



QUANTROS

Pharmacy Quality & Safety Summit September 25-26, 2013

Patient Safety Organizations: Legal Protection Opportunities and Challenges

Michael R. Callahan

Katten Muchin Rosenman LLP

Chicago, Illinois

+1.312.902.5634

michael.callahan@kattenlaw.com

(bio/events/publications) www.kattenlaw.com/callahan

Katten

Katten Muchin Rosenman LLP

Industry Overview and Developments

- Provider Consolidation
 - Hospitals
 - Physician groups
 - Nursing homes
 - Pharmacies
- Shift from volume to value as basis of reimbursement

Industry Overview and Developments (cont'd)

- Increasing number of CMS certified Accountable Care Organizations
 - 250 total
 - Three ACOs established by Walgreens
 - Advocate Walgreens Well Network
 - Diagnostic Clinic Walgreens Well Network
 - Scott & White Healthcare Walgreen Well Network

Industry Overview and Developments (cont'd)

- Continued development of quality metrics and P4P standards
 - ACO - 33 quality metrics
 - Value Based Purchasing standards
 - Hospital acquired conditions
 - Never events
 - Core measures

Industry Overview and Developments (cont'd)

- American Society of Health System Pharmacists Pharmacy Practice Model Initiative
 - 5 key goals and 26 individual measures tied to improving medication use, optimize outcomes and improving patient safety and efficiencies.
- NCQA

Industry Overview and Developments (cont'd)

- National Action Plan for Adverse Drug Event Prevention
 - Draft issued September, 2013 by HHS Office of Disease Prevention and Health Promotion.
 - Two key objectives:
 - Identify common clinically significant, preventable and measurable adverse drug events (ADEs).
 - Align the effort of federal health agencies to reduce patient harm from ADEs.

Industry Overview and Developments (cont'd)

- Statistics

- ADEs occur in all health care settings and during transitions of care.
- ADEs are the largest contributors to hospital related complications and comprise one-third of all hospital adverse events, affect 2 million hospital stays annually and increase ALOS from 1.7 to 4.6 days.

Industry Overview and Developments (cont'd)

- In outpatient settings, ADEs account for 3.5 million office visits, 1 million ED visits and 125,000 hospital admissions
- ADEs cost up to \$5.6 million/hospital and add an additional \$3.5 billion to U.S. health care costs, not including lost wages and lower productivity
- 1.5 million Americans are sickened, impaired or killed by ADEs

Industry Overview and Developments (cont'd)

- Common Prescription Errors
 - Physicians
 - Inappropriate dosing
 - Prescribing wrong medication
 - Failure to monitor side effects

Industry Overview and Developments (cont'd)

- Pharmacists
 - Mechanical errors
 - ❖ Dispensing wrong drug
 - ❖ Dosage form
 - ❖ Directions
 - ❖ Quantity
 - ❖ Strength or dose

Industry Overview and Developments (cont'd)

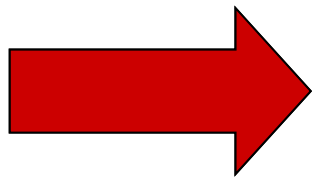
- Judgment errors
 - ❖ Improper or no counseling
 - ❖ Failure to detect drug interactions
 - ❖ Inadequate drug use review

What is the Purpose of a Patient Safety Organization (“PSO”) Under the Patient Safety and Quality Improvement Act (“PSA”)

- To encourage the expansion of voluntary, provider-driven initiatives to improve the quality and safety of health care; to promote rapid learning about the underlying causes of risks and harms in the delivery of health care; and to share those findings widely, thus speeding the pace of improvement.
 - Strategy to Accomplish its Purpose
 - Encourage the development of PSOs
 - Establish strong Federal and greater confidentiality and privilege protections
 - Facilitate the aggregation of a sufficient number of events in a protected legal environment.

What is the Purpose of a Patient Safety Organization (“PSO”) Under the Patient Safety and Quality Improvement Act (“PSA”) (continued)

- Create the Network of Patient Safety Databases (NPSD) to provide an interactive, evidence-based management resource for providers that will receive, analyze, and report on de-identified and aggregated patient safety event information



Further accelerating the speed with which solutions can be identified for the risks and hazards associated with patient care through the magnifying effect of data aggregation

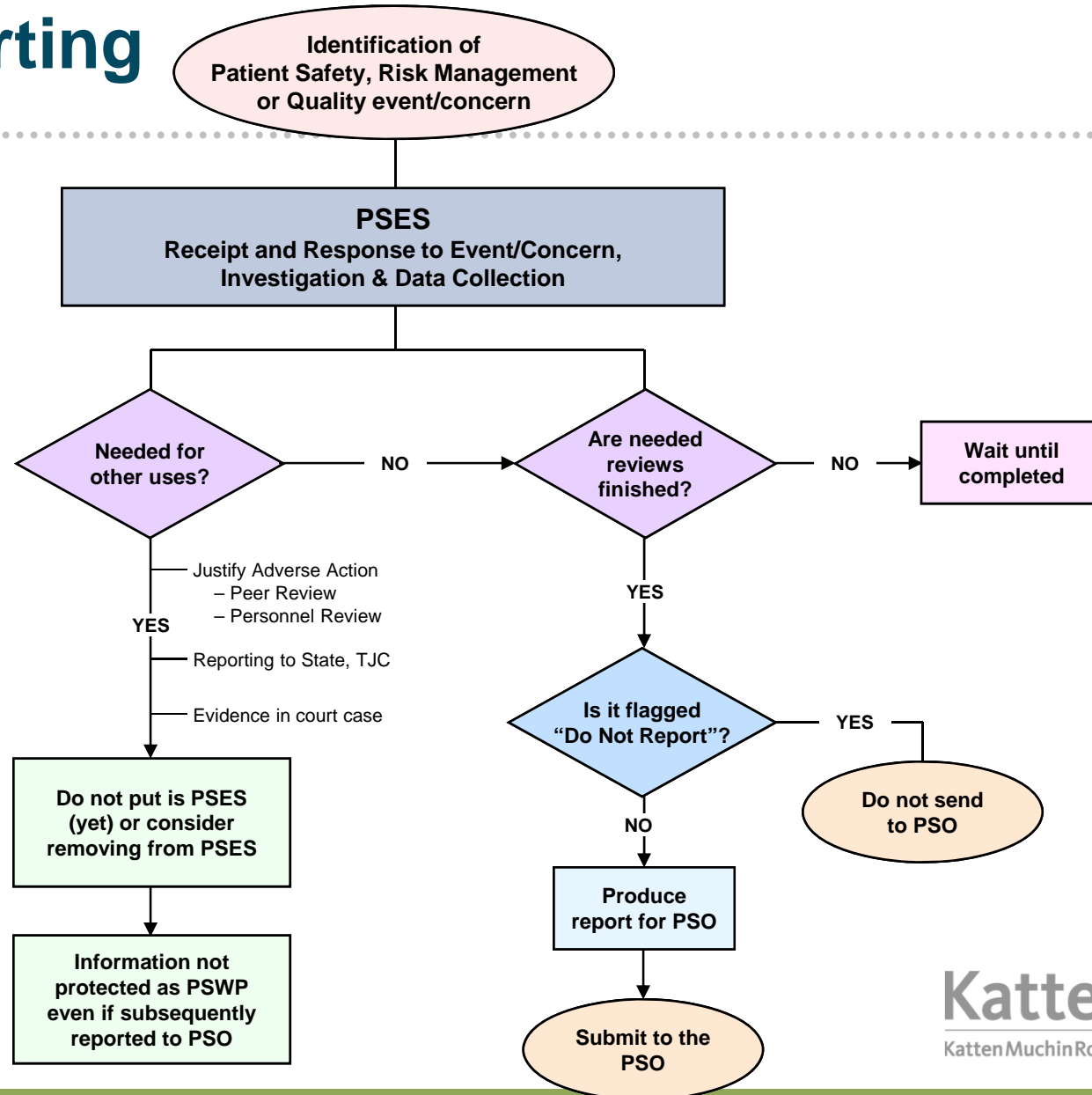
Definition of a Patient Safety Evaluation System (“PSES”)

- PSES Definition – Development, Documentation and Implementation is Key to Obtaining and Maintaining Confidentiality/Privilege Protections
 - Body that manages the collection, management, or analysis of information for reporting to or by a PSO (CFR Part 3.20 (b)(2))
 - Determines which data collected for the PSO is actually sent to the PSO and becomes Patient Safety Work Product (PSWP)
 - PSES analysis to determine which data is sent to the PSO is protected from discovery as PSWP

Definition of a Patient Safety Evaluation System ("PSES") (continued)

- Establish and Implement a Patient Safety Evaluation System (PSES), that:
 - Collects data to improve patient safety, healthcare quality and healthcare outcomes
 - Reviews data and takes action when needed to mitigate harm or improve care
 - Analyzes data and makes recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes
 - Conducts RCAs, Proactive Risk Assessments, in-depth reviews, and aggregate RCAs
 - Determines which data will/will not be reported to the PSO
 - Reports to PSO(s)

PSO Reporting



Definition of a Patient Safety Evaluation System ("PSES") (continued)

- Designing Your PSES
 - Events or Processes to be Reported
 - Adverse events, sentinel events, never events, near misses, HAC, unsafe conditions, RCA, etc.
 - Committee Reports/Minutes Regarding Events
 - PI/Quality Committee, Patient Safety Committee, Risk Management Committee, Pharmacy Committee, MEC, BOD
 - Structures to Support PSES
 - PI plan, safety plan, RM plan, event reporting and investigation policies, procedures and practices, grievance policies and procedures

Definition of a Patient Safety Evaluation System (“PSES”) (continued)

- Criteria-based Prioritization
 - Suggested criteria
 - Promotes culture of safety/improves care
 - Impressions/subjective data that is not available in the medical record
 - Information that could be damaging during litigation
 - Not required to report elsewhere
 - Required to report elsewhere, but data for reporting could be obtained from medical record
 - Data will not be used to make adverse employment decisions

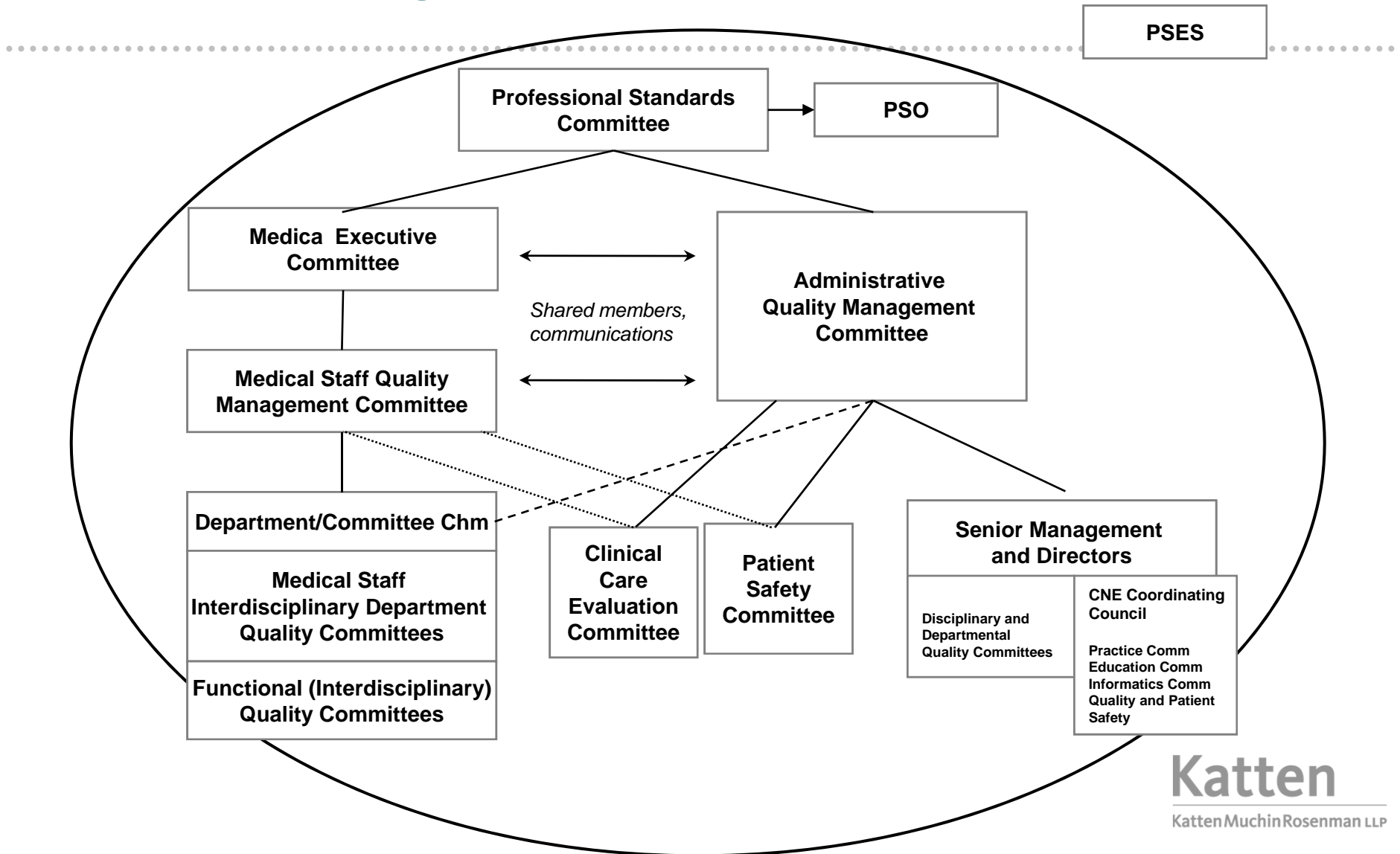
What Types of Data can the PSES Collect and Report To The PSO?

- Medical Error or Proactive Risk Assessments, Root Cause Analysis
- Prescription Errors
- Risk Management – incident reports, investigation notes, interview notes, RCA notes, notes rec'd phone calls or hallway conversations, notes from PS rounds

What Types of Data can the PSES Collect and Report To The PSO? (continued)

- Outcome/Quality—may be practitioner specific, sedation, complications, blood utilization etc.
- Peer Review
- Committee minutes—Safety, Quality, Quality, Pharmacy and Safety Committee of the Board, Medication, Blood, Physician Peer Review

PSO Reporting Process



Definition of Patient Safety Work Product (“PSWP”)?

- Any data, reports, records, memoranda, analyses (such as Root Cause Analyses (RCA)), or written or oral statements (or copies of any of this material) which could improve patient safety, health care quality, or health care outcomes;

And that:

- Are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, either physically or “functionally”, which includes information that is documented as within a PSES for reporting to a PSO, and such documentation includes the **date the information entered the PSES**; or
- Are developed by a PSO for the conduct of patient safety activities; or
- Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES

What is NOT PSWP?

- Patient's medical record, billing and discharge information, or any other original patient or provider information
- Information that is collected, maintained, or developed separately, or exists separately, from a PSES. *Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered PSWP*
- PSWP assembled or developed by a provider for reporting to a PSO but removed from a PSES and no longer considered PSWP if:
 - Information has not yet been reported to a PSO; and
 - Provider documents the act and date of removal of such information from the PSES

What confidentiality/privilege protections does a provider have today – does a PSO enhance that?

- The confidentiality and privilege protections afforded under the PSA generally apply to reports, minutes, analyses, data, discussions, recommendations, etc., that relate to patient safety and quality if generated or managed, or analyzed and collected for the purpose of reporting to a PSO.
- The scope of what can be protected, generally speaking, is broader than most current state statutes.
- Any licensed provider, i.e., physician, physician group, surgicenters, pharmacy, clinic, hospital, nursing home, home health facility, etc., can be covered under the PSA whereas in many states the kinds of providers that can be protected is more limited.

What confidentiality/privilege protections does a provider have today – does a PSO enhance that? (continued)

- The protections apply in both state and, for the first time, federal proceedings.
- The protections can never be waived.
- If the protections are greater than those offered under state law the PSA pre-empts state law.
- PSWP is not admissible into evidence nor is it subject to discovery.
- Key to these protections is the design of the provider's and PSO's patient safety evaluation system ("PSES").

Once data/reports come back to an organization from a PSO, is that data discoverable again or is it still protected?

Example:

- Data is submitted to a PSO, it is aggregated and a report comes back stating that hospital shows variations in practice. Is that statement/outcome/finding discoverable or not?
 - Not discoverable
 - Need to set up appropriate PSES policies and paper trail to establish that data sent was part of providers' PSES and collected for the purpose of reporting to a PSO so that the PSO can analyze and produce reports which identify variances/outliers in order for modifications to be made to improve patient safety and quality.
 - Definition of PSWP includes “data reports, records, memoranda, analyses (such as root cause analysis), or written or oral statements (or copies of any of these materials) (1) which could improve patient safety, health care quality, or health care outcomes . . . or are developed by a PSO for the conduct of patient safety activities. . . .”

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.

Katten

Katten Muchin Rosenman LLP

Walgreens Trial Court Decision

- 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.

Walgreens Trial Court Decision

- 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

- 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 Appellate Court Decision

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

“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

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).”

Katten

Katten Muchin Rosenman LLP

Walgreens Appellate Court Decision

- 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 curiam)) did identify documents used by Walgreens to terminate the employee.

Walgreens Appellate Court Decision

- 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

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)

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.

Katten

Katten Muchin Rosenman LLP

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 Francher Court, citing to K.D., stated:

Recent PSO Trial Court Decisions (Cont'd)

- “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 (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.

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)

- 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.”

Tibbs v. Bunnell; 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.

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

- 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.

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? 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?