



# 4<sup>th</sup> Annual Meeting of PSOs

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## *Legal Issues Involving PSOs*

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## Recent PSO Trial Court Decisions

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### *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.



## Recent PSO Trial Court Decisions (cont'd)

- Consequently, Walgreens declined to produce the reports arguing they were PSWP and therefore not subject to discovery under the PSQIA.
- The IDFPR sued Walgreens which responded by filing a Motion to Dismiss.
- Although the IDFPR acknowledged that the PSQIA preempts conflicting state law, it essentially argued that Walgreens had not met its burden of establishing that:
  - That the incident report was actually or functionally reported to a PSO; and
  - That the reports were also not maintained separately from a PSES thereby waiving the privilege.



## Recent PSO Trial Court Decisions (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.



## Recent PSO Trial Court Decisions (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



## Recent PSO Trial Court Decisions (cont'd)

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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 2<sup>nd</sup> District Illinois Appellate Court took place on March 6, 2012.
- A decision is expected in two to three months.
- Two amicus curiae briefs were submitted in support of Walgreens by numerous PSOs from around the country and the AMA.



## Recent PSO Trial Court Decisions

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### *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 (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 (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 (cont'd)

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### *Francher v. Shields* (Kentucky, 8/16/11)

- 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 (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

(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 Fancher Court, citing to K.D., stated:



# Recent PSO Trial Court Decisions

(cont'd)

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“The Court then went on to discuss the Patient 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

(cont'd)

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- 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.



## Recent PSO Trial Court Decisions (cont'd)

- “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 (cont'd)

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- 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.”





# Lessons Learned and Questions Raised (cont'd)

- 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 or 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?  
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

- 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.
- 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?



# Lessons Learned and Questions Raised (cont'd)

- 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.
- 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?



# Questions

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