

## **VIA HAND DELIVERY**

Michael O. Leavitt, Secretary  
U.S. Department of Health and Human Services  
Center for Quality Improvement and Patient Safety  
Attention: Patient Safety Act NPRM Comments  
Agency for Healthcare Research Quality  
540 Gaither Road  
Rockville, MD 20850

**Re: Department of Health and Human Services; Notice of Proposed Rulemaking; Patient Safety and Quality Improvement, 73 Fed. Reg. 8113 (February 12, 2008)**

***RIN 0919-AA01***

Dear Secretary Leavitt:

The American Health Care Association (“AHCA”) appreciates the opportunity to comment on the Proposed Rule, “Patient Safety and Quality Improvement,” 73 Fed. Reg. 8112 (February 12, 2008) (“the Proposed Rule”). AHCA represents more than 10,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation’s frail, elderly and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities. AHCA is the nation’s leading long term care organization, and both the Association and its members are committed to *Advancing Excellence*, an unprecedented initiative among providers, caregivers, consumers and the federal government, forming a coalition to promote quality around measurable clinical and operational goals, which establish targets and benchmarks for quality improvement in nursing facilities. Nevertheless, AHCA members are among those providers who have been as the proposed rule describes “reluctant to participate in certain quality review activities for fear of liability, regulatory and professional sanctions, or injuries to their reputation.”

The AHCA and its membership are committed to continuing quality improvements in the delivery of care and services to our nation’s rapidly increasing frail elderly and disabled population. It is this commitment that gives AHCA a strong desire and interest in submitting comments intended to address, what we believe are serious limitations in the proposed rule to ensuring confidentiality and privilege protections for information that may be voluntarily disclosed by our member providers. We respectfully submit our comments in the hope that HHS will consider recommended changes to strengthen the privilege protection and modify the patient safety requirements and agency procedures in its final rule.

## **GENERAL COMMENT**

Developed to implement, in part, the Patient Safety & Quality Improvement Act of 2005 (Patient Safety Act), the proposed rule, according to the Agency for Healthcare Research, the Office of Civil Rights, and Health and Human Services (collectively “HHS”) is intended to address the current regulatory and litigation environments that have

discouraged healthcare providers from sharing information regarding adverse events, medical errors, or near misses thought to be essential to improving safety and quality in our healthcare delivery system. According to HHS, state peer review laws that currently comprise the legal framework for protecting certain health care information are limited in that they vary between states, apply only to hospitals and other limited healthcare entities, and significantly fail to protect information transmitted outside the covered entity. AHCA applauds and supports HHS attempt to create a system that will allow providers, including long term care facilities, to more freely share patient safety information, for the purpose of encouraging a culture of safety and assisting providers to effectively minimize patient risk. We fully support the concept that sharing patient safety information among and between providers and PSOs and most importantly, the aggregation of this data, could result in the development of best practices that will enhance continuous quality improvement and further provider efforts to ensure patient safety.

However, despite HHS' good intentions, AHCA believes that the proposed rule fails to go far enough to adequately protect from potential liability providers who share information with PSOs. The rule sets forth proposed confidentiality and privilege protections for patient safety information, termed Patient Safety Work Product (PSWP). PSWP is defined as information that (1) is gathered for purposes of reporting to a PSO *and* is actually reported, (2) is developed by a PSO in the conduct of defined patient safety activities, or (3) reveals the internal deliberations or analysis regarding reporting pursuant to a patient safety evaluation system. Without extending further protection, the provider may waive or lose existing confidentiality and privilege protections for information that it currently collects through peer review, risk management, quality assurance or some other function and subsequently reports that same or similar information to a PSO. Providers reasonably may be put in the position of having to weigh the risk of waiving or losing state peer review and other protections against the quality improvement and patient safety benefits that may be gained from participation in the proposed PSO framework. HHS will not have accomplished its goal of enabling all health care providers "to share data within a protected legal environment, both within and across states, without the threat of information being used against the subject providers" See 73 Fed. Reg. 8133 (February 12, 2008).

Another significant limitation is the failure of the rule as proposed to protect patient safety information reported to the PSO that underlies PSWP when it is also reported subject to other regulatory, accreditation, licensure or other accountability requirements. While AHCA understands and agrees that the PSO framework cannot relieve or shield a provider from meeting its obligations under existing reporting requirements, the failure to extend the privilege to required reports that often will form the basis of a voluntary report to the PSO may minimize incentive to make a voluntary report. AHCA also notes that the proposed rule does not protect original data such as medical records, billing, or discharge information that was collected and reported to a PSO which is also used for purposes other than reporting to a PSO. Regulatory and investigative agencies will have access to the required reports and all the original data, such as the underlying medical records. They do not need access to the facilities PSO report.

Despite the fact that the proposed rule grants a federal privilege to PSWP, making it generally not subject to subpoena, discovery, or disclosure in disciplinary proceedings against a physician or other healthcare practitioner and inadmissible as evidence in civil, administrative, and criminal proceedings, significant exceptions apply. The proposed rule, for example, permits disclosure of PSWP for use in criminal proceedings and for proceedings in which whistleblowers are seeking equitable relief for adverse employment actions. These exceptions may create an unintended consequence of less protection under the provisions in the proposed rule than is anticipated. It will encourage litigation to obtain data once it is disclosed to a PSO by expanding the use of pre-trial discovery to identify a privilege log of items disclosed to a PSO and then through in-camera review of the log in jurisdictions with judges known to favor plaintiffs' cases to ultimately obtain the actual reports themselves.

The proposed rule sets forth the requirements and procedures for organizations to become PSOs. The Agency for Healthcare Research and Quality (AHRQ) is designated as the certifying body under an attestation process leading to listing of approved PSOs. The types of organizations (public, private, for-profit, and not-for-profit) that can become PSOs are broad. While regulatory or accrediting bodies may not generally qualify as PSOs, subject to the Secretary's review, these bodies may qualify as component organizations. AHCA believes that regulatory and accrediting bodies, such as state agencies responsible for ensuring Medicare and Medicaid program compliance through enforcement actions that conceivably could apply to establish a component PSO, should be explicitly excluded in the same way that healthcare insurers are excluded under the proposed rule rather than leaving the determination to the discretion of the Secretary.

The proposed rule imposes specific requirements on organizations that are deemed component organizations, defined as units of corporations or multi-organizational enterprises or separate organizations that are owned, managed, or controlled by one or more parent organizations. Among those requirements, the proposed rule mandates that information technology systems of the PSO need to be separate from its sponsoring or parent organization. This represents a significant cost to those provider organizations that seek to establish their own PSOs. Yet, the proposed rule fails to establish any funding stream for PSOs or providers who participate in a PSO. AHCA recommends Congress fund PSO programs with subsidies and grants for the information technology systems.

AHCA offers its specific comments below, in hopes that its recommendations will be seriously considered and move the final rule in a direction that includes greater incentive and opportunity for more providers to commit to the spirit and mission of designing healthcare systems that improve patient safety. We hope that our comments will assist HHS in publishing a final rule that creates the type of comprehensive patient safety framework that achieves what is best described by HHS itself in the proposed rule preamble as system that will "...accelerate the development of new, voluntary provider-driven opportunities for improvement, increase the willingness of health care providers to participate in such efforts, and most notable, set the stage for breakthrough understanding of how best to improve patient safety."

## **SPECIFIC COMMENTS**

In the preamble, the Secretary of HHS requests public comment on key areas of the rule that establishes the authorities and process necessary to implement the Patient Safety Quality Improvement Act of 2005 (the Act). AHCA provides the following specific comments on those identified key areas:

### ***Subpart A – General Provisions and Definitions***

#### **Patient Safety Organizations (PSOs)**

1. The proposed rule broadly defines “provider” as an individual or entity licensed or otherwise authorized under State law to provide health care services with what appears to be a nonexclusive list of specific types of providers that can legitimately be PSOs.

AHCA seeks clarification that “assisted living, residential care and other community based care” providers are included in the broader term “long term care facilities, identified in the list of covered providers. An increasing number of these types of providers are delivering health care and services, including medication management, that expose them to the liabilities this rule is addressing and we believe that these providers are equally committed to patient safety.

2. AHCA is concerned that the very broad definition of “provider” for the purposes of qualifying as a PSO includes agencies within the Federal, state and local governments. At Sec. 3.102(a)(2) “Entities that may not seek listing as a PSO . . . .Any other entity public or private, that conducts regulatory oversight of health care providers, such as accreditation or licensure, may not seek listing, except that a component of such an entity may seek listing as a component PSO. As one of the most heavily regulated and scrutinized providers of healthcare, long term care facilities could be at significant risk should a state health agency whose mission it is to monitor and enforce compliance with regulations and requirements imposed by the Medicare and Medicaid conditions of participation for skilled nursing facilities, were named a component PSO. In fact, this would create a disincentive for long-term care facilities to report to such entities. The agency could have inappropriate access to information that could be used in a way that negatively impacts facilities. AHCA recommends that regulatory agencies, accrediting and licensing bodies be explicitly excluded as component PSO. This prohibition should also extend to the licensing and regulatory bodies that monitor assisted living, residential care and other community based care programs.

3. AHCA supports the proposed rule’s designation of parent organizations as providers and thus authorized to establish their own component PSOs. HHS discusses in the preamble that it does not see the requirement for entities, seeking a listing as a PSO under the proposed rule, to disclose whether they have a parent organization or are part of a multifacility organizational enterprise as “piercing the corporate veil, but does not address nor make any provision to prevent the courts from interpreting the disclosure in

just that way. AHCA recommends that HHS specifically address this issue in the final rule. HHS should propose limitations on any downstream use of the entity disclosures. For example, HHS may limit use of the entity relationship disclosures to the findings required by Section 924(c)(3) of the Patient Safety Act, 42 U.S.C. 299b-24 that the PSO can fairly and accurately perform PSO functions. Any public disclosure of entity relationships by HHS should include the disclaimer similar to the one on page 8116 of proposed rule's preamble that states "neither the statute nor the final regulations impose any legal responsibilities, obligations or liability on the organization(s) of which the component PSO is a part."

HHS should ensure that there is no inference to a component PSO being the alter-ego of the parent organization and further, that any disclosure regarding the parent organization made to the Secretary when the organization seeks to list a component PSO be privileged information, especially since the proposed rule provides that at least some of this information will be made public at the discretion of the Secretary.

#### **Patient Safety Work Product (PSWP)**

1. AHCA supports HHS' position on avoiding the regulation of PSWP use, transfer of, or sharing by internal disclosure within and between the legal PSO and provider entities for the reasons HHS has articulated in the proposed rule preamble. AHCA agrees that more stringent confidentiality and/or disclosure requirements should be left to the discretion of the PSO and providers under contract. The PSWP information must be able to move freely to and from contractors to develop the understanding needed to prevent and/or minimize injury from future adverse events.

2. In the preamble HHS suggests that patient safety work product (PSWP) as defined in the proposed rule means that patient safety information collected or developed by the provider and reported to the PSO or developed by the PSO when conducting "patient safety activities" or that reveals the deliberations of a provider or PSO within a "patient safety evaluation system" is protected. At the same time, discussion in the preamble notes that by statute, the protection afforded the PSWP does not relieve any provider from its obligation to comply with other legal, regulatory, accreditation, licensure or other accountability requirements that it would otherwise need to meet. What the proposed rule fails to address is that the information that a provider would voluntarily report to the PSO in the hopes of attaining PSWP protection is the precise information that it may be required to report under the above specified requirements. AHCA recommends that HHS extend privilege protection to information, that forms the basis of a PSWP, when that information is disclosed for the limited purpose of meeting otherwise required reporting mandates, such as incident or accident reports. Furthermore, the actual form in which the information is reported must be under the privilege so facilities are not

penalized for taking the time and effort to synthesize information in an understandable format for the PSO. There must be a balance achieved to interdict a system which currently is “name and blame” to one which favors “disclose and correct.” HHS should start with the assumption that providers are first collecting the information for the purpose of voluntarily reporting to a PSO where the information becomes protected PSWP. That same information collected for and reported to a PSO that is disclosed for the limited purpose of meeting a legal regulatory, licensure or accreditation requirement does not constitute waiver of the privilege granted the information as PSWP. Expanding privilege protection for this limited disclosure would go a long way not only to encourage provider participation in voluntary reporting to a PSO but potentially could significantly enhance the quality of the required reports filed. Regulatory and investigative agencies have access to their required reports and all the original data, such as the underlying medical records. They do not need access to the facilities PSO report.

3. HHS discussion in the preamble to the proposed rule suggests PSO recommendations developed as PSWP, within the context of patient safety activities disclosed to participating provider, for the purpose of implementing patient safety improvements will only be protected to the extent that those recommendations are rejected. AHCA urges HHS to provide privilege protection for those recommendations that are, in fact, instituted within the facility to further its safety mission. While the confidentiality of this PSWP is obviously breached when safety recommendations are implemented within the facility, providers should not have its commitment to improve quality used by plaintiff’s attorneys to establish or prove conditions existed in the facility that allegedly resulted in adverse events or patient harm. Further, the implementation of improvement plans and/or corrective actions should not lead to after the fact deficiency findings by state and federal teams surveying facilities for compliance with Medicare and Medicaid conditions of participation that subsequently may lead to serious enforcement consequences. This recommendation is consistent with the common law principle that the fact of correction of a defect cannot be used as evidence of liability. Additionally, such after the fact exposure to liability will act as a serious deterrent to providers voluntarily reporting “near miss” events in the first place and thus significantly deter the analysis of aggregated patient safety event data thwarting one of HHS’ anticipated outcomes of the regulation, i.e., “Advancement of such large volumes of patient safety events is expected to significantly advance our understanding of the patterns and commonalities of the underlying causes of the risk and hazards in the delivery of patient care” See Fed. Reg. 8113 (February 12, 2008).

4. AHCA also recommends that HHS ensure providers who conduct and/or report patient safety work product under existing federal or state confidentiality and privilege protections continuation of such protections when it reports similar and/or same information to its PSO, by preempting any waiver provisions.

5. AHCA, in recognition of the lack of any designated funding for the proposed PSO framework for either PSOs or participating providers, support alternative reporting systems, such as functional reporting, to relieve the potentially substantial burden associated with the transmission of every piece of information assembled by the provider related to specific patient safety events to the PSO. We recommend that any alternative reporting, e.g. the sharing of patient and event information databases, should only be considered after a relationship has been established or a contract executed between the PSO and the provider and an initial report on a specific event has been transmitted to the PSO. We also support HHS' position that a PSO under the proposed rule does not have an unfettered access to any provider information by virtue of its relationship or contract with the provider and that such access not be provided via any functional reporting provision in the final rule.

6. As currently proposed, the rule does not protect information assembled or developed by the provider in anticipation the information being reported to the PSO. AHCA recommends that HHS create a minimum 30 day period of protection for any information being collected and assembled with an assumption that the provider intends to report the information to the PSO. Additionally, AHCA recommends that the provider should be considered to be collecting information for the purposes of reporting to a PSO from the time of an adverse event is identified for purposes of creating a PSWP until 30 days thereafter.

### **Patient Safety Evaluation System**

1. AHCA agrees with HHS' position that PSO and/or provider documentation of a patient safety evaluation system is sound and prudent business practice but should not be a regulated function. The designation of a formal patient safety evaluation system left to the discretion of the PSO and provider will allow the flexibility and scalability of patient safety activities and level of engagement in those activities to meet the needs of individual providers and PSOs. We appreciate the discussion within the rule' preamble of the benefits of a patient safety evaluation system and what might be considered possible functions of such a system and recommend that the Secretary direct AHRQ and OCR, in consultation with provider organizations, to publish non-mandatory guidelines for patient safety evaluation system for PSO and providers who may be in need of such guidance.

### ***Subpart B – PSO Requirements and Agency Procedures***

1. Responding to HHS' inquiry, AHCA recommends that a PSO be required to notify providers when PSWP is impermissibly disclosed or a security breach occurs under the rule. The timing and terms of this notice can be spelled out in contract provisions.

2. As in our previous discussion regarding what entities can be PSOs under the proposed rule “provider” definition, AHCA reiterates its objection to the idea of a component PSO formed by any federal or state agency, where in the case of long term care, it is the purpose of the federal and state survey system that designated surveyor teams inspect for and enforce compliance with federal and state laws utilizing a variety of punitive measures. Also of significance is the fact that these survey teams are under fairly strict agency prohibitions for consultation with providers and therefore couldn’t meet the requirements for “patient safety activities,” i.e., the utilization of PSWP “for the purposes of “providing direct feedback and assistance to providers to effectively minimize patient risk” (Sec. 3.102(b)(2)(vii). AHCA further believes that allowing federal and state regulatory agencies to establish component PSOs should be prohibited under Sec. 3.102(c)(3) that requires that the pursuit of the mission of a component PSO must not create a conflict of interest with the rest of the parent.

3. Under Section 3.102(a) (1) HHS proposes that the PSO will certify that it will promptly notify the Secretary during the period of listing that it can no longer comply with any of the criteria in this section. This raises questions as to whether this notice is an admission of a deficiency by the PSO that would subject it to the correction of deficiencies in section 3.108 and whether the notice will prompt a preliminary finding by the Secretary, for example. AHCA recommends that HHS further clarify the relationship between prompt notification and correction of the deficiencies that could lead to revocation or voluntary relinquishment.

4. Also, according to the preamble, the rule does not require a provider to enter into a contract with a PSO to establish a relationship for the purpose of having a PSO receive and review PSWP. AHCA requests that HHS clarify whether the establishment of a relationship is sufficient to meet the “contract” requirement under Sec. 3.102 (b) (2) (iii). Finally, AHCA recognizes that some of its larger multifacility organizations may wish to establish a component PSO to service only its own facilities without taking on the burden and potential costs of serving as a PSO for other providers. AHCA requests clarification on whether a multifacility organization (that meets the rule’s definition of provider) and seeks to establish a component PSO and that PSO contracts with a minimum of two of the organization’s facilities has met the 2 “bona fide” contract requirement for listing.

5. HHS seeks comment on whether PSO certification for an entity should be conditioned on the entity’s agreement to use the Secretary’s guidance on definitions and common formats, to the extent it is practical and appropriate. While AHCA appreciates the agency’s rationale for identifying this certification condition, we don’t believe it is prudent to support nor necessarily oppose the requirement without having some advanced knowledge of what those formats and definitions will be and how the phrase “to the

extent practical and appropriate” would be interpreted by the Secretary upon reviewing an entity seeking PSO listing.

6. The proposed rule under Sec.3.102 requires significant disclosures by an entity submitting a certification seeking PSO listing, including, but not limited to, the entity’s relationship with contracting providers. Also in accordance with the provisions of this Sec. of the rule, the Secretary will make the disclosure statements available to the public along with related findings regarding each disclosure. AHCA requests that the information required to be disclosed and the information subsequently disclosed to the public should be limited to only that information that is necessary to meet those relevant and specific provisions and requirements of the final regulation.

7. Under Section 3.110 the Secretary may survey PSOs to verify compliance. AHCA recommends that HHS disclose who is likely to be designated this task and how it will be funded. Obviously there will be a fiscal impact on the agency designated to perform these reviews and other enforcement actions. AHCA requests that the Secretary should not designate this task to the any of the HHS or CMS regional offices or to contracted state offices that conduct licensing, certification or other regulatory actions of providers.

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

1. While AHCA agrees that traditional state-based legal protections for quality improvement activities are limited in scope, the proposed rule does not guarantee that reporting patient safety information that is protected under these peer review statutes and other regulatory quality assurance programs is not waived once that information is disclosed to the PSO. AHCA recommends that HHS explicitly preempt any waiver of existing confidentiality and privilege protections under Federal quality assurance or state peer review laws.

2. In accordance with the Patient Safety Act, AHCA recommends that HHS add specific language in the rule at Sec. 3.206 (b)(1)-(3) that, PSWP once disclosed for use in a criminal proceeding, to permit equitable relief and under provider authorization continues to be privileged and cannot be used or reused as evidence in any civil proceeding or in any context prohibited by the privilege protection, even though the PSWP is no longer confidential, as discussed at page 8143-44 of the preamble to the proposed rule.

3. Section 3.206(b) (2) allows disclosure of PSWP to the extent required to permit equitable relief under section 922(f) (4) (A). AHCA believes that HHS should issue a regulation that a protective order should be a condition for this disclosure. That would prevent open court and in brief disclosures.

4. Sec. 3.206(b)(8)(ii) of the proposed rule protects providers from accrediting action based on “good faith participation ...in the collection, development, reporting or maintenance of patient safety work product..” but the rule is unclear as to whether this protection extends to actions by survey and licensure bodies specific to those that oversee long term care providers. AHCA requests clarification of the definition of accrediting bodies to include the addition of survey and licensure bodies as precluded from taking action against a provider based on PSWP that is voluntarily disclosed under this rule. We agree with HHS, that where PSWP disclosure is excepted from confidentiality and privilege, the exception should be drawn as narrowly as possible to maintain PSWP confidentiality and privilege in the hands of all subsequent holders in the spirit of minimizing liability risk to providers who voluntarily report patient safety information.

#### ***Subpart D – Enforcement Program***

In response to HHS question whether a self-reported, impermissible disclosure should be a considered factor in determining the amount of a civil money penalty (CMP), AHCA recommends that self-reporting a potential violation should be a mitigating factor at Sec. 3.408 (c). The proposed rule sets forth a voluntary initiative, which is implemented under a relatively complex yet discretionary framework and where confidentiality concerns traverse two significant and substantive laws. While we recognize and support the proposed rule’s “knowing or reckless” standards for establishing a confidentiality violation [Sec. 3.404(a)], we believe that every effort must be made to reduce the risk of liability to encourage organization and provider participation.

#### **CONCLUSION**

AHCA commends HHS for all of its efforts to address barriers to patient safety and health care quality improvement activities that exist for providers. We also greatly appreciate that the agency has allowed for necessary flexibility in the design and implementation of the patient safety framework to encourage the formation of patient safety organizations (PSO) and the event reporting and safety activity participation by health care providers who voluntarily develop relationships with a PSO. Nevertheless, without some modifications to the proposed rule as indicated in our above comments, AHCA believes that many of its long term care provider members will not be assured that the necessary protection from liability that is associated with reporting information, voluntary or not.

Respectfully submitted,

Bruce Yarwood,  
President and CEO

Attachments