

Akerman Practice Update

HEALTHCARE

February 2009

The Case for Using Patient Safety Organizations in Florida

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Florida healthcare providers reeling from the effects of Amendment 7 allowing broad access to health records may find refuge in the Patient Safety Quality and Improvement Act (the "Act")¹. The Act seeks to balance two key objectives. First, the Act seeks to promote the sharing of information about adverse patient safety events among providers and Patient Safety Organizations (PSOs) for the purpose of learning from those events to improve patient safety and the quality of care. Second, the Act addresses provider concerns about the potential for information to serve as a roadmap for provider liability from negative patient outcomes.

To achieve both of these objectives, the Act provides substantial and robust privilege and confidentiality protections to providers reporting sensitive health information (called "Patient Safety Work Product" or "PSWP") to a federally certified PSO (such as the Florida Patient Safety Corporation - the first PSO in the country to become federally certified).

Under the Act, information becomes PSWP (and is thus protected) when it is assembled or developed by a provider for reporting to a PSO and is reported to a PSO. PSWP is also information that is developed by a PSO for the conduct of patient safety activities. PSWP reported by a provider to a PSO is privileged and confidential. Although certain exceptions exist to privilege and confidentiality, the exceptions are narrowly tailored to encourage maximum provider participation in patient safety reporting.

PSWP does not include a patient's original medical record, billing and discharge information, or any other original patient or provider record. Additionally, information

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¹ Patient Safety Quality and Improvement Act, 42 U.S.C. 299b-21 through b-26, and the final rules at 42 CFR Part 3.

P R O V I D E R T I P S

Providers working with a PSO should have robust policies and procedures such as:

- **Documenting collection of information for reporting to PSO**
- **Documenting date of collection of information**
- **Designating information as PSWP**

that is collected to comply with external reporting obligations (such as state incident reports, FDA adverse drug event reports, information to comply with health oversight agency requirements, National Practitioner Data Bank reports and disclosures required by conditions of participation or conditions of coverage) is not PSWP and is not protected.

To avail themselves of the protections of the Act, providers must establish a Patient Safety Evaluation System (PSES) which is the provider's mechanism for collecting, managing, analyzing and communicating information for reporting to or by a PSO. Providers, and PSOs, should have policies and procedures describing the PSES including:

- how information enters the PSES;
- what processes, activities, physical space(s) and equipment comprise or are used by the PSES;
- which personnel or categories of personnel need access to PSWP to carry out their duties involving operation of, or interaction with, the PSES;
- the category of PSWP to which access is needed and any conditions appropriate to such access; and,
- what procedures the PSES uses to report information to a PSO or disseminate information outside of the PSES.

Providers should also create policies and procedures for working with a certified PSO to include how information is identified and separated, how its PSES will operate, a description of the space where deliberations and analyses are conducted, how information will be reported to the PSO and how the PSO will provide feedback to the provider.

Build or buy?

Providers wanting to take advantage of the protections afforded by the Act must decide whether to utilize an existing PSO or build their own.

Considerations for using an existing PSO

Providers wanting to contract with an existing PSO will not need to seek Federal certification or craft the necessary policies and procedures required for certification. Further, providers will have the opportunity to take immediate advantage of privilege and confidentiality protections at known costs. Operational concerns such as patient safety being the primary activity and mission of the entity, and satisfying the requirement for having 2 contracts with different licensed providers within 24 months of listing are not a provider responsibility. Working with an existing PSO will allow a provider's data to be aggregated with other clients of the PSO (which is likely to be a more broad and diverse database), and, for some providers, will achieve desired anonymity if the PSO contract is the provider's sole relationship with the PSO.

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Considerations for creating a component PSO

If a provider opts to create a “component” PSO, policies and procedures consistent with Federal PSO rules must be crafted, the component organization must be created and Federal certification must be obtained. These activities will delay protections and involve unknown costs and expenses. Some component PSOs will have difficulty making patient safety a primary activity and mission if they are units of a provider, and may encounter difficulty satisfying the requirement for having 2 contracts with different licensed providers within 24 months of listing. Data aggregation will be limited to the component PSO’s clients, and the PSO may be required to disclose certain other relationships between it and the provider. Those interested in component PSOs should be aware of certain restrictions between the PSO and its provider plus additional attestation requirements for certification purposes.

In short, the Act provides much needed relief for Florida providers in responding to concerns raised by Amendment 7 by creating a safe haven for sensitive information. Rather than a patchwork of state-by-state protections (that have been severely eroded in some states including Florida), there will now be national uniform protections for clinicians and entities performing quality and safety activities.

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- Healthcare Cost Analysis
- Physician
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