



April 14, 2008

Center for Quality Improvement and Patient Safety
Attention: Patient Safety Act NPRM Comments
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, Maryland 20850

RE: Patient Safety and Quality Improvement Proposed Rule

Dear Administrator:

The American College of Physicians (ACP), representing more than 125,000 internal medicine physicians and medical students, is pleased to offer comments on the U.S. Department of Health and Human Services (HHS) proposed rule on Patient Safety and Quality Improvement, 42 CFR Part 3 (February 12, 2008) (Agency for Healthcare Research and Quality and the Office for Civil Rights, HHS, RIN 0919—AA01). ACP strongly supports the establishment of a federal framework for physicians, hospitals, and other health care professionals and entities to voluntarily report “patient safety work product” to patient safety organizations (PSOs) on a privileged and confidential basis. What follows are ACP’s comments on Subparts B, C and D of the proposed rule.

Subpart B—PSO Requirements and Agency Procedures

This subpart outlines the certification and notification requirements that PSOs must meet, the actions that the Secretary may and will take relating to PSOs, the requirements that PSOs must meet for the security of patient safety work product (PSWP), the processes governing correction of PSO deficiencies, revocation, and voluntary relinquishment, and related administrative authorities and implementation responsibilities.

§3.101 HIPAA Privacy Rule

The ACP recommends that the regulations specify that a PSO should notify the organizational source of an impermissible use or disclosure of PSWP, or that the information reported may not meet the definition of PSWP (e.g., the reporting of an event that is prima facie criminal). The value of a well-structured patient safety evaluation system (PSES) is to prevent reporting of

information that is not PSWP. In the event of impermissible disclosure, the final regulations should encourage PSOs to notify the reporter that the information submitted is not PSWP.

§3.102(a) Eligibility and Process for Initial and Continued Listing as a PSO

The College agrees that HHS should establish a streamlined certification process that minimizes barriers to entry for eligible entities that seek to be initially or continually listed as PSOs. We are also in agreement with HHS' assessment that exceptions for eligibility should include entities that conduct regulatory oversight of health care providers. As indicated in the proposed regulations, public and private entities that conduct regulatory oversight of health care providers, including accreditation and licensure, should be prohibited from seeking eligibility as a PSO.

The proposed rule would allow a component of a regulatory entity to seek listing as a PSO. Such component, as with components of non-regulatory entities, would be required to establish and maintain a strong firewall between a component PSO and its parent regulatory entity with respect to its activities as a PSO, including adequate safeguards for PSWP. Providers would have access to the name of the parent regulatory entity, and such information would be publicly available. We believe that the intent of the statute is to establish an environment that assures providers that information they voluntarily report to PSOs will be used to promote and improve patient safety, not for regulatory or punitive purposes. If a component of a regulatory entity cannot establish such an environment, then it should not be certified as a PSO. As pointed out in the proposed rule, some regulatory entities that cannot themselves become PSOs could nonetheless try to circumvent the firewalls required between parent organizations and components; they could also attempt to compel providers to report to their component PSO over other PSOs. Even the perception that such activity by a regulatory entity is possible could be enough to completely undermine the intent of the law.

Consequently, we urge HHS to take additional measures to ensure that a component of any regulatory entity meets the criteria to be listed as a PSO. Components of regulatory entities should be required to explicitly identify their parent organization as a regulator, specify the scope of the parent organization's regulatory authority, and submit attestations from contracting provider(s) that such providers are informed of the nature and scope of the parent organization's regulatory authority. Further, HHS should prohibit any "individual" or "unit" access to PSWP under section 3.102(c)(1)(ii) if the individual or unit is part of the parent regulatory entity.

Health insurance issuers and components of health insurance issuers, including but not limited to Health Maintenance Organizations, should also be prohibited from seeking eligibility as a PSO. The ACP recommends that HHS clearly define health insurance issuers and components of health insurance issuers in the regulations.

§3.102(b)(2) Minimum Contracts Requirement

The College recommends that, in order to encourage use, the regulations not impose contract requirements that specify specific time periods and/or specific tasks. The regulations should clearly indicate that health care providers and PSOs have the ability to enter customized agreements on patient safety topics and activities. However, contracts between health care

providers and PSOs, at a minimum, should contain all safeguards, including but not limited to, privacy and confidentiality requirements that are outlined in the Patient Safety Act and should also address legal remedies for any breach. Also, the final rule should clarify that providers cannot be compelled to or prevented from reporting to a PSO under an employment or other contract.

§3.102(b)(2) Collecting Data in a Standardized Manner

ACP agrees that the Secretary should provide ongoing recommendations to PSOs on formats and definitions in order to facilitate aggregating PSWP. Facilitating reporting of patient safety events will lead to improvements in patient safety. To ensure that information is collected that is required to support improvement, it is critical to have standardized formats for use in data collection. In addition, using this standardized format will conserve resources by not having every PSO create their own formats.

The common formats and standards should be developed and tested by those involved in the delivery of health care services. Ongoing refinement of the formats and definitions should not negate the value of previously reported information. The Secretary's process for developing and maintaining recommended common formats and definitions, through its Patient Safety Work Group, should be a transparent consensus process that includes representatives of national physician and other health professional specialty organizations, experts from aviation, and others who have experience in safety events reporting formats. This Patient Safety Work Group should be required to meet on a regular basis in order to develop and update common formats and definitions. We look forward to reviewing and commenting on the common formats that are expected to be published in July/August 2008.

§3.102(c) Additional Certifications Required of Component Organizations

The regulation calls for three additional statutory certification requirements for a component PSO which are the following: secure maintenance of documents and information separate from the rest of the parent organization(s); avoid unauthorized disclosures of PSWP to the parent organization(s); and ensure that the mission of the component PSO does not create a conflict of interest with the rest of the parent organization(s).

The component PSO and parent organization should maintain a substantial firewall to ensure compliance with the privilege and confidentiality requirements of the Patient Safety Act. A component PSO should be able to contract with a unit of its parent organization(s) for services involving the PSO. For example, the component PSO and parent organization(s) should be able to share staff (e.g., clerical, custodial, administrative, accountants, etc.) as long as there is no direct conflict between the PSWP functions and the non-PSWP functions. In addition, any information exchanged between PSOs and their subcontractors should not waive the confidentiality of PSWP. The degree and manner of their activities and potential conflicts of interest should be carefully considered. For example, many units of parent organizations may have regulatory or oversight duties that immediately or ultimately affect providers, and thus may pose a conflict of interest (e.g., investor-owned hospitals; legal relationships providers may have

with parent or its subsidiaries, etc.). Please review additional comments noted above in §3.102(a).

§3.102(d) Required Notifications

The ACP agrees that in order for a PSO to meet its statutory obligation of entering at least two bona fide contracts that meet the requirements of proposed §3.102(b)(2), PSOs should be allowed to notify the Secretary of their compliance within a reasonable time frame; 45 calendar days before the last day of the period that is 24 months after the date of its initial listing and 45 day calendar days prior to the last day of every 24-month period.

§3.102(d)(1) Notification Regarding PSO Compliance with the Minimum Contract Requirement

The ACP agrees that a PSO be provided with adequate time (i.e., period of correction extends until midnight of the last day of the applicable 24-month assessment period for the PSO) to respond to a preliminary finding of alleged deficiency.

§3.102(d)(2) Notification Regarding PSO's Relationships with its Contracting Providers

The College agrees with the proposed time frame for the Secretary to receive the disclosure statement regarding its relationship(s) with any contracting provider(s); within 45 calendar days of the PSO's determination that the PSO's relationship with a contracting provider warrants disclosure. However, we are concerned about the unintended consequences of disclosure of the PSO's relationship with its contracting providers to the public (e.g., disclosing names of physicians undermines the privacy and confidentiality protections outlined in the Patient Safety Act). The NPRM did not fully address the issue of disclosure. We recommend that AHRQ foster the development of well-defined, minimum standards for disclosures so that providers can make informed decisions regarding contractual relationships with PSOs.

The attestation provided by the PSO should include reason(s) (e.g., data breach, insolvency, no reports, etc.) for any delisting. The Secretary should have discretion in releasing identities of workforce members, staff, or private parties. For example, a data breach may be attributable to substandard security rather than individuals disclosing protected information; financial difficulties, or insolvency may be attributed solely to the entity.

§3.104(c) Actions Regarding Required Disclosures by PSOs of Relationships with Contracting Providers

The Patient Safety Work Group that will develop common formats should also be responsible for determining the required content for the PSO disclosure statement. We caution against the unintended consequences of disclosure of the PSO's relationship with its contracting providers to the public (e.g., disclosing names of physicians undermines the privacy and confidentiality protections outlined in the Patient Safety Act).

§3.104(d) Maintaining a List of PSOs

At a minimum, we recommend that the PSO Web site include the following information in accordance with section 924(d) of the Public Health Service Act, 42 U.S.C. 299b–24(d):

- 1) contact information for each PSO;
- 2) the effective date and time of listing of the PSO;
- 3) a copy of each certification form and disclosure statement that the Secretary receives from the entity;
- 4) information on whether the PSO has certified that it has met the two contract requirement in each 24-month assessment period; and
- 5) if applicable, a copy of the Secretary’s findings regarding any disclosure statements filed by each PSO, including whether any conditions have been placed on the listing of the entity as a PSO and other information that the Secretary is authorized to make to the public.

Additionally, the College recommends that the PSO Website include the actual names of the subsidiary, the parent organization, and their affiliates. The PSO should also identify the parent company’s business objectives and whether the parent company is a profit/ non-profit organization. Furthermore, the PSO should identify all of the states where the parent company conducts business.

§3.104(e) Three-Year Period of Listing

The College agrees that the regulations should require the Secretary to provide a written notice of imminent expiration to a PSO no later than 45 calendar days before the date on which the PSO’s three-year period of listing expires, if the Secretary has not received a certification seeking continued listing. To ensure that health care providers have adequate notice to make alternative arrangements, information regarding the PSO’s imminent expiration should also be posted on the PSO web site. The Secretary should also require that PSOs facing imminent expiration be required to notify all affected providers who have reported to them.

§3.106 Security Requirements

The regulations should require PSOs to implement adequate measures for the security of PSWP including security management, separation of systems, security control and monitoring, and security assessment. PSOs should be provided with sufficient flexibility to develop standards. We believe that data security and maintenance of data security are essential to ensuring the protection of PSWP.

§3.108(a) and (a)(2) Correction of Deficiencies, Revocation and Voluntary Relinquishment

It is important that the regulations clearly indicate that PSOs have the right, including a procedural right, to appeal alleged deficiencies, regardless of how “egregious” the alleged conduct is. HHS should provide a definition for conduct that is so serious that it cannot be corrected. The Secretary should also consider whether the PSO has acted in good faith in correcting and remedying an alleged deficiency. The PSO should be given an automatic right to

appeal a proposed revocation and/or delisting. The PSO should be provided adequate time to provide a written appeal. The proposed rule indicates that a PSO has 30 calendar days from receipt of notice of a proposed revocation and/or delisting to respond to such notice. The College recommends that the time frame be extended to 45 calendar days to allow adequate time to appeal such notice. In addition, PSOs should be given an opportunity to take appropriate action to correct an alleged deficiency.

§3.108(b)(2) Required Notification of Providers and Status of Data

The College believes that the 15 calendar days required notice time period to inform the Secretary that the PSO has taken reasonable steps to notify each provider is adequate, with respect to the required notification of providers of a revocation. The PSO should also be responsible for notifying all affected providers and reporters within 15 calendar days from notice of revocation and should provide a list of affected providers and reporters to the Secretary within the same time period.

§3.108(b)(3) Disposition of Patient Safety Work Product and Data

We recommend that the timeframe and process to complete disposition of the PSWP held by a PSO, which has been revoked for cause, be similar to the timeframe and process imposed under the HIPAA Privacy Rule.

§3.108(c)(2) Notification of Voluntary Relinquishment

There should be a 30-day window for providers to report data to a PSO after the PSO has been delisted regardless of whether the delisting was voluntary or involuntary. The intent of the Patient Safety Act is to provide protections for PSWP. The provider may send information to a PSO not realizing that the PSO was subject to revocation and/or delisting or had already been revoked or delisted. Thus, the information should be deemed PSWP and confidential. The PSO should be responsible for notifying the provider of its revocation and/or delisting and the appropriate disposition of PSWP in its possession.

§3.108(c)(5) Non-Applicability of Certain Procedures and Requirements

In cases of explicit or implied voluntary relinquishment, PSOs should have an opportunity to appeal or challenge their removal from the listing. PSOs should be required to post procedures for transferring information and have adequate time to establish new relationships for transition purposes.

§3.110 Assessment of PSO Compliance

We agree that the Secretary's inspection authority to ensure that PSOs are meeting their statutory obligations does not extend to health care providers. As indicated by AHRQ, AHRQ's regulatory authority in accordance with the Patient Safety Act only extends to PSOs; AHRQ will not regulate providers that work with PSOs.

Subpart C—Confidentiality and Privilege Protections of PSWP

§3.204(c) Implementation and Enforcement of the Patient Safety Act

In order to implement and enforce the Patient Safety Act, an exception should be narrowly drawn to permit the Secretary to perform enforcement and operational duties against a PSO. PSWP must be protected and the risk of improper disclosure of PSWP must be minimized. The College strongly recommends that the Secretary use judicious restraint with respect to requesting disclosure of PSWP for compliance and enforcement activities in order to preserve the integrity of the reporting system, to prevent being viewed as overly regulatory, and to maintain focus on the intent of the law—encouraging an environment for reporting information to improve patient safety. The full authority of the Secretary’s enforcement power should therefore be reserved for the most egregious breaches and failures and that those working with the Secretary in this activity should protect the PSWP, regardless of the breach or failure and be mindful that these types of incidences have the potential to erode trust in the reporting system.

§3.206(b) Exceptions to Confidentiality

The College requests that the Secretary provide a definition and examples of “redisclosures.” We ask the Secretary to consider the consequences of redisclosures and unrestricted redisclosures, rather than focusing solely on negative implications of limiting redisclosures. Redisclosures can be compared to “hand-offs,” an informal term for a whole series of activities that need to take place when an individual transitions in care from one setting to another, from one clinician to another, etc. (Carolyn Clancy, MD, “Consumer Insider Medical Handoffs,” April 25, 2007). Robust systems are needed to prevent dangers inherent to multiple handoffs such as loss of information and diffusion of responsibility (Tejal K. Gandhi, MD, MPH; *Ann Intern Med* 2005; 142: 352-358). Similarly, redisclosures of confidential, protected information (i.e., PSWP) may involve multiple transfers through systems that are not equally robust, thus providing opportunity for breaches in confidentiality or unauthorized disclosures. In addition, redisclosures, like handoffs, are subject to diffusion of responsibility, information loss, misuse of information, and unauthorized disclosure.

§3.206(b)(2) Equitable Relief for Reporters

The ACP agrees that the regulations should specify that a protective order is required for disclosure, as authorized by the regulations, where an employee seeks redress for adverse employment actions for good faith reporting of information to a PSO directly or to a health care provider with the intended disclosure to a PSO. Although the reporter is afforded discretion to disclose the relevant PSWP to seek and obtain equitable relief, all subsequent holders receiving the PSWP from the reporter should be bound by the continued privilege and confidentiality protections.

§3.206(b)(3) Authorized by Identified Providers

Although HIPAA is intended to protect patients from consequences of impermissible use and disclosure of protected health information (e.g. discrimination), the intent of the Patient Safety

Act is to apply the HIPAA Privacy Rule to providers and protect them from consequences of misuse (e.g., defamation and loss of economic opportunity).

The Patient Safety Act does not specify the form of the authorization by a provider to come within this disclosure exception or a timeframe for record keeping. We agree with the proposal that an authorization be in writing, be signed by the authorizing provider, and give adequate notice to the provider of the nature and scope of each disclosure authorized. The content of the authorization should explicitly inform the provider as to the nature and scope of the identifiable patient safety work product to be disclosed to ensure the provider is making a knowing authorization.

§3.206(b)(4) Patient Safety Activities—Disclosure between a Provider and a PSO

The ACP agrees that PSOs should be allowed to reciprocally disclose PSWP back to health care providers with respect to patient safety activities. This information exchange is necessary to ensure that the goal of the Patient Safety Act is met—advancing patient safety improvements. PSOs should also be permitted to disclose PSWP to other PSOs with respect to patient safety activities in accordance with the Patient Safety Act. Any information exchanged between PSOs and their subcontractors does not waive the confidentiality of PSWP.

Compliance with the HIPAA Privacy Rule

The College believes that the exchange of PSWP for patient safety activities among providers and PSOs in accordance with the Patient Safety Act is critical for improving patient safety. The HIPAA Privacy Rule definition for health care operations should contain a specific reference to patient safety activities conducted pursuant to the Patient Safety Act.

§3.206(b)(5) and (6) Disclosure of Non-Identifiable PSWP

The risks of disclosing identifiable PSWP must be carefully considered. Identifiable information about a nondisclosing provider should **not** be released. De-identification of identifiable PSWP is a complex undertaking. Adequate safeguards must be in place to ensure that identifiable information is not released. We recommend that AHRQ establish a work group to further evaluate the proposed standards and approaches identified in the regulations.

§3.206(b)(7) To the Food and Drug Administration (FDA)

Because Congress did not expressly include disclosure to FDA-regulated entities, we request that AHRQ provide examples that would cause disclosures under this provision.

§3.206(b)(8) Voluntary Disclosure to an Accrediting Body

Given the potential for unintended consequences of voluntary disclosures, the College cautions against promoting such disclosures to an accrediting body. The Patient Safety Act includes provisions that limit the actions an accrediting body may take to seek PSWP. The regulations should provide a definition for accrediting bodies.

§3.206(b)(9) Business Operations

The ACP recommends that the regulations allow for disclosures of PSWP for business operations purposes by a health care provider or a PSO to associated professionals such as attorneys, accountants, etc. The regulations should clearly specify that business operations disclosures do not waive privilege of PSWP and therefore PSWP cannot be subpoenaed, ordered, or entered into evidence in a criminal or civil proceeding through this exception. Any additional business operation disclosures should comply with the HIPAA Privacy Rule and confidentiality requirements. Hence, the business operations exception should be broad enough to cover all activities and functions listed as “health care operations” under HIPAA. Additionally, the Secretary should only use the rule-making process for the adoption of business operations exceptions from confidentiality requirements since the rule-making process allows the opportunity for public comments.

§3.206(b)(10) Disclosure to Law Enforcement

The College recommends that the regulations should clearly specify that business operations disclosures do not waive privileges of PSWP and therefore PSWP cannot be subpoenaed, ordered, or entered into evidence in a criminal or civil proceeding through this exception.

§3.206(c) Safe Harbor

The regulations create a safe harbor for provider(s) and responsible person(s) when a member of its workforce discloses PSWP that does not include information that assesses the quality of care of an identifiable provider, or describes or pertains to one or more actions or failures to act by an identifiable provider. This safe harbor also be extended to PSOs.

§3.210 Required Disclosure of PSWP to the Secretary

Disclosure of PSWP should be limited to only what is needed for the investigation and enforcement activities or what is needed in seeking and imposing civil money penalties in accordance with the Patient Safety Act. The PSWP should be kept confidential.

Subpart D—Enforcement Program

The College agrees that PSOs should be encouraged but not required to post on their website narrative statements regarding their capabilities.

§ 3.408—Factors Considered in Determining the Amount of a Civil Money Penalty

ACP agrees with the use of detailed, multiple factors outlined in the proposed regulations for calculating civil money penalties. Self-report disclosures should not be included in the list of factors given that self-report disclosures may be viewed as an additional reporting obligation.

The College is committed to improving patient safety and quality in the nation's health care system. We commend your leadership on this important health care issue. We look forward to reviewing additional regulations that will be issued for comment regarding the common format to be used by PSOs and a network of patient safety databases. In addition, we are committed to working with you and our partners in patient safety initiatives on this effort.

Sincerely,

J. Fred Ralston, MD, FACP
Chair, Health and Public Policy Committee
American College of Physicians