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Illinois Appellate Court Upholds Application of Patient Safety Act to Deny Access to State's Subpoena for Walgreens' Medication Error Incident Reports

Background

In the first reported appellate decision of its kind in the country, the Illinois Second District Appellate Court (*The Department of Financial and Professional Regulation v. Walgreen Company* (2012 Ill. App. 2d 110452, filed May 29, 2012) affirmed the dismissal of a lawsuit filed by the Illinois Department of Financial and Professional Regulation (IDFPR) against Walgreens when it refused to turn over subpoenaed "reports of medication error" involving three of its employed pharmacists. Walgreens had previously submitted written objections to the IDFPR which contended that these reports were collected as part of its patient safety evaluation system (PSES) and then reported to the Patient Safety Research Foundation, Inc. (PSRF), a patient safety organization (PSO) created by Walgreens and certified by the Agency for Healthcare Research and Quality (AHRQ) in January of 2009. Walgreens argued that the incident reports qualified as patient safety work product (PSWP) and therefore were not subject to discovery or admissibility into evidence under the federal Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) (42 U.S.C. Sections 299b-21-26 (2006)).

The Patient Safety Act was passed by Congress to encourage voluntary provider-driven initiatives to improve the quality and safety of health care services through the development of PSOs, the establishment of broad federal confidentiality and privilege protections, and to facilitate the aggregation, analysis and dissemination of de-identified quality information at the local, regional and national levels in a protected legal environment.

Walgreens took advantage of these protections when it established its PSES to collect, manage and analyze patient safety activities, including medication error incident reports, which it furnished to PSRF. These incidents were collected as part of Walgreens' "STARS" system, and were tracked and evaluated in order to improve the quality of its pharmacy services.

In its motion to dismiss the IDFPR's lawsuit, Walgreens included two affidavits from its vice president of pharmacy services which essentially stated that:

- Walgreens did not have any other reports responsive to the IDFPR's request and did not possess or create other incident reports that were collected or maintained separately from the STARS system.
- The STARS reports are prepared to address an "improperly processed or filled prescription that is dispensed to the customer."
- Reports must be prepared for each such event and are to be submitted to the PSRF.
- The STARS system is maintained electronically and all reporting is confidential.

The IDFPR had contended through a counter-affidavit that information supplied by Walgreens in its defense of a prior federal age discrimination case by a former employee included other documents separate from the STARS reports, with different titles, that allegedly referenced medication errors. Consequently, the IDFPR argued that these documents were either separate and/or different incident reports that were used for a purpose other than as part of Walgreens' PSES, and therefore should not be deemed confidential under the Patient Safety Act.

Appellate Court Decision

The appellate court, in examining the Patient Safety Act, found that the language and intent of Congress was quite clear. Specifically, the court stated:

> "The Patient Safety Act 'announces a more general approval of the medical peer review process and more sweeping evidentiary protections for materials used therein' *KD ex rel. Dieffenbach v. United States, 715* F. Supp. 2d 587,595 (D. Del. 2010). According to Senate Report No. 108-196 (2003), the purpose of the Patient Safety Act is to encourage a 'culture of' Safety' and quality in the United States health care 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.' S. Rep. No. 108-196, at 3 (2003). The Patient Safety Act provides that 'patient safety work product shall be privileged and shall not be ***subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding.' 42 U.S.C. § 299b-22(a) (2006). Patient safety work product includes any data, reports, records, memoranda, analyses, or written or oral statements that are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization. 42 U.S.C. § 299b-21(7) (2006). Excluded as patient safety work product is 'information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system [PSO].' 42 U.S.C. § 299b-21(7)(B)(ii) (2006)."

The court rejected the IDFPR's arguments that the STARS reports could have been used for a purpose other than reporting to a PSO or that other incident reports were prepared by Walgreens which were responsive to the subpoenas because both claims were sufficiently rebutted by the two affidavits submitted by Walgreens. Although the age discrimination suit (See *Lindsey v. Walgreen Co.* (2009 WL 4730953 (N.D. Ill. Dec. 8, 2009, aff'd 615 F. 3d 873 (7th Cir. 2010)) (per curium)) did identify documents used by Walgreens to terminate the employee, such as a "Pharmacy Manager Performance Review" and "Case Inquiry Report," the court determined that these were "about policy violations, i.e., giving out medications for free and failing to follow directions from supervisors." Because none of these documents were considered "incident reports of medication error," which were the sole materials requested by the IDFPR, the court found them immaterial and affirmed the trial court's decision to grant Walgreens' motion to dismiss because no genuine issue of material fact existed.

The IDFPR's remaining arguments relating to its attempt to obtain additional discovery were rejected on procedural grounds. In any event, the court found that additional discovery would not "cure the defect in petitioner's subpoenas" because the Walgreens affidavit stated that the only responsive documents were the STARS reports.

Impact of Decision

The *Walgreens* decision is significant because it represents the first appellate court decision in the country to interpret and hold that the privilege protections afforded under the Patient Safety Act not only effectively preempt more restrictive state law, but also protect from discovery the minutes, reports, analyses and other information relating to patient safety activities if collected for the purpose of reporting to a PSO. Although the precedential effect of this decision is limited to Illinois, it joins at least one other trial court decision that has similarly applied the Patient Safety Act to bar discovery requests. (See *Fancher v. Shields*, No. 10 CI-4219, Jefferson Circuit Court, Kentucky (August 16, 2011)). (But see *Morgan v. Community Medical Center* No. 08 CV 4850, Lackawanna County, Pennsylvania (June 14, 2011), where the trial court ruled against a hospital seeking to bar discovery under the Act based on the hospital's failure to meet its burden that the Act protected the incident report being sought.)

Although the privilege and confidentiality protections of a PSO have technically been available since 2005, and participation in or establishment of a PSO became an option in January 2009 when the patient safety regulations became final, comparatively few licensed providers have taken advantage of these very broad safeguards. Following are some of the reasons that have contributed to this overall reluctance to embrace the Patient Safety Act:

- Every new statute causes a certain "lag time" in gaining an understanding of the law and how it is to be interpreted.
- Most providers are quite familiar with available statute court peer review protections and therefore movement toward the Patient Safety Act adds a prohibitive element of uncertainty, especially when attempting to educate physicians and employees and then to effectively implement the new standards.

- In order for providers to take full advantage of a PSO, a multidisciplinary team must review and coordinate the establishment of a provider's patient safety evaluation system. This is not an easy task for many organizations.
- There are very few trial and appellate court decisions that have interpreted the Patient Safety Act in order to give guidance to providers on how the courts will respond to subpoena and other discovery requests or lawsuits.

On the other hand, there are many reasons for moving forward with participation in a PSO:

- The Patient Safety Act applies to all state licensed providers, including hospitals, physicians, nursing homes, home heath agencies, nurses, hospice providers and others.
- The protections offered under the Patient Safety Act to patient safety activities and providers are much broader than those provided, if at all, under the state law.
- The confidentiality and privileging protections can be immediately implemented with a simple board resolution in advance of actually establishing a provider's patient safety evaluation system or contracting with or establishing its own component PSO. Documentation of this decision and all patient safety activities is extremely important in order to successfully defend against discovery requests such as in the Walgreens case.
- As a practical matter, a provider's PSES can start with its existing peer review, quality management and risk management policies and procedures.
- The PSO protections can coexist with current state confidentiality and privilege laws.
- A CMS certified Accountable Care Organization (ACO) must participate in a PSO in order to negotiate with the yet-to-be-established state insurance exchanges.
- Some states, such as Missouri, require providers to participate in a PSO in order to treat Medicaid patients.
- Providers can create their own PSO.
- Providers can contract with any of the nearly 80 certified PSOs around the country, even if not established in their own state.
- For the first time, licensed providers can now take advantage of a statute that offers protections in both the state and federal courts and administrative proceedings.
- Providers participating in PSOs can obtain independent analysis and studies provided by the PSO in terms of peer benchmarking, identification of best practices, comparative and internal quality evaluations, etc.

Recommendations to Minimize Risk of Discovery Orders

For those providers that have moved forward to participate in or create a component PSO, we would offer the following recommendations in order to best protect against expected or potential legal challenges.

- Most plaintiffs/agencies will make the following types of arguments in seeking access to claimed patient safety work product:
  - Did the provider or PSO establish a PSES?
  - Was the subpoenaed information identified by the provider/PSO as part of its PSES?
  - Was it actually collected and either actually or functionally reported to the PSO? Is there evidence/documentation of this report?
    - Plaintiff will seek to discover your PSES and documentation policies.
    - If not yet reported to the PSO, what is the justification for not doing so? How long has information been held? Does your PSES policy reflect this practice or standard for retention?
    - Has information been dropped out and used for a different purpose?
    - Is the information even eligible for protection?
    - Was the information subject to mandatory federal or state reporting requirements?
- What was the date information was collected as compared to the date on which the provider evidenced intent to participate in a PSO, and how was it documented?

- Is the provider/PSO attempting to use information that was reported or that cannot be dropped out, e.g., an analysis, for another purpose, such as to defend itself in a lawsuit or a government investigation?

Now that the *Walgreens* case has been favorably decided (click here to see decision), the hope is that more providers will be encouraged to further explore this PSO option.

For additional information regarding PSOs you can refer to the following presentations, also available at www.kattenlaw.com/callahan.

- Legal Issues Involving PSOs (Presented at the AHRQ's 4th Annual Meeting of PSOs)
- Patient Safety Organizations Overview, Benefits and Practical Applications Under Health Care Reform (Presented at October 2011 Chicago Bar Association Health Law Committee Meeting)
- Patient Safety Organizations—To Participate or Not, That Is the Question (Presented at the CHRMS 30th Annual Meeting)

Should you have any questions regarding the *Walgreens* decision and its implications or about patient safety organizations in general, please feel free to contact Michael Callahan, a partner in Katten's Health Care Practice, at 312.902.5634. (Michael Callahan assisted Walgreens and its litigation counsel in preparing its defense in this case and, along with Wells Hutchison, head of Katten's Health Care Civil Litigation Practice, prepared one of the amicus curiae briefs in support of Walgreens before the Illinois Appellate Court.)