The 2015 Morrisey Technology and Educational Conference

PSO Update and MCCM Risk Management Demonstration, Including the New PSO Module

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Health Care Reform, ACOs and PSOs

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Supreme Court Decisions

- National Federation of Independent Business v. Sebilius, (132 S. Ct. 2566 (2012) (5-4 decision)
  - Upheld the ACA's Medicaid expansion but expansion is voluntary – cannot compel participation and cannot cut off entire Medicaid funding if state declines.
  - 31 states have adopted Medicaid expansion.
- King v. Burwell, June 25, 2015 (6-3 decision)
  - Plaintiff challenged whether the federal government could provide subsidies to those states which opted out of running their own insurance exchange programs and instead let the feds control the exchange.
  - 85% of the 6 million patients using exchanges qualify for subsidies.
  - Court upheld the subsidies.

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ACOs – Patient Protection and Affordable Care Act

- As of January, 2015 there were 744 public and private accountable care organization ("ACOs") in the U.S. Over 450 are Medicare Shared Savings Program ACOs.
- There are 23.5 million covered ACO lives, but only 7.8 million are in the MSSP – the rest are in the commercial and Medicaid sectors.
- There are multiple Medicare ACO programs which began with the Pioneer Model. Medicare announced its Next Generation ACO Model this past March in which participants take on greater performance risks in return for sharing in a greater portion of the savings.
- By 2018, HHS wants 50% of its patient population covered by alternative models which reimburses providers based on quality outcome measures and greater coordination of care.

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PSOs–Patient Safety and Affordable Care Act of 2005

- In response to public and private payors' movement toward reimbursing providers based on the value versus the volume of services provided, and the ever increasing use of quality and outcome metrics to measure value, providers are generating a lot more sensitive quality, peer review and risk reports and analyses.
- The PSQIA was passed in 2005 to address the concern that these reports and information could be discoverable and used in malpractice cases and other similar challenges.
- In addition, the scope of state protections and types of entities covered varies greatly from state to state.

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PSOs – Patient Safety and Affordable Care Act (cont'd)

- Under the PSQIA, information relating to patient safety events designed to improve care and reduce risk are privileged and confidential and not subject to discovery or admissible into evidence in any state or federal proceeding if collected within a licensed provider's Patient Safety Evaluation System and reported to a PSO.
- Furthermore, the quality of health care services will improve if there is a method by which de-identified patient data, adverse events, can be collected in a uniform manner and shared with all providers.
- There are currently 82 AHRQ certified PSOs in the country.
- There are over 5,000 hospital physician groups and other provides which have contracted with one or more PSOs.

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PSOs – Patient Safety and Affordable Care Act (cont'd)

- Under Section 1311 of the ACA, all hospitals with more than 50 beds must have a Patient Safety Evaluation System ("PSES") in order to provide health care services to a qualified health plan participating in a state health insurance exchange program.
- The required participation date of January 1, 2015 was changed to January 1, 2017.

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PSO LEGAL DECISIONS

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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.

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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.

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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.

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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

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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.

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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.'

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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)."

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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.

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Walgreens Appellate Court Decision (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.

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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.

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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."

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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.

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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)

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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.

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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.

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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.

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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.

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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.

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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.

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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

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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 tot he facts if permitted.

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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

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