to learn how providers can reduce preventable medical errors, state public health agencies or other state organizations may begin to focus their attention on this aggregate data. By gaining access to this data rich system, states may begin the development of mandates which may place additional reporting or data collection requirements on providers. AHIMA recommends AHRQ consider this future potential when publishing and implementing the final rule.

Standardization of clinical documents and definitions of data will improve data collection and aggregation initiatives. Through efforts to standardize, providers and the PSOs will realize a reduction in costs and improved efficiencies across the entire work flow which will enable improved data integrity. As AHRQ develops the final rule for the development of a PSO framework, AHIMA recommends AHRQ continue to consider the need for a national health data stewardship entity.

AHIMA appreciates the opportunity to comment on the proposed rule. Overall, we believe these requirements have approached the needs for patient safety data and provide the safeguards which will permit active participation by this nation's healthcare providers who strive to improve the healthcare of all individuals. If AHIMA can provide any further information, or if there are any questions regarding this letter and its recommendations, please contact Allison Viola, MBA, RHIA, AHIMA's director of federal relations at (202) 659-9440 or Allison.viola@ahima.org, or me at (202) 659-9440 or dan.rode@ahima.org. Thank you for your time and consideration.

Sincerely,

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Vice President, Policy and Government Relations

cc: Allison Viola, MBA, RHIA