



Vizient Legal and Compliance Network Meeting

# Maximizing Quality and Safety, Minimizing Risk

## Patient Safety Organizations

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# Disclaimer

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The opinions expressed in this presentation are those of the presenter and do not constitute legal advice or legal opinions nor do they reflect the official position of Department of Health and Human Services (HHS), the Agency for Healthcare Research and Quality (AHRQ), the Office for Civil Rights (OCR) and Vizient PSO.

The speaker has no financial relationships to disclose.

# Today's Presenter



**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.

# Objectives

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- Inform regarding current PSO legal developments
- Identify potential impact on PSO and providers
- Present recommendations on how to defend against discovery requests.

# Topics to Be Covered

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1. Overview of the HHS Guidance Regarding PSWP and Providers' External Obligations
2. Impact of the Guidance on PSES design – What are your options?
3. How to Respond to Government's Request for PSWP
4. Overview of the Guides for PSOs and Providers for Determining Parent Organizations and Affected Providers
5. What is the Difference Between “Deliberations or Analysis” Pathway from the Reporting Pathway for Creating PSWP?
6. Contrast and Comparison of Illinois Medical Studies Act Versus Patient Safety Act Privilege Protections

# Overview of HHS PSO Guidance

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- Title is “Guidance Regarding Patient Safety Work Product and Providers’ External Obligations”.
- Published in Federal Register on May 24, 2016 (81 FR 32655) at the same time the U.S. Solicitor General filed its amicus curie brief in Tibbs v. Bunnell.

# Overview of HHS PSO Guidance (cont'd)

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- PSOs and providers have recognized that information and records that must be legally reported to a state and/or federal agency, such as mandated adverse event reports or a Data Bank report, and cannot be collected in a PSES and reported to a PSO.
- The Guidance, however, goes further by stating that information which is subject to “external record keeping requirements, even if not required to also be reported, cannot qualify or is not eligible to be treated as PSWP.
- PSWP cannot be used to meet external obligations.

# Overview of HHS PSO Guidance (cont'd)

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## Expansion of What Constitutes an “Original Record”

- HHS also has “clarified” that “original patient or provider information” such as a “medical record, billing or discharge information” now applies to the following:
  - “Original record (e.g., reports or documents) that are required of a provider to meet any Federal, state, or local public health or health oversight requirement regardless of whether such records are maintained inside or outside of the provider’s PSES; and
  - Copies of records residing within the provider’s PSES that were prepared to satisfy a federal, state, or local public health or health oversight record maintenance requirement if such records are only maintained within the PSES and any original records are either not maintained outside of the PSES or were lost or destroyed.

# Overview of HHS PSO Guidance (cont'd)

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- HHS identifies hypothetical examples to illustrate what it considers to be original provider records that are not PSWP-eligible:
  - Original records maintained separately from the PSES;
  - Original records maintained outside of PSES, if lost or destroyed, then duplicate records in the PSES for reporting to a PSO for further analysis are no longer considered PSWP;
  - Duplicate records in the PSES for reporting to a PSO for further analysis are no longer considered PSWP; are not PSWP eligible.

# Overview of HHS PSO Guidance (cont'd)

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## “Sole Purpose” Reference

- In its effort to clarify whether the purpose for which the information being collected in a PSES can be treated as PSWP, the Guidance created a chart which has three categories. The third category of the examples (see pages 6- 7 in attached HHS Guidance) states are as follows:
  - “Could be PSWP if information is not required for another purpose and is prepared solely for reporting to a PSO” (emphasis added).
- This confusing and ambiguous term appears nowhere in the Act or the Final Rule.
- PSOs have sent questions asking AHRQ to clarify this term.
- PSO Work Group has requested opportunity to provide its position on “sole purpose” before AHRQ responds.

# Overview of HHS PSO Guidance (cont'd)

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## Possible responses

- Only logical interpretation is that information and records which must be reported or collected and maintained pursuant to Federal, state or local laws are not and cannot be collected for the sole purpose of reporting to a PSO.
- All other patient safety activity information collected in a PSES for reporting to a PSO for the purpose of improving quality and reducing risk can qualify as PSWP.
- Kentucky Supreme Court's holding on Baptist Redmond Hospital v. Clouse arguably rejects or at least did not address or rely on a “sole purpose” argument in reaching its decision even though trial and appellate courts relied on this approach in the discovery dispute.

# Overview of HHS PSO Guidance (cont'd)

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## Available Options When Government Requests Disclosure of PSWP

- HHS identifies the following options if records, which the provider in good faith believes were not created and maintained to fulfill external obligations, are now sought by an agency even though they have been reported to a PSO and therefore are PSWP.
  - If mistakenly treated as PSWP and you determine that it was not eligible, it can be removed or dropped out because it was not PSWP eligible in the first place.
  - Consider use of disclosure exceptions:
    - Identified provider's written authorization
    - FDA disclosure permission
    - Voluntary disclosure to an accrediting body
  - Conduct a separate analysis on non-PSWP, i.e., medical records, outside of the PSES

# Summary

Guidance issues	Guidance clarifications	Supplemental Brief
The providers reporting pathway (PSPW and non PSPW)	Not PSWP if prepared for purposes other than reporting to a PSO expanded to “sole” purpose	Privilege exceptions authorize use of info for a variety of purposes Use of “solely” inserted by the government
Meeting external obligations	Expands definitions “original record” to include recordkeeping obligations	Expansion interjects state law above statute
Separate systems	Two systems or spaces: (1) PSES for PSWP (2) separate place where it maintains records for external obligations	Leverage existing infrastructure
Options for PSWP that can’t be dropped out	Providers should work with regulatory bodies to provide information needed. An option is to exercise a disclosure exception.	Disclosure of PSWP must have applicable disclosure permission and a State may not require that PSWP be disclosed

# What To Do Now?

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- Wait for Future Developments before modifying PSES
  - U.S. Supreme Court met on June 23rd and denied the petition in Tibbs v. Bunnell case.
  - Two new state supreme court cases:
    - Charles v. Southern Baptist in Florida
    - Carron v. Newport Hospital in Rhode Island – pending
    - Baptist Redmond Hospital v. Clouse – see discussion (attachment)
- PSOs sent questions to AHRQ seeking further clarification

# What to Do Now? (cont'd)

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- Attempt Good Faith Compliance under the Guidance



**Mandated  
reports**



**External  
obligations**



**Everything else  
to improve  
quality, safety,  
outcomes**

# What to Do Now? (cont'd)

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## Bucket 1

- Mandated Reports

## Bucket 2

- External Obligations
  - Need to review Medicare CoPs, in particular QAPI standards.
  - Need to review other applicable Federal, state and local record keeping requirements.
  - Compare these laws to what you are currently collecting and reporting or functionally reporting to the PSO.
  - Modify PSES if necessary.

# What to Do Now? (cont'd)

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- Where laws on what records you need to collect and maintain are not clear or are ambiguous, you can:
  - Keep in your PSES and not report in order to remove if necessary;
  - If reported to PSO you can utilize the written authorization disclosure exception, information is still PSWP
  - If the laws identify a record that must be collected and maintained but there is no required form and the law does not identify what must be included, develop your own form.

## **Bucket 3**

- What is not in Bucket 1 or 2 and is collected in the PSES for reporting to a PSO and is reported is PSWP

# What to Do Now? (cont'd)

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- Treat the Guidance as Non-Binding.
  - Rely on supportive state and/or federal court decisions.
  - Prepare for possible legal challenges knowing that attorneys and courts may or will look to the Guidance to support the challenge.
  - You always have the option to drop out if not reported or to use written authorization to disclose.

# Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers

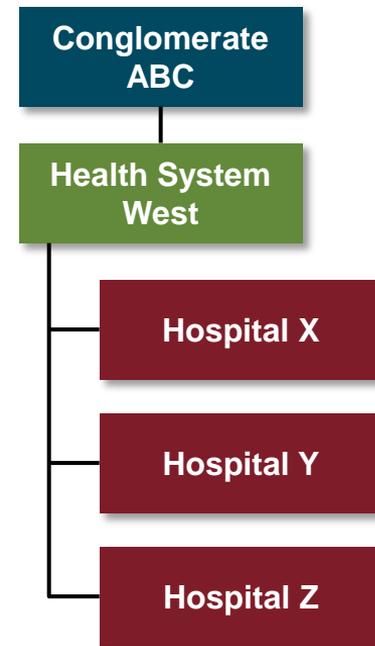
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- The Patient Safety Rule (“Rule”) defines a parent organization as follows:
  - An organization that owns a controlling interest or a majority interest in a component organization.
  - Has the authority to control or manage agenda setting, project management, or day-to-day operations;
  - Or has the authority to review and override decisions of a component organization. The component organization may be a provider.
- The Rule defines a component organization as an entity that is a “unit or division of a legal entity” (including a corporation and other examples) or is “owned, managed, or controlled by one or more legally separate parent organizations.”
- The concept and intent behind the term “parent organization” is to be more inclusive and is not limited to the definitions used in corporate law. Organizational structure alone will not determine whether a corporate entity is a parent organization.

# Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

## Example 1 – Direct Organizational Control

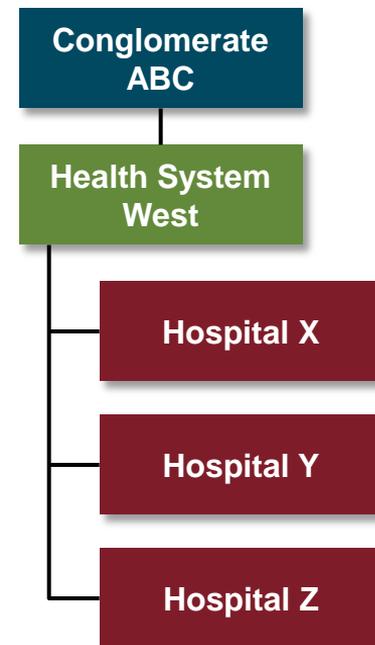
- In this organizational chart, Conglomerate ABC directly manages or controls Health System West and Health System West manages and controls Hospital X.
- Conglomerate ABC is the parent organization of Health System West, and Health System West is the parent organization of Hospital X.
- Conglomerate ABC would not be a parent organization of Hospital X based solely on its ownership and management of Health System West.



# Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

## Example 1 – Direct Organizational Control

- However, if Conglomerate ABC owns a controlling or majority interest in Hospital X, or has the authority to control or manage the agenda setting, project management, or day-to-day operations of Hospital X, or if it has the authority to review and override decisions of Hospital X, then Conglomerate ABC can be considered a parent organization of Hospital X.
- Consequently, if Conglomerate ABC meets any of these definitions of a parent organization, Hospital X could have two parents, Conglomerate ABC and Health System West.



# Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

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## Example 1 – Direct Organizational Control

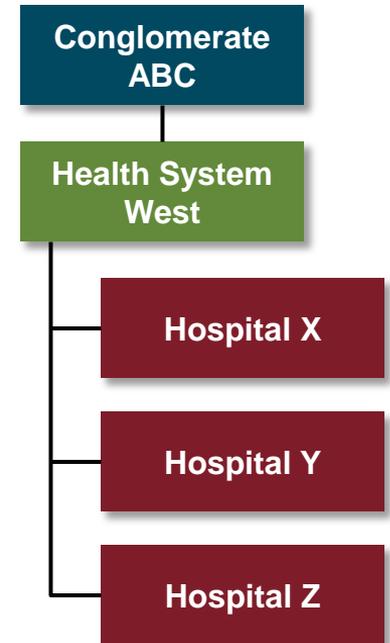
Determining Which Entities are Providers and Which Entities Are Affiliated Providers Under the Final Rule

- Under the Rule, a provider is defined as an individual or entity licensed or otherwise authorized under state law to provide health care services.
- The typical examples include a hospital, nursing facility, out-patient rehab facility, home health agency, a physician, a physician assistant, registered nurse, nurse practitioner, etc.
- Aside from public health care entities, which are also considered providers even if not authorized or licensed under state law, a parent organization of a licensed provider is considered a provider even though the parent is not itself a licensed provider.
- The intent behind this standard that a non-licensed parent organization of a licensed provider qualifies as a provider is “to permit the parent organization...to enter into a system-wide contract with the PSO” on behalf of itself as well as its affiliated providers (see discussion below).

# Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

## Example 2 – Determining Which Entities Are Providers and Which Entities are Affiliated Providers

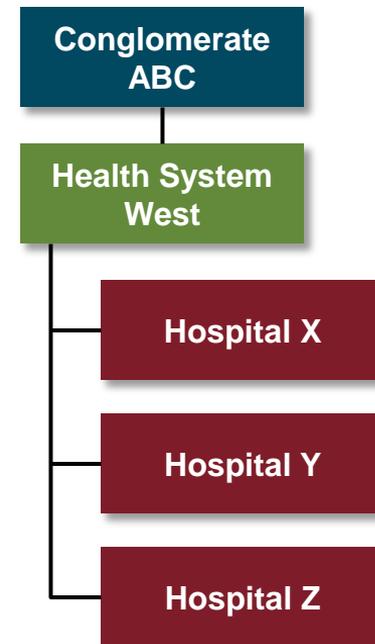
- Which are the providers?
  - Hospitals X, Y and Z are licensed providers under state law.
  - Because Health System West in this example owns, manages, or controls Hospitals X, Y and Z, it too is considered a provider under the Rule even though it is not a licensed provider.
  - Conglomerate ABC is not also a provider unless it meets one of the definitions of a parent organization.



# Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

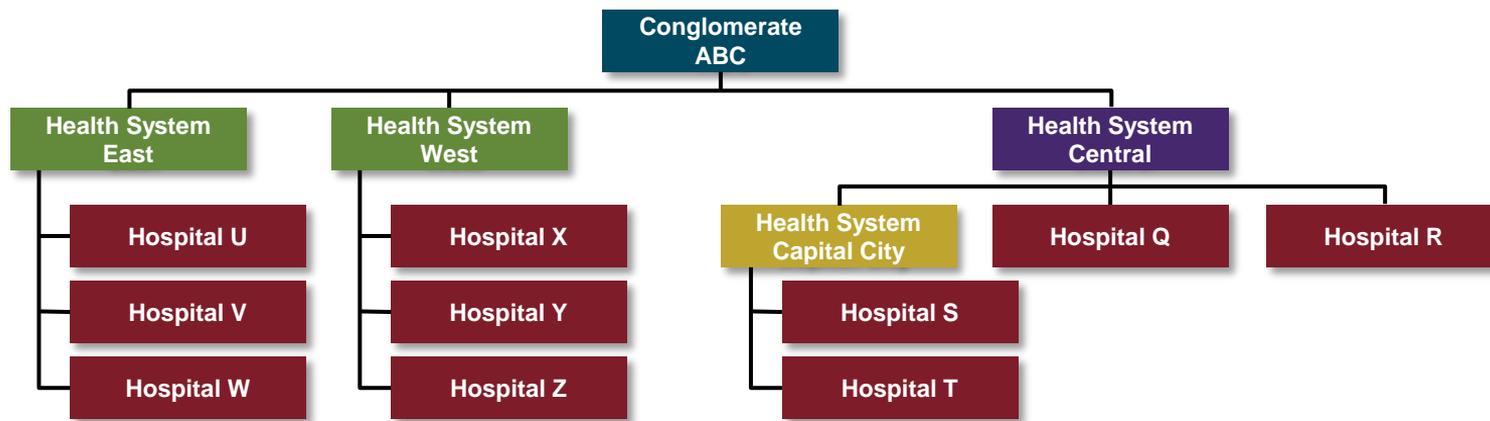
## Example 2 – Determining Which Entities Are Providers and Which Entities are Affiliated Providers

- Which are affiliated providers?
  - Conglomerate ABC is not an affiliated provider unless it meets the definition of a parent organization.
  - Hospitals X, Y and Z are affiliated providers because they are legally separate entities, meet the definition of a provider, and are under common management or control with Hospital X.
  - Health System West also is an affiliated provider because it is a legally separate entity and qualifies as a provider because it manages and controls Hospital X.



# Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

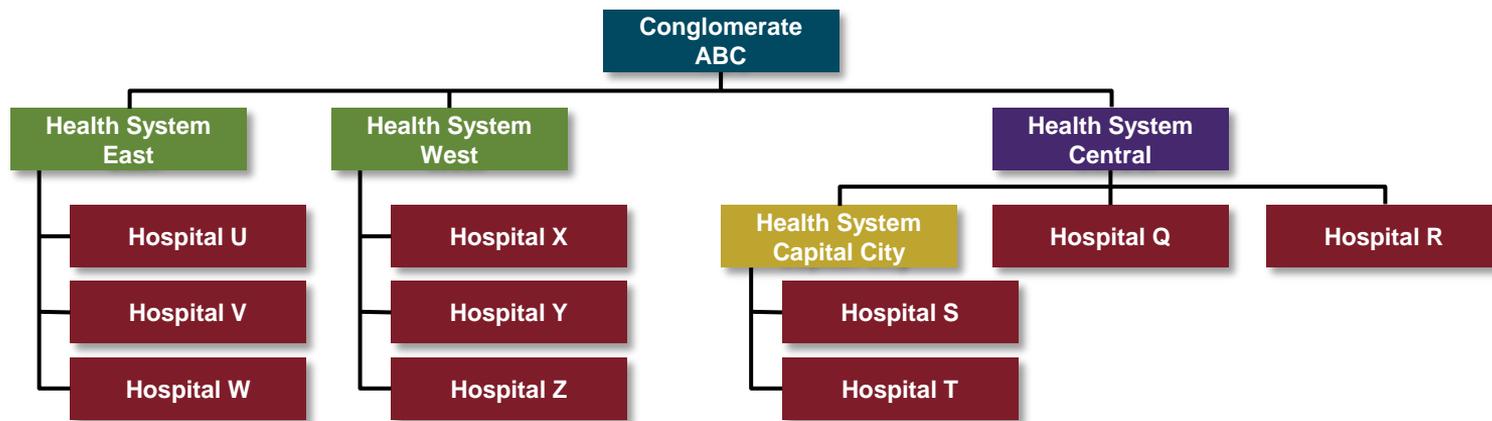
## Example 3 – Multisystem Corporate Organization



- Which are the providers?
  - Hospitals U, V, W, X, Y, Z, S, T, Q, R are all licensed providers.
  - Health System East is an affiliated provider of hospitals U, V and W because it owns and controls these hospitals.
  - Health System West is an affiliated provider because it owns and controls Hospitals X, Y and Z.
  - Health System Capital City is an affiliated provider of Hospitals S and T for the same reason.
  - Health System Central is the affiliated provider for hospitals Q and R.

# Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

## Example 3 – Multisystem Corporate Organization



- Conglomerate ABC is not an affiliated provider because it is not a licensed provider and unless it meets the definition of a parent organization of the actual licensed providers, it cannot be considered an affiliated provider.
- Which are affiliated providers?
  - Health Systems East, West, Central and Capital City along with all of the licensed hospitals are considered affiliated providers because they are all separate legal entities, meet one of the definitions of a provider and are under common management or control by being part of a multi-organizational enterprise.

# Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

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## Example 3 – Multisystem Corporate Organization

- The benefits of participating in a multi-organizational enterprise with affiliated providers includes the following:
  - If Conglomerate ABC in fact met the definition of a parent organization, it can enter into a contract with a PSO on behalf of all of the other affiliated entities in this example.
  - If Conglomerate ABC does not qualify as a parent organization, then each system would have the ability to contract on behalf of the affiliated licensed providers under its management and control.
  - The other option is that each licensed provider can contract separately with a PSO.
- Affiliated entities are allowed to share identifiable and non-anonymized PSWP by and among other affiliated providers, although this is not a requirement and the affiliated providers have the option of not disclosing identifiable PSWP.

# How Does the Illinois Medical Studies Act Confidentiality/Privilege Protections Compare to those Offered under the Patient Safety Act?

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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

# How Does the Illinois Medical Studies Act Confidentiality/Privilege Protections Compare to those Offered under the Patient Safety Act?

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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

## How Does the Illinois Medical Studies Act Confidentiality/Privilege Protections Compare to those Offered under the Patient Safety Act?

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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.
- 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.

# How Does the Illinois Medical Studies Act Confidentiality/Privilege Protections Compare to those Offered under the Patient Safety Act?

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- 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.
  - The scope of what patient safety activities can be protected, generally speaking, is broader than the Medical Studies Act.
  - The scope of what entities can seek protection is generally greater. Any licensed provider, i.e., physician, physician group, surgicenters, clinic, hospital, nursing home, home health facility, etc., can be covered under the PSA.

## How Does the Illinois Medical Studies Act Confidentiality/Privilege Protections Compare to those Offered under the Patient Safety Act?

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- 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 – Walgreens case
- Non-provider corporate parent organization involved in patient safety activities as well as owned, controlled or managed provider affiliates can be included in a system-wide PSES and be protected.
- 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").

# 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® event report at 1415.
6. Patient complained to Nurse B that she has a headache at 1700.

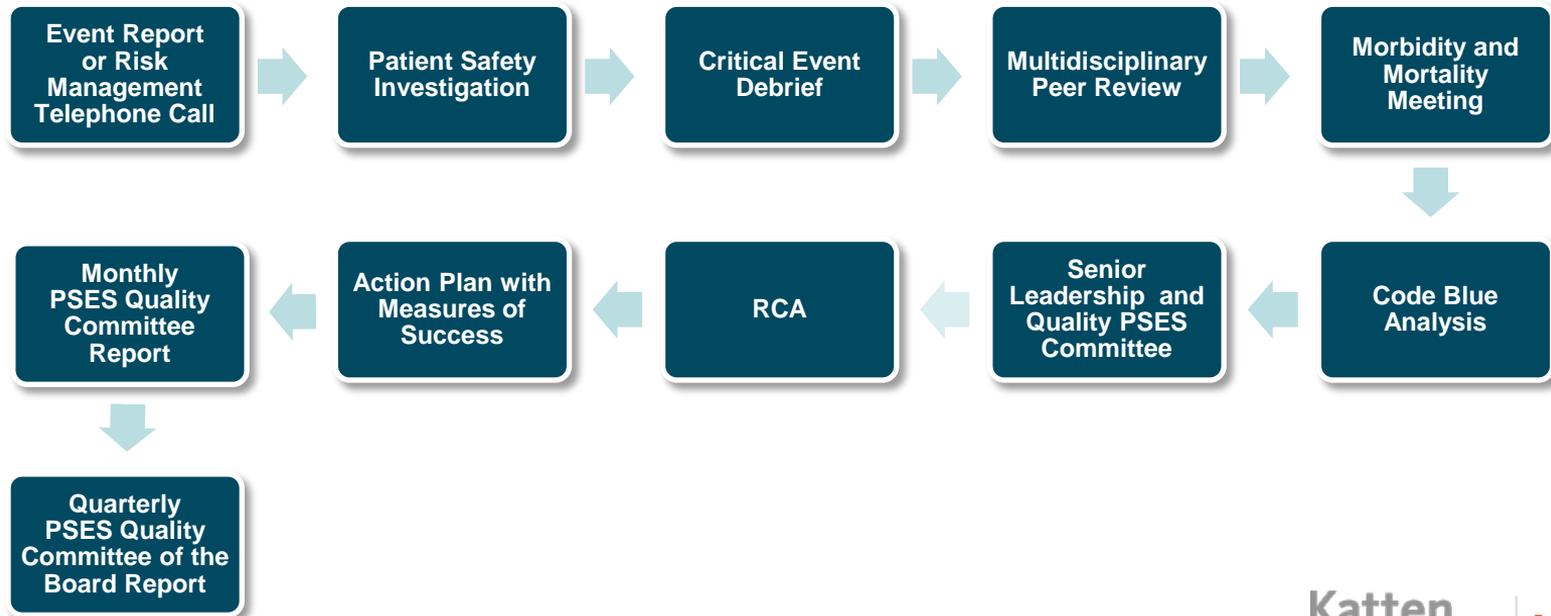
# Patient Fall Case Study (cont'd)

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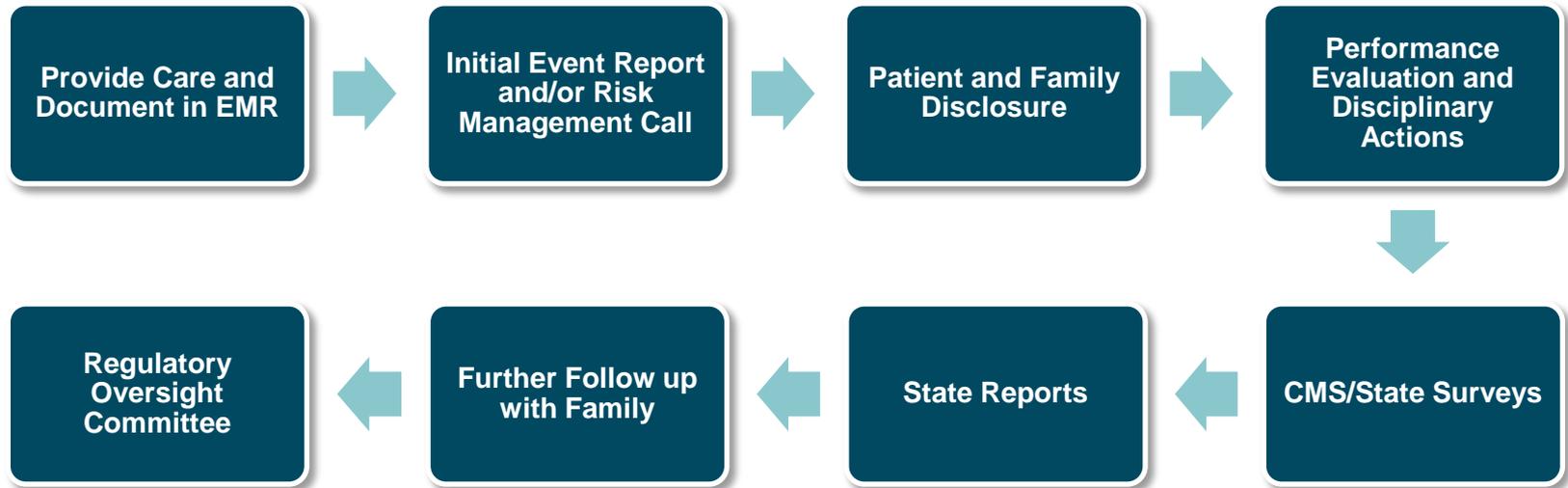
7. Nurse B call resident B and received an order for Tylenol 500 mg prn headache.
8. Nurse B found patient on floor nonresponsive at 1800 and called a code blue.
9. Code team arrived at 1830 but patient could not be resuscitated.
10. Family was called and they came to the hospital. Family agreed to have 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

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## 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.

# 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.
- Does state or federal law have mandated reporting or record keeping requirements?
- Deliberation and analysis must be conducted within PSES to be considered PSWP – should document when this occurs.
- RCA may be conducted by PSO workforce which could 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 but AHRQ takes the position that if it was a Bucket 1 (mandated report) or a Bucket 2 (record keeping) report it does not qualify as PSWP.
- 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.

# 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.