

6300 North River Road
Rosemont, Illinois 60018

P. 847.823.7186
F. 847.823.8125

www.aaos.org

April 14, 2008

Carolyn M. Clancy, M.D.
Director, Agency for Healthcare Research and Quality
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: RIN 0919-AA01;
Patient Safety and Quality Improvement
Notice of Proposed Rulemaking Comments of the American Academy of
Orthopaedic Surgeons

Dear Dr. Clancy:

The American Academy of Orthopaedic Surgeons (“AAOS”), on behalf of more than 17,000 Board-certified orthopaedic surgeons, is pleased to submit comments in response to the proposed rule “Patient Safety Organizations and Patient Safety Work Product” (the “Rule”) published in the Federal Register on February 12, 2008.

The AAOS has championed efforts to develop a national joint replacement registry for a considerable period of time. The mission of the AAOS national joint registry initiative is to foster a national center for data collection and research on total hip and knee replacements with far-reaching benefits to society including, but not limited to:

- Reduced morbidity and mortality;
- Improved patient safety;
- Enhanced quality of care and medical decision-making;
- More appropriate resource utilization; and
- Advances in orthopaedic science and bioengineering research.

One of the prime concerns of the AAOS and its members regarding this initiative is ensuring the confidentiality and privileges of its members and hospitals who would report information concerning joint replacements, failures, and the like. The AAOS envisions that the joint replacement registry would be a Patient Safety Organization

(“PSO”) that would be entitled to the protections set forth in the Rule and the Patient Safety and Quality Improvement Act of 2005 (the “Act”).

While the AAOS generally agrees with the contents of the Rule as proposed, we offer the following comments on various sections of the Rule for your consideration.

COMMENTS

1. Section 3.20 (Patient Safety Evaluation System). The Rule solicits comments as to whether a Patient Safety Evaluation System (“PSES”) should be required to be documented. We firmly believe that there should be a requirement for a PSES to be documented. A PSES is a critical element of the structure for ensuring the confidentiality and privileged nature of Patient Safety Work Product (“PSWP”). The definition of PSWP states that it includes data, reports, etc., “...which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.” Whether an action, deliberation, analysis, or other activity is done in the context of a PSES will determine, in many instances, whether such actions, deliberations or analyses are entitled to the privilege and confidentiality protections of the Act and the Rule. Given the acknowledged importance of ensuring such confidentiality and privilege protections in order to encourage providers to report information to PSOs, the determination of the boundaries or confines of a PSES should not be left to chance. Rather, the Rule should be modified to outline the required characteristics and documentation for a PSES. This will provide certainty to providers regarding how a PSES can be structured, and documented, in order to ensure that what they intend to be confidential and privileged actually benefits from those protections.
2. Section 3.20 (Patient Safety Work Product). As noted in the introduction to these comments, the AAOS envisions supporting a joint replacement registry that would qualify as a PSO under the Act and Rule. The registry would be a long-term data collection and follow-up project that would gather data on patients in hospitals with total joint replacements of the hip and knee. The purpose of the registry would be to improve patient safety, reduce morbidity and mortality, and reduce medical spending. The registry would allow for tracking and identification of poorly performing implants, identification of patients who may need follow-up evaluation based on the information regarding implants, and periodic reporting of registry findings regarding implants and the risks associated with the use of different products.

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We believe that the registry concept easily fit under the definition of a PSO. However, we acknowledge that the information to be reported to the registry is somewhat different than the information that is likely to be reported to the typical PSO (e.g., adverse events or fall data). The AAOS seeks clarification that the data from excluded sources, when combined with other data and reported to the PSO will be protected as PSWP. We include this comment here not to suggest any modifications but because we believe it is important to recognize that the definition of PSWP under the Act and the Rule is very broad and that the Agency should anticipate that there will be some PSOs that are very specialized and narrowly focused in the data that they collect and analyze. Such specialization should not be a consideration in the listing of an entity as a PSO so long as it fulfills the requirements for a PSO as set forth in the Act and Rule.

3. Section 3.20 (Patient Safety Work Product). Comment has been requested on whether providers that establish relationships or contracts with PSOs should be permitted to take advantage of alternative reporting arrangements (functional reporting). We firmly believe that the answer to this question should be in the affirmative. Functional reporting arrangements that are established between a provider and a PSO would allow for the reporting of information to a PSO to be more efficient and effective. Because of the sensitivity of the information being reported, we recommend that there be a requirement for a written contract between a provider and PSO if the provider is going to take advantage of functional reporting arrangements. This will encourage more reporting by providers because, if properly set up, the reporting could become something that takes very little effort by the provider other than its gathering the information into a database that is then made accessible to the PSO. This will also provide a PSO with a better sense of when new reports will be received from its contracted providers and allow the PSO to be more efficient in its operations. We believe that this clearly furthers the intention of the Act to encourage reporting by providers in order to further the development of more effective patient safety recommendations.

We do not believe that functional reporting should be limited to the reporting of subsequent information to a PSO after an initial report (by a method other than functional reporting) of information by a provider to the same PSO. As noted above, we do believe that there is a need for a written contract requirement between a provider and a PSO before functional reporting should be permitted. However, if the written contract is in place that outlines how the functional reporting is to occur, we see no reason that this should be restricted to only subsequent reports, as opposed to initial reports, by a provider to a PSO.

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4. Section 3.20 (Patient Safety Work Product). Comment was requested regarding whether a short period of protection should be provided to information assembled for reporting, but not yet reported to a PSO and, if so, what the appropriate time limit should be for protection and should the protection be conditioned on a demonstrated intent to report the assembled information. We believe that the Act requires that this question be answered in the affirmative.

The Act (and the Rule) defines PSWP (in part) as data which are assembled by a provider for reporting to a PSO and are reported to a PSO. As a practical matter, Congress must have recognized that the assembly of information for reporting to a PSO, and the actual reporting of that information to a PSO, cannot and will not occur simultaneously. Therefore, we believe the appropriate inquiry is first, whether it is appropriate to impose any limitation on how long data can be held by a provider without reporting and still be entitled to the protections of the Act and Rule, and second, if it is appropriate to impose a limitation, how long should that limitation be?

We believe that it is appropriate to impose some time limitation for how long a provider can hold data assembled to be reported without reporting that data and still be entitled to the protections of the Act. The reason for this is that the Act expressly states that in order for the data to become PSWP, it must be reported. Just as the Act clearly contemplates that the assembling of data to be reported and the actual reporting of that data cannot occur simultaneously, the Act also clearly states that the data must be reported at some time in order to become PSWP. As a result, we believe that some time limitation is appropriate.

The harder question is what that time limitation should be. Any time limitation has to allow a provider ample time to conduct analyses (such as root cause analyses) of raw data and to “develop” (this term is used in the definition of PSWP) the data and analyses before reporting as well as contemplate the normal flow of internal reporting of such data that will occur within a provider’s administrative structure. Any time limitation also has to account for the fact that all providers are not created equal, i.e., some providers will have extensive resources devoted to the collection and reporting of information while others will not have such resources and will take a much longer period of time to finalize their handling of the data before actually reporting it.

Given these concerns, we do not believe that a defined period of time for how long a provider can hold data assembled to be reported without reporting that data and still be entitled to the protections of the Act is appropriate. A defined period of

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time, regardless of the length of that period of time, cannot adequately anticipate the various factors, issues, and problems that providers may encounter in the future as they “assemble and develop” data for reporting to a PSO. An attempt to impose a defined period of time may have the unanticipated consequence of discouraging providers from reporting (because of an inability to comply with the period of time imposed) or of causing data that a provider sought to be PSWP to not have such status (and therefore not be protected) despite the good faith efforts of the provider. In addition, in light of the clear legislative recognition that there must be a time lag between the assembly and development of data and the actual reporting of that data, the creation of a defined period for this time lag may well be inconsistent with the language of the Act.

For all of the above reasons, we do not support establishing a defined period of time for how long a provider can hold data assembled to be reported without reporting that data and still be entitled to the protections of the Act. Rather, we believe the appropriate standard should be flexible and one which recognizes that providers will need to take various actions before reporting data collected. These actions could include, among others, the collection of the data, the analysis and development of the data for their internal patient safety concerns, and internal reporting of the data to and consideration of the data by different areas within the provider’s organization. So long as a provider can demonstrate that it is engaging in activities geared toward preparing the data for reporting to a PSO, or that it is taking any action regarding the data that is within the confines of the provider’s documented PSES, the data should then be considered to be PSWP.

5. Section 3.20 (Patient Safety Work Product). An issue closely related to the above issue is whether there should be any time limitation on how far back in time a provider can go to collect information for reporting to a PSO for the purpose of creating PSWP. We do not believe that there should be any limitation on how far back a provider can go to collect information for reporting to a PSO for the purpose of creating PSWP. The intention of the Act is to improve patient safety by providing important protections to providers so that providers will be encouraged to report information to a PSO. The PSO will then review and aggregate information reported from various providers and provide feedback to providers regarding better patient safety practices. If a provider chooses to collect historical data for reporting to a PSO this will simply result in more information being available to a PSO for review and analysis. Since the clear purpose of the Act is to encourage reporting by providers, we see no reason whatsoever to impose an artificial date before which providers cannot collect data if they want that data to be protected under the Act. In

fact, imposing such a “floor” would appear to be in direct conflict with the purpose of the Act.

6. Section 3.20 (Patient Safety Work Product). The Act and the Rule provide significant confidentiality and privilege protections for the PSWP that providers assemble and report information to PSOs. However, there will be many instances encountered by providers in which they collect data that is not reported to a PSO and does not constitute the deliberations or analysis of a PSES but which may still be protected by applicable state laws. We would appreciate confirmation that the Rule is not intended and does not nullify any applicable state law privileges or protections which may attach to activities or data of providers that are in addition to those provided by the Act and Rule.

7. Section 3.102(b)(2). We strongly agree that to the extent practical and appropriate, the Secretary will provide guidance on definitions and common formats for use by PSOs. There are numerous benefits, and few, if any, detriments, for PSOs to adopt the Secretary’s guidance on definitions and common formats. These benefits include:

- The use of common definitions, formats and understandings will result in the use of “one language” by all parties involved in the process so that aggregated data, and recommendations that emanate from that data, are useful and have the same meaning across the spectrum of users of the data;
- The conservation of resources so that each PSO is not required to create its own format; and
- Minimizing the burden on providers to report information to a PSO, especially if a provider has a contract or arrangement with more than one PSO to whom it reports information.

However, in order to expeditiously implement the activities of PSOs and allow for the Secretary to have ample time to review and reach consensus upon definitions and common formats, the AAOS requests that, at least initially, adherence to definitions and common formats not be a necessary in order to meet certification requirements.

8. Section 3.206(b)(4). This section provides an exception to the confidentiality protection of PSWP for disclosures of PSWP for patient safety activities by a provider to a PSO or by a PSO to a provider. We agree that this is necessary in order to allow for the flow of information between a provider and PSO in order to advance patient safety activities. We would like confirmation that a

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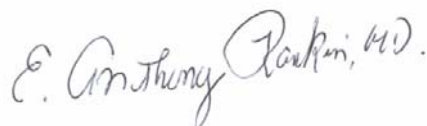
disclosure of PSWP that identifies other institutional or individual providers by a provider to a PSO and, subsequently, by that PSO to the provider, is permissible and within the scope of this exception without the need to obtain the permission of the providers identified in the PSWP. We believe that this should be permissible because the exception does not limit the disclosure by a provider to a PSO, or vice versa, to nonidentifiable PSWP and it is foreseeable that data that is reported by providers, especially institutional providers, will contain information that would allow many providers to be identified. However, we would appreciate confirmation that this is the intent of the Rule.

9. Preamble Impact Statement. As a part of the discussion of the impact of the Rule in the Preamble, there is a discussion that the Agency has no hard information on the number of entities that may want to become a PSO. The Agency then estimates that between fifty to one hundred entities may apply to become listed as a PSO in the first three years after publication of the final rule. This estimate is further refined by the Agency to anticipate fifty such applications in the first year and twenty-five in each of the second and third years after publication of the final rule. We understand that these estimates are made for the purpose of estimating the impact of the Rule and do not believe that they are intended to restrict the number of entities that can apply to be listed as a PSO. We would appreciate your confirmation of this understanding in the final rule.

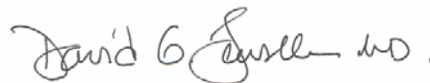
CONCLUSION

The AAOS appreciates the opportunity to comment on this important proposed regulation. We encourage AHRQ to consider the recommendations contained herein and to provide for consistent, yet flexible regulations to govern PSO activities. The AAOS looks forward to the final regulations and the implementation of this program.

Sincerely,



E. Anthony Rankin, MD
President
American Academy of Orthopaedic Surgeons



David G. Lewallen, MD
Chair
AAOS AJRR Oversight Board