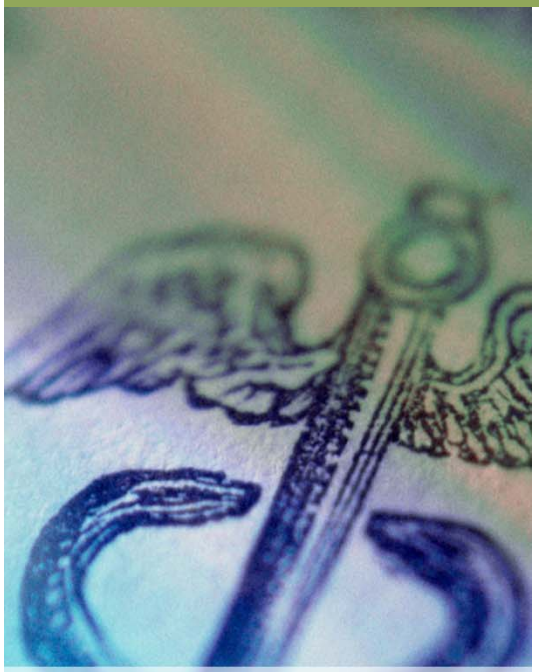

Children's Hospital Association

Risk Managers Forum

PSO Updates

April 7th, 2014

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Statistics

- Current member of listed PSOs
  - 77 in 29 states and the District of Columbia
- States where there is no listed PSO include:
  - Oregon
  - Washington
  - Nevada
  - Utah
  - Montana

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Statistics (Cont'd)

- North and South Dakota
- Iowa
- Colorado
- Utah
- Idaho
- Indiana

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Statistics (cont'd)

- Illinois has the most listed PSOs (10) followed by Florida (8)
- Of the 77 PSOs, 64 are component PSOs
  - State hospital associations
  - Specialty societies
  - Health care systems

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Statistics (cont'd)

- Number of De-Listed PSOs
  - 54
- Percentage of Participating Hospitals
  - 50%

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Federal Legislative Developments - Affordable Care Act

- ACA includes section 1311(h) titled “Quality Improvement” under “Part 2 – Consumer Choices and Insurance Competition Through Health Benefit Exchanges”.
- This section states as follows:
  - (1) ENHANCING PATIENT SAFETY—Beginning on January 1, 2015, a qualified health plan may contract with
    - (A) A hospital with greater than 50 beds only if such hospital—
      - Utilizes a patient safety evaluation system as described in part C of title IX of the Public Health Service Act; and

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Federal Legislative Developments - Affordable Care Act

- Implements a mechanism to ensure that each patient receives a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional; or
- (B) a health care provider only if such provider implements such mechanisms to improve health care quality as the Secretary may by regulation require.

- (2) EXCEPTIONS—The Secretary may establish reasonable exceptions to the requirements described in paragraph (1).
- (3) ADJUSTMENT—The Secretary may by regulation adjust the number of beds described in paragraph (1)(A).

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Federal Legislative Developments – Affordable Care Act (cont'd)

- A PSES is defined under the PSQIA as information collected, managed or analyzed for reporting to an AHRQ approved PSO.
- Therefore, many PSOs and others have interpreted the provision and cross reference to the PSQIA as requiring hospitals to contract with a listed PSO in order to contract with a qualified health plan offered through a state insurance exchange even though Congress did not clearly express this intention in the ACA.
- Various questions remain.
  - Many of the 77 AHRQ approved PSOs have a specialty focus, i.e., breast cancer, pediatric anesthesia. It is not clear whether a hospital participating in a specialty PSO will satisfy this ACA provision.

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Federal Legislative Developments – Affordable Care Act (cont'd)

- Provision allows for exceptions to the requirements in Part (1) such as the number of beds or an alternative mechanism to contracting with a PSO.
- Some states require hospitals to contract with a PSO agency and under state law. There are differences in the state and federal provisions. If ACA requires a hospital to contract with an AHRQ listed PSO, then hospital may be required to contact with both.
- Is contracting with a PSO sufficient? How is the term "utilize" to be interpreted?

- Proposed Regulation
  - HHS Notice of Benefit and Payment Parameters for 2015; Proposed Rule (Vol. 78, No. 231) December 2, 12013

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PSO Updates (cont'd)

- Delayed the January 1, 2015 effective date but no specific deadline identified
- During the interim period, CMS has proposed that insurance exchanges can contract with a hospital with greater than 50 beds as long as it is Medicare certified or has been issued a CMS Medicaid only certification
- Because these hospitals must have both a Quality Assurance & Performance Improvement plan ("QAPI") and a comprehensive discharge planning program in place in order to comply with the Medicare/Medicaid CoPs, this was viewed as sufficient for the time being

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PSO Updates (cont'd)

  - CMS concerned that there may be an insufficient number of PSOs to accommodate all of the hospitals
  - Also concerned about the costs of participation or forming a component PSO
- Final regulations on this issue have not been adopted
  - See attached proposed regulations
  - See attached comments prepared by California Hospital Patient Safety Organization

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QAPI Survey Developments

- One of the lingering issues and concerns expressed by hospitals is demands made by CMS, or their state surveyor representatives, to access PSWP in order to determine compliance with the Medicare/Medicaid Conditions of Participation
- Although CMS has communicated to surveyors that they cannot access PSWP to make this determination, some surveyors have threated hospitals with a finding of "immediate jeopardy" unless the documents are turned over

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QAPI Survey Developments (cont'd)

- AHRQ considers the decision to disclose PSWP in any form to be a violation of the Patient Safety Act
- To attempt to address this tension in the law representatives from AHRQ, CMS, The Joint Commission, the AHA and several PSOs have periodically met to try and resolve this issue in order to satisfy QAPI requirements without jeopardizing or violating the protections under the PSA
- The parties are currently reviewing and developing a revised QAPI survey tool when investigating a complaint or violation

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2014 OIG Work Plan

- Page 57 of the 2014 OIG Work Plan, under the category of "AHRQ – Early Implementation of Patient Safety Organizations" states the following:
  - We will review the policies and activities of Patient Safety Organizations to determine the extent of hospitals' participation in such activities, identify PSOs practices for receiving and analyzing adverse event reports, and determine the extent to which PSOs provide information to health care providers and the Network of Patient Safety Databases maintained by AHRQ

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2014 OIG Work Plan (cont'd)

- We will evaluate PSOs' efforts to identify and resolve patient safety problems in hospitals and identify barriers to the full and effective implementation of the PSO program

- Initiative largely driven by OIG January, 2012 report on hospitals' failure to accurately report adverse events

- In two calls with the OIG, the following information was obtained:

  - The OIG attorneys who are in charge of this PSO initiative are from the Evaluation Branch and not the Investigations and Audit Branch of the OIG. In other words, this is an information gathering exercise.

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2014 OIG Work Plan (cont'd)

- The individuals involved in this initiative are clinicians and non-attorneys who have been tracking the PSA, PSOs and AHRQ at lease since 2007
- One area of concern they expressed is whether hospitals are outsourcing their internal quality, peer review and related patient safety activities to PSOs in lieu of conducting their own internal studies and analysis. They do not see this as good development if true and if such outsourcing is extensive

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2014 OIG Work Plan (cont'd)

- We discussed how few decisions have been published so as to give PSOs and, in particular, participating providers, sufficient comfort that courts will uphold the protections. While the decisions to date are encouraging courts will have to address these questions on a state by state basis
- Other reasons for less participation than expected include continued confusion about scope of the protections, the delayed implementation of the ACA requirement that hospitals participate in PSOs if seeking to provide health care services to patients insured through the insurance exchanges, and state surveyors insisting that PSWP be disclosed under threat of a finding of immediate jeopardy or threat to their Medicare eligibility.

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2014 OIG Work Plan (cont'd)

- Although the OIG is still formulating next steps, their basic plan is to send a survey to ALL PSOs requesting information including the following:
  - Number and kinds of participating providers
  - What percentage are reporting and what kind of information, especially adverse events, are being reported?
  - What information is the PSO reporting to the NPSD

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2014 OIG Work Plan (cont'd)

- The OIG also will survey a sampling of participating hospitals and ask similar questions including what barriers exist to reporting, what value is the hospital getting in return from the PSOs in furthering patient safety and the delivery of quality health care services
- This Branch of the OIG is a strong advocate for patient safety and therefore a strong supporter of PSOs. Their basic goal is to try to determine the effectiveness of PSOs in furthering patient safety and the delivery of quality health care services

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CASE LAW DEVELOPMENTS

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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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Recent 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.

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Recent 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.

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Recent PSO Trial Court Decisions

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

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

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Recent PSO Trial Court Decisions (cont'd)

- Hospital argued that the incident report was privileged and not subject to discovery under both its state confidentiality statute and the PSQIA.
- With respect to the state statute, as is true in many states, the protection only applies if the hospital meets its burden of establishing that the report was solely prepared for the purpose of complying with the Pennsylvania Safety Act.
- Plaintiff argued, and the court agreed, that the report could have been prepared principally for other purposes such as for insurance, police reports, risk management, etc. and therefore the report was subject to discovery even if later submitted to a patient safety committee on the board of directors.

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Recent PSO Trial Court Decisions (cont'd)

With respect to the PSQIA, the court applied a similar analysis – was the incident report collected, maintained or developed separately or does it exist separately from a PSES. If so, even if reported to a PSO, it is not protected.

- As with the state statute, court determined that hospital had not met its burden of establishing that the report "was prepared solely for reporting to a patient safety organization and not also for another purpose."

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Recent 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.

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Recent PSO Trial Court Decisions (cont'd)

- Keep in mind that the Kentucky Supreme Court has struck down three legislative attempts to provide confidentiality protection for peer review activity in malpractice cases.

- Because the requested documents were prepared for the "purpose of complying [with] [T]he Joint Commission's requirements and for the purpose of providing information to its patient safety organization", it was not intended for or prepared solely for the purpose rendering legal services and therefore, documents were not protected under any of the attorney-client privileges.

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Recent PSO Trial Court Decisions (cont'd)

- In noting that no Kentucky court had addressed either the issue of PSQIA protections or the issue of pre-emption, i.e., "a state law that conflicts with federal law is without effect", court cited favorably to *K.D. ex rel Dieffebach v. U.S.* (715 F Supp 2d 587) (D. Del. 2010).
- Although it did not apply the PSQIA in the context of a request to discover an NIH cardiac study, the Francher Court, citing to K.D., stated:

> "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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Recent PSO Trial Court Decisions (cont'd)

- Regarding the issue of pre-emption, the Court identified the Senate's intent under the PSQIA to move beyond blame and punishment relating to health care errors and instead to encourage a "culture of safety" by providing broad confidentiality and privilege protections.

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Recent PSO Trial Court Decisions (cont'd)

- "Thus, there is a clear statement of a Congressional intent that such communications be protected in order to foster openness in the interest of improved patient safety. The court therefore finds that the area has been preempted by federal law."
- In addressing Section 3.20, Subsection 2(B)(iii)(A), which defines "patient safety work product," and would seem to allow for the discovery of PSWP in a "criminal, civil or administrative proceeding", the court determined that such discovery "could have a chilling effect on accurate reporting of such events."

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Recent PSO Trial Court Decisions (cont'd)

- Court fails to note that this section only applies to information that is not PSWP.

- Court further noted that the underlying facts, (such as a medical record) are not protected and can be given to an expert for analysis.
- That this information is submitted to other entities, such as the Joint Commission was "not dispositive."
- Court granted a protective order "as to the sentinel event and root cause analysis materials reported to its patient safety organization as well as its policies and procedures."

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

- Both cases involve medical malpractice actions in which the plaintiffs sought to discover incident reports, patient safety and quality improvement reports and peer review information.
- Each of the defendants refused to turn over the requested materials arguing that they had been collected as part of their respective PSEDS for the purpose of reporting to a PSO.
- Trial court in each case ordered the production of the requested documents and the defendants filed a writ of prohibition with the Kentucky Court of Appeals.

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

- The Court, in nearly identical decisions, ruled that:
  - The Patient Safety Act pre-empted Kentucky state law.
  - BUT, the scope of protection under the PSA extended only to documents that "contain self-examining analysis". In other words, only those materials prepared by the actual treatment provider would be protected.
- Both hospitals filed an appeal as a matter of right to the Supreme Court of Kentucky
- Case were assigned in February, 2013 but decision still pending.
- Amicus curie briefs submitted and parties included AHA, AMA, The Joint Commission and approximately forty other parties.

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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 v. Ingalls Memorial Hospital (Ill. Circuit Court, No. 2012 L 008010 (10/28/2013))

- 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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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.

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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?

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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.
- Protections are not waiveable.

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