CHRMS Law Day 2015

Maximizing Privileges for Peer Review Activities – State Law Protection or the Patient Safety Act?

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Significant PSO Legal Decisions

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Illinois Department of Financial and Professional Regulation v. Walgreens 2012 Il. App (2d) 110452

- 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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***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.

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Horvath Trial Court Decision (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.

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Morgan v. Community Medical Center Healthcare System (Pennsylvania, 6/15/2011)

- Case involves a malpractice suit filed against a hospital claiming that it negligently discharged the plaintiff from the emergency room who had sustained injuries as a result of a motorcycle injury.
- Plaintiff contends that he received IV morphine while in the ED but did not receive any evaluation of his condition prior to discharge contrary to hospital policy. He subsequently walked out of the ED but fell, struck his head on concrete and was readmitted with a subdural hematoma.
- Plaintiff sought and obtained a trial court order for the hospital to produce an incident report regarding the event. The hospital appealed.

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Morgan Trial Court Decision (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.

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Morgan Trial Court Decision (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."

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***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.

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Francher Trial Court Decision (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.

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Francher Trial Court Decision (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."

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Francher Trial Court Decision (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.

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Francher Trial Court Decision (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."

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Francher Trial Court Decision (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."

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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

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Craig Trial Court Decision (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.

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Tibbs v. Bunnell (No. 2012-SC-000603-MR (Ky. Aug. 21, 2014)

- 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 (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 (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.

- 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 (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 (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 (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 (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 (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

- 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 but 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)

- Respondent's brief filed on August 21, 2015.
- Solicitor General invited to file an amicus brief "expressing the views of the United States".
- Brief due in December. Court's decision expected in December or January.

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

- Involves a medical malpractice action in which the plaintiff suffered a catastrophic neurological injury after undergoing an alleged unnecessary and contra-indicated surgery.
- Pursuant to Article 10 Section W of the Florida Constitution (Amendment 7), plaintiff requested that hospital produce adverse incidents that were created or maintained by the hospital pursuant to state or federal rule, law or regulation.
- While producing many documents, including mandated state reports, the hospital refused to produce others that were prepared separately from mandated reports in its PSES claiming protection under the PSQIA.

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Southern Baptist Trial Court Decision

- Plaintiff filed Motion to Compel which the court granted holding:
  - Amendment 7 gives patients broad access to adverse incidents from medical providers.
  - These include documents that are required by state or federal law to be reported to a government agency and incidents reported by any health care facility peer review, risk management, quality assurance, credentials or similar committee.
  - Information collected, maintained or developed to fulfill purposes other than submission to a PSO are not privileged and confidential and therefore do not constitute PSWP.

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Southern Baptist Trial Court Decision (cont'd)

- Because Florida law requires that adverse incident reports be collected, maintained and reported and that the state be able to access them, they cannot be considered PSWP.
- Court rejected hospital's argument that the PSQIA protects documents that must be maintained and collected under state law but not reported to the state.

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Appellate Court Decision

- Appellate court reversed unanimously.
- Citing to the definition of PSWP under the PSQIA, the court ruled that the documents at issue clearly met the definition of PSWP because they were placed in Baptist's PSES system where they remained pending submission to a PSO (citing to 42 U.S.C. §299b-21(7)(A).
- Documents may be collected in a PSES and therefore be protected but then removed if required to be reported to the state or federal government before it is reported to a PSO. Once removed they are no longer PSWP.
- Providers make the decision on what to include in the PSES, what to remove and what to report and must face any consequences for non-compliance with reporting requirements.

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Appellate Court Decision (cont'd)

- Hospital produced the Code 15 reports and Annual Reports required to be reported to the state but not the other reports it collected in PSES and reported to a PSO.
- Court also held that the PSQIA expressly and impliedly preempted Amendment 7.
- To hold otherwise "would render [the Act] 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."

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Johnson v. Cook County (No. 15C741, N.D. Illinois, August 31, 2015) (2015 WL 5144365)

- Case involves a lawsuit filed against Cook County under 42 U.S.C. §1983 regarding the death of a Joliet inmate resulting from a failure to prescribe medication for the inmate's identified seizure disorder. Inmate ultimately died from a seizure three days after incarceration and after a nurse only provided him over-the-counter medication for an upset stomach.
- Cook County prepared a morbidity and mortality report in accordance with jail policy which addressed the processes that led to the inmate's death.
- Plaintiff filed a motion to compel seeking discovery of the report.

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Johnson Trial Court Decision

- Cook County asserted protection under both the Illinois Medical Studies Act and the PSQIA.
- Court rejected the IMSA argument because:
  - Precedent holds that a state privilege and confidentiality statute cannot be used as a basis to preempt a federal court of action (citing to Memorial Hosp. for McHenry County v. Shadur, 66 F.2d 1058, 1061).
  - IMSA was not intended to apply to reports that primarily focus on "systems and processes" and not medical errors resulting from a practitioner's actions.

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Johnson Trial Court Decision (cont'd)

- With respect to the PSQIA, the court ruled that Cook County had failed to meet its burden that the report was PSWP.
  - The affidavit submitted by Cook County contained no statement or proof that the report was functionally reported, or that the PSO received or relied on the report to conduct any analysis.
  - Cook County simply submitted its PSO agreement which made reference to functional reporting but court viewed this as insufficient to meet its burden.
  - Cook County also failed to establish that report was prepared within its PSES for reporting to the PSO.
  - The jail policy provided details as to the review process and committees and individuals involved but again made no reference to collecting with its PSES or reporting to the PSO.

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Lessons Learned and Questions Raised

- Courts are generally inclined to strictly construe all privilege and confidentiality statues and therefore detailed documentation of compliance is imperative.
- Courts will not rely on a party's mere assertion that they have established a PSES and are participating in a PSO.
- 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?

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Lessons Learned and Questions Raised (cont'd)

- 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.
- 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?

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Lessons Learned and Questions Raised (cont'd)

- 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?

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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?

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Lessons Learned and Questions Raised (cont'd)

- Detailed affidavits are critical in establishing compliance. You should also consider submitting the template reporting forms or screen shorts of the forms utilized for PSO reporting.
- Attach the PSO agreement which should make reference to the compliance obligations of both the provider and the PSO AND which should address the issue of functional reporting.
- Consider including the provider's PSES, and perhaps that of the PSO, which hopefully identifies the documents or category of documents the parties are seeking to protect.
- Consider including an affidavit prepared by the PSO demonstrating compliance with the Act.

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Lessons Learned and Questions Raised (cont'd)

- An affidavit and/or a memorandum of law needs to explain the concept of functional reporting to the court. You also need to demonstrate that the documents in question were in fact functionally reported. Documenting when this occurs is a required under the Act. Although information collected within a PSES remains privileged and confidential as soon as it is collected and before it is reported one way or the other, most courts do not understand this concept.
- Need to educate courts on the process for developing and implementing a PSES and how reports are made to a PSO.
- PSOs and providers need to work together when faced with these discovery challenges. At some point in time, PSOs also will be subpoenaed and/or dragged into these cases. Even if they are not, assisting provider members in these disputes is of critical importance to all involved.

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