

## **Special Edition PSO Brief: Appeals Court Upholds PSO Protections**

In an opinion filed May 29, 2012, an Illinois appellate court upheld a lower court's decision that patient safety work product (PSWP) is privileged under the Patient Safety and Quality Improvement Act (PSQIA) of 2005, and therefore, is not discoverable "in connection with a federal, state, or local civil, criminal, or administrative proceeding." (42 U.S.C. § 299b-22(a))

"The decision affirms important legal protections that can be derived from creating a patient safety evaluation system and reporting safety and quality data to a federally listed Patient Safety Organization," says Ronni P. Solomon, J.D., executive vice president and general counsel of ECRI Institute. "PSQIA encourages hospitals, physicians, pharmacies and other licensed providers to submit patient safety and quality information to PSOs. The decision shows that the court was willing to apply the federal law beyond state privilege laws and thus give providers a legal tool that may work to close gaps in their state peer review privilege laws."

The Illinois Department of Financial and Professional Regulation (IDFPR) sent subpoenas to Walgreen Company, requesting "all incident reports of medication error" involving certain pharmacists. Walgreens contended that such materials constituted PSWP and thus were not discoverable, and explained the operation of its patient safety evaluation system (PSES) to the court: as each report of medical error is generated in the organization's own system for confidential and privileged quality improvement, it is then transmitted electronically to a federally certified patient safety organization (PSO). IDFPR asserted that Walgreens also retained the documents for purposes other than reporting to a PSO, and thus they were not privileged under the PSQIA. However, Walgreens responded with affidavits stating that no incident reports pertaining to medication error are collected or maintained separately or outside of its reporting system.

The lower court granted Walgreens' motion to dismiss the agency's petition to enforce its subpoenas and found that the incident reports of medication error are PSWP under 42 U.S.C. § 299b-22, and thus privileged and protected. IDFPR appealed.

In its review, the appellate court examined the specific language of the PSQIA and the intent of Congress in enacting it. The court noted that the purpose of the PSQIA was to encourage "a culture of safety" and quality in the U.S. healthcare system by "providing for broad confidentiality and legal protections of information collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety." The court noted that PSWP is defined as any data, reports, records, memoranda, analyses, or written or oral statements which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, and that information collected, maintained, or developed separately, or that exists separately, from a patient safety evaluation system is not considered PSWP. The appeals court determined that two affidavits prepared by Walgreens' vice president of pharmacy services made it clear that the organization satisfied the requirements of the PSQIA and that the documents subpoenaed were entitled to privilege from discovery.

The appeals court addressed the petitioner's contention that Walgreens retained other documents (e.g., case inquiry reports) noting employees' errors in dispensing medication. The court found that such reports were immaterial because they were not

incident reports of medication error as requested in the subpoena. Instead, the reports concerned employee violations of policy, such as giving out medications for free and failing to follow directions from supervisors.

The court also addressed the state agency's contention that Illinois' Medical Studies Act permitted discovery of the medication error incident reports because the act excludes pharmacies from its privilege protections. The appeals court agreed, finding that the state law's privilege did not apply to pharmacies. Nevertheless, the court concluded that the agency's argument that the Medical Studies Act applied to this case lacked merit. While not specifically discussing federal preemption, the court cited the broad language of the PSQIA in protecting PSWP from discovery in connection with a federal, state, or local civil, criminal, or administrative proceeding. In so ruling, the court applied the broader federal protections provided under the PSQIA.

## Lessons for Providers

This case illustrates organizations' need to demonstrate to the court that the information they seek to protect from discovery was assembled or developed for the purpose of reporting to a PSO, as defined in the statute. In the Walgreens case, the court accepted affidavits from Walgreens personnel as evidence rather than seeking direct evidence. That said, providers should pay attention to how they define, structure, document and operationalize their patient safety evaluation system, which in essence is the protected space in which patient safety activities that lead to improvements in safety and quality are conducted. Providers have a lot of flexibility in designing the scope of their PSES since the PSQIA has no specific requirements regarding how a patient safety evaluation system should be established. The regulations state that documentation is a best practice.

ECRI Institute PSO recommends that organizations consider labeling PSWP as such to reduce the risk of inappropriate disclosures. A legend might state, for example, "CONFIDENTIAL PATIENT SAFETY WORK PRODUCT. Protected under the Patient Safety and Quality Improvement Act. Do not disclose unless authorized by [insert name of governing document, office, or body]."

ECRI Institute PSO also recommends documenting the following:

- ▶ Processes, activities, physical space, and computer systems that comprise the patient safety evaluation system.
- ▶ Procedures for entering data into or removing data from the patient safety evaluation system.
- ▶ Identities of staff members with access to the patient safety evaluation system and for what purposes.
- ▶ Procedures for reporting information to the PSO and receiving feedback from the PSO.
- ▶ A flowchart that visualizes how information enters the patient safety evaluation system.
- ▶ Definitions of what constitutes PSWP in the patient safety evaluation system.



### How Can We Help You?

Whether you have questions about the final rule or want to learn more about ECRI Institute PSO and/or support for other PSOs, we would be happy to hear from you. Please contact ECRI Institute at [psa@ecri.org](mailto:psa@ecri.org) or call (610) 825-6000, ext. 5558.