



# NC Quality Center PSO and Center for Patient Safety

## PSO Participation and Protections— a Practical and Legal Perspective July 17, 2014

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# Disclaimer

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

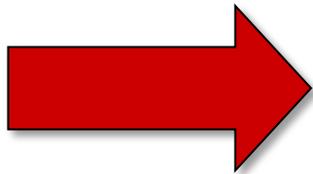
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- To encourage the expansion of voluntary, provider-driven initiatives to improve the quality and safety of health care; to promote rapid learning about the underlying causes of risks and harms in the delivery of health care; and to share those findings 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)

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- 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”)

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- 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)

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- 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)

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

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- Designing Your PSES
  - Examples of events or processes to be considered for inclusion in PSES
    - Adverse events, patient incident reports, sentinel events, near misses, unsafe conditions, RCA, etc.
  - Portions of Committee Reports/Minutes relevant to a patient safety or quality event that can be considered for inclusion in the PSES
    - PI/Quality Committee, Patient Safety Committee, MEC, BOD
    - Example: That portion of an MEC meeting which reviewed a quality of care/peer review event which is part of the PSES
  - Structures to Support PSES
    - Performance improvement plan, safety plan, event reporting and investigation policies, procedures and practices

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

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- Criteria-based Prioritization
  - Suggested criteria to consider in deciding what events and information to include in the PSES for reporting to a PSO
    - Promotes culture of safety/improves care
    - Impressions/subjective data that is not available in nor required to be in the medical record
    - Not required to report elsewhere, i.e., a never event has to be reported to CMS and therefore the original cannot be considered PSWP but a copy can be reported to a PSO and be protected
    - Data for reporting could be obtained from medical record and analyzed separately such as an RCA triggered by a reported never event or HAC, both of which are otherwise subject to mandatory reporting
    - Data that will not be used to make adverse employment decisions

### 3. What types of data can be considered for inclusion in the PSES for collection and reporting to the PSO if used to promote patient safety and quality?

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- Medical Error or Proactive Risk Assessments, Root Cause Analysis
- Risk Management – Not all activities will qualify such as claims management, but incident reports, investigation notes, interview notes, RCA notes, etc., tied to activities within the PSES can be protected
- Outcome/Quality—may be practitioner specific
- Peer Review
- Relevant portions of Committee minutes for activities included in the PSES relating to improving patient quality and reducing risks

### 3. What types of data can be considered for inclusion in the PSES for collection and reporting to the PSO if used to promote patient safety and quality? (cont'd)

#### ■ PA Patient Safety Authority: Reports Identify Trends

Remember: Facts and conclusions cannot be protected but a subsequent analysis, which becomes PSWP even without the need to report, and subsequent reports can be protected if included in PSES

- 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

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

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- 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:

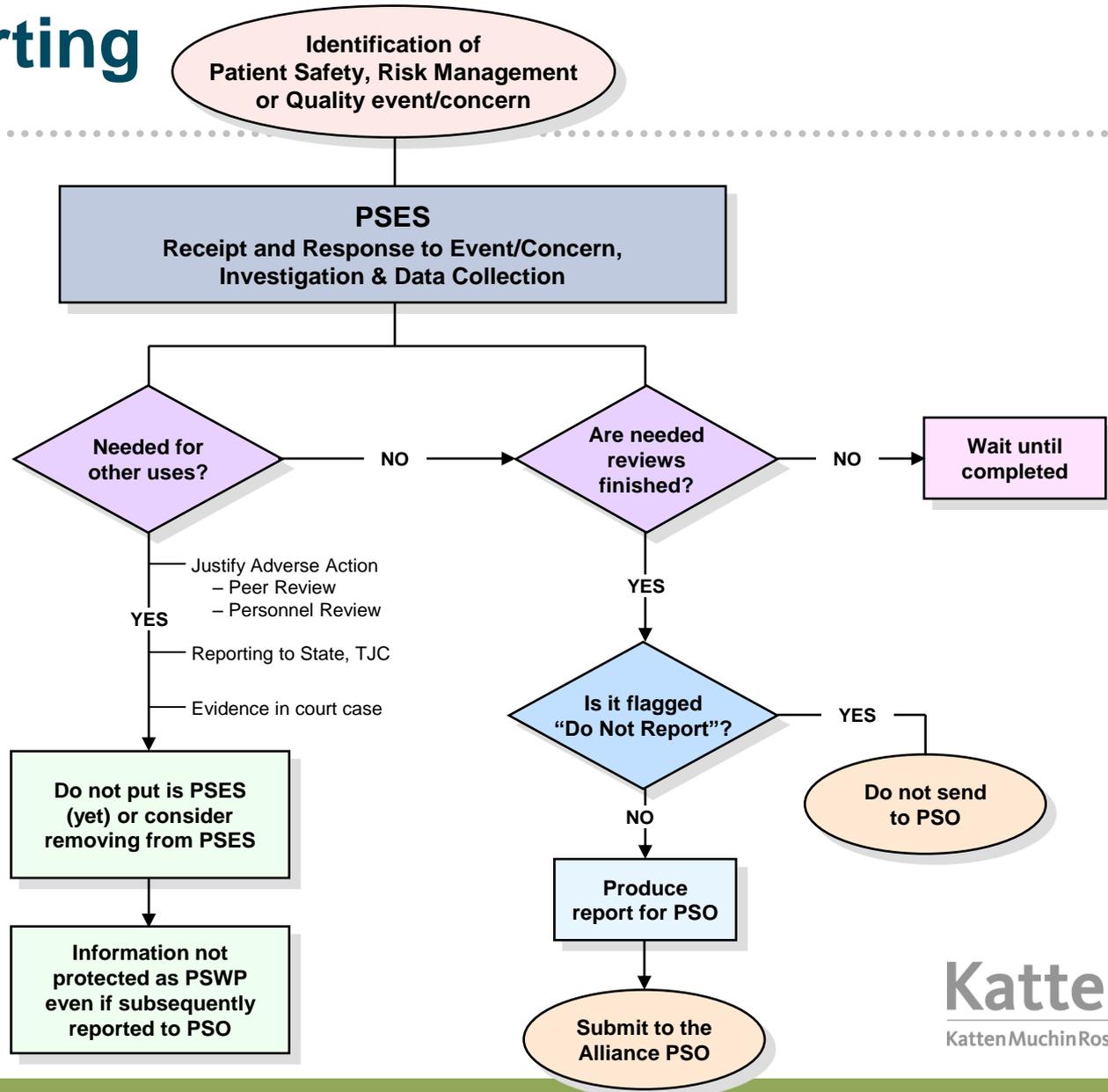
- Are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a PSES for reporting to a PSO, and such documentation includes the **date the information entered the PSES**; or
- Are developed by a PSO for the conduct 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?

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- 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

# PSO Reporting



# PSES and PSO Reporting Process

PSES

Professional and Quality Standards Committee

PSO

Medical Executive Committee

Administrative Quality Management Committee

Shared members, communications

Medical Staff Quality Management Committee

Department/Committee Chm

Medical Staff Interdisciplinary Department Quality Committees

Functional (Interdisciplinary) Quality Committees

Clinical Care Evaluation Committee

Patient Safety Committee

Senior Management and Directors

Disciplinary and Departmental Quality Committees

CNE Coordinating Council

Practice Comm  
Education Comm  
Informatics Comm  
Quality and Patient Safety

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## 6. How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act?

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- North Carolina
  - N.C. Gen. Stat. § 131E-95(B)
    - Proceedings of a medical review committee, the records and materials it produces and the materials it considers shall be confidential and not subject to discovery or introduction into evidence in any civil action against a hospital, surgicenter or provider of health services which results from matters which are subject to evaluation and review by the committee.
    - If information is otherwise available, it cannot be protected.

## 6. How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

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- 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.
- 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 within the PSES for reporting to a PSO.
- The scope of what can be protected, generally speaking, is broader than most current state statutes.

## 6. How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

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- Information can be disclosed to a professional standards review organization, such as The Joint Commission, or to a PSO or its designated contractors.
- Minimum necessary standard applies.
- Protections arguably apply to peer review conducted in a physician group, but no case law on this question.
- Can be sent to a PSO and still be kept confidential.
- Appears that protections could be waived if information is disclosed outside of peer review process.

## 6. How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

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- One court held that protections do apply in federal proceedings.
- Not clear if information can be shared throughout system.

## 6. How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

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- Missouri
  - Missouri Revised Statutes, Chapter 537, Section 537.035
    - “Peer Review Committee” is a committee of health care professionals (physician, surgeon, dentist, podiatrist, pharmacist, psychologist, nurse, social worker, professional counselor or mental health professional) with the responsibility to evaluate, maintain, or monitor the quality and utilization of health care services or to exercise any combination of such responsibilities.

## 6. How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

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- Entities covered include committees of:
  - Health care professional societies
  - Professional corporation of health care professionals
  - Health care professionals employed by or affiliated with a university
  - Licensed hospitals or other health care facilities, including long term care
  - Organizations formed pursuant to state or federal law to exercise responsibilities of a peer review committee
  - HMOs

## 6. How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

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- Interviews, memorandums, proceedings, findings, deliberations, reports and minutes concerning the health care provided any patient are not subject to discovery and is not admissible into evidence in any judicial or administrative action for failure to provide appropriate care.
- Persons in attendance not required to disclose or testify.
- Information is discoverable if otherwise available.
- Can be required to testify as to personal knowledge.
- Protections cannot be waived.
- Protections do not apply in peer review litigation.
- Not clear whether the state protections would apply where plaintiff brings a federal cause of action in federal court, i.e., antitrust, discrimination.
- Not clear as to whether information can be freely shared throughout the system

## 6. How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

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- Illinois
  - 735 ILCS 5/8-2101
    - All information, interviews, reports, statements, memoranda, recommendations, letters of reference or other third party confidential assessments of a health care practitioner's professional competence, or other data of
    - Allied medical societies, health maintenance organizations, medical organizations under contract with health maintenance organizations or with insurance or other health care delivery entities or facilities
    - Their agents, committees of ambulatory surgical treatment centers or post-surgical recovery centers or their medical staffs, or committees of licensed or accredited hospitals or their medical staffs

## 6. How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

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- Including Patient Care Audit Committees, Medical Care Evaluation Committees, Utilization Review committees, Credential Committees and Executive Committees,, or their designees (but not the medical records pertaining to the patient), used in the course of internal quality control or of medical study for the purpose of reducing morbidity or mortality, or for improving patient care or increasing organ and tissue donation
- Shall be privileged, strictly confidential and shall be used only for medical research, the evaluation and improvement of quality care, or granting, limiting or revoking staff privileges or agreements for services
- Information can be used in disciplinary hearings and subsequent judicial review

## 6. How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

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- Protections have been interpreted fairly broadly but information produced for a different purpose, i.e., risk management, is not protected even if used by a peer review committee.
- 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. How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

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- Protections cannot be waived if used for statutory purposes.
  - Information arguably can be shared throughout the system among controlled affiliates subject to physician authorization.
  - Protections do not apply to federal claims brought in federal court.
- Patient Safety Act
    - 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 within the PSES and collected for reporting to a PSO.

## 6. How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

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- The scope of what can be protected, generally speaking, is broader than the North Carolina, Missouri and Illinois statutes.
- Any licensed provider, i.e., physician, physician group, surgicenters, clinic, hospital, nursing home, home health facility, etc., can be covered under the PSA.
- The protections apply in both state and, for the first time, federal proceedings.
- The protections can never be waived.
- If the protections are greater than those offered under state law the PSA pre-empts state law.

## 6. How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? (cont'd)

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- PSWP is not admissible into evidence nor is it subject to discovery.
- Key to these protections is the design of the provider's and PSO's patient safety evaluation system ("PSES").

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

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- 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)

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- (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)

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- 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)

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- 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.

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

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### ■ Final Rule

- CMS issues final rule on March 11, 2014.
- Rule establishes a Phase 1 and Phase 2 approach.
- Effective January 1, 2015, a qualified health plan (“QHP”) through a state’s health insurance exchange, as per the proposed rule, can contract with a hospital with more than 50 beds if it is either a Medicare-certified or a Medicaid-only CMS certified facility even if they do not use a PSES.
- Phase 2 lasts two years, or until CMS issues further regulations, until January, 2017, before hospitals need to participate in a PSO.

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

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- 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 operation.

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

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- Have to decide if data and/or the analysis of the data relating to improving quality and patient safety is eligible for protection and not for some other purpose and is not subject to mandatory reporting.
- Related patient safety activity needs to be included in the PSES for reporting to the PSO.
- Data/information can be 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)

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- Concept of functional reporting does not require actual submissions to PSO but you must determine when the PSO has access to the physical information in order to be considered “reported.”
- Timing of when information is functionally reported is important.
- Must establish appropriate security measures and policies which limit access to PSWP to Work Force members, i.e., those individuals who need this PSWP in order to carry out their responsibilities.

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## 10. How will data be used?

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- A PSO can perform studies, benchmark reports, identify good and bad practice patterns and other similar analyses requested of the PSO. It may make recommendations but decisions should be left to the provider.
- 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. Will we have the ability to see individual reports and records created within the hospital or system through the PSO reporting?

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- If the facilities and providers are owned, controlled or managed by Corporate or by an affiliated entity and are part of a single system-wide PSES, information can be accessed and shared consistent with PSES policies for appropriate use.
- Access should be limited to Work Force members.
- May need to obtain practitioner (i.e., physicians) authorizations for releases of information depending on whether the PSWP needs to be identifiable but this requirement can be made a condition of employment and medical staff membership.
- Information can be provided and generally obtained in identified or de-identified form.

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

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- No. Any information that is PSWP, whether generated internally and functionally or actually reported, or generated by the PSO, can be used for internal operations to advance patient safety and quality of care.
- But information can only be disclosed as permitted under the PSA to those employees, physicians, contractors, etc., engaged in relevant patient safety activities identified in the PSES.
- Remember, protections are never waived but improper disclosures and breaches can subject the provider or PSO to civil penalties.

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

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Example:

- Data collected within the PSES 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. . . .”

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

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- 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.
- Contract with a PSO or your policies should clearly include corporate parent as being covered and able to access information if engaged in patient safety activities set forth in the PSES.

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

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- 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.

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

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- Because one purpose of the PSO is to protect from discovery and admissibility sensitive information collected in the PSES for reporting to a PSO 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, however, that PSWP cannot be dropped out and used in defense of a liability claim or other external purpose unless for a permissible disclosure.

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

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- 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.
  - But, any analysis within the PSES cannot be dropped out. It automatically becomes PSWP without being reported.
  - Once it is reported it cannot be dropped out or removed for external (versus internal) purposes.

## 16. Provide real examples of how the PSO has benefited the organization

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- 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.

## 16. Provide real examples of how the PSO has benefited the organization (cont'd)

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- *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.”

## 16. Provide real examples of how the PSO has benefited the organization (cont'd)

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### ■ 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 recently obtained certification for a second component PSO 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.

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

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- Yes, but need to look to degree of ownership, control or management over the facilities and providers and if licensed or authorized to provide health care services in the state. (See ACO/PSO memo)

## 18. Should the data collected be the same for all entities?

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- 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.

**19. 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?**

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- 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.

**19. 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? (cont’d)**

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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 – may need to have the hospital “authorize” the release of PSWP as set forth under the PSA.
- 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.

**19. 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? (cont’d)**

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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 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.

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

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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.
- This patient safety activity and the non-factual information and reports are included in hospital's PSES.

## 20. Give an example on how to operationalize information, reports, recommendations from PSO? (cont'd)

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- Information is gathered within each group/facility through appropriate personnel/committees.
- 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.

## 20. Give an example on how to operationalize information, reports, recommendations from PSO? (cont'd)

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- These PSO reports are PSWP and can be shared with regional hospitals and Corporate (will 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.