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PSO 301: Discussion of PSO Court Cases and the Litigation Lessons Learned

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Speaker Bios

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Michael R. Callahan assists hospital, health system and medical staff clients on a variety of health care legal issues related to accountable care organizations (ACOs), patient safety organizations (PSOs), health care antitrust issues, Health Insurance Portability and Accountability Act (HIPAA) and regulatory compliance, accreditation matters, general corporate transactions, medical staff credentialing and hospital/medical staff relations.

Michael's peers regard him as "one of the top guys […] for credentialing—he's got a wealth of experience" (Chambers USA). Additionally, his clients describe him as "always responsive and timely with assistance," and say he is "informed, professional and extremely helpful" and "would recommend him without reservation" (Chambers USA). Michael's clients also commend his versatility, and say "He is willing to put on the hat of an executive or entrepreneur while still giving legal advice," according to Chambers USA.

He is a frequent speaker on topics including ACOs, health care reform, PSOs, health care liability and peer review matters. He has presented around the country before organizations such as the American Health Lawyers Association, the American Medical Association, the American Hospital Association, the American Bar Association, the American College of Healthcare Executives, the National Association Medical Staff Services, the National Association for Healthcare Quality and the American Society for Healthcare Risk Management.

Michael was recently appointed as chair of the Medical Staff Credentialing and Peer Review Practice Group of the American Health Lawyers Association. He also was appointed as the public member representative on the board of directors of the National Association Medical Staff Services.

He was an adjunct professor in DePaul University's Master of Laws in Health Law Program, where he taught a course on managed care. After law school, he served as a law clerk to Justice Daniel P. Ward of the Illinois Supreme Court.

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Speaker Bios

Ellen Flynn RN, MBA, JD, CPPS - flynn@uhc.edu

Ellen Flynn RN, MBA, JD is currently the AVP, Patient Safety and Accreditation Programs for the UHC Safety Intelligence® PSO. Previously, she held the position of Director of Quality at UHC. Ellen has over 30 years of healthcare experience and managed quality, safety, and patient experience departments in large academic medical centers and health systems including Rush System for Health, Children's Hospital of Wisconsin, and Universal Health Services. Prior to returning to UHC, Ellen was the Manager, Health Industries Advisory Services at PricewaterhouseCoopers LLP. Ellen has a Juris Doctor degree from Loyola University School of Law, an MBA, Management Information System from DePaul University and a Bachelor of Science in Nursing from Loyola University.

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Mr. Pavkovic brings a diverse background to his current role as the Senior Director of Patient Safety at Vizient the nation's largest member-owned health care company. While working as an operating room nurse and manager, he earned advanced degrees in public health and law. His legal career included defending healthcare providers from claims of professional malpractice, working for county government as a health law attorney and practicing as a healthcare risk manager at an academic medical center. At Vizient, he draws on these professional experiences to assist members in identifying patient safety improvement and loss control opportunities. He is a frequent national presenter and published author on a variety of risk management and patient safety topics.

THE GOOD

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.

Illinois Department of Financial and Professional Regulation v. Walgreens (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.

Illinois Department of Financial and Professional Regulation v. Walgreens (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.

Illinois Department of Financial and Professional Regulation v. Walgreens (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

Illinois Department of Financial and Professional Regulation v. Walgreens (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.

Illinois Department of Financial and Professional Regulation v. Walgreens (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.'

Illinois Department of Financial and Professional Regulation v. Walgreens (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)."

Illinois Department of Financial and Professional Regulation v. Walgreens (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.

Illinois Department of Financial and Professional Regulation v. Walgreens (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.

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.

Francher v. Shields (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.

Francher v. Shields (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."

Francher v. Shields (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.

Francher v. Shields (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."

Francher v. Shields (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."

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.

Horvath v. Iasis Healthcare Holdings, Inc. (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.

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

Craig v. Ingalls Memorial Hospital (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.

Southern Baptist Hospital of Florida, Inc. v. Charles (October 28, 2015 (Case No. 1D15-0109)

Trial Court

- Case involves a medical malpractice action filed by the guardian of a patient who suffered a catastrophic neurological injury allegedly due to the hospital's negligence.
- Plaintiff filed three requests for production pursuant to the state's Amendment 7 which allows patients access to reports of adverse medical incidents defined as "any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient (Act X, Section 25(c)(3), Fla. Const).

Southern Baptist Hospital of Florida, Inc. v. Charles (cont'd)

- Plaintiff specially sought:
  - Documents related to adverse medical incidents.
  - Documents related to any physician who worked for Baptist or arose from care and treatment rendered by Baptist during the three year period preceding the plaintiff's care and treatment up to and through the date of the request.
- Hospital produced:
  - Code 15 reports – mandated adverse event reports required under state law.
  - Two occurrence reports specific to the plaintiff which had been removed from Hospital's PSES before they were reported to the PSO.

Southern Baptist Hospital of Florida, Inc. v. Charles (cont'd)

- Hospital argued:
  - Reports and other documents were collected within Hospital's PSES and reported to a PSO and therefore, based on the clear language of the PSA should be treated as PSWP.
    - The PSA preempts Amendment 7.
- Plaintiffs argued:
  - PSA only protects documents created solely for the purpose of reporting to a PSO.
  - Information cannot be considered PSWP if it was collected and maintained for another purpose or for dual purposes.
  - Information cannot be considered PSWP if it is "in any way related" to an health care provider's obligation to comply with federal, state, or local laws or accrediting or licensing requirements.

Southern Baptist Hospital of Florida, Inc. v. Charles (cont'd)

Trial Court

- Trial court ruled in plaintiff's favor based on the arguments presented even if the information were collected within the PSES for reporting to a PSO and did not exist outside the PSES.

Appellate Court

- Appellate Court granted hospital's petition for certiorari because it made a sufficient showing of irreparable harm, production under trial court's ruling was inevitable and no other remedy was available.

Southern Baptist Hospital of Florida, Inc. v. Charles (cont'd)

- Court states that the PSA is clear and unambiguous in defining what information is and is not protected PSWP and that the Act also makes clear that providers are obligated to provide mandated federal, state and local reports as required.
- "Here, the documents in question are PSWP because they were placed into Baptist's PSE system where they remained pending submission to a PSO (citing to 42 USC Section 299b-21(7)(A) and are not original patient records which are not protected."
- Court rejected plaintiff's arguments that documents are not protected because they may be required to be collected and maintained under a state statute, rule or licensing or accreditation requirement or that the state Agency for Healthcare Administration has access to the documents.

Southern Baptist Hospital of Florida, Inc. v. Charles (cont'd)

- Court notes that the PSA allows a provider to collect information and reports in its PSES, even if required to be reported to the state, but can drop out this information to satisfy its reporting obligation or "face any consequences of non-compliance" with these requirements.
- There is no allegation that the hospital failed to meet its mandated reporting requirements and in fact these reports were produced.
- Even if a hospital attempted to hide mandated reports in its PSES and were reported to a PSO it would be subject to state or federal consequences. The remedy "would not be for the trial court to 'rummage through' the provider's PSE system, in plain intervention to the purpose of the Act, in search of documents that could possibly serve a 'dual purpose'". (Citing to the dissent in Tibbs v. Bunnell, 448 S.W. 2d. 796, 9-0, 815 Ky. 2014)

Southern Baptist Hospital of Florida, Inc. v. Charles (cont'd)

- Appellate Court refused to issue a Certificate of Importance requested by the Plaintiff for consideration by the Supreme Court.
- Court also held that the PSA expressly and implicitly preempts state laws, including Amendment 7, if the Act provides greater protections than do state laws.
- "The dispositive question that should have been asked below is whether or not the documents met the definition of PSWP in the Act."
- "The respondent's interpretation of the Act would render it a 'dead letter' and is contrary to Congress's intent to cultivate a culture of safety to improve and better the healthcare community as a whole."

Southern Baptist Hospital of Florida, Inc. v. Charles (cont'd)

Supreme Court of Florida

- Plaintiff has filed a Petition for Certiorari arguing that it can appeal as a matter of right because the effect of the trial court's order is to hold that Amendment 7 is unconstitutional.
- In the alternative, the plaintiff requests that the Court exercise its discretionary authority to accept the case on appeal.
- Hospital has filed a Motion to Dismiss which is under consideration.
- Parties expect that the Supreme Court will take the case.

THE BAD

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.

Morgan v. Community Medical Center Healthcare System (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.

Morgan v. Community Medical Center Healthcare System (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."

Johnson v. Cook County (N.D. Ill. August 31, 2015) (2015 WL 5144365)

Background

- Administrator bought a Section 1983 action against Cook County for alleged constitutional violations relating to plaintiff's death while he was a jailed inmate in November, 2013, related to failed medical screenings and "deliberate indifference to Mr. Johnson's medical needs [which] caused his death."
- Prior incarcerations noted that Johnson required various prescriptions for serious medical needs including hypertension and seizure disorder.
- After Johnson's most recent incarceration on November 14, 2013, his need for medication and his seizure disorder were identified by various medical personnel, including a physician, but none were prescribed or received during his incarceration.

Johnson v. Cook County (N.D. Ill. August 31, 2015) (2015 WL 5144365) (cont'd)

- On November 17th, Johnson reported that the had vomited 10 times since lunch. Jail nurse saw that he had a seizure disorder but did not provide the required medications. Instead, he was given an over-the-counter medication for an upset stomach.
- Shortly after he returned to his cell, he suffered a seizure and died.
- Pursuant to jail policy, Cermak Health Services conducted a morbidity and mortality review of Johnson's death which included findings and recommendations.
- In response to plaintiff's motion to compel production of the report, Cook County argued that the report was privileged under the Illinois Medical Studies Act and the PSA.

Johnson v. Cook County (N.D. Ill. August 31, 2015) (2015 WL 5144365) (cont'd)

- While the trial court cites at length to various provisions of the PSA and does not challenge the protections provided, it concluded that Cook County "has not met its burden of establishing the Report as patient safety work product" for the following reasons:
  - Failed to demonstrate that the Report was actually reported to a PSO.
    - County argued that Report had been functionally reported but offered no proof.
      - No affidavit that Report was functionally reported or made available to PSO.
      - Risk managers did not even know which PSO it was using.

Johnson v. Cook County (N.D. Ill. August 31, 2015) (2015 WL 5144365) (cont'd)

- While PSO contract references functional reporting, there was no documentation to support their claim or that it had an established PSES, or made the report part of its PSES or allowed the PSO access to the Report, or that the Report was utilized by the PSO.
- A copy of the contract was insufficient.

- The jail's policy on M&M reports provide a detailed discussion as to the process followed and committees utilized as part of its own patient safety and quality improvement system but: "Nowhere does the Policy mention the report will be provided to a PSO or a patient safety evaluation system, that the review and report are completed for the purpose of providing information to a PSO or a [PSES], or even that a PSO will have access to the report."

Johnson v. Cook County (N.D. Ill. August 31, 2015) (2015 WL 5144365) (cont'd)

- Court essentially states that a mere contract with a PSO is insufficient as is the fact that the County had an internal quality contract process and committee. Court saw this as a process separate and apart from required PSES and demonstrated reporting to a PSO.

THE UGLY

Tibbs v. Bunnell

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 (cont'd)

Trial Court

- 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.

Tibbs v. Bunnell (cont'd)

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 (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.

Tibbs v. Bunnell (cont'd)

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 (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 (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 (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 (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 (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.
- Amicus motions in support of Petition for Rehearing were denied. In a 3 to 3 deadlocked vote, UK's Petition also was denied.

Tibbs v. Bunnell (cont'd)

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.
- Response filed on August 21, 2015.
- Solicitor General "invited to file a brief in this case expressing the views of the United states" on October 5, 2015.
- Brief not yet filed.

Carron v. Newport Hospital (R.I., No. 15-C.A. No. NC 2013-0479)

Background

- Plaintiffs allege that the negligence of a physician employed by the hospital during the labor and emergency delivery caused the death of a newborn infant who lived for only 7 days on June 29, 2013.
- Hospital established its PSES and contracted with a PSO along with all 13 Rhode Island hospitals earlier in 2013.
- Hospitals adopted a statewide "safe harbor" PSO reporting system known as the Medical Event Reporting System ("MERS") to collect reports relating to a Patient Safety Event.
- Rhode Island has a parallel Rhode Island Patient Safety Act of 2008.

Carron v. Newport Hospital (R.I., No. 15-C.A. No. NC 2013-0479) (cont'd)

- The case at issue generated two MERS reports authored by two separate nurses which the hospital submitted to the PSO consistent with its PSES procedure to submit all reports relating to every Patient Safety Event.
- The reports were received and reviewed by the risk manager as a member of the patient Safety Committee before submission to the PSO.
- Rhode Island also has a mandated adverse event reporting requirement.
- Hospital met their reporting requirement as per the statute. The MERS reports were different reports conducted separately within its PSES for reporting to the PSO.

Carron v. Newport Hospital (R.I., No. 15-C.A. No. NC 2013-0479) (cont'd)

Arguments

- Plaintiff relied almost exclusively on Tibbs and the holding that information and reports which state statutes require to be developed, collected and maintained cannot be treated as PSWP.
- Hospital distinguished Tibbs by noting that the University of Kentucky Hospital collected the patient incident report required by state law in its PSES whereas the MERS report is not a report required by state law to be collected or reported. The state's mandated report is submitted on a specific and distinct form different from the MERS report.
- Hospital also argued that Rhode Island does not mandate the preparation and/or maintenance of patient incident reports as required by Kentucky.
- To support its arguments the hospital submitted an affidavit from its risk manager detailing its PSES process and procedures and attached its Patient Safety Policy and Program (PSES).

Carron v. Newport Hospital (R.I., No. 15-C.A. No. NC 2013-0479) (cont'd)

Trial Court

- Trial court ruled in plaintiff's favor and ordered the production of the MERS reports with no written analyses but apparently relying on Tibbs. Hospital's motion for reconsideration was denied.

Carron v. Newport Hospital (R.I., No. 15-C.A. No. NC 2013-0479) (cont'd)

Appeal

- Hospital filed a Petition for Issuance of a Writ of Certiorari for the Supreme Court of Rhode Island on June 29, 2015.
  - Rhode Island has no appellate court. Final judgments in trial courts are appealable as a matter of right.
  - Because this is a discovery dispute in a case where a final judgment has not been reached, the Supreme Court has the discretion to accept or reject the Petition.
- The Supreme Court granted the Petition on January 21, 2016. Appeal is now being briefed by the parties. Amicus briefs are expected to be filed.

Lessons Learned and Questions Raised

- Most plaintiffs/agencies will make the following types of challenges in seeking access to claimed PSWP:
  - Has the provider contracted with a PSO? When?
  - Is the PSO certified? Was it recertified?
  - Did the provider and PSO establish a PSES? When?
  - Was the information sought identified by the provider/PSO as being collected with a 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.

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 a practice or standard for retention?
- Has information been dropped out? Do you document this action?
- Is it eligible for protection?
- Has it been used for another purpose? What was the 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)

- Is provider/PSO asserting multiple protections?
  - If collected for another purpose, even if for attorney-client, or in 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?

Lessons Learned and Questions Raised (cont'd)

- Document, document, document
  - PSO member agreement
  - PSES policies
  - Forms
  - Documentation of how and when PSWP is collected, reported or dropped out
  - Detailed affidavits

Lessons Learned and Questions Raised (cont'd)

- Advise PSO when served with discovery request.
- Educate defense counsel in advance – work with outside counsel if needed.
- Get a handle on how adverse discovery rulings can be challenged on appeal.

Final Considerations

- Obtain executive/Board guidance
- Obtain legal guidance
- Determine the participating entities
- Define your PSES
- Define your PSO submission practices
- Report cases to your PSO
- Monitor PSO activities
- Document so that you are ready to share these processes
- Avoid mapping exercises
- Determine if you will submit to the NPSD
- Keep an eye on January 1, 2017

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QUESTIONS

Katten's Health Care Practice

- Katten offers one of the largest health care practices in the nation—both in terms of the number of practitioners and the scope of representation
- The integrated nature of our practice allows us to provide timely, practical and strategic advice in virtually all areas of law affecting the health care industry
- Our experience encompasses regulatory compliance, fraud and abuse counseling, tax exemption issues, antitrust, financings for taxable and tax-exempt entities, reimbursement, and a variety of other issues specific to the health care industry
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- To view other Health Care presentations by Katten, please click here

UHC Safety Intelligence® PSO – Fast Facts

- National patient safety leader since 2001
- Listed as PSO in 2008 by AHRQ and Certified through 2017
- National PSO Membership model
- AHRQ Common Formats (v1.1) based taxonomy
- Additional proprietary and customized taxonomy items
- Integrated submission with UHC SI Event reporting module
- National leadership role in PSO and Patient Safety activities
- Regular NPSD submissions via PSOPPC
- Multiple participation models
- Consistent ongoing feedback, comparative data, ongoing collaboration with other PSO members via safe tables, in person meetings, and webinars

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