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“The Changing PSO Landscape: National & Legal Perspectives – A Deeper Dive”

2nd of a 2-Webinar Series

Thursday, July 16

Thursday, July 30

@ 12 Noon Central, 1 PM Eastern



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Center for Patient Safety, North Carolina Quality and
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Patient Safety

*The Changing PSO Landscape: Legal
Perspective and Lessons Learned*

July 30, 2015



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What is the 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, 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.

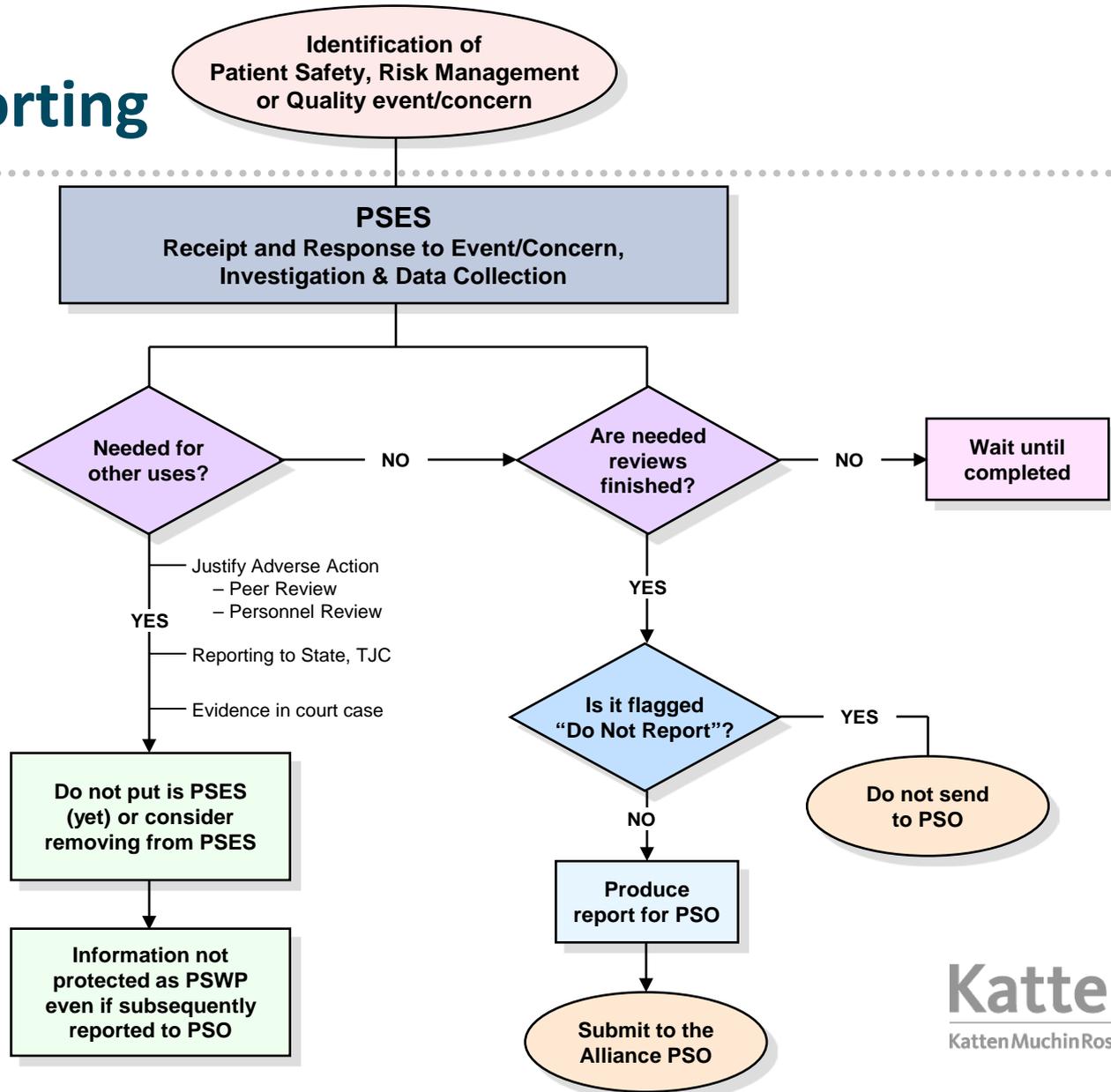
What types of data can be considered for inclusion in the PSES for collection and reporting to the PSO if used to promote patient safety and quality?

- Medical Error or Proactive Risk Assessments, Root Cause Analysis
- Risk Management – Not all activities will qualify such as claims management, but incident reports, investigation notes, interview notes, RCA notes, etc., tied to activities within the PSES can be protected
- Outcome/Quality—may be practitioner specific
- Peer Review
- Relevant portions of Committee minutes for activities included in the PSES relating to improving patient quality and reducing risks

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 is 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

PSO Reporting



How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act?

- North Carolina
 - N.C. Gen. Stat. § 131E-95(B)
 - Proceedings of a medical review committee, the records and materials it produces and the materials it considers shall be confidential and not subject to discovery or introduction into evidence in any civil action against a hospital, surgicenter or provider of health services which results from matters which are subject to evaluation and review by the committee.
 - If information is otherwise available, it cannot be protected.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

- Information can be disclosed to a professional standards review organization, such as The Joint Commission, or to a PSO or its designated contractors.
- Minimum necessary standard applies.
- Protections arguably apply to peer review conducted in a physician group, but no case law on this question.
- Can be sent to a PSO and still be kept confidential.
- Appears that protections could be waived if information is disclosed outside of peer review process.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

- One court held that protections do apply in federal proceedings.
- Not clear if information can be shared throughout system.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

- Missouri
 - Missouri Revised Statutes, Chapter 537, Section 537.035
 - “Peer Review Committee” is a committee of health care professionals (physician, surgeon, dentist, podiatrist, pharmacist, psychologist, nurse, social worker, professional counselor or mental health professional) with the responsibility to evaluate, maintain, or monitor the quality and utilization of health care services or to exercise any combination of such responsibilities.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

- Entities covered include committees of:
 - Health care professional societies
 - Professional corporation of health care professionals
 - Health care professionals employed by or affiliated with a university
 - Licensed hospitals or other health care facilities, including long term care
 - Organizations formed pursuant to state or federal law to exercise responsibilities of a peer review committee
 - HMOs

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

- Interviews, memorandums, proceedings, findings, deliberations, reports and minutes concerning the health care provided any patient are not subject to discovery and is not admissible into evidence in any judicial or administrative action for failure to provide appropriate care.
- Persons in attendance not required to disclose or testify.
- Information is discoverable if otherwise available.
- Can be required to testify as to personal knowledge.
- Protections cannot be waived.
- Protections do not apply in peer review litigation.
- Not clear whether the state protections would apply where plaintiff brings a federal cause of action in federal court, i.e., antitrust, discrimination.
- Not clear as to whether information can be freely shared throughout the system

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

- Illinois
 - 735 ILCS 5/8-2101
 - All information, interviews, reports, statements, memoranda, recommendations, letters of reference or other third party confidential assessments of a health care practitioner's professional competence, or other data of
 - Allied medical societies, health maintenance organizations, medical organizations under contract with health maintenance organizations or with insurance or other health care delivery entities or facilities
 - Their agents, committees of ambulatory surgical treatment centers or post-surgical recovery centers or their medical staffs, or committees of licensed or accredited hospitals or their medical staffs

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

- Including Patient Care Audit Committees, Medical Care Evaluation Committees, Utilization Review committees, Credential Committees and Executive Committees,, or their designees (but not the medical records pertaining to the patient), used in the course of internal quality control or of medical study for the purpose of reducing morbidity or mortality, or for improving patient care or increasing organ and tissue donation
- Shall be privileged, strictly confidential and shall be used only for medical research, the evaluation and improvement of quality care, or granting, limiting or revoking staff privileges or agreements for services
- Information can be used in disciplinary hearings and subsequent judicial review

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

- Protections have been interpreted fairly broadly but information produced for a different purpose, i.e., risk management, is not protected even if used by a peer review committee.
- Although the Medical Studies Act references “medical organizations” under contract with HMOs or other healthcare delivery entities or facilities, surgicenters and hospitals, Appellate Courts have not extended protections to nursing homes or pharmacies.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

- Protections cannot be waived if used for statutory purposes.
- Information arguably can be shared throughout the system among controlled affiliates subject to physician authorization.
- Protections do not apply to federal claims brought in federal court.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

- Patient Safety Act
 - 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 within the PSES and collected for reporting to a PSO.
 - The scope of what patient safety activities can be protected, generally speaking, is broader than the North Carolina, Missouri and Illinois statutes.
 - The scope of what entities can seek protection is generally greater. Any licensed provider, i.e., physician, physician group, surgicenters, clinic, hospital, nursing home, home health facility, etc., can be covered under the PSA.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

- Any licensed provider, i.e., physician, physician group, surgicenters, 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.
- 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 within the PSES for reporting to a PSO.
- The scope of what can be protected, generally speaking, is broader than most current state statutes.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

- 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.
- Non-provider corporate parent organization involved in patient safety activities as well as owned, controlled or managed provider affiliates can be included in a system-wide PSES and be protected.
- 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").

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 (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.

Walgreens Trial Court Decision (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 (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 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 (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 (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 (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.

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.

PSO Trial Court Decisions (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.

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.

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.

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.”

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.

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.

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:

“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.”

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.

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.”

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.”

PSO Trial Court Decisions (cont'd)

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

PSO Trial Court Decisions (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.

Tibbs v. Bunnell - U.S. Supreme Court

■ Background

- This is a medical malpractice action involving a 64 year old woman who died unexpectedly due to a bleeding complication at the end of an elective spine surgery at University of Kentucky Hospital (“Hospital”).
- Plaintiff’s estate filed action against three Hospital employed surgeons.
- Plaintiff requested copies of any post-incident event reports regarding patient’s care.
- Defendants moved for a protective order arguing that the report had been created and collected through UK Health Care’s PSES and reported to its PSO, the UHC Performance Improvement PSO and therefore was PSWP and not subject to discovery.

Tibbs v. Bunnell - U.S. Supreme Court (cont'd)

- Trial court held that the report was not PSWP under the Patient Safety Act (“PSA”) because it did not fall within the statutory definition.
- UK filed a Writ of Prohibition with the Appellate Court to prevent trial court from requiring production of the report.
- Appellate Court Decision
 - Appellate Court granted the writ.
 - In its opinion, the Court correctly ruled that the PSA pre-empted state law that otherwise would not have protected the report from discovery.
 - Under its interpretation of the scope of PSA protection, however, the Court held that the privilege only applies to documents that contain “self-examining analysis.”

Tibbs v. Bunnell - U.S. Supreme Court (cont'd)

- In other words, the only documents subject to protection are those created by the physician, nurse or other caregivers, which analyzes their own actions.
- Because this decision erroneously narrowed the PSA protections to a very limited set of materials, UK again filed a Writ of Prohibition to the Supreme Court of Kentucky as a matter of right.
- Kentucky Supreme Court Decision
 - Court granted the Writ and the case was assigned to a judge in February, 2013.
 - Decision was issued on August 21, 2014, 18 months later in a divided 4-2 opinion.

Tibbs v. Bunnell - U.S. Supreme Court (cont'd)

- Court reversed the Appellate Court's narrow construction of the PSA protections as being contrary to the clear intent of Congress which was to:

“encourage health care providers to voluntarily associate and communicate [PSWP] among themselves through in-house [PSES] and with and through affiliated [PSOs] in order to hopefully create an enduring national system capable of studying, analyzing, disseminating and acting on events, solutions, and recommendations for the betterment of national patient safety, healthcare quality, and healthcare outcomes” (Opinion at p. 5) (also citing to Walgreens case)

Tibbs v. Bunnell - U.S. Supreme Court (cont'd)

- The Court, however, went on to rule that reports, analyses and documents that hospitals are required to establish, maintain and utilize “as necessary to guide the operation, measure of productivity and reflect the program of the facility” must be collected outside of the PSES and therefore cannot be protected under the PSA.
- Because the report in question fell into this category of documents required to be “established, maintained and utilized” under state law, the Court held it was subject to discovery.
- Court ordered that the based on this statutory construction analysis, matter must be remanded to the trial court for an in camera review to determine what aspects, if any, of the report are privileged and not subject to discovery and what information must be produced.

Tibbs v. Bunnell - U.S. Supreme Court (cont'd)

- UK filed a Motion and Petition for Rehearing for the purpose of remanding the case back to the Appellate Court because the statutory construction argument was never presented to the trial and Appellate Court and therefore was never addressed by the parties.
- This Petition was supported in separate motions by the AHA, AMA, The Joint Commission and over 30 other amicus parties along with additional arguments as to how the Court erred. These include the following:
 - Court did not correctly interpret Congress's intent as to the full scope of the PSA's protections.

Tibbs v. Bunnell - U.S. Supreme Court (cont'd)

- PSA does not preclude a hospital from collecting and maintaining incident reports within its PSES unless required to submit these reports to the state or federal government.
- Court glossed over the fact that Kentucky does not require these incident reports to be reported to the state.
- While information collected outside the PSES cannot be protected, the report in question clearly was collected and maintained in UK's PSES.
- The fact that a state mandated the establishment, collection and maintenance of a record does not automatically mean it cannot be accomplished within a PSES – it can be dropped out later and reported if required.

Tibbs v. Bunnell - U.S. Supreme Court (cont'd)

- Even if a mandated report was incorrectly reported to a PSO, the hospital cannot disclose unless it specifically authorizes disclosure consistent with the PSA requirements.
- If not disclosed, the hospital runs the risk of being cited, fined or otherwise penalized unless it can otherwise demonstrate compliance with state/federal laws.
 - Neither CMS nor TJC requires a PSO or provider to turn over PSWP.

Tibbs v. Bunnell - U.S. Supreme Court (cont'd)

- Amicus motions in support of Petition for Rehearing were denied. In a 3 to 3 deadlocked vote, UK's Petition also was denied.
- U.S. Supreme Court
 - UK filed a Petition for a Writ of Certiorari to the Supreme Court of the United States on March 18, 2015.
 - Amicus briefs supporting UK filed on April 20, 2015.
 - Court requested a written response from Respondent which was due June 12, 2015.
 - Deadline passed by at the request of Respondent, Court granted an extension until August 21, 2015.

Tibbs v. Bunnell - U.S. Supreme Court (cont'd)

- What Legal Impact Does Tibbs Have?
 - Decision is not really final until Petition is resolved.
 - Even if Court does not review Tibbs, it is only binding on courts, PSOs, and providers located in Kentucky and no other state.

Tibbs v. Bunnell - U.S. Supreme Court (cont'd)

- There are still procedural issues and potential discovery disputes being played out in the Tibbs case and therefore the final outcome on what information ultimately needs to be produced has not been determined.
- Once issue that has been raised is whether AHRQ/OCR would fine UK if it turned over the report – AHRQ/OCR has not made any such decision but could serve as another vehicle to get into federal court because you would have a state court decision conflicting with a federal statute and potential agency action.
- A concern is that the wrong analysis in Tibbs could be embraced by other courts looking for a way to limit the PSA protections, but keep in mind trial court decisions in other jurisdictions are only binding on the parties involved in the litigation

Tibbs v. Bunnell - U.S. Supreme Court (cont'd)

- Should PSOs/Hospitals limit scope of what to collect in their PSES consistent with Tibbs decision?
 - No!
 - These issues/disputes will be decided in each state. The only binding decisions in your state affecting state versus federal claims are decisions issued by state supreme court or appellate courts – not trial courts.
- Reminders
 - In a state with mandated reporting, only provide what is minimally required – limit reports to the facts if permitted.

Tibbs v. Bunnell - U.S. Supreme Court (cont'd)

- What are you not required to report to the state (or federal government) can be collected in your PSES and reported to the PSO.
 - To protect against a Tibbs analysis consider re-titling reports. In other words, the patient incident report you may be required to collect and maintain under state law can be limited to the facts and the impressions, reviews and assessments can be included in a separate “quality assessment report” or “occurrence report”, collected in your PSES and reported to the PSO.
- Southern Baptist Hospital Case – Florida Appellate Court
 - Carron v. Newport Hospital Case – Rhode Island Supreme Court

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.
- 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?
 - Once it becomes PSWP, a provider may not disclose to a third party or introduce as evidence to establish a defense.
- Is the provider required to collect and maintain the disputed documents pursuant to a state or federal statute, regulation or other law or pursuant to an accreditation standard?

QUESTIONS & ANSWERS

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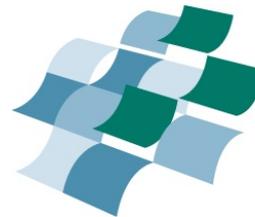
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