



## Patient Safety Organizations: What Every Health Care Provider Needs to Know

### PSO 201: PSO Standards Applied to Real-World Scenarios

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# Speaker Bios



## **Michael R. Callahan, Partner - [michael.callahan@kattenlaw.com](mailto:michael.callahan@kattenlaw.com)**

Michael R. Callahan assists hospital, health system and medical staff clients on a variety of health care legal issues related to accountable care organizations (ACOs), patient safety organizations (PSOs), health care antitrust issues, Health Insurance Portability and Accountability Act (HIPAA) and regulatory compliance, accreditation matters, general corporate transactions, medical staff credentialing and hospital/medical staff relations.

Michael's peers regard him as "one of the top guys [...] for credentialing—he's got a wealth of experience" (Chambers USA). Additionally, his clients describe him as "always responsive and timely with assistance," and say he is "informed, professional and extremely helpful" and "would recommend him without reservation" (Chambers USA). Michael's clients also commend his versatility, and say "He is willing to put on the hat of an executive or entrepreneur while still giving legal advice," according to Chambers USA.

He is a frequent speaker on topics including ACOs, health care reform, PSOs, health care liability and peer review matters. He has presented around the country before organizations such as the American Health Lawyers Association, the American Medical Association, the American Hospital Association, the American Bar Association, the American College of Healthcare Executives, the National Association Medical Staff Services, the National Association for Healthcare Quality and the American Society for Healthcare Risk Management.

Michael was recently appointed as chair of the Medical Staff Credentialing and Peer Review Practice Group of the American Health Lawyers Association. He also was appointed as the public member representative on the board of directors of the National Association Medical Staff Services.

He was an adjunct professor in DePaul University's Master of Laws in Health Law Program, where he taught a course on managed care. After law school, he served as a law clerk to Justice Daniel P. Ward of the Illinois Supreme Court.

# Speaker Bios

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## **Ellen Flynn RN, MBA, JD, CPPS - [flynn@uhc.edu](mailto:flynn@uhc.edu)**

Ellen Flynn RN, MBA, JD is currently the AVP, Patient Safety and Accreditation Programs for the UHC Safety Intelligence® PSO. Previously, she held the position of Director of Quality at UHC. Ellen has over 30 years of healthcare experience and managed quality, safety, and patient experience departments in large academic medical centers and health systems including Rush System for Health, Children's Hospital of Wisconsin, and Universal Health Services. Prior to returning to UHC, Ellen was the Manager, Health Industries Advisory Services at PricewaterhouseCoopers LLP. Ellen has a Juris Doctor degree from Loyola University School of Law, an MBA, Management Information System from DePaul University and a Bachelor of Science in Nursing from Loyola University.



## **Stephen Pavkovic, RN, MPH, JD - [Pavkovic@uhc.edu](mailto:Pavkovic@uhc.edu)**

Mr. Pavkovic brings a diverse background to his current role as the Senior Director of Patient Safety at Vizient the nation's largest member-owned health care company. While working as an operating room nurse and manager, he earned advanced degrees in public health and law. His legal career included defending healthcare providers from claims of professional malpractice, working for county government as a health law attorney and practicing as a healthcare risk manager at an academic medical center. At Vizient, he draws on these professional experiences to assist members in identifying patient safety improvement and loss control opportunities. He is a frequent national presenter and published author on a variety of risk management and patient safety topics.

# PSO 201: PSO Standards Applied to Real-World Scenarios

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Based on the basic principles and requirements described in the PSO 101 presentation, this program will review a number of patient safety scenarios involving adverse events, patient injuries, peer review issues and malpractice litigation. Among the areas to be addressed are the following:

- What information can be collected within a PSES and shared internally and externally?
- What if the state, CMS or The Joint Commission come knocking? Do I have to turn over my PSWP?
- Can peer review information be included in a PSES? What are the pros and cons?

# PSO 201: PSO Standards Applied to Real-World Scenarios (cont'd)

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- How is patient safety information collected in the PSES and actually reported to a PSO?
- Can PSWP be shared with third parties? If so, how?
- Are the protections ever waived?
- What are the disclosure exceptions?

# PSO 301: Discussion of PSO Court Cases and the Litigation Lessons Learned

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One of the reasons providers have been reluctant to participate in PSOs is because there have been very few reported trial and appellate court decisions which have interpreted the Patient Safety Act. Most challenges to date have involved malpractice plaintiffs who have sought to discover PSWP including incident reports, peer review and other quality improvement information.

The purpose of this program is as follows:

- Review of some of the key appellate court cases, including:
  - *Tibbs v. Bunnell*, currently before the US Supreme Court
  - *Walgreen v. Illinois Department of Financial and Professional Services*
  - *Charles v. Southern Baptist Medical Center*

# PSO 301: Discussion of PSO Court Cases and the Litigation Lessons Learned (cont'd)

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- What are the litigation lessons learned?
- What arguments are plaintiffs making to gain access to PSWP?
- What steps do providers need to take in anticipation of these arguments?
- What are the best ways to educate courts when contesting a discovery request?

# Disclaimer

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- The opinions expressed in this presentation do not reflect the official position of the Agency for Healthcare Research and Quality (AHRQ) or the Office of Civil Rights (OCR).
- This information is not being offered as legal or medical advice.





# PSO 101 Follow Up Questions

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- Are you going to talk about the difference between "original" and "copy" of data?
- Could you clarify "copy rule"? If a report is submitted to state, could the copy of the report sent to PSO be considered PSWP?
- If the original record is sent to the state and a copy sent to the PSO, should the provider maintain a copy of the record sent to the state and PSO?
- I am unclear on the "copy" submission to a PSO. How can that information have privilege and confidentiality protections when the exact information has been dropped out of the PSES and used for another purpose(e.g., disciplinary action)?

# PSO 101 Follow up Questions (cont'd)

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- What is the relevance to the PSO if it is receiving a copy or PSWP? Does it use that data in a different manner? Or is it really only relevant to the provider as it determines if documentation submitted to its PSO is discoverable?
- Should the provider's electronic PSWP record be destroyed or removed once submitted to a PSO?

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# How to Structure Health Care Systems, Clinically Integrated Networks and Other Affiliated Providers in Order to Benefit From Patient Safety Act Protections

# Healthcare Systems Data Sharing

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- Patient safety rule allows healthcare systems to share data within a protected legal environment, both within and across states, without the threat that the information will be used against the subject providers.
- These protections do not relieve a provider from its obligation to comply with other Federal, State, or local laws pertaining to information that is not privileged or confidential under the Patient Safety Act .
- The Patient Safety Act is clear that it is not intended to interfere with the implementation of any provision of the HIPAA Privacy Rule.

# Healthcare Systems Data Sharing (cont'd)

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- Health System may require facilities and/or providers to report to a designated PSO.
- A patient safety event reporting requirement can be consistent with the statutory goal of encouraging organizational providers to develop a protected confidential sphere for examination of patient safety issues.

# Healthcare Systems Data Sharing (cont'd)

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- Affiliated providers may disclose identifiable PSWP.
- Certain provider entities with a common corporate affiliation, such as integrated health systems, may have a need, just as a single legal entity, to share identifiable and non-anonymized patient safety work product among the various provider affiliates and their parent organization for patient safety activities. Provider entities can choose not to use this disclosure mechanism if they believe that doing so would adversely affect provider participation, given that patient safety work product would be shared more broadly across the affiliated entities.

# Key Steps, Terms and Requirements

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- Identify and implement your PSES
  - Create list of all peer review, quality, risk management and other patient safety activities
  - Identify the committee, reports and analyses related to these activities that you want to collect in the PSES for reporting to a PSO
- Identify individuals who need to access and work with PSWP as part of their jobs or responsibilities – these people are your Work Force members
- Identify what PSWP information you want to collect and share within your health care system/CIN

# Key Steps, Terms and Requirements (cont'd)

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- Identify the affiliated providers, unaffiliated providers, joint venture entities and other licensed entities you want to include in your PSES or to participate in the PSO
  - Identifiable or non-identifiable?
- Do you intend to use attorneys, accountants and/or contractors to assist you in furthering identified PSES patient safety activities?
  - You will need appropriate BAAs, confidentiality agreements and contracts



# Key Steps, Terms and Requirements (cont'd)

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## Definitions

- Provider

“An individual or entity licensed or otherwise authorized under state law to provide health care services. . .”

“A parent organization of one or more [licensed providers] that manages or controls one or more [licensed providers]”

- Provider examples include:
  - Hospitals
  - Physicians and physician groups
  - Nursing facilities

# Key Steps, Terms and Requirements (cont'd)

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- Patient centered medical homes
- Surgicenters
- Pharmacies
- APNs, PAs, SAs

## ■ **Parent Organization**

“Owns a controlling interest or a majority interest in a component organization; or

Has the authority to control or manage agenda setting, project management, or day-to-day operations;

Or authority to review and override decisions of a component organization.

The component organization may be a provider.”

# Key Steps, Terms and Requirements (cont'd)

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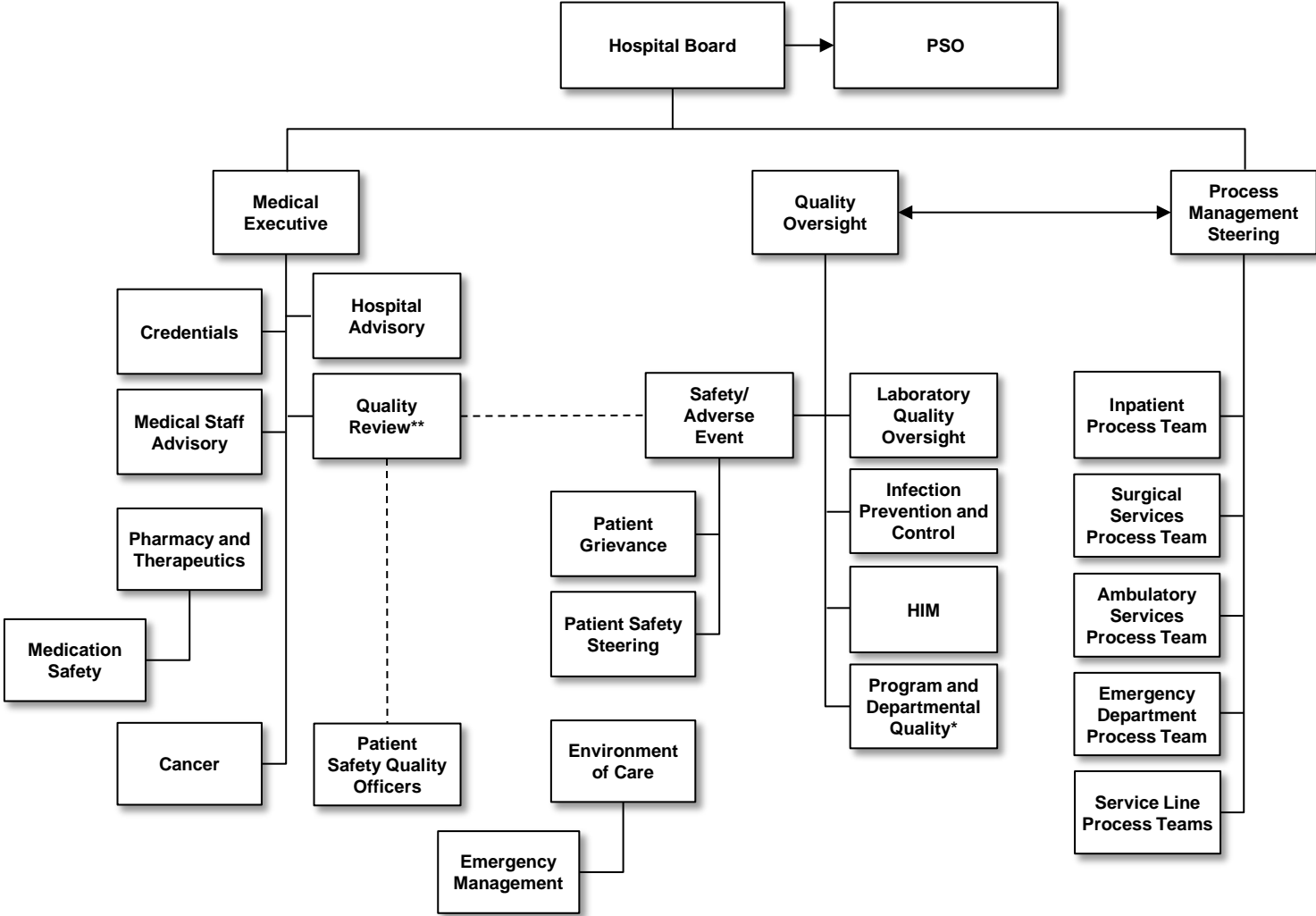
## Component Organization

- “Is a unit or division of a legal entity (including a corporation, partnership, or a Federal, State, local or Tribal agency or organization);” or
- “Is owned, managed, or controlled by one or more separate organizations”

## Affiliated Provider

- “With respect to a provider, a legally separate provider that is the parent organization of the provider, is under common ownership, management or control of the provider, or is owned, managed, or controlled by the provider.”

# Quality Committee Structure

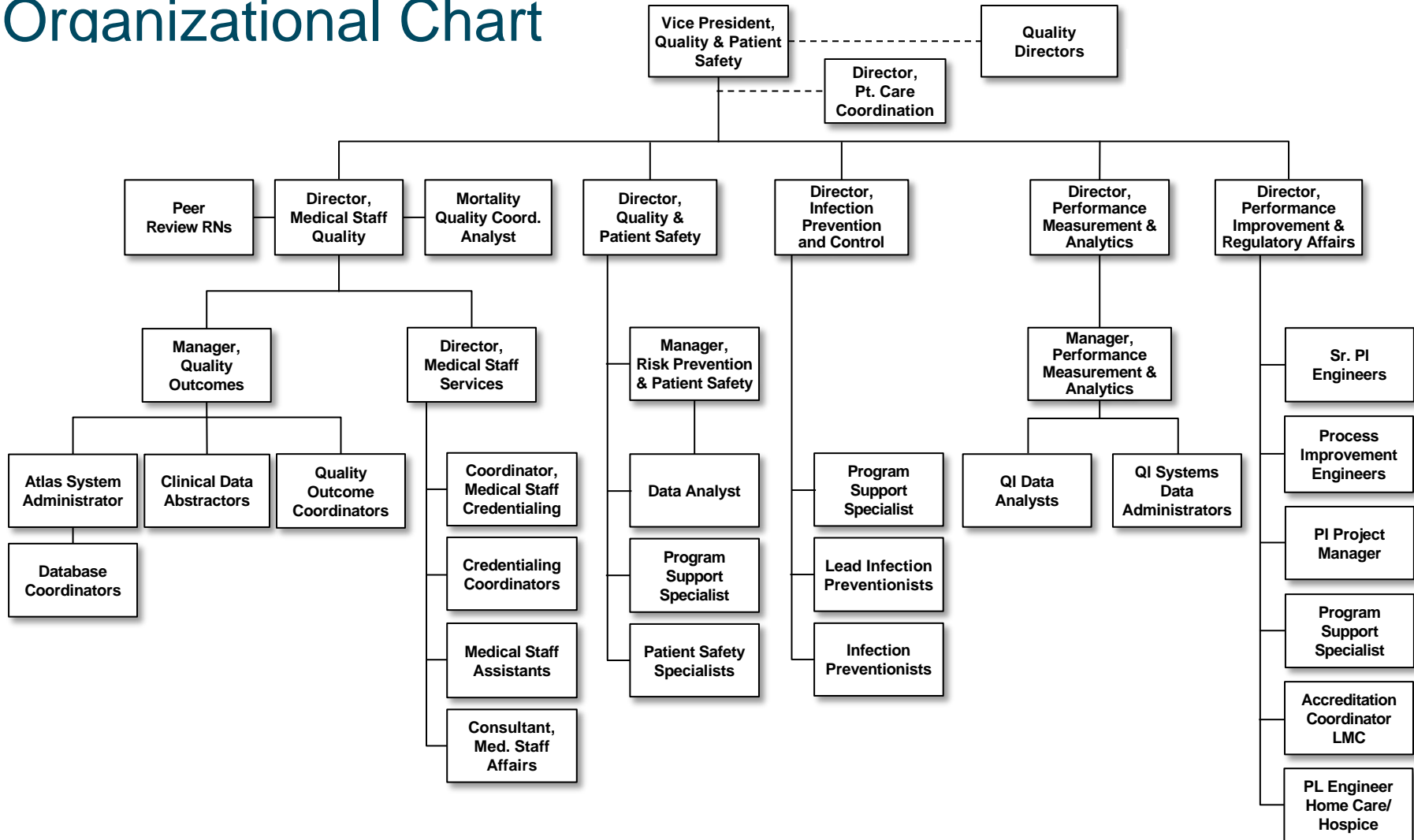


\*Programs such as Transplant and Departments such as Radiology, Pharmacy, Nursing, Environmental Services.

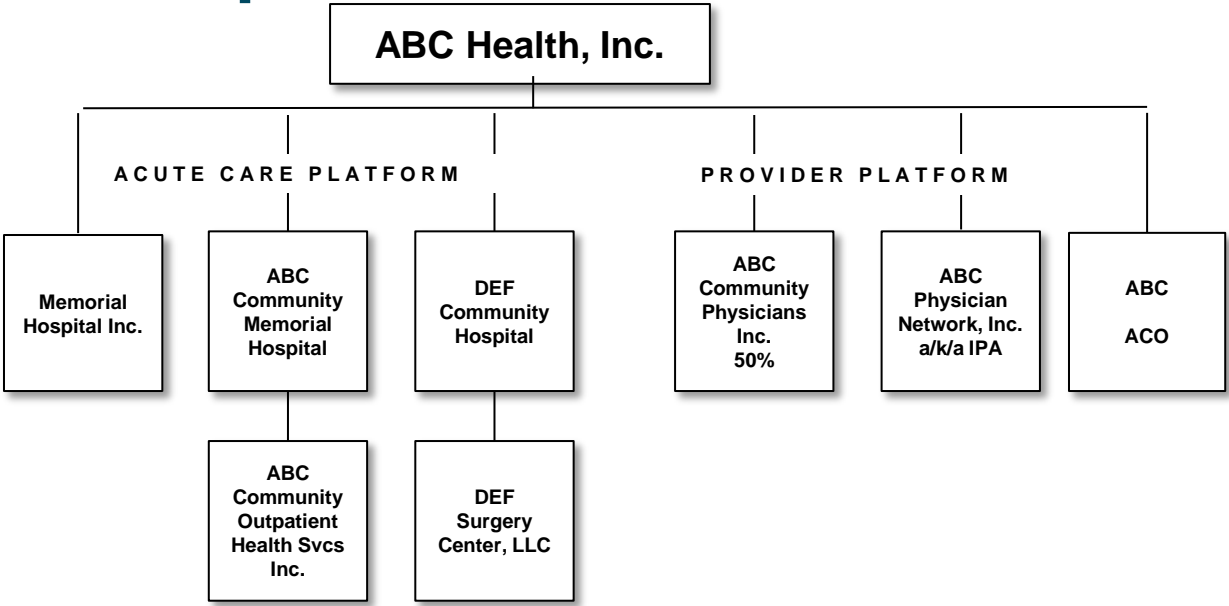
\*\*Potential issue(s) in LIP practice identified during interdisciplinary review of clinical activities are referred to the Medical Executive Quality Review Committee for evaluation.

# QUALITY AND PATIENT SAFETY

## Organizational Chart



# Health System Corporate Structure



## Joint Venture and Member Relationships

Cardiology Joint Venture, LLC 40%	Sports Training LLC 51%	Rehab, LLC 60%	Fitness Development LLC 40%	Midwest Dialysis, LLC 15%	Surgery Center, LLC 50%	Renal Care Group, LLC 35%
Home Care & Hospice, Inc. 50%	Integrated Health Network 16.7%	Diagnostic Imaging, LLC 40%	Clinical Imaging, Inc. 10%	Real Estate Ventures, LLC 50%	Regional Medical Center, Inc. Member	Medical CyberKnife, LLC 7.5%

Consolidated LLC's & Corporations in green (>50% governance and/or economic control)  
 Members of the obligated group in blue (excluded from the obligated group = FSC, COHS, WBSC, PPN and CP)  
 Non-controlled entities in red

# Key Take Aways

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- PSWP can be shared within the provider among Work Force members for internal patient safety activities
- PSWP can be shared among affiliated providers
  - If disclosing identities of providers, incorporate written authorization for identified purposes within PSO agreement or other agreement/resolution
  - If wanting to disclose identity of other providers, i.e., physicians, you will need their written authorization which can be built into the appointment/reappointment application and/or employment agreement

# Key Take Aways (cont'd)

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- Need to be mindful of HIPAA implications if PSWP contains PHI. Is system organized as an OHCA or are providers considered affiliated covered entities under HIPAA?
- Non-provider parent organization can be included in PSES and obtain access to PSWP
- If the health care system has a component PSO then PSWP can only be disclosed by the PSO to the parent if you meet one of the disclosure exceptions
- IPAs, PHOs and other managed care arrangements are not considered providers under the Act – but check state law if they are authorized to provider health care services



# Key Take Aways (cont'd)

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- Component PSOs in health care systems tend to be more scrutinized by AHRQ in terms of access to and disclosure of PHI
- With respect to non-affiliated providers you need to determine if they fall under definition of owned, controlled or managed
- Make sure you meet one of the disclosure exceptions if releasing to a third party

# PSO 201: Patient Fall Case Study

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**Behavioral Health Unit nurse manager calls risk management and reports that a patient who fell yesterday experienced a cardiac arrest during the night.**

1. Patient fell at 1400 on 12/1/2015.
2. Nurse contacted the assigned resident physician at 1415.
3. Resident A examined patient, documented the event in the medical record and ordered a knee x-ray because the patient was complaining of knee pain.
4. Resident A documented no apparent injury after x-ray reviewed.
5. Nurse A entered a Safety Intelligence<sup>®</sup> event report at 1415.
6. Patient complained to Nurse B that she has a headache at 1700.

# PSO 201: Patient Fall Case Study (cont'd)

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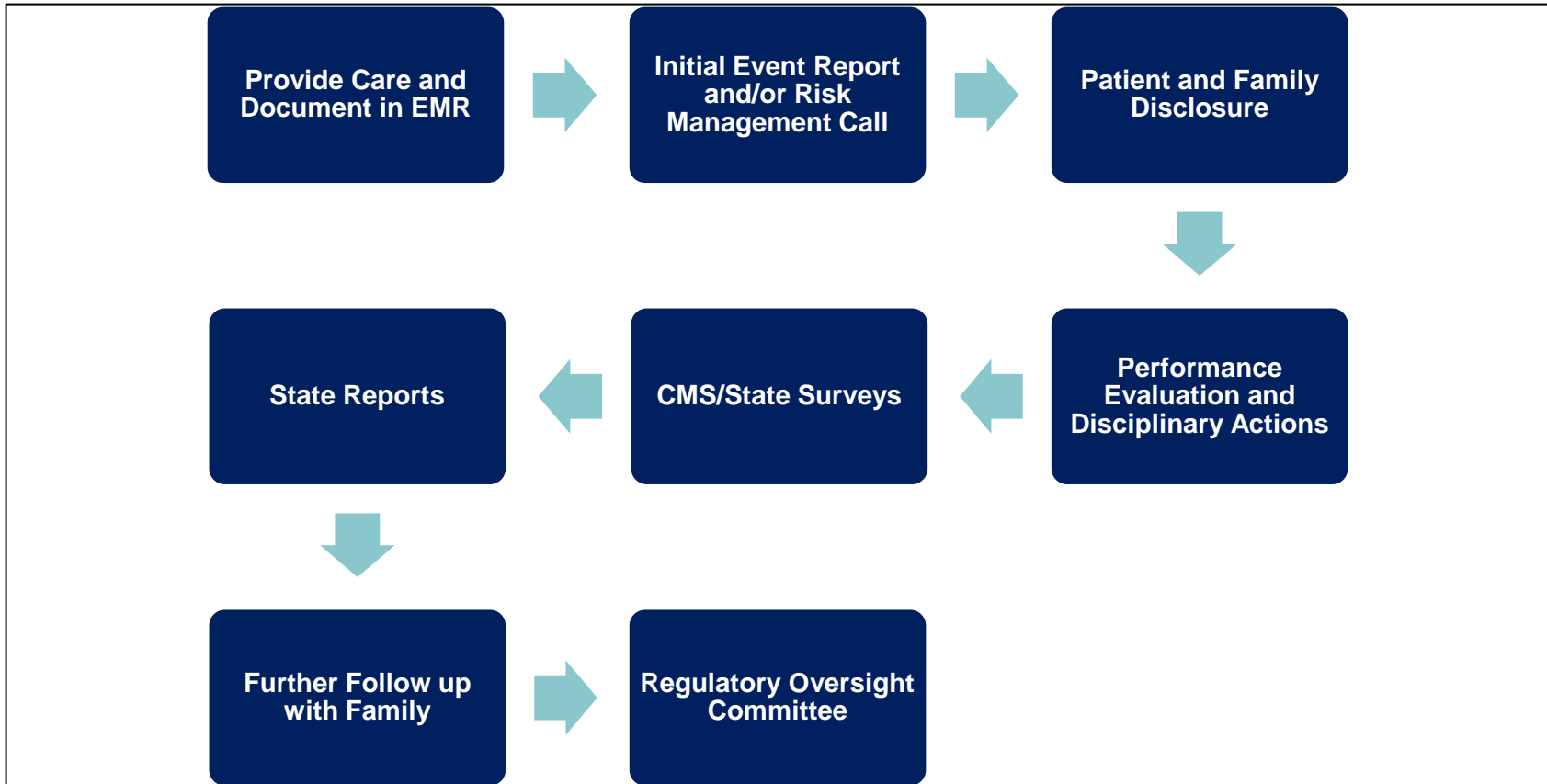
7. Nurse B call resident B and received an order for Tylenol 500 mg prn headache.
8. Nurse B found patient on floor nonresponsive at 1800 and called a code blue.
9. Code team arrived at 1830 but patient could not be resuscitated.
10. Family was called and they came to the hospital. Family agreed to have an autopsy performed.
11. Autopsy results revealed a subdural hematoma was the cause of death.
12. Hospital staff and family meet to discuss what happen and actions taken to prevent a similar event.

# Patient Fall Case Study: PSES Activity

*Develop a plan to conduct all deliberations, analysis and communication within the PSES*



# Patient Fall Case Study: Meet Regulatory and Ethical Obligations Outside PSES



# PSES Documentation is a Best Practice and Will Be Needed, if Privilege and Confidentiality Challenged

## Section A of PSES policy provides as follows:

- Activities, documents and systems that comprise Hospital A's PSES include but are not limited to the following:
  - Patient Safety investigations
  - Incident/Event Reporting System
  - Morbidity/Mortality and Peer reviews
  - Code Blue evaluations
  - Critical event debrief sessions and RCA
  - Patient Safety PSES Committee
  - Quality Committee of the Board PSES Session Reports
  - And other activities or actions that could improve patient safety, health care quality or health care outcomes.

# Conduct RCA Within the PSES and Report to the PSO or Functionally Report

**My Dashboard** | Actions | Contacts | Medications | Admin | Logout | UHC Safety Intelligence  
Events ▾ | Complaints ▾ | Claims ▾ | Ellen Flynn

**TRAINING SITE**  
UHC Safety Intelligence: Q/R Manager Review Form with RCA

**DISCLAIMER:** This is a demonstration database for training and educational purposes. Any similarities to actual people, organizations or events is purely coincidental. ©UHC Safety Intelligence™. All rights reserved.

SI-212 | MOUSE MICKEY | Fall

**PSWP**

**RCA**

Description of the event and timeline

Date RCA was Performed

Attendees

Past Medical/Psychiatric History

Problem List at Time of Event

Describe how the patient's care was within the scope of the facility's mission, staffing and support service resources?

**RCA conducted within PSES**

**Event Report - NOT PSWP**  
Manager Review for Event  
Pharmacy manager review  
Q/R Manager Review

**RCA**  
Common Cause Analysis

Attachments  
Linked records  
Data migrated from PSN

**Actions**  
Print  
Show DIF1 snapshot  
Show original FLR values  
Audit trail

+ Add a new event  
+ Generate from  
My reports  
Design a report  
New search  
Saved queries  
Show staff responsibilities

# Patient Fall Case Study: Analysis

My Dashboard | Actions | Contacts | Medications | Admin | Logout | PSWP | UHC Safety Intelligence | Ellen Flynn

Events | Complaints | Claims

### Action Form

Action Details

- List all actions
- There are 233 overdue Actions
- My reports
- Design a report
- New search
- Saved queries

Action Details	
Priority	High priority
Strength - Type of action	Strong - Standardize on equipment or process or care maps
* Description	Implement virtual bedside monitoring
Start date (MM/dd/yyyy)	01/14/2016
Due date (MM/dd/yyyy)	01/28/2016
Done date (MM/dd/yyyy)	
Assigned by ("From")	
* Assigned to	Flynn, Ellen - Patient Safety Officer
Completed by	
Progress	Contacted the vendor. They will come in to demo equip next week. Please push out due date until 2/1.

Submit action | Cancel

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**Maintain All PSWP Communication Within the Secure PSES Environment**



# Patient Fall Case Study: Questions

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- Which information can become PSWP?
- Does it matter whether analysis and deliberations are conducted within or sent to the PSES?
- Could the PSO conduct the RCA within its PSES and what are the benefits?
- Can deliberations and analysis conducted within the PSES be shared with CMS, State, or The Joint Commission (TJC)?
- If the morbidity and mortality deliberation and analysis occurred within the PSES, what can be shared with during an ACGME survey?

# Patient Fall Case Study: Analysis

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- Factual information documented into the medical record cannot be PSWP.
- Facts collected for state reports are not PSWP.
- Deliberation and analysis must be conducted within PSES to be considered PSWP.
- RCA may be conducted by PSO. PSO workforce may offer an objective analysis of the event.
- PSWP cannot and should not be shared with anyone outside of the organization except when limited disclosure exceptions are met.

# Patient Fall Case Study: Analysis (cont'd)

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- Morbidity and Mortality sessions can be completed within the PSES.
  - The following data may be shared during an ACGME survey:
    - Meeting date
    - Factual information and/or
    - Actions taken to improve care.

# Patient Fall Case Study: Questions

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- Safety Liaison wants to submit the RCA to the PSO as PSWP.
- Risk Manager, however, needs the RCA for mandatory state reporting and disciplinary actions, therefore does not want it reported to the PSO.

## Questions

- Was the RCA created and maintained within the PSES?
- If reported to the PSO, can it be dropped out in order to report to the state?
- If removed from PSES before reporting, could a copy be sent to the PSO?
- What information must actually be given to the state where adverse event reporting is required?

# Patient Fall Case Study: Analysis

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- RCA conducted within PSES may not be removed.
- Information reported to the PSO may not be removed to use for another purpose e.g., disciplinary action, state reports. It may be used for internal patient safety activities, educational and remedial measures. Data collected may be removed from the PSES before reporting to the PSO and used for disciplinary actions.
- If reported to the state, a provider may choose to send a copy to its PSO and the information may become PSWP, but the original provider records remain unprotected (non-PSWP).
- During a survey, the state may be given facts about the event that are documented in the EMR, regulatory incident report and actions taken to improve care.

# Prepare for State/CMS Survey and Meet Regulatory Obligations

## Factual Incident Report

Not PSWP

MR #	Date	Event Type	Actions Taken	Date completed
12345	1/1/15	Patient Fall	Implement virtual sitter program	1/10/16

### Patient Safety Committee

# falls

# falls with injury

Actions taken to reduce falls and falls with Injury

**This activity does not occur within PSES**

# Patient Fall Case Study: Questions

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## Disclosure by Attending physician, nurse and risk manager

- Physician wants to share with family details about what happened.
- Family has also requested information about what is being done to prevent this from happening to someone else.

## Questions

- What information may the team share with the family?
- Can the team share with the family actions taken to prevent this type of event from recurring?
- May the team share contributing factors identified during the RCA?

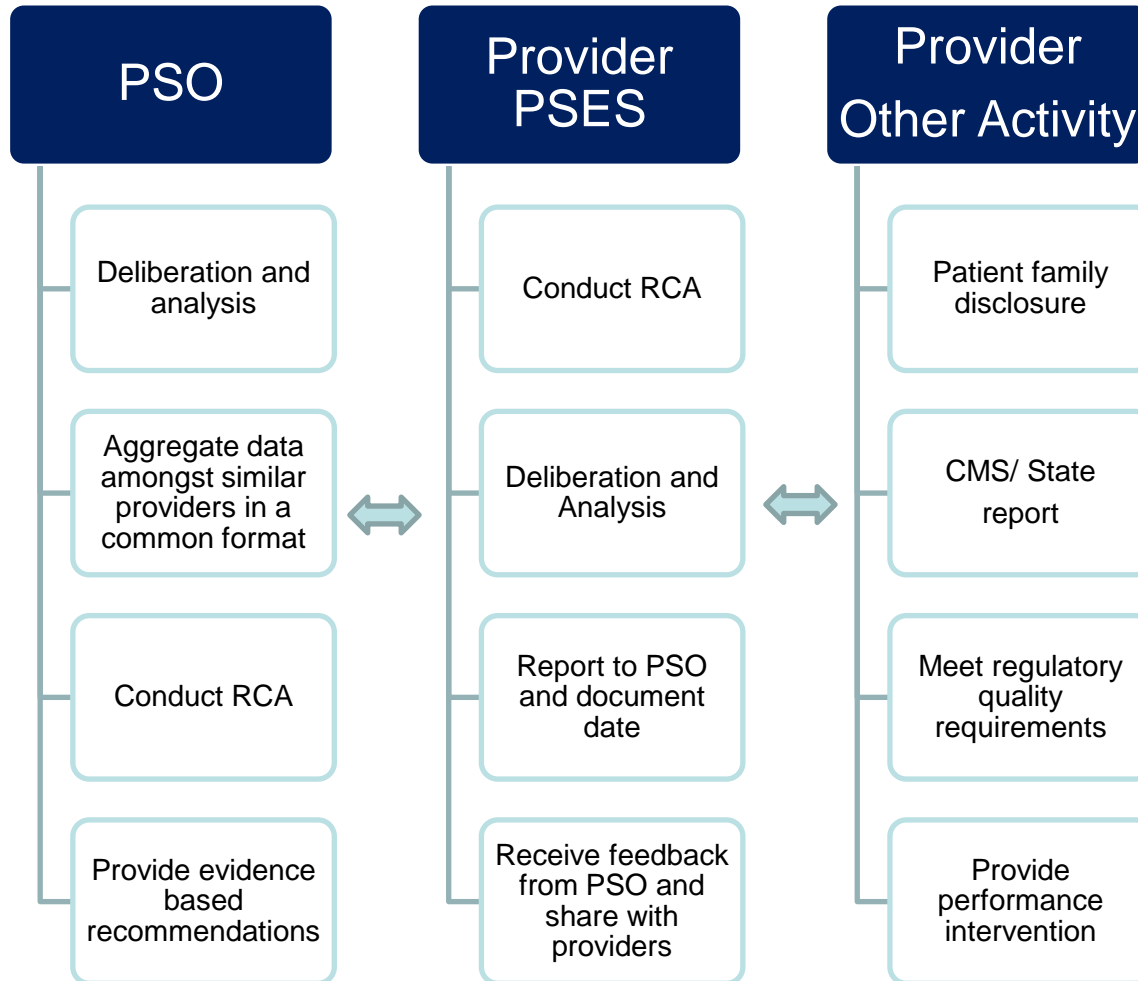
# Patient Fall Case Study: Analysis

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- Share facts about what happened with the patient and family. These facts should be documented in the EMR. These facts are not PSWP.
- Share actions taken to improve care with the patient and family. Actions taken are not PSWP.
- Do not share privileged and confidential PSWP with the patient and family e.g., event contributing factors.



# Work with a PSO to Create a Safe Learning Space for Improvement



# PSO 201: Health System Proactive Risk Assessment

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1. Health system ABC has a process where it conducts proactive risk assessments within its PSES and reports results to PSO.
2. Health system ABC has 2 Divisions (A and B) with 10 hospitals reporting to each division.
3. Health system ABC has identified that Division A organizations have not been following policy for sterilization of equipment and has identified that a trend in orthopedic infections may be related to this finding.
4. Health system ABC also has identified a trend in serious infections in Division B.
5. Health system ABC determined that it will disclose information to families.

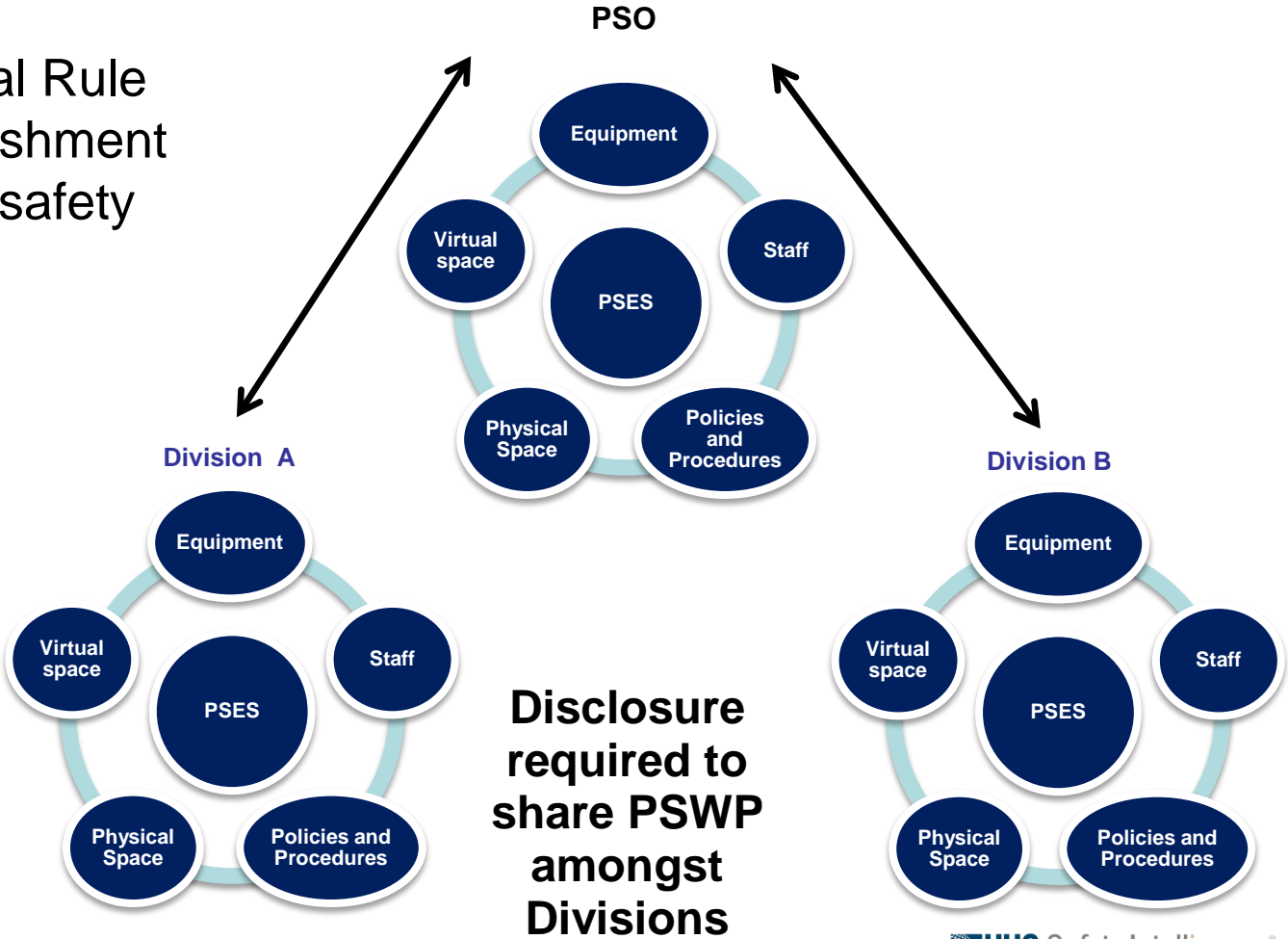
# PSO 201: Health System Proactive Risk Assessment

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6. Health system ABC will be implementing a new process to improve equipment sterilization.
7. Health system ABC has reported results of findings to their quality committee of the board , its recommended action plan and measures of success.

# Patient Safety Evaluation System (PSES)

- Patient Safety Final Rule permits the establishment of a single patient safety evaluation system



# Health System Proactive Risk Assessment Case Study: PSES Activity



# Health System Proactive Risk Assessment Case Study: Non-PSES Activity

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**Identify patients who  
developed an infection**

**Make disclosure to  
patient and family**

**Share actions taken to  
prevent future events  
with the state**

# Health System Proactive Risk Assessment Case Study: Questions

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- Can legally separate providers share data within a health system PSES?
  - What if they have different parent organizations but the same corporate parent?
  - Would a disclosure be required for Division A and B to share data?
  - Can PHI be shared across affiliated providers?

# Health System Proactive Risk Assessment Case Study: Analysis

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- Patient safety rule allows healthcare systems to share data within a protected legal environment, both within and across states, without the threat that the information will be used against the subject providers.
- Division A and B would need to make a disclosure amongst affiliated providers.
- These protections do not relieve a provider from its obligation to comply with other Federal, State, or Local laws pertaining to information that is not privileged or confidential under the Patient Safety Act.
- The Patient Safety Act is clear that it is not intended to interfere with the implementation of any provision of the HIPAA Privacy Rule.



# Health System Proactive Risk Assessment Case Study: Questions

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CMS has requested to see copies of the proactive risk assessment maintained within Division A's PSES.

- Is the provider required to share data with CMS?
- If the provider chooses to share data, what data may it share?
- If Division A disclosed to Division B patient safety events, did they waive the privilege and confidentiality protections?

# Health System Proactive Risk Assessment Case Study: Analysis

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- Provider's PSES is not required to share data with CMS.
- If the provider chooses to share data, the provider should share factual information and actions taken to improve care.
- Privilege and confidentiality protections cannot be waived.
- The organization must meet all rules related to PHI when sharing PSWP.

# Health System Proactive Risk Assessment Case Study: Questions

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A court orders a motion to compel results of proactive risk assessments conducted within the PSES

- Should the Provider disclose the requested information?
- What should the provider do to assert the privilege and confidentiality protections?
- If the organization or provider submits an affidavit to the court when asserting the privilege and confidentiality protections, what data should be provided in the affidavit?

# Health System Proactive Risk Assessment Case Study: Analysis

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- The Provider should not disclose the requested information.
- The provider should inform the PSO about the information reported.
- Affidavit should contain the date PSWP was created or collected, the date PSWP was reported to the PSO, primary purpose for collecting data, and analyses conducted with the data to improve patient safety, healthcare quality and outcomes.
- In response to a subpoena, consider introducing PSES policy and forms.

# Peer Review Case Study

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- A loyal, highly respected senior orthopedic surgeon, who is one of the hospital's biggest admitters, had the following adverse patient events within a two month period of time:
  - Wrong site pre-operative procedure;
  - Used the wrong orthopedic medical device in two patients, one of which was chosen by a medical device rep who was in the operating room;
  - Two other patients who were morbidly obese with cardiac conditions, died shortly after their respective orthopedic procedures. The operations went forward despite objections from the surgeon's partners.
- After the second patient's death, a meeting was requested by the Chief Medical Officer at which the Department Chair, the Risk Manager, the Quality Manager, and the PSO Liaison were present. The following comments, questions and concerns were expressed.

# Peer Review Case Study: Questions

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## Risk Manager

- Needs to contact insurance carrier and defense counsel regarding possible litigation in one or more of the adverse events.

## Questions/Concerns

- Can she share PSWP with carrier?
- Can she share PSWP with defense counsel?

# Peer Review Case Study: Analysis

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- Under the Final Rule, there are a limited number of PSWP disclosure exceptions. Section 3.206(b)(9) allows disclosure for business operations to “professionals” including attorneys and accountants, in part, because they also owe a fiduciary obligation to their clients. Therefore, PSWP can be shared with defense counsel.
- However, the question you should ask is whether counsel needs PSWP in order to defend any suit. This depends on the nature of the claims and what information is needed. Also, has the information been reported as PSWP to a PSO (actually or functionally), or is it being held within the PSES?

# Peer Review Case Study: Analysis

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- With respect to the insurance carrier, the business operations exception specifically was not extended to this category “at this time”. However, if the carrier is conducting, in part, patient safety activities such as benchmarking, risk analysis, studies, etc., and in order to do so needs access to some PSWP, Section 3.206(b)(4) allows disclosure of PSWP to contractors involved in patient safety activities. If not, the only other way is through a written authorization under Section 3.206(b)(3) “by the parties from whom the authorization is sought.”



# Peer Review Case Study: Analysis (cont'd)

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- **REMEMBER** – Once it has been reported to the PSO it CANNOT be disclosed to an outside independent party, such as a court. Because the attorney is an agent/fiduciary, PSWP can be disclosed to him/her even if it already has been reported. If not reported it can be removed, but it is no longer PSWP. However, the state confidentiality protections might apply.

# Peer Review Case Study: Questions

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## Quality Manager

- Needs to send three never events reports to CMS. She is concerned that a CMS/state surveyor will show up to investigate and will demand to see any root cause analyses that are generated as well as some or all of the peer review materials that are developed as a result of the plan. What, if anything, does she have to give to CMS, The Joint Commission or any other third party?
  - Can the proposed morbidity/mortality study be done within the PSES and results shared? What entity should conduct the study?
  - What documents and records can or should be protected?

# Peer Review Case Study: Analysis

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- Final rule requires that reports that must be filed with the state or federal government and agencies, i.e., never events, adverse events, must still be reported. These reports should not be reported to a PSO, but a copy may be sent.
- Everything else can be collected in the PSES for reporting to a PSO.
- CMS is on record as saying it will not require providers to turn over PSWP BUT you otherwise have to demonstrate compliance with QAPI requirements.
  - Be prepared to turn over the resulting action plan which is generated as part of the RCA.

# Peer Review Case Study: Analysis

- TJC has taken the same position and will not require the hospital to turn over PSWP BUT Section 3.206(b)(8) allows for a voluntary disclosure to an accrediting body as long as certain identifiers are removed and the non-disclosing provider agrees to the disclosure, e.g., the physician.
- Keep in mind, if information collected in the PSES has not been functionally or actually reported it can be dropped out and turned over to a third party.
- With respect to the M&M study, this is a patient safety activity and thus can be included in the hospital's PSES. PSO can collect this PSWP from participating hospitals, create a study/report and send back to all. The report also is considered PSWP. It must be decided whether hospitals included in the study will or will not be identified.
- If hospitals/providers are identified, you must obtain written authorization in accordance with requirements in the final rule.

# Peer Review Case Study: Analysis

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## List of Documents – What can or should be protected?

- Medical records – not protected under Patient Safety Act. Patients have legal right to obtain their records under state laws.
- Internal incident reports – if collected within PSES for reporting to a PSO, they are PSWP. Can be used for internal purposes and can be shared with counsel.
- Fitness for duty report – if physician is an employee, is the evaluation being conducted for HR purposes or for improving patient care and reducing risk? If being collected outside of PSES and/or for a purpose different from a patient safety activity, it will not qualify as PSWP. Physician in this Scenario is independent and not employed or under contract.

# Peer Review Case Study: Analysis

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- You have to make this call on the front end when designing your PSES. Because there may be a corporate negligence claim, patient complaint, CMS/state surveyor, investigation, etc., you will want to take steps to maximize your confidentiality/privilege protections under state and/or federal law.

## CMO and Department Chair

- Both have agreed to authorize a fitness for duty assessment. Depending on outcome, a 360 degree FPPE assessment will be conducted which will include peer interviews, direct proctoring of 10 cases and a requirement that he meet with the Department Chair when wanting to operate on morbidly obese patients. The report also is considered PSWP.

# Peer Review Case Study: Question

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- Can peer review activities and documents such as committee reports, peer review analyses, outside reviews, disciplinary proceedings, etc., be collected in a PSES for reporting to a PSO and therefore be considered PSWP?

# Peer Review Case Study: Analysis

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- YES! Factors to consider when comparing PSQIA protections to state statutes/case law protections:
  - Scope of protected activities.
  - Scope of covered entities.



# Peer Review Case Study: Questions

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- Can the protections be waived if not properly disclosed?
- Can a corporate parent and/or ACO be covered even though it is not a licensed provider?
- Will federal courts in your jurisdiction allow a state court confidentiality statute to pre-empt a federal claim, i.e., antitrust, discrimination?
- Can the protected information be shared through your CIN?

# Peer Review Case Study: Analysis

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- The decision on whether to seek PSQIA and/or state protection is your choice. Some or all can be included in PSES because these clearly are patient safety activities.

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# QUESTIONS

# Katten's Health Care Practice

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- [Katten](#) offers one of the largest [health care](#) practices in the nation—both in terms of the number of practitioners and the scope of representation
- The integrated nature of our practice allows us to provide timely, practical and strategic advice in virtually all areas of law affecting the [health care](#) industry
- Our experience encompasses regulatory compliance, fraud and abuse counseling, tax exemption issues, antitrust, financings for taxable and tax-exempt entities, reimbursement, and a variety of other issues specific to the [health care](#) industry
- We also advise on transactions of all types, including mergers and affiliations, the development of clinically integrated networks, physician practice acquisition and compensation matters
- To view other Health Care presentations by Katten, please [click here](#)

# UHC Safety Intelligence® PSO – Fast Facts

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- National patient safety leader since 2001
- Listed as PSO in 2008 by AHRQ and Certified through 2017
- National PSO Membership model
- AHRQ Common Formats (v1.1) based taxonomy
- Additional proprietary and customized taxonomy items
- Integrated submission with UHC SI Event reporting module
- National leadership role in PSO and Patient Safety activities
- Regular NPSD submissions via PSOPPC
- Multiple participation models
- Consistent ongoing feedback, comparative data, ongoing collaboration with other PSO members via safe tables, in person meetings, and webinars



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