

## Proposed Regulations for the Patient Safety and Quality Improvement Act

On July 29, 2005, the Patient Safety and Quality Improvement Act of 2005 (the "Act") was signed into law in response to reports that preventable adverse events result in millions of dollars of health care costs each year, which could be avoided if the health care system was better designed to improve safety. On February 12, 2008, almost two and a half years after the law was enacted, The Agency for Healthcare Research and Quality (AHRQ) published the proposed regulations implementing the Act. Members of the public are invited to comment on the proposed regulation until April 14, 2008. Comments will be considered in formulating the final regulation. The following is a summary of the proposed regulations.

The Patient Safety Act and proposed regulations create a framework for voluntary reporting to Patient Safety Organizations (PSOs) of adverse events, medical errors or near misses by hospital and health care providers. A PSO may be public or private, for profit or non-profit, but it cannot be a regulatory or accreditation entity that oversees healthcare providers or health insurance issuers.

Providers will collect information for the purpose of reporting to a PSO through a "patient safety evaluation system." Providers then may report "patient safety work product" to a PSO without fear of waiving confidentiality and privilege protections. Aside from a few exceptions, the patient safety work product reported to the PSO remains privileged and confidential.

Patient safety work product includes data, reports, records, memoranda, analyses, or written or oral statements which could result in improved patient safety and are assembled or developed by a provider for reporting to a PSO, or are developed by the PSO for patient safety activities, or constitute deliberations of a patient safety evaluation system.

Medical records, billing, discharge information, any other original patient or provider information, and information that was collected, maintained, or developed separately or that exists separately from a patient safety evaluation system are not protected as patient safety work product. The proposed regulation provides an example of a hospital reviewing a list of near-misses reported within the past 30 days.



Hancock, Daniel, Johnson & Nagle, PC (HDJN) provides assistance and guidance to healthcare providers in virtually all legal matters affecting healthcare. Generally, these include corporate, employment, administrative, and transactional matters; litigation; and governmental affairs.

The analysis of whether to report to the PSO remains protected, regardless of whether the provider reports the information. However, the list of near misses is not protected unless reported.

PSOs can also disclose patient safety work product back to the providers for patient safety activities, allowing a free flow of protected information. Furthermore, the regulations propose that PSOs be permitted to disclose patient safety work product to other PSOs or to other providers that have reported to the PSO, and that providers be permitted to share information to other providers for patient safety activities as long as the provider and reporter identifiers are anonymized.

In order to be listed as a PSO, an organization must certify that it meets 15 general requirements. Eight of the requirements are related to patient safety activities. They are:

- (1) Efforts to improve patient safety and quality,
- (2) Collection and analysis of patient safety work product,
- (3) Development and dissemination of information with respect to improving patient safety,
- (4) Utilization of patient safety work product for the purposes of encouraging a culture of safety and providing feedback and assistance,
- (5) Utilization of qualified staff are utilized,
- (6) Operation of a patient safety evaluation system,
- (7) Preservation of confidentiality of patient safety work product, and
- (8) Provision of appropriate security measures for patient safety work product.

There are also seven requirements that govern PSO operations:

- (1) Patient safety is the mission and primary activity of the entity,

- (2) Appropriate qualified staff,
- (3) Patient safety work product for the provision of direct feedback and assistance to providers are utilized to effectively minimize patient risk,
- (4) Health insurance issuers and components of health insurance issuers are precluded from being PSOs,
- (5) Requirements for submitting disclosure statements are followed,
- (6) Minimum contract requirement are followed (i.e., each PSO must have more than one contract with multiple providers, the contract period must be for a “reasonable period of time” and be a bona fide contract),
- (7) The collection of data must be completed in a standardized manner.

It is likely that health systems and hospitals will set up PSOs. They will be categorized as “component PSOs” if they have one or more parent organization, or are part of a multi-organizational enterprise. Examples would be a subsidiary entity created by a health system or a joint venture created by several organizations. As a component PSO, they will have three requirements in addition to the 15 listed above. These additional requirements are intended to ensure that the PSO’s activities are separate and distinct from its parent organization. They are as follows:

- (1) Create a “firewall” or secure maintenance of documents and information separate from the rest of the organization of which it is a part
- (2) Avoid unauthorized disclosures to the organization of which it is a part
- (3) Ensure the absence of a conflict between its mission and the rest of the organization of which it is a part.

The proposed regulations allow a component PSO to share accounting or administrative staff, but it cannot share staff whose knowledge of patient safety work product could influence decisions in areas such as credentialing and peer review.



In-depth, up-to-date knowledge of the law along with responsiveness and personal attention to our clients are priorities at HDJN.

However, a clinician whose work is solely provision of patient care could undertake work for the PSO.

Although there are a number of important issues to resolve, PSOs may provide a great benefit to hospitals by protecting patient safety work product that to date may not have retained confidentiality and privilege protections.

The Secretary of Health and Human Services will develop a network of patient safety databases. Healthcare providers and other PSOs will be able to access the information, and analyze national or regional trends. AHRQ will also issue a National

Healthcare Quality Report with the findings for each year.

PSOs will be privately funded and the regulations do not provide for any government assistance.

Our firm has worked with a number of providers in developing PSO strategies. For more information on the topic please contact B. Page Gravely, Jr. or Molly A. Huffman at (804) 967-9604 or by email ([pgravely@hdjn.com](mailto:pgravely@hdjn.com) or [mhuffman@hdjn.com](mailto:mhuffman@hdjn.com)).

*The information contained in this advisory is for general educational purposes only. It is presented with the understanding that neither the author nor Hancock, Daniel, Johnson & Nagle, PC, is offering any legal or other professional services. Since the law in many areas is complex and can change rapidly, this information may not apply to a given factual situation and can become outdated. Individuals desiring legal advice should consult legal counsel for up-to-date and fact-specific advice. Under no circumstances will the author or Hancock, Daniel, Johnson & Nagle, PC be liable for any direct, indirect, or consequential damages resulting from the use of this material.*

<p><b>Richmond</b>  4701 Cox Road  Suite 400  Glen Allen, VA 23060  PO Box 72050  Richmond, VA 23255-2050  O (804) 967-9604</p>	<p><b>Fairfax</b>  3975 Fair Ridge Drive  Suite 475 South  Fairfax, VA 22033  O (703) 591-3440</p>
<p><b>Harrisonburg</b>  3210 Peoples Drive  Harrisonburg, VA 22801  O (866) 967-9604</p>	<p><b>Virginia Beach</b>  One Columbus Center  283 Constitution Drive  Suite 301  Virginia Beach, VA 23462  O (757) 321-6555</p>

For more information about HDJN visit the firm website at: [www.hdjn.com](http://www.hdjn.com)