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# The Final Rule for Patient Safety Organizations Pursuant to The Patient Safety and Quality Improvement Act

On November 21, 2008, the Agency for Healthcare Research and Quality (AHRQ) published the Final Rule which will officially govern the creation and operation of Patient Safety Organizations (PSOs) and provide the operating mechanisms for the Patient Safety and Quality Improvement Act of 2005 (the "Act") which was signed into law on July 29, 2005. Prior to this Final Rule, a Proposed Rule was issued on February 12, 2008, interim guidelines were released on October 8, 2008 and twenty organizations have been certified to operate as PSOs since then. Effective January 19, 2009, those groups, and all other entities seeking certification, will have to certify that they are in compliance with the Final Rule in order to be designated as a PSO.

There were several significant changes from the Proposed Rule and interim guidance to the publication of the Final Rule, including the following:

- Modification of several definitions including those for Component

Organization, Parent Organization, Provider, Disclosure, and Patient Safety Work Product (PSWP). A definition for "Affiliated Provider" was added.

- Expansion of the types of organizations that cannot operate PSOs to include organizations that accredit or license health care providers; oversee or enforce statutory or regulatory requirements; act as an agent of a regulatory organization; or operate a federal, state or local patient-safety reporting system through which the providers are mandated to report information.
- Requirement for PSOs to notify reporting providers of inappropriate disclosures or security breaches related to the information they reported.
- Specification of compliance with the requirement regarding collection of PSWP.
- Elimination of requirements for



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separate information systems and restrictions on shared staff for most component PSOs, but added additional restrictions and limitations for PSOs that are components of excluded entities.

- Narrowing and clarification of disclosure requirements that PSOs must file regarding contracting providers with whom they have additional relationships.
- Modification of security requirements to provide flexibility for PSOs to determine whether to maintain PSWP separately from unprotected information.
- Addition of a new expedited revocation process for exceptional circumstances that require prompt action.
- Elimination of implied voluntary relinquishment. Instead, a PSO's listing will automatically expire at the end of 3 years, unless it is revoked for cause, voluntarily relinquished, or its certifications for continued listing are approved.
- Allowance of disclosures of identifiable, non-anonymized PSWP among affiliated providers for PSAs.
- Requirement for providers voluntarily disclosing PSWP to accrediting bodies either to obtain the agreement of identified non-disclosing providers or to anonymize the information with respect to the non-disclosing providers prior to disclosure.

Of these changes, the most notable ones are (1) elimination of the requirement for component PSOs to have separate information systems and (2) elimination of prohibition on shared staff in component PSOs (except for components of entities excluded from listing, which will not affect private healthcare providers and hospitals).

Eliminating the requirement for separate information systems may largely decrease the cost of forming and maintaining a PSO for component PSOs, which include those for corporate hospital entities and medical associations. The Department concluded that there are a number of cost-effective alternatives for achieving the goal of separate PSWP. In its place, the Final Rule requires component PSOs to ensure the information system maintaining PSWP will not permit unauthorized access by any individuals in, or units of, the rest of its parent organization.

Eliminating the prohibition on shared staff in component PSOs should also reduce the overhead expenditures and costs associated with maintaining a PSO. The Department concluded that parent organizations would not likely jeopardize patient safety work product protections. In place of requiring separate staff, the Final Rule restates the statutory requirement that the component organization, along with its workforce and contractors, may not make unauthorized disclosures to the rest of the organization of which the PSO is a part. Allowing corporate entities to share their staff with the PSO they form will be advantageous in regard to the expenditure of resources and the time required to begin operating as a PSO since they will not have to hire an entirely separate staff.

Please see our prior Client Advisory on The Proposed Regulations of the Patient Safety and Quality Improvement Act for additional background information on the Act and its components.

Also, if you would like more information on the Patient Safety Act or the Final Rule, 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)).



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