



Midwest Alliance for Patient Safety

Patient Safety Organization Overview – a Legal Perspective October 3, 2013

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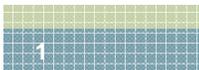
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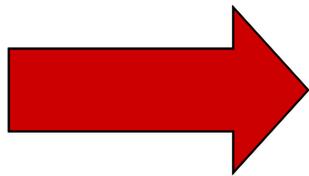
1. What is the Purpose of a Patient Safety Organization (“PSO”) Under the Patient Safety and Quality Improvement Act (“PSA”)

- To encourage the expansion of voluntary, provider-driven initiatives to improve the quality and safety of health care; to promote rapid learning about the underlying causes of risks and harms in the delivery of health care; and to share those findings widely, thus speeding the pace of improvement.
 - Strategy to Accomplish its Purpose
 - Encourage the development of PSOs
 - Establish strong Federal and greater confidentiality and privilege protections
 - Facilitate the aggregation of a sufficient number of events in a protected legal environment.



1. What is the Purpose of a Patient Safety Organization (“PSO”) Under the Patient Safety and Quality Improvement Act (“PSA”) (continued)

- Create the Network of Patient Safety Databases (NPSD) to provide an interactive, evidence-based management resource for providers that will receive, analyze, and report on de-identified and aggregated patient safety event information



Further accelerating the speed with which solutions can be identified for the risks and hazards associated with patient care through the magnifying effect of data aggregation

2. Define a Patient Safety Evaluation System (“PSES”)

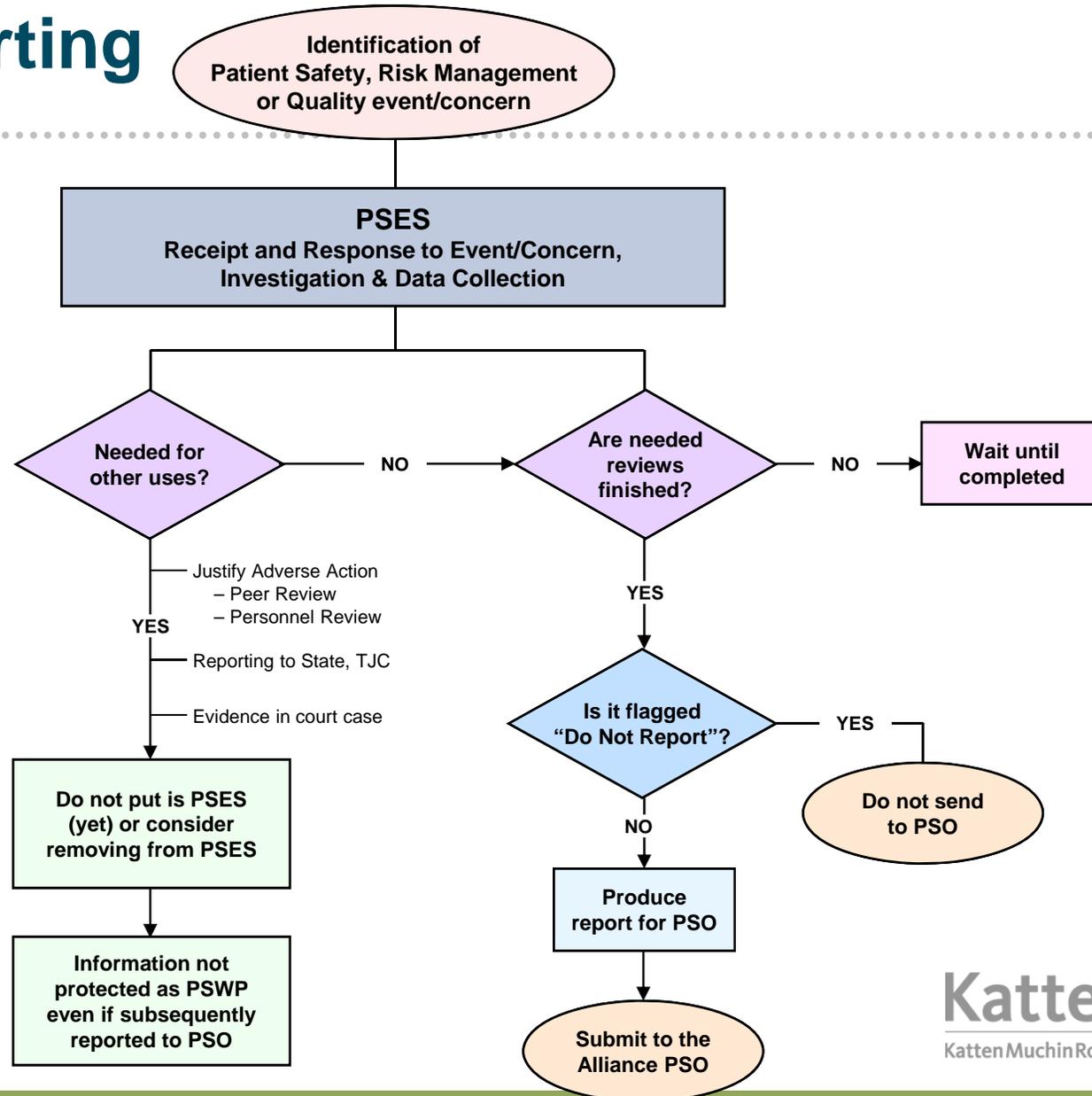
- PSES Definition

- Body that manages the collection, management, or analysis of information for reporting to or by a PSO (CFR Part 3.20 (b)(2))
 - Determines which data collected for the PSO is actually sent to the PSO and becomes Patient Safety Work Product (PSWP)
 - PSES analysis to determine which data is sent to the PSO is protected from discovery as PSWP

2. Define a Patient Safety Evaluation System (“PSES”) (continued)

- Establish and Implement a Patient Safety Evaluation System (PSES), that:
 - Collects data to improve patient safety, healthcare quality and healthcare outcomes
 - Reviews data and takes action when needed to mitigate harm or improve care
 - Analyzes data and makes recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes
 - Conducts RCAs, Proactive Risk Assessments, in-depth reviews, and aggregate RCAs
 - Determines which data will/will not be reported to the PSO
 - Reports to PSO(s)

PSO Reporting



2. Define a Patient Safety Evaluation System (“PSES”) (continued)

- Designing Your PSES
 - Events or Processes to be Review and Analyze
 - Adverse events, sentinel events, never events, near misses, HAC, unsafe conditions, RCA, etc.
 - Committee Reports/Minutes Regarding Events
 - PI/Quality committee, Patient safety committee, Risk Management committee, MEC, BOD
 - Structures to Support PSES
 - PI plan, safety plan, RM plan, event reporting and investigation policies, procedures and practices, grievance policies and procedures

2. Define a Patient Safety Evaluation System (“PSES”) (continued)

- Criteria-based Prioritization
 - Suggested criteria
 - Promotes culture of safety/improves care
 - Impressions/subjective data that is not available in the medical record
 - Information that could be damaging during litigation
 - Not required to report elsewhere
 - Required to report elsewhere, but data for reporting could be obtained from medical record and analyzed
 - Data will not be used to make adverse employment decisions

3. What types of data can the PSES collect and report to the PSO?

- Medical Error or Proactive Risk Assessments, Root Cause Analysis
- Risk Management – incident reports, investigation notes, interview notes, RCA notes, notes rec'd phone calls or hallway conversations, notes from PS rounds
- Outcome/Quality—may be practitioner specific, sedation, complications, blood utilization etc.
- Peer Review
- Committee minutes—Safety, Quality, Quality and Safety Committee of the Board, Medication, Blood, Physician Peer Review

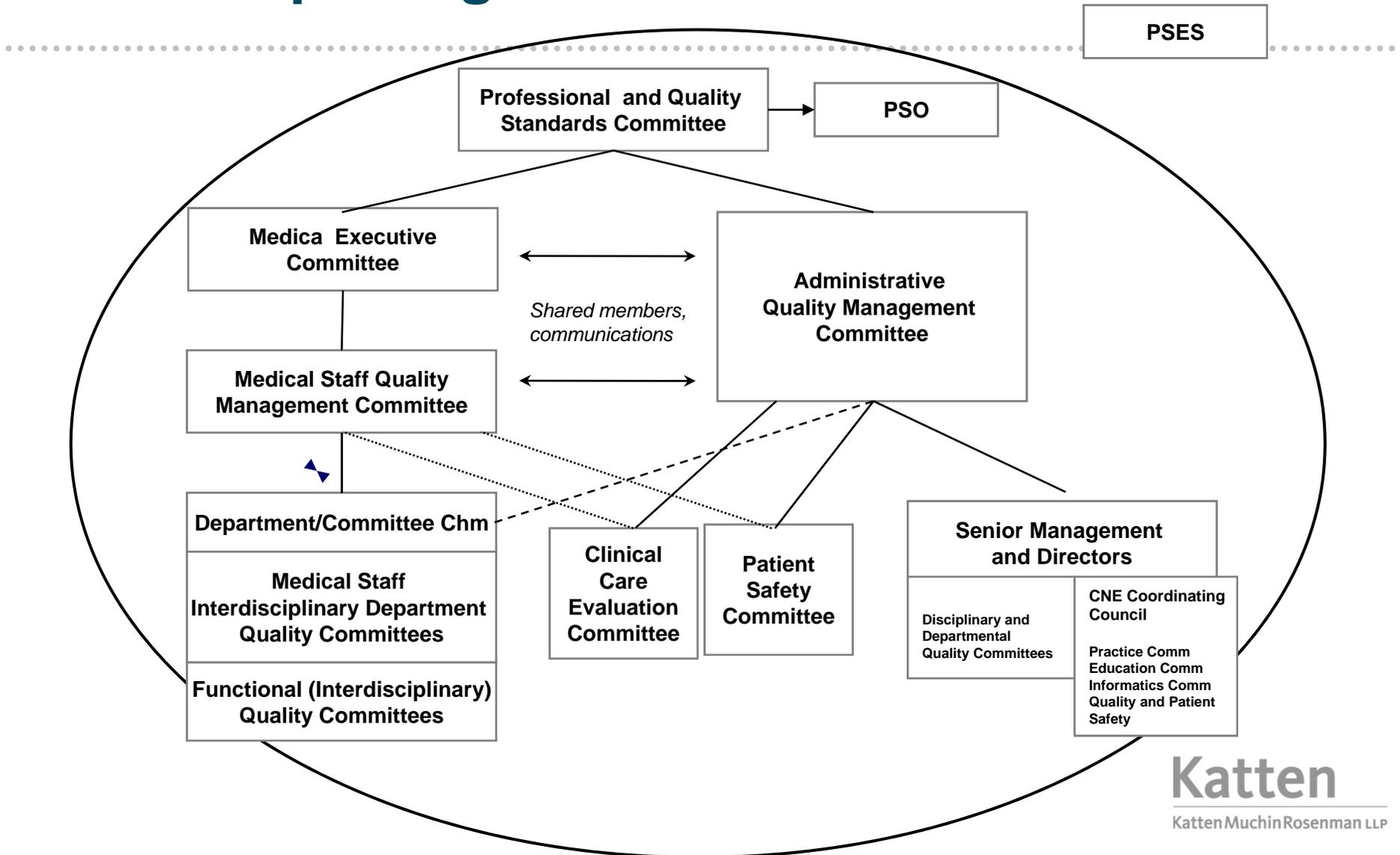
3. What types of data can the PSES collect and report to the PSO? (continued)

- PA Patient Safety Authority: Reports Identify Trends
 - Hidden sources of Latex in Healthcare Products
 - Use of X-Rays for Incorrect Needle Counts
 - Patient Identification Issues
 - Falls Associated with Wheelchairs
 - Electrosurgical Units and the Risk of Surgical Fires
 - A Rare but Potentially Fatal Complication of Colonoscopy
 - Fetal Lacerations Associated with Cesarean Section
 - Medication Errors Linked to Name Confusion
 - When Patients Speak-Collaboration in Patient Safety
 - Anesthesia Awareness
 - Problems Related to Informed Consent
 - Dangerous Abbreviations in Surgery
 - Focus on High Alert Medications
 - Bed Exit Alarms to Reduce Falls
 - Confusion between Insulin and Tuberculin Syringes (Supplementary)
 - The Role of Empowerment in Patient Safety
 - Risk of Unnecessary Gallbladder Surgery
 - Changing Catheters Over a Wire (Supplementary)
 - Abbreviations: A Shortcut to Medication Errors
 - Lost Surgical Specimens

3. What types of data can the PSES collect and report to the PSO? (continued)

- PA Patient Safety Authority: Reports provide useful information
 - Examples:
 - One misunderstood colored wristband led to regional standardization
 - A hospital had a “sandbag” fly into the MRI core & screened their other sandbags throughout the facility
 - A report from a behavioral health unit of patients getting implements of self-harm in the ED

PSO Reporting Process



3. What types of data can the PSES collect and report to the PSO? (continued)

- Learning lessons the easy way
 - Examples:
 - Insulin given to the wrong patient
 - Wrong patient taken to the OR/procedure room
 - Patient with pacemaker scheduled for MRI
 - Patients found with multiple fentanyl patches
 - Neonates or infants given excessive doses of heparin
 - Wrong tissue type

4. What is the definition of Patient Safety Work Product (“PSWP”)?

- Any data, reports, records, memoranda, analyses (such as Root Cause Analyses (RCA)), or written or oral statements (or copies of any of this material) which could improve patient safety, health care quality, or health care outcomes;

And that:

- Are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a PSES for reporting to a PSO, and such documentation includes the **date the information entered the PSES**; or
- Are developed by a PSO for the conduct of patient safety activities; or
- Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES

5. What is NOT PSWP?

- Patient's medical record, billing and discharge information, or any other original patient or provider information
- Information that is collected, maintained, or developed separately, or exists separately, from a PSES. *Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered PSWP*
- PSWP assembled or developed by a provider for reporting to a PSO but removed from a PSES is no longer considered PSWP if:
 - Information has not yet been reported to a PSO; and
 - Provider documents the act and date of removal of such information from the PSES

6. What confidentiality/privilege protections do we have today under the Medical Studies Act – does a PSO enhance that?

- The confidentiality and privilege protections afforded under the PSA generally apply to reports, minutes, analyses, data, discussions, recommendations, etc., that relate to patient safety and quality if generated or managed, or analyzed and collected for the purpose of reporting to a PSO.
- The scope of what can be protected, generally speaking, is broader than most current state statutes.
- Any licensed provider, i.e., physician, physician group, surgicenters, clinic, hospital, nursing home, home health facility, etc., can be covered under the PSA whereas in many states the kinds of providers that can be protected is more limited.

6. What confidentiality/privilege protections do we have today under the Medical Studies Act – does a PSO enhance that? (cont'd)

- Although the Medical Studies Act references “medical organizations” under contract with HMOs or other healthcare delivery entities or facilities, surgicenters and hospitals, Appellate Courts have not extended protections to nursing homes or pharmacies.

6. What confidentiality/privilege protections do we have today under the Medical Studies Act – does a PSO enhance that? (cont'd)

- The protections apply in both state and, for the first time, federal proceedings.
- The protections can never be waived - same for MSA, with exceptions.
- If the protections are greater than those offered under state law the PSA pre-empts state law.
- PSWP is not admissible into evidence nor is it subject to discovery – MSA same but only applied in state courts and state claims in federal court.

6. What confidentiality/privilege protections do we have today under the Medical Studies Act – does a PSO enhance that? (cont'd)

- Key to these protections is the design of the provider's and PSO's patient safety evaluation system ("PSES").
- IDFPR v. Walgreens

7. Is participation in a PSO required in order to contract with the state insurance exchange?

- 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
 - ❖ 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

7. Is participation in a PSO required in order to contract with the state insurance exchange? (Cont'd)

- (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).

7. Is participation in a PSO required in order to contract with the state insurance exchange? (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 79 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.

7. Is participation in a PSO required in order to contract with the state insurance exchange? (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?
- AHA has been working with the Center for Consumer Information and Insurance Oversight (“CCIIO”) within HHS which is responsible for promulgating regulations related to health insurance marketplaces.
 - Regulations are expected but date of issuance not yet known.

8. How does participation in a PSO affect internal use of the data, info and documents (PSWP)?

- PSWP can be shared for internal use to support and implement hospital operations and quality, peer review and risk management initiatives. Disclosure should be limited to those individuals participating in a relevant hospital operation.

9. What data is needed to be sent to a PSO and how do we handle that data? What is functional reporting?

- Have to decide if data and/or the analysis of the data needs to be protected whether created or performed by the provider and/or the PSO and/or Corporate.
- Whatever data you want protected that relates to patient safety activities and is used for the purpose of collecting and reporting to a PSO and not for some other purpose and is not subject to mandatory reporting can be protected by either electronically/physically reporting to the PSO or if it is “functionally reported”.

9. What data is needed to be sent to a PSO and how do we handle that data? What is functional reporting? (cont'd)

- Concept of functional reporting does not require actual submissions to PSO but PSO must be able to access information in order to be considered “reported.”
- Timing of when information is functionally reported is important.

10. How will data be used?

- If referring to data sent to a PSO, it can perform studies, benchmark reports, identify good and bad practice patterns and whatever provider requests of the PSO. It may make recommendations but decisions should be left to Corporate or to individual facilities/providers.
- If referring to data received from a PSO, which also is considered PSWP, it can be used internally to develop/revise quality plans, reports, recommendations and decisions. All but final decisions and actions can be kept confidential.

11. What do we get back?

- Depends on what you want and what you need.
- Keep in mind that these reviews can be conducted internally and never actually sent to the PSO. They still will be protected if part of the PSES and documented as functionally reported.

12. Once the data has been submitted to the PSO, what can or can't we get back out?

- Information sent to a PSO still belongs to the provider and can be used for internal PSES purposes. Again, providers will send only a limited amount of information to the PSO. The large majority will be “functionally reported” and therefore will never physically leave the facility.

13. Will we have the ability to see individual reports and records created within the hospital or system through the PSO reporting?

- If the facilities are owned, controlled or managed by Corporate and part of a single system-wide PSES, information can be accessed and shared consistent with PSES policies for appropriate use, including individual reports and records.
- May need to obtain practitioner (i.e., physicians) authorizations for releases of information but this requirement can be made a condition of employment and medical staff membership.
- Information can be provided and generally obtain in identified or de-identified form.

14. Can we use a PSO and/or PSO data to benchmark quality indicators?

- Absolutely. This is one of the intended purposes.

15. Once data has been submitted to a PSO do we have to pretend that data does not exist anymore because it is protected?

- No. Any information that is PSWP, whether generated internally and functionally or actually reported, or generated by the PSO, can be used to advance patient safety and quality of care.
- But information can only be disclosed to those employees, physicians, contractors, etc., engaged in these activities.
- Remember, protections are never waived.

16. Once data/reports come back to an organization from a PSO, is that data discoverable again or is it still protected?

Example:

- Data is submitted to a PSO, it is aggregated and a report comes back stating that hospital shows variations in practice. Is that statement/outcome/finding discoverable or not?
 - Not discoverable.
 - Need to set up appropriate PSES policies and paper trail to establish that data sent was part of providers' PSES and collected for the purpose of reporting to a PSO so that the PSO can analyze and produce reports which identify variances/outliers in order for modifications to be made to improve patient safety and quality.
 - Definition of PSWP includes “data reports, records, memoranda, analyses (such as root cause analysis), or written or oral statements (or copies of any of these materials) (1) which could improve patient safety, health care quality, or health care outcomes . . . or are developed by a PSO for the conduct of patient safety activities. . . .”

17. Will the PSO protect patient safety activities of the corporate parent and not just the hospital?

- The PSA allows a non-provider corporate parent to access the same confidentiality/privilege protections of its participating provider facilities as long as it exercises sufficient ownership, control or management over the facilities.

18. Will a PSO lower or increase the corporate parent's level of legal protection?

- If referring to corporate liability, PSOs are not designed to be “decision makers” with respect to final corporate quality, peer review and other separate or system-wide initiatives.
- PSOs instead are established to help facilitate these initiatives by being able to receive and access PSWP from provider facilities in order to provide reports, analysis, comparative studies, recommendations, etc., that can be shared with the facilities and Corporate for the purpose of improving patient care and quality.

18. Will a PSO lower or increase the corporate parent's level of corporate protection? (cont'd)

- Because the purpose of the PSO is to protect from discovery and admissibility sensitive information that could be used against the hospital or health system in med mal cases, peer review disputes, government investigations, etc., it likely will have the effect of reducing liability exposure – keep in mind that PSWP cannot be dropped out and used in defense of a liability claim.

18. Will a PSO lower or increase the corporate parent's level of corporate protection? (Cont'd)

- Corporate will still be liable for any of its final decisions and those of its controlled affiliates.
 - Keep in mind that the hospital or health system has the option of collecting information as part of its PSES but holding onto the information if needed for another purpose such as mandated state reporting or to assist in defending a med mal or other case. Until the information is actually or functionally reported to the PSO it can be “dropped out” and used for a different purpose. PSES should document reason and ability to hold on to information. It is no longer PSWP once it is dropped out but state protections could apply.
 - Once it is reported it cannot be dropped out or removed for external (versus internal) purposes.

19. Provide real examples of how the PSO has benefited the organization.

- Walgreens (Illinois, 6/20/12)
 - Walgreens developed a component PSO in 2009.
 - Walgreens was served with a subpoena from the Illinois Department of Financial and Professional Regulation to produce medication error incident reports on three of its pharmacists.
 - Walgreens refused on grounds that the reports were part of its PSES and were reported to its PSO and therefore were not subject to discovery nor admissible into evidence under the PSO because they qualified as PSWP.
 - IDFPR sued Walgreens.
 - Trial court granted Walgreens motion to dismiss holding that the PSA preempted state law that otherwise would have permitted discovery (no state protection for pharmacies) and that Walgreens complied with the PSA with respect to its PSES and reporting to a PSO.
 - Appellate court affirmed.

19. Provide real examples of how the PSO has benefited the organization. (Cont'd)

- *Francher v. Shield* (Kentucky, 8/16/11)
 - Medical malpractice case in which plaintiff sought to compel discovery of documents including sentinel event and a root cause analysis.
 - Hospital asserted attorney-client communications, work product and PSA protections.
 - Court found that documents prepared for purposes of compliance with Joint Commission standards and for reporting to a PSO cannot also be protected under any of the attorney-client privileges.
 - Court granted a protective order “as to sentinel event and root cause analysis material reported to its patient safety organization as well as its policies and procedures.”

19. Provide real examples of how the PSO has benefited the organization. (continued)

■ Universal Health Services

- Large, for profit health care systems which purchased a behavioral health system with over 200 facilities.
- Has around 25 acute care hospitals.
- UHS has an established and re-certified component PSO (PsychSafe) for its behavioral health facilities and has submitted a component PSO application to AHRQ for its acute care hospitals.
- Goal is to have a system wide PSES for its behavioral health facilities and a separate system wide PSES for its hospitals that report to the respective PSOs.
- Goal is for the PSOs to assist Corporate into developing uniform practices and standards, to develop and compare performance measures, identify best practices and areas in need of improvement so as to increase efficiencies, reduce costs and improve patient care services.

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20. Our hospital/health system is comprised of many different provider entities. Can they all be in the PSO?

- Yes, but need to look to degree of ownership, control or management over the facilities and providers and if licensed or authorized to provider health care services in the state.

21. Should the data collected be the same for all entities?

- Makes sense in order to maximize benefits of benchmarking and other comparisons, at least within the same category of providers, i.e., hospitals, surgicenters, clinics, but is not required.

22. And to whom are the data/reports sent?

- To designated individual(s) who will review information and use for the intended patient safety purpose. Should not be shared with any one if not needed to carry out a patient safety activity set forth in the PSES.

23. Outline the pros and cons of creating a PSO internally versus participation in external PSO in terms of infrastructure, IT needs, staffing requirements, regulatory implications and jurisdictional differences.

- Requirements common to Component versus external PSO.
 - Develop PSES for each provider or have option of creating system-wide PSES.
 - PSO needs its own PSES.
 - Policies and procedures to evidence compliance with PSA requirements (eight patient safety activities).
 - Identification of PSO work force within each facility and PSO - can be employees with dual provider/PSO roles.
 - Each participating provider must contract with the PSO.
 - Must meet confidentiality/security requirements.
 - Must have a PSO compliance plan.
 - Must seek certification from AHRQ using required application form.

23. Outline the pros and cons of creating a PSO internally versus participation in external PSO in terms of infrastructure, IT needs, staffing requirements, regulatory implications and jurisdictional differences. (continued)

- Certification requirements:
 - What patient safety activities does PSO offer to providers?
 - How will PSO accept PSWP (paper or secured electronic submission, secure portal)?
 - What analytical services will be provided?
 - What is scope of PSO's planned dissemination activities and how is validity and reliability measured?
 - Need documentation on how PSWP is used to encourage a culture of safety and to assist in minimizing risk to patients.
 - Need documentation to establish how PSWP is kept secure internally and with BAs.
 - Compliance with security requirements (largely tracks HIPAA security).

23. Outline the pros and cons of creating a PSO internally versus participation in external PSO in terms of infrastructure, IT needs, staffing requirements, regulatory implications and jurisdictional differences. (continued)

- Documentation of PSO work force including licensed or certified medical professionals.
- How does PSO document how it will communicate with and provide feedback to participants in each PSES?
- Certification that it has two contracts.
- Can have shared staff but must develop means by which to keep PSWP separate from non-PSWP.
- Must collect PSWP in a standardized manner that permits valid comparisons of similar cases among similar providers.
- Any disclosure of PSWP to Corporate must be authorized.
- Component PSO can release or provide access to identifiable patient safety work product to individuals or to one or more units of the parent if it enters into an agreement between component and individual/units that will only provide access to enable component to assist in its conduct of patient safety activities.

23. Outline the pros and cons of creating a PSO internally versus participation in external PSO in terms of infrastructure, IT needs, staffing requirements, regulatory implications and jurisdictional differences. (continued)

- Individual/units can only use or disclose information for patient safety and quality purposes and will take appropriate security measures to prevent unauthorized disclosures.
- Component must disclose the nature of its relationship with each provider if it has relationship other than a PSO.

23. Outline the pros and cons of creating a PSO internally versus participation in external PSO in terms of infrastructure, IT needs, staffing requirements, regulatory implications and jurisdictional differences. (continued)

■ Pro/Con of Component PSO

● Pro

- PSWP stays within hospital or health system.
- PSO likely to be more robust and attuned to hospital or health system's patient safety activities and needs than most existing AHRQ listed PSOs.
- Better able to coordinate quality, peer review and risk management activities and initiatives.
- PSO fees charged depending on scope of purchased services.
- More likely to maintain compliance with ACA requirement on PSOs relating to insurance exchanges depending on the PSO.
- Less likely that component PSO will be delisted as long as it complies with all requirements.

23. Outline the pros and cons of creating a PSO internally versus participation in external PSO in terms of infrastructure, IT needs, staffing requirements, regulatory implications and jurisdictional differences. (continued)

■ Pro/Con of Component PSO

● Con

- Additional requirements imposed on a component PSO compared to a contracted PSO.
- Additional requirements may make it more difficult to manage.
- Protections can be more immediately obtained.
- Need to develop PSES and required policies internally unless getting assistance from third parties.
- AHRQ is sensitive to release of identifiable PSWP to Corporate if in a position to terminate/suspend employees and providers – undermines goal of “just culture”.
- Only hospital facilities will be involved in benchmarking and related studies – keep in mind that PSOs can share de-identified information with other PSOs.

23. Outline the pros and cons of creating a PSO internally versus participation in external PSO in terms of infrastructure, IT needs, staffing requirements, regulatory implications and jurisdictional differences. (continued)

■ Pro/Con of External PSO

● Pro

- PSOs have form provider agreements.
- Depending on sophistication of PSO, it can assist in development of PSES, policies and procedures.
- Depending on number of participating providers, health system may be able to obtain reports, bench marking, analyses, etc. which include comparable health system facilities.
- Avoids the additional requirements for Component PSOs.
- PSOs have already been certified and many have been re-certified.
- PSOs have existing and working relationship with AHRQ.
- PSO may be in a better position to analyze and prepare reports.
- Can initially contract with a PSO and once up and running, can later develop a Component PSO.

23. Outline the pros and cons of creating a PSO internally versus participation in external PSO in terms of infrastructure, IT needs, staffing requirements, regulatory implications and jurisdictional differences. (continued)

■ Pro/Con of External PSO

• Con

- Fees.
- There are probably a limited number of PSOs to accommodate hospital/health system's needs and volume depending on what services hospital/health system requires.
- Risk of delisting.
- Risk of not complying with ACA insurance exchange requirement.
- A third party now has your information and access to internal PSWP (although scope of PSO disclosure, if any, can be controlled by hospital/health system).

23. Outline the pros and cons of creating a PSO internally versus participation in external PSO in terms of infrastructure, IT needs, staffing requirements, regulatory implications and jurisdictional differences. (continued)

- Needed infrastructure, IT needs, staffing requirements, cost, regulatory implications, jurisdictional differences.
 - Infrastructure
 - Component PSO should be a separate legal entity (could be a division) with an independent staff (could be shared) to collect PSWP and perform PSO services.
 - Extent and cost of staff depends on scope of PSO activities.
 - If developing a system-wide PSES, local hospital needs to adopt the PSES as well and will need to identify its PSO work force. Need not be new positions.
 - Infrastructure currently in place for existing quality, peer review, risk management and other patient safety activities, can be utilized – redundancy not required.
 - Scope of PSO activities tied in part to hospital's strategic plan for improving quality and reducing utilization – PSO does not control this activity.

23. Outline the pros and cons of creating a PSO internally versus participation in external PSO in terms of infrastructure, IT needs, staffing requirements, regulatory implications and jurisdictional differences. (continued)

- IT Needs
 - Component PSO needs to be able to segregate PSWP from non-PSWP but can use a shared sewer.
 - Need to decide what is going to be electronically or physically submitted to PSO.
 - At some point in time, component will need to report consistent with Common Formats.
 - Need to comply with security measures although these generally follow HIPAA security requirements.
- Cost
 - Depends on scope of PSO services and what infrastructure changes need to be made.

23. Outline the pros and cons of creating a PSO internally versus participation in external PSO in terms of infrastructure, IT needs, staffing requirements, regulatory implications and jurisdictional differences. (continued)

- Regulatory Implications
 - PSA pre-empts state laws if less protective both in terms of scope and entities covered.
 - State protections may still be available depending on circumstances.
 - Component PSO must comply with all PSA certifications and other requirements.
 - PSOs can be fined and de-listed.

24. Do we need controls around PSWP or other data “harvested” by others? For example, if a physician group submits the same data to a PSO does hospital or health system have any control/rights to determine what can and cannot be submitted? What about rights to the PSO output and results? Will access result in loss of protection?

- Data, reports, analysis and other information that is collected and reported to a PSO can be used for internal versus external purposes.
- Information that is developed internally via committees and identified work force and the decision on what is actually or functionally reported by the hospital/provider should be controlled by hospital or health system.
- If hospital or health system is providing information to an independent group, i.e., not employed, non-hospital based and non-contracted physicians, you need to determine what level of information actually needs to be provided as well as the degree of sensitivity or need for protection, assuming it is protected at all.
 - **Examples:**
 - Non-protected information: Average length of stay, cost per patient visit, number of meds ordered, number of consultants used, etc.
 - Protected information: Quality outcomes, analysis, recommendations if collected for purposes of reporting to the PSO in order to improve patient care.

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- If physicians are members of the medical staff, surgi-center, etc., the release of this information should qualify as a “hospital operation” in furtherance of improving patient care and therefore protected. Documentation to support this argument/position is important.
- Group should not independently report the same information unless it also participates in the same PSO.
- If group uses information to develop or engage in independent peer review/quality activities, documentation will not be protected depending on scope of protections under state law unless group contracts with a PSO, sets up its own PSES, and otherwise complies with the PSA.

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- Hospital-based group under contract:
 - Independent hospital-based groups, especially those which serve multiple sites not controlled by hospital or health system, oftentimes generate patient safety and quality information relevant to the group practice that is not shared with the hospital.
 - If, however, information could adversely affect hospital or health system if subject to discovery then control via the contract or other means needs to be considered.
- Purposeful or inadvertent disclosure of PSWP by any party should subject them to potential disciplinary action and could give rise to civil fines by AHRQ but will not result in a waiver of the protections.
- Hospital or health system would not be able to access independent information submitted by group to a PSO unless authorized by the group. Hospital or health system would want to make this access a condition of any independent contractor/joint venture arrangement.

25. Give an example on how to operationalize information, reports, recommendations from PSO?

Example:

- Hospital or health system identifies a high incidence of post op infections in one of its orthopedic surgical groups.
- Decision is made to evaluate incidence of post op infections in all orthopedic cases of all groups and/or regional hospitals in order to identify cause as well as best practices in order to improve quality and patient safety.

25. Give an example on how to operationalize information, reports, recommendations from PSO? (continued)

- Information is gathered within each group/facility through appropriate personnel/committees.
- This patient safety activity is identified in system-wide and hospital PSES.
- Data sent to PSO for evaluation.
 - Data can be protected
- PSO analyzes, evaluates and prepares a report reflecting benchmark study of regional hospitals in the aggregate and for each group/hospital and makes a series of recommendations to reduce post-op infections. Report also provides analysis on causes of post-op infections by outlier orthopedic group.

25. Give an example on how to operationalize information, reports, recommendations from PSO? (continued)

- These PSO reports are PSWP and can be shared with regional hospitals and Corporate (may need authorizations if groups/hospitals are to be identified).
- Hospital/health system receives reports and then develops plan, guidelines, protocols to address deficiencies and implement recommendations.
 - Any additional studies, reports, recommendations triggered by PSO reports are protected but not final decision, guidelines, protocols.

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

- Consequently, Walgreens declined to produce the reports arguing they were PSWP and therefore not subject to discovery under the PSQIA.
- The IDFPR sued Walgreens which responded by filing a Motion to Dismiss.
- Although the IDFPR acknowledged that the PSQIA preempts conflicting state law, it essentially argued that Walgreens had not met its burden of establishing that:
 - That the incident report was actually or functionally reported to a PSO; and
 - That the reports were also not maintained separately from a PSES thereby waiving the privilege.

Walgreens Appellate Court Decision

- Walgreens submitted affidavits to contend that the responsive documents were collected as part of its Strategic Reporting and Analytical Reporting System (“STARS”) that are reported to PSRF and further, that it did not create, maintain or otherwise have in its possession any other incident reports other than the STARS reports.
- IDFPR had submitted its own affidavits which attempted to show that in defense of an age discrimination case brought by one of its pharmacy managers, Walgreens had introduced case inquiry and other reports similar to STARS to establish that the manager was terminated for cause.

Walgreens Appellate Court Decision

- IDFPR argued that this served as evidence that reports, other than STARS reports existed and, further, that such reports were used for different purposes, in this case, to support the manager's termination.
 - It should be noted that these reports were prepared in 2006 and 2007.
- Trial court ruled in favor of Walgreens Motion to Dismiss finding that: "Walgreens STARS reports are incident reports of medication errors sought by the Department in its subpoenas and are patient safety work product and are confidential, privileged and protected from discovery under The Federal Patient Safety and Quality

Walgreens Appellate Court Decision

Improvement Act (citation), which preempts contrary state laws purporting to permit the Department to obtain such reports. . . .”

- The IDFPR appealed and oral argument before the 2nd District Illinois Appellate Court took place on March 6, 2012.
- Two amicus curiae briefs were submitted in support of Walgreens by numerous PSOs from around the country including the AMA.
- On May 29, 2012, the Appellate Court affirmed that the trial court’s decision to dismiss the IDFPR lawsuit.

Walgreens Appellate Court Decision

“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

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

- 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 by 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 curiam)) did identify documents used by Walgreens to terminate the employee.

Walgreens Appellate Court Decision

- 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.

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.

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.

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.”

Recent PSO Trial Court Decisions (cont'd)

Francher v. Shields (Kentucky, 8/16/11)

- 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.

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:

Recent PSO Trial Court Decisions (Cont'd)

- “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.”

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.

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.”

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.”

Tibbs v. Bunnell; 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.

Tibbs v. Bunnell; 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.

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? What evidence/documentation?
 - Plaintiff will seek to discover your PSES and documentation policies.
 - Contrary to the court's comments in Francher, policies and procedures probably are discoverable.

Lessons Learned and Questions Raised

- If not yet reported, what is the justification for not doing so? How long has information been held? Does your PSES policy reflect practice or standard for retention?
- Has information been dropped out?
- Is it eligible for protection?
- Has it been used for another purpose?
- Was it subject to mandatory reporting? Will use for “any” other purposes result in loss of protection?
 - May be protected under state law.
- What was the date it was collected as compared to date on which provider evidenced intent to participate in a PSO and how was this documented?
 - Contract?
 - Resolution?

Lessons Learned and Questions Raised (cont'd)

- Is provider/PSO asserting multiple protections?
 - If collected for another purpose, even if for attorney-client, or anticipation of litigation or protected under state statute, plaintiff can argue information was collected for another purpose and therefore the PSQIA protections do not apply.
- Is provider/PSO attempting to use information that was reported or which cannot be dropped out, i.e., an analysis, for another purpose, such as to defend itself in a lawsuit or government investigation?

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