Katten
Katten Muchin Rosenman LLP

Walgreens Trial Court Decision

Illinois Department of Financial and Professional Regulation v. Walgreens (Illinois, 4/7/11)

- On July 1, 2010, Walgreens was served with separate subpoenas requesting "all incident reports of medication errors" from 10/31/07 through 7/1/10, involving three of its pharmacists who apparently were under investigation by the Illinois Department of Professional Regulation ("IDFPR") and the Pharmacy Board.
- Walgreens, which had created The Patient Safety Research Foundation, Inc. ("PSRF"), a component PSO that was certified by AHRQ on January 9, 2009, only retained such reports for a single year. What reports it had were collected as part of its PSES and reported to PSRF.

Walgreens Trial Court Decision

Illinois Department of Financial and Professional Regulation v. Walgreens (Illinois, 4/7/11) (cont'd)

- Walgreens submitted affidavits to contend that the responsive documents were collected as part of its Strategic Reporting and Analytical Reporting System ("STARS") that are reported to PSRF and further, that it did not create, maintain or otherwise have in its possession any other incident reports other than the STARS reports.
- IDFPR had submitted its own affidavits which attempted to show that in defense of an age discrimination case brought by one of its pharmacy managers, Walgreens had introduced case inquiry and other reports similar to STARS to establish that the manager was terminated for cause.

Walgreens Trial Court Decision

Illinois Department of Financial and Professional Regulation v. Walgreens (Illinois, 4/7/11) (cont'd)

- IDFPR argued that this served as **evidence** that reports, other than STARS reports existed and, further, that such reports were used for different purposes, in this case, to support the manager's termination.
  - It should be noted that these reports were prepared in 2006 and 2007.
- Trial court ruled in favor of Walgreens Motion to Dismiss finding that: "Walgreens STARS reports are incident reports of medication errors sought by the Department in its subpoenas and are patient safety work product and are confidential, privileged and protected from discovery under The Federal Patient Safety and Quality

Walgreens Trial Court Decision

Illinois Department of Financial and Professional Regulation v. Walgreens (Illinois, 4/7/11) (cont'd)

Improvement Act (citation), which preempts contrary state laws purporting to permit the Department to obtain such reports. . . ."

- The IDFPR appealed and oral argument before the 2nd District Illinois Appellate Court took place on March 6, 2012.
- Two amicus curiae briefs were submitted in support of Walgreens by numerous PSOs from around the country including the AMA.
- On May 29, 2012, the Appellate Court affirmed that the trial court's decision to dismiss the IDFPR lawsuit.

Walgreens Appellate Court Decision

Illinois Department of Financial and Professional Regulation v. Walgreens (Illinois, 4/7/11) (cont'd)

"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 legal protections of information collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety.'

Walgreens Appellate Court Decision

Illinois Department of Financial and Professional Regulation v. Walgreens (Illinois, 4/7/11) (cont'd)

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)."

Walgreens Appellate Court Decision

Illinois Department of Financial and Professional Regulation v. Walgreens (Illinois, 4/7/11) (cont'd)

- 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 b 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.

Walgreens Appellate Court Decision

Illinois Department of Financial and Professional Regulation v. Walgreens (Illinois, 4/7/11) (cont'd)

- 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 materials fact existed.

Recent PSO Trial Court Decisions

Horvath v. Iasis Healthcare Holdings, Inc. (Florida, 10/16/2012)

- Plaintiff in a medical malpractice action filed a motion to compel the discovery of records "related to adverse medical incidents occurring in the care and treatment" of the plaintiff.
- Defendant stated in an affidavit that the only incident report relating to the plaintiff is a STARS report which was patient safety work product under the PSA and therefore was protected from discovery.
- Defendant further argued that the PSA pre-empts state law, in particular Amendment 7, which otherwise would permit discovery of this report.

Recent PSO Trial Court Decisions

Horvath v. Iasis Healthcare Holdings, Inc. (Florida, 10/16/2012) (cont'd)

- Court concluded, and the plaintiff did not contest a finding, that the report apparently was collected as part of the hospital's PSES and reported to a PSO or "a PSO-type organization".
- Relying, in part, on the Walgreens case, the trial court ruled that the report was PSWP.
- The court further ruled that the PSA expressly pre-empts Amendment 7 where the adverse medical incident record in question is determined to be PSWP.
- Based on this analysis, trial court denied the plaintiffs motion to compel.

Recent PSO *Trial* Court Decisions

Morgan v. Community Medical Center Healthcare System (Pennsylvania, 6/15/2011)

- Case involves a malpractice suit filed against a hospital claiming that it negligently discharged the plaintiff from the emergency room who had sustained injuries as a result of a motorcycle injury.
- Plaintiff contends that he received IV morphine while in the ED but did not receive any evaluation of his condition prior to discharge contrary to hospital policy. He subsequently walked out of the ED but fell, struck his head on concrete and was readmitted with a subdural hematoma.
- Plaintiff sought and obtained a trial court order for the hospital to produce an incident report regarding the event. The hospital appealed.

Recent PSO *Trial* Court Decisions

Morgan v. Community Medical Center Healthcare System (Pennsylvania, 6/15/2011) (cont'd)

- Hospital argued that the incident report was privileged and not subject to discovery under both its state confidentiality statute and the PSQIA.
- With respect to the state statute, as is true in many states, the protection only applies if the hospital meets its burden of establishing that the report was solely prepared for the purpose of complying with the Pennsylvania Safety Act.
- Plaintiff argued, and the court agreed, that the report could have been prepared principally for other purposes such as for insurance, police reports, risk management, etc. and therefore the report was subject to discovery even if later submitted to a patient safety committee on the board of directors.

Recent PSO *Trial* Court Decisions

Morgan v. Community Medical Center Healthcare System (Pennsylvania, 6/15/2011) (cont'd)

With respect to the PSQIA, the court applied a similar analysis – was the incident report collected, maintained or developed separately or does it exist separately from a PSES. If so, even if reported to a PSO, it is not protected.

- As with the state statute, court determined that hospital had not met its burden of establishing that the report "was prepared solely for reporting to a patient safety organization and not also for another purpose."

Recent PSO *Trial* Court Decisions

Francher v. Shields (Kentucky, 8/16/2011)

- Case involved a medical malpractice action in which plaintiff sought to compel discovery of documents including sentinel event record and a root cause analysis prepared by defendant hospital.
- Hospital asserted attorney-client communications, work product and PSQIA protections.

Recent PSO *Trial* Court Decisions

Francher v. Shields (Kentucky, 8/16/2011) (cont'd)

- Keep in mind that the Kentucky Supreme Court has struck down three legislative attempts to provide confidentiality protection for peer review activity in malpractice cases.

- Because the requested documents were prepared for the "purpose of complying [with] [T]he Joint Commission's requirements and for the purpose of providing information to its patient safety organization", it was not intended for or prepared solely for the purpose rendering legal services and therefore, documents were not protected under any of the attorney-client privileges.

Recent PSO *Trial* Court Decisions

Francher v. Shields (Kentucky, 8/16/2011) (cont'd)

- In noting that no Kentucky court had addressed either the issue of PSQIA protections or the issue of pre-emption, i.e., "a state law that conflicts with federal law is without effect", court cited favorably to *K.D. ex rel Dieffebach v. U.S.* (715 F Supp 2d 587) (D. Del. 2010).
- Although it did not apply the PSQIA in the context of a request to discover an NIH cardiac study, the Francher Court, citing to K.D., stated:

> "The Court then went on to discuss the Patent Safety Quality improvement Act of 2005. The Court noted that the Act, 'announces a more general approval of the medical peer review process and more sweeping evidentiary protections for materials used therein', and then concluded that, since the same type of peer review system was in place at the National Institutes of Health, the privilege should apply to protect data from discovery."

Recent PSO *Trial* Court Decisions

Francher v. Shields (Kentucky, 8/16/2011) (cont'd)

- Regarding the issue of pre-emption, the Court identified the Senate's intent under the PSQIA to move beyond blame and punishment relating to health care errors and instead to encourage a "culture of safety" by providing broad confidentiality and privilege protections.
- "Thus, there is a clear statement of a Congressional intent that such communications be protected in order to foster openness in the interest of improved patient safety. The court therefore finds that the area has been preempted by federal law."
- In addressing Section 3.20, Subsection 2(B)(iii)(A), which defines "patient safety work product," and would seem to allow for the discovery of PSWP in a "criminal, civil or administrative proceeding", the court determined that such discovery "could have a chilling effect on accurate reporting of such events."

Recent PSO *Trial* Court Decisions

Francher v. Shields (Kentucky, 8/16/2011) (cont'd)

- Court fails to note that this section only applies to information that is not PSWP.

- Court further noted that the underlying facts, (such as a medical record) are not protected and can be given to an expert for analysis.
- That this information is submitted to other entities, such as the Joint Commission was "not dispositive."
- Court granted a protective order "as to the sentinel event and root cause analysis materials reported to its patient safety organization as well as its policies and procedures."

Recent PSO *Trial* Court Decisions

Tibbs v. Bunnel; Norton v. Cunningham (2012)

- Both cases involve medical malpractice actions in which the plaintiffs sought to discover incident reports, patient safety and quality improvement reports and peer review information.
- Each of the defendants refused to turn over the requested materials arguing that they had been collected as part of their respective PSEDS for the purpose of reporting to a PSO.
- Trial court in each case ordered the production of the requested documents and the defendants filed a writ of prohibition with the Kentucky Court of Appeals.

Recent PSO *Trial* Court Decisions

Tibbs v. Bunnel; Norton v. Cunningham (2012) (cont'd)

- The Court, in nearly identical decisions, ruled that:
  - The Patient Safety Act pre-empted Kentucky state law.
  - BUT, the scope of protection under the PSA extended only to documents that "contain self-examining analysis". In other words, only those materials prepared by the actual treatment provider would be protected.
- Both hospitals filed an appeal as a matter of right to the Supreme Court of Kentucky
- Case were assigned in February, 2013 but decision still pending.
- Amicus curie briefs submitted and parties included AHA, AMA, The Joint Commission and approximately forty other parties.
- Norton was dismissed as moot because jury found in favor of the defendant and plaintiff decided not to appeal the decision.

Recent PSO *Trial* Court Decisions

Craig v. Ingalls Memorial Hospital (Ill. Circuit Court, No. 2012 L 008010 (10/28/2013))

- Case involves a medical malpractice action files against the hospital and physicians.
- Hospital entered into a participating provider agreement with Clarity PSO on January 1, 2009.
- Plaintiff served a discovery request seeking:
  - Two patient incident reports
  - Morbidity and mortality case review worksheet prepared pursuant to the University of Chicago Medical Center Network Perinatal Affiliation Agreement

Recent PSO *Trial* Court Decisions

Craig v. Ingalls Memorial Hospital (Ill. Circuit Court, No. 2012 L 008010 (10/28/2013)) (cont'd)

- Minutes of the Executive & Clinical Review Committee and Department of Pediatrics

- Hospital argued that the incident reports and M&M worksheets "were created, proposed and generated within Ingalls for submission to the Clarity PSO" and thus were patient safety work product under the Patient Safety Act and therefore privileged and confidential and not subject to discovery.
- Hospital further argued that the Committee minutes were protected under the MSA.
- On October 28, 2013, after an in camera inspection, trial court denied plaintiff's motion to compel.

Lessons Learned and Questions Raised

Most plaintiffs/agencies will make the following types of challenges in seeking access to claimed PSWP in seeking access to claimed PSWP:

- Did the provider and PSO establish a PSES?
- Was the information sought identified by the provider/PSO as part of the PSES?
- Was it actually collected and either actually or functionally reported to the PSO? What evidence/documentation?
  - Plaintiff will seek to discover your PSES and documentation policies.
  - Contrary to the court's comments in Francher, policies and procedures probably are discoverable.

Lessons Learned and Questions Raised (cont'd)

- If not yet reported, what is the justification for not doing so? How long has information been held? Does your PSES policy reflect practice or standard for retention?
- Has information been dropped out?
- Is it eligible for protection?
- Has it been used for another purpose?
- Was it subject to mandatory reporting? Will use for "any" other purposes result in loss of protection?
  - May be protected under state law.

Lessons Learned and Questions Raised (cont'd)

- What was the date it was collected as compared to date on which provider evidenced intent to participate in a PSO and how was this documented?
  - Contract?
  - Resolution?
- Is provider/PSO asserting multiple protections?
  - If collected for another purpose, even if for attorney-client, or anticipation of litigation or protected under state statute, plaintiff can argue information was collected for another purpose and therefore the PSQIA protections do not apply.

Lessons Learned and Questions Raised (cont'd)

- Is provider/PSO attempting to use information that was reported or which cannot be dropped out, i.e., an analysis, for another purpose, such as to defend itself in a lawsuit or government investigation?
  - Once it becomes PSWP, a provider may not disclose to a third party or introduce as evidence to establish a defense.

- Protections are not waiveable.