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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, MD 20850

RE: Patient Safety and Quality Improvement Proposed Rule (RIN 0919-AA01)

Dear Administrator:

The North American Spine Society (NASS) appreciates the opportunity to provide comments regarding the US 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 Office for Civil Rights, HHS, RIN 0919 – AA01). NASS commends HHS and the Agency for Healthcare Research and Quality (AHRQ) on the effort made to implement the Patient Safety and Quality Improvement Act of 2005 by drafting these regulations and fully supports voluntary reporting of “patient safety work product” (PSWP) to patient safety organizations on a privileged and confidential basis.

**General Comments:**

- The proposed rule creates separate streams of information for reportable incidents/issues that are protected through the patient safety evaluation system, but in no way protects the same information in other streams (ie, risk management, etc). This could allow recipients of impermissible disclosures to pursue streams of information outside the patient safety evaluation system to target providers punitively.
- NASS understands the desire for marketplace regulation of PSO operation, however, the business marketplace operates on a different set of standards and goals than that of medicine (ie, FDA relies on medical industry to report study results “on its honor”). Providers need more structure and security as an incentive to participation.
- Despite the Congressional act that created this initiative, providers need additional assurance that it cannot be challenged by the Judicial Branch under the Freedom of Information Act, resulting in the release of patient safety work product to the detriment of patients and providers.

**Subpart A – General Provisions**

**§3.20 Definitions**

*Component Organization:*

It is appropriate to consider a subsidiary a component organization. It recognizes the potential oversight/control of a parent organization over its subsidiary at a real or perceived level that contradicts the sought after independence and separation needed by a PSO and requires the safeguarding of a “firewall” between the parent and component described in the proposed rules.

*Disclosure:*

Uses of patient safety work product should be regulated to prevent inappropriate use of information. Clear definition of appropriate uses within or between entities could prevent uses that would be contrary to the original intent of the act. For instance, because the purpose of the act is to facilitate research and encourage data aggregation for patient safety purposes, use of information and best practices derived from it, should be prohibited for use for commercial gain, advertising/promotion, etc.

*Patient Safety Evaluation System:*

According to proposed rules, documentation of the patient safety evaluation system is not required by providers or PSOs. However, documentation will provide substantial proof to support claims of privilege and confidentiality. It seems documentation should be required, at minimum, for PSOs alone, if not for providers as well, in order to inspire confidence among providers that these entities are exercising due diligence in the protection of the patient safety work product, which would further encourage provider participation. Required documentation by providers of the patient safety evaluation system also will provide maximum protection to the provider and patient safety work product.

*Patient Safety Work Product:*

When materials can be collected outside a patient safety evaluations system, which may be duplicative to those submitted to a PSO, which are protected, and those duplicates are not protected patient safety work product, the level of protection and incentive to the provider is significantly diminished. In effect, all that has been achieved is the ability to aggregately collect patient safety data without adequate provider protections.

Providers who establish relationships or contracts with PSOs should be permitted to take advantage of alternative reporting arrangements, as long as those arrangements are clearly defined and documented as part of the relationship, secure, protected and do not allow impermissible disclosures or access to materials other than those indicated for PSO use. In addition, providers that contract with a PSO should be permitted to satisfy the reporting requirement for PSWP by giving a PSO access to information (functional reporting), but only following any initial report by a different method. Functional reporting should be clearly defined and document the process and uses between the provider and PSO limiting access only to materials appropriate to the reporting. HIPAA, disclosure rules etc. must be followed and the process must conform to the rules of the act in all other manners. Functional reporting should be limited to interaction between the provider and PSO only, with no middlemen or intermediaries, to prevent unanticipated disclosures.

A short period of protection should be extended to PSWP collected, but not yet transmitted. This period should be identified through documentation by the provider that a patient safety evaluation system process has been triggered. Consideration should

also be given to advocating for PSWP protections as soon as information is collected for purposes of patient safety evaluation, even if the data is not later analyzed or reported to a PSO.

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

### **§3.101 HIPAA Privacy Rule**

The regulation should require PSOs to notify providers when PSWP is impermissibly disclosed or a security breach occurs. The provider carries a disproportionate amount of risk related to any inappropriate disclosures and should be notified when that occurs. In addition, similar to disclosures related to potential identity theft, patients, if identifiable, should be notified of inappropriate disclosures as the release of personal health information could have detrimental effect on their employment, insurability, etc.

PSOs should also clearly indicate through documentation or contract with a provider how data will be used once submitted (terms of aggregation, subject to analysis, etc.). Uses of the data should not be left to the discretion of the PSO, but clearly articulated and agreed to between both parties in advance of submission to prevent any unanticipated or unwanted uses or disclosures.

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

Although NASS understands the desire of the Secretary to minimize regulatory burden and expediently develop PSOs, there is very little emphasis on what qualifies an entity to become a PSO. Without ensuring appropriate qualifications to act as such, some patient safety activities and data aggregation may be doomed to failure if not in the hands of qualified entities. NASS does agree and support the Secretary's proposal to disclose and make transparent all PSO conflict of interest disclosures, and further suggests that all financial relationships, including dollar amounts paid to providers, should be disclosed.

Components of regulatory bodies should not be allowed to list as PSOs. The link between the regulatory body and any related PSO would be a barrier to provider participation due to concerns about disclosures between the entities. Specific entities that come to mind for prohibition include: components of US military, Medicare/Medicaid programs, licensure programs, etc. where ties to provider career and livelihood are closely related, especially when many patient safety errors are system based as opposed to individual. In contrast, it may be appropriate to allow facility accreditation entities to have component PSOs, as many patient safety issues are systemic in nature. If the Secretary deems to allow regulatory components to list as PSOs, it should be with the proviso that parent or regulatory organizations may not compel providers to use a prescribed PSO entity or facilities within a health system to facilitate contractual obligations under duress from a system-wide PSO. In addition, regulatory bodies, health care insurers and others prohibited from PSO status, should be prohibited from funding PSOs.

### **§3.102(b) Fifteen General Certification Requirements**

NASS has concerns that the requirement for PSO listing is subject only to an attestation process. The information being provided not only is protected health information, but may also expose providers “doing the right thing” by helping advance the cause of the patient safety to undue risk of legal exposure for incidents that may be result of issues beyond their control. Attesting to the fact that an organization is qualified and able to handle, secure and analyze sensitive health data is insufficient to assure providers’ participation and security in doing so. In addition, in a commercial marketplace, there is substantial risk that an entity standing to make commercial gain will not voluntarily notify the Secretary if it is no longer able to meet the necessary requirements. More substantial oversight and auditing of the PSO system is necessary.

### **§3.102(b)(2) Required Certification Regarding Seven PSO Criteria**

#### *Minimum Contract Requirement*

Additional clarification is needed regarding the minimum contract requirement, specifically the permissibility of splitting a contract with a large 50 hospital health system into two separate contracts to meet the minimum contract requirement. NASS questions whether two contracts with the same health system simply to document two contracts should satisfy this minimum contract requirement. More diversity may be required.

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.

#### *Collecting Data in a Standardized Fashion*

NASS suggests that de-identification of data should be required for all PSO submissions. De-identification would provide further protection and if data auditing is not being undertaken, then this information is unnecessary.

Data should only be submitted to one PSO by providers to prevent duplication in submission leading to skewed data and misleading conclusions (ie, a hospital submits its data to two regional PSOs, which in turn submit their data to an aggregate source, in turn skewing results because of the duplicate submission). PSOs should, to the extent practicable and appropriate, use the Secretary’s guidance on definitions and common formats in order to obtain and maintain certification. This standardization will facilitate data aggregation to the greatest extent possible.

### **§3.102(c) Additional Certifications Required of Component Organizations**

In the spirit and practice of operating independently and keeping PSWP completely separate from a parent organization and preventing improper disclosures, the component PSO should be prohibited from contracting or subcontracting work related to or using PSWP to its parent organization. NASS agrees that separation of component PSO information systems from their parent is a reasonable and expected operation. Further, NASS suggests that two years should elapse prior to an employee of a PSO, with knowledge of PSWP that could inform or influence work done at the parent organization, is permitted to work for the parent organization.

The rule should include some basic standards for when a conflict exists between the mission of a component PSO and its parent organization. The conflict should take into consideration at least whether the information in the PSO’s possession could be used/sold for commercial gain. Patient safety information aggregated and used by PSOs

should be used in good faith to improve the quality of patient care without cost for access, outside those perhaps related to cost recovery of the transaction. Another consideration would be whether health entities would create an oasis for patient safety information related to their organization for their own protection and use. It may be useful to create standards for a minimum level of sharing aggregate data to prevent information hoarding and self-protective behaviors.

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

The attestation provided by the PSO should include reason(s) for any delisting.

### **§3.104(a) Actions in Response to Certification Submissions for Initial and Continued Listing as a PSO**

NASS would assert that listed PSOs should notify the Secretary in the event of an organizational name change, or changes in control, leadership or ownership of the PSO or its parent organization.

### **§3.104(d) Maintaining a List of PSOs.**

NASS recommends that the PSO Web site include, at a minimum, the following information in accordance with section 924(d) of the Public Health Services 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 to public.

In addition, NASS recommends that the PSO Web site 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.

The Secretary may want to consider adding to the listing materials any areas of topic specialty the PSO may have or have interest in.

### **§3.104(e) Three-Year Period of Listing**

Given that PSOs are mandated to have a minimum of two contracts for a two year period, it may be operationally useful to make the listing period consistent with the minimum contract period (either two or three years). NASS also agrees that the Secretary should include on the public list of PSOs a listing of which PSOs for which list

expiration is imminent to give providers potential notice or the opportunity to investigate such changes before selecting to report. In addition, an option to join an e-mail list notifying providers of these potential delistings would be beneficial.

### **§3.108(a)(2) Notice of Preliminary Finding of Deficiency and Establishment of an Opportunity for Correction of a Deficiency**

In the instance that a PSO has exhibited egregious disregard for regulations, requirements and confidentiality of the patient safety work product, including disrespect for time and efforts of the provider reporters or failure to correct deficiencies requested by the Secretary, the Secretary should have the option to allow for preliminary notice so that the PSO may correct any factual errors with an opportunity for further "cure," that would not be sufficient, meaningful or appropriate.

### **§3.108(a)(4) Opportunity to be Heard in Writing Following a Notice of Proposed Revocation and Delisting**

NASS sees no reason for an exception to the 30 day time period to submit a written response to proposed revocation and delisting of PSO charter where the revocation is due to failure to meet the minimum contract requirement of two contracts per 24 month period. Five days may not be an adequate timeframe in which to formulate a response. NASS proposes that the 30 day time period should also be granted in such instances.

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

With respect to the required notification of providers of a revocation, we believe 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. 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**

NASS would encourage formulation of a timeframe for a revoked PSO to complete disposition of its data and patient safety work product to encourage timely disposition; NASS believes six months would be a reasonable timeframe.

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

If a PSO voluntarily relinquishes its PSO status, the data and patient safety work product should be protected as in the cases of revocation. In each instance the loss of status affects and is likely the responsibility of the organization; providers reporting should not be subject to loss of protection in the instance a PSO chooses to relinquish its status any more than if it is revoked. Providers should be given every opportunity for protection as should the patients whose data is being submitted.

### **§3.110 Assessment of PSO Compliance**

NASS agrees 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 Patient Safety Work Product**

#### **§3.204(b)(1) Criminal Proceedings**

NASS fully supports the provision that before a judge can rule on an exception to privileged information, “the court must make an *in camera* determination that the PSWP contains evidence of a criminal act, is material to the proceedings, and is not reasonably available from other sources.” This is an appropriate protection mechanism.

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

It is reasonable that the Secretary be responsible for determining when privilege exceptions are necessary to perform enforcement and operational duties in implementing the Patient Safety Act.

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

Authorizations by providers for disclosure should be specific and time-limited, rather than general in nature.

#### **§3.206(b)(5) Disclosure of Nonidentifiable Patient Safety Work Product**

##### *Re-identification of Data*

NASS proposes that any keys used for re-identification of data be protected from discovery and given the same protections as patient safety work product to prevent inappropriate re-identification of data by unintended parties.

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

The regulations should clearly specify that such disclosures do not waive privileges or PSWP and therefore PSWP cannot be subpoenaed, ordered, or entered into evidence in a criminal or civil proceeding through this exception. Further, it should be clearly stated that any inappropriate disclosures (eg, to the public or media) would result in civil monetary penalties.

#### **§3.208 Continued Protection of Patient Safety Work Product**

Notification of the confidential and/or privileged nature of the PSWP should be required with each disclosure to ensure due diligence on the part of all handlers.

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

#### **§3.304 Principles for Achieving Compliance**

Additional clarification is needed related to how and when the Secretary would provide technical assistance to providers, PSOs and responsible persons to assist in bringing

them into compliance with the confidentiality provisions. The importance of adequate disclosure of steps that the Secretary feels are necessary or advisable to avoid prosecution or penalties for violation of confidentiality have to be emphasized and clarified. NASS would suggest that the government agencies provide adequate training opportunities and technical assistance at the onset of this endeavor to prevent inadvertent noncompliance.

### **§3.402 Basis for a Civil Monetary Penalty**

A \$10,000 civil monetary penalty may be inadequate to function as a deterrent for some organizations and is too high for inconsequential or harmless disclosures. The dollar amount of the proposed maximum penalty may well deter accidental or incidental disclosures of PSWP, but the Secretary may want to consider that there may be instances when such disclosures are intentional. There should be stiffer penalties if information is disclosed with the purpose or result of litigation. If such intentional disclosures by those willing to pay a \$10,000 fine are not prevented, the program will be undermined to the extent that providers will be reluctant to report the cases with the most legal risk even though such cases may be the most important to study from the standpoint of process improvement.

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

In circumstances where entities involved in the Patient Safety Act identify a violation, take steps to correct and avoid the violation in the future, and promptly report that violation to the governmental agency(ies) involved in the administration of this program, there is no doubt that self reporting should be considered when assessing a civil money penalty. This encourages the intention of maintaining compliance with confidentiality by self-policing and also encourages obtaining the technical assistance that may be available.

### **§3.418 Exclusivity of Penalty**

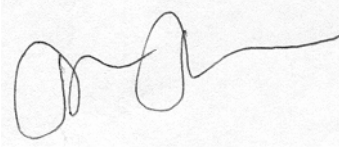
NASS strongly supports the stipulation that a civil violation of both the confidentiality provisions and the HIPAA Privacy Rule would be enforceable under either authority, but not both.

### **§3.504(p) The Hearing**

Protecting PSWP is paramount and open hearings where identifiable PSWP may be disclosed go contrary to the intent of this program. Each time there is a suspected confidentiality violation or noncompliance the subsequent open hearing could be damaging to the entity participating in the program. We strongly suggest that any time PSWP may be disclosed, the hearings be closed to the public.

In conclusion, we again wish to thank you for the opportunity to submit the above comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tom Faciszewski', with a long horizontal line extending to the right.

Tom Faciszewski, MD  
President

A handwritten signature in black ink, appearing to read 'David A. Wong', with a long horizontal line extending to the right.

David A. Wong, MD, MSc  
Patient Safety Task Force Co-Chair