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PSO 101: Overview of Patient Safety Act

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Speaker Bios

Michael R. Callahan, Partner - 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.

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Speaker Bios

Ellen Flynn RN, MBA, JD, CPPS - 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

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.

Disclaimer

- 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.

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PSO 101: Overview of Patient Safety Act

The purpose of this program is to provide an overview of the Patient Safety Act and the fundamental principles and requirements under the Act. It is designed for hospitals and other licensed health care providers and facilities considering whether to participate in a PSO as well as to serve as a refresher course for current PSO participants. Topics to be discussed including the following:

- Overview of Patient Safety Act
- What is a Patient Safety Evaluation System (PSES) and how is it formed?

PSO 101: Overview of Patient Safety Act
(cont'd)

- What information can be considered privileged and confidential patient Safety Work Product (PSWP), which is not subject to discovery or admissibility into evidence?
- What patient safety activity benefits can a PSO provide?
- Do the protections apply to all state and federal proceedings?
- What is "functional reporting" to a PSO?
- How can a clinically integrated network participate in a PSO?

PSO 201: PSO Standards Applied to Real-World Scenarios

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)

- 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

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

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

- *Walgreen v. Illinois Department of Financial and Professional Services*
- *Charles v. Southern Baptist Medical Center*

- 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?

Health Care Reform and PSOs

- Medicare/Medicaid and private payers are now reimbursing providers based on documented compliance with established quality metrics and outcome measures.
- Examples of this shift from volume to value as a condition of payment include:
  - Medicare Shared Savings ACOs
  - Value-based purchasing outcome standards
  - Pay for performance standards
  - Readmission rate penalties
  - Hospital acquired condition/Infection penalties
  - HHS has set a goal of tying 85% of all of its traditional Medicare payments to quality or value metrics

Health Care Reform and PSOs (cont'd)

- In order to meet these ever evolving standards, clinically integrated networks, hospitals and other providers will need to implement these standards into their appointment, reappointment, ongoing monitoring and similar processes in order to track performance and implement remedial measures, including disciplinary action for non-compliance not only because of the potential adverse impact on patients but also because it will result in reduced reimbursement.
- The result of these efforts will be the creation of very sensitive quality, risk and peer review analyses, reports, studies, and other information, most of which may not be protected under existing state laws.

Health Care Reform and PSOs (cont'd)

- As will be discussed during this presentation, participation in PSOs therefore play a very important role in being able to conduct these patient safety, quality and risk activities in a protected space in order to continue to improve patient care services.

Background

Congress enacted the Patient Safety and Quality Improvement Act of 2005 in response to the IOM report “To Err is Human” to address national concerns over number of preventable errors that were occurring

By granting privilege and confidentiality protections to providers who work with a federally-listed Patient Safety Organization (PSO), the Act was intended to nationally enhance health care quality and safety

AHRQ created the Common Formats to help providers uniformly report to PSOs patient safety event for aggregation and analysis

PSOs are required to collect and analyze data in a standardized manner using the AHRQ Common Formats to identify safety improvement opportunities, and share learnings widely.

Background

Legislative History:

- Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act)
- Signed into law July 29, 2005
- Final rule released November 21, 2008
- Rule took effect January 19, 2009
- CMS issued final regulations for Sec. 1311 of the Affordable Care Act in March of 2014
  - *All hospitals > 50 beds are required to have a Patient Safety Evaluation System (PSES), which may mean a relationship with a PSO, to be part of a qualified health plan (QHP) participating in a Health Insurance Exchange (HIE).* There is a two-year phase-in period: Jan 1, 2015 to Jan 1, 2017.

Background (cont'd)

- CMS issued a proposed regulation which affirms the January 1, 2017 but would allow a QHP to enter into a hospital provider agreement if it has a PSES or participates in a Health Enterprise Network (HEN) or has a contract with a Quality Improvement Organization (QIO).
- The privilege and confidentiality protections, however, are only afforded to licensed providers which participate in a PSO and not those which only are in a HEN or a QIO arrangement.

The Patient Safety and Quality Improvement Act of 2005

- The goal of the Act was to improve patient safety by encouraging voluntary and confidential reporting of health care events that adversely affect patients. To implement the Patient Safety Act, the Department of Health and Human Services issued the Patient Safety and Quality Improvement Rule (Patient Safety Rule).
- The Patient Safety Act and the Patient Safety Rule authorize the creation of PSOs to improve quality and safety through the collection and analysis of aggregated, confidential data on patient safety events. This process enables PSOs to more quickly identify patterns of failures and develop strategies to eliminate patient safety risks and hazards.

The Patient Safety and Quality Improvement Act of 2005 (cont'd)

- Provides privilege & confidentiality protections for information when providers work with Federally listed PSOs to improve quality, safety and healthcare outcomes
- Authorizes establishment of "Common Formats" for reporting patient safety events
- Establishes "Network of Patient Safety Databases" (NPSD)
- Requires reporting of findings annually in AHRQ's National Health Quality / Disparities Reports

Patient Safety Act

Learning environment

- Facilitates development of a safe and protected learning space where providers focus on improving care versus legal or disciplinary implications of findings.
- Allows provider organizations to maintain a “Just” culture of accountability with deliberate PSES set-up.

Equal consistent enforcement

- Enables all licensed providers to receive equal protections.
- Supports new healthcare models that place more and more responsibility on non-physician healthcare providers and corporate parent organizations.

Nationwide and Uniform

- Enables healthcare providers to collaborate and learn from quality, safety and healthcare outcome initiatives that cross state lines without legal ramifications.

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Early recognition

- Supports risk mitigation by creating awareness of provider opportunities that can be gleaned by a PSO that aggregates large volumes of event data across many similar providers.

Meaningful comparison

- Encourages data collection, aggregation and analysis amongst similar providers in a common format to allow for meaningful comparisons and easier identification of improvement opportunities.

Flexible Participation

- Allows providers to negotiate with PSOs about the quantity and type of data reported and the type of analysis and feedback provided by the PSO.

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Key Components of Patient Safety Act

- **PSOs** – Almost any entity can be or have a PSO.
- PSOs serve as independent, external experts who can collect, analyze, and aggregate Patient Safety Work Product to develop insights into the underlying causes of quality and patient safety events.
- **Providers –** An individual or entity licensed or otherwise authorized under State law to provide health care services and/or a parent organization of one or more entities licensed or otherwise authorized to provide health care services.
- **Patient Safety Events –** Incidents or near misses or unsafe conditions
- Any type of event that adversely effects healthcare quality, patient safety or healthcare outcomes
- **Common Formats –** Provide a uniform way to measure patient safety events clinically & electronically and to permit aggregation & analysis locally, regionally, & nationally.

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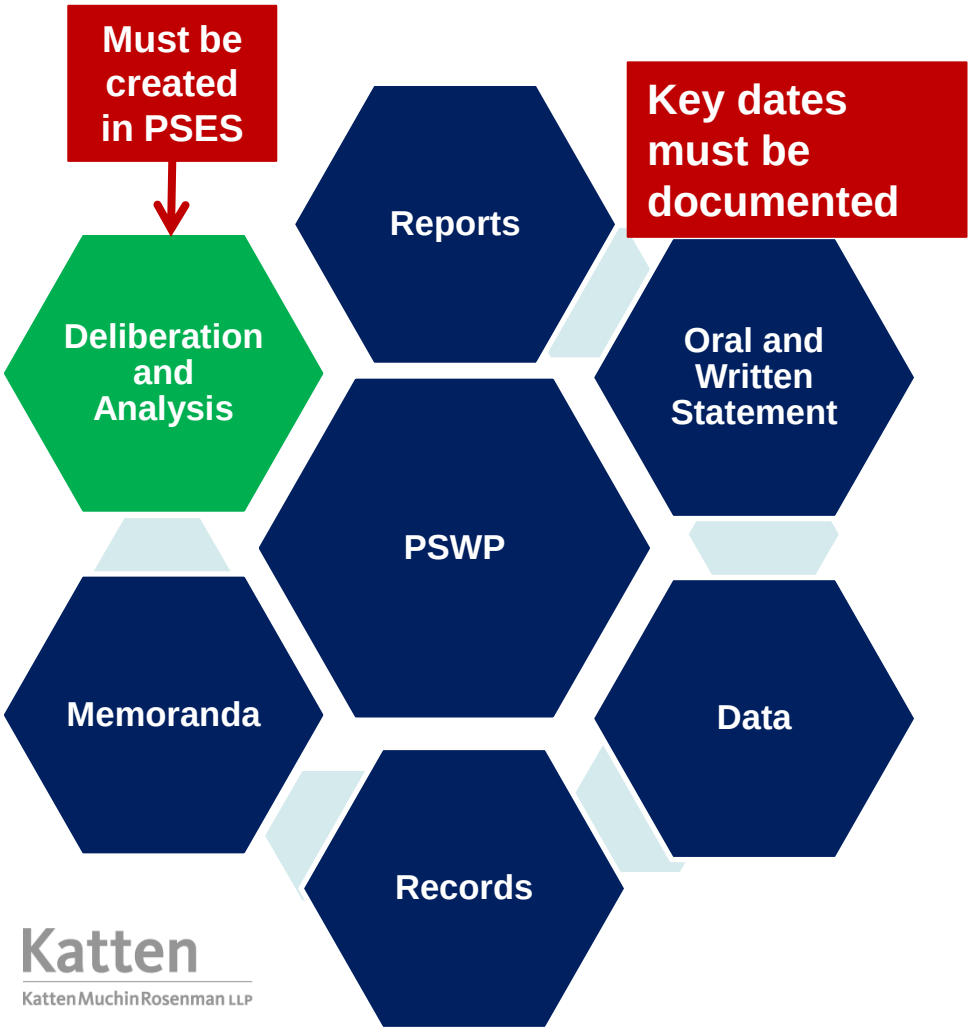
Patient Safety Activities

- Efforts to improve patient safety and the quality of health care delivery;
- The collection and analysis of patient safety work product;
- The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
- The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;

Patient Safety Activities (cont'd)

- The maintenance of procedures to preserve confidentiality with respect to patient safety work product;
- The provision of appropriate security measures with respect to patient safety work product;
- The utilization of qualified staff; and
- Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

What is Patient Safety Work Product (PSWP)?



Requirements

Data which could improve patient safety, health care quality, or health care outcomes

- Data assembled or developed by a provider for reporting to a PSO and are reported to a PSO

Analysis and deliberations conducted within a PSES

- Data developed by a PSO to conduct of patient safety activities

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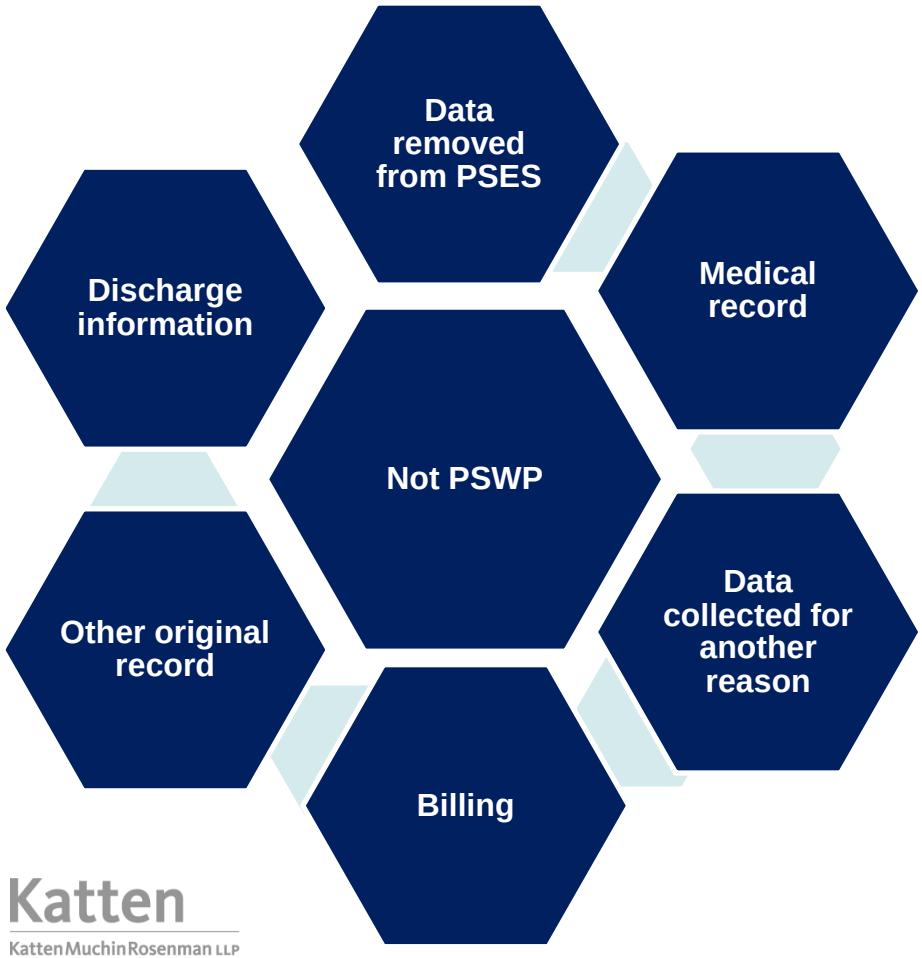
What is Not PSWP?



Requirements

Information collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.

- **Data removed from a patient safety evaluation system**

Data collected for another reason

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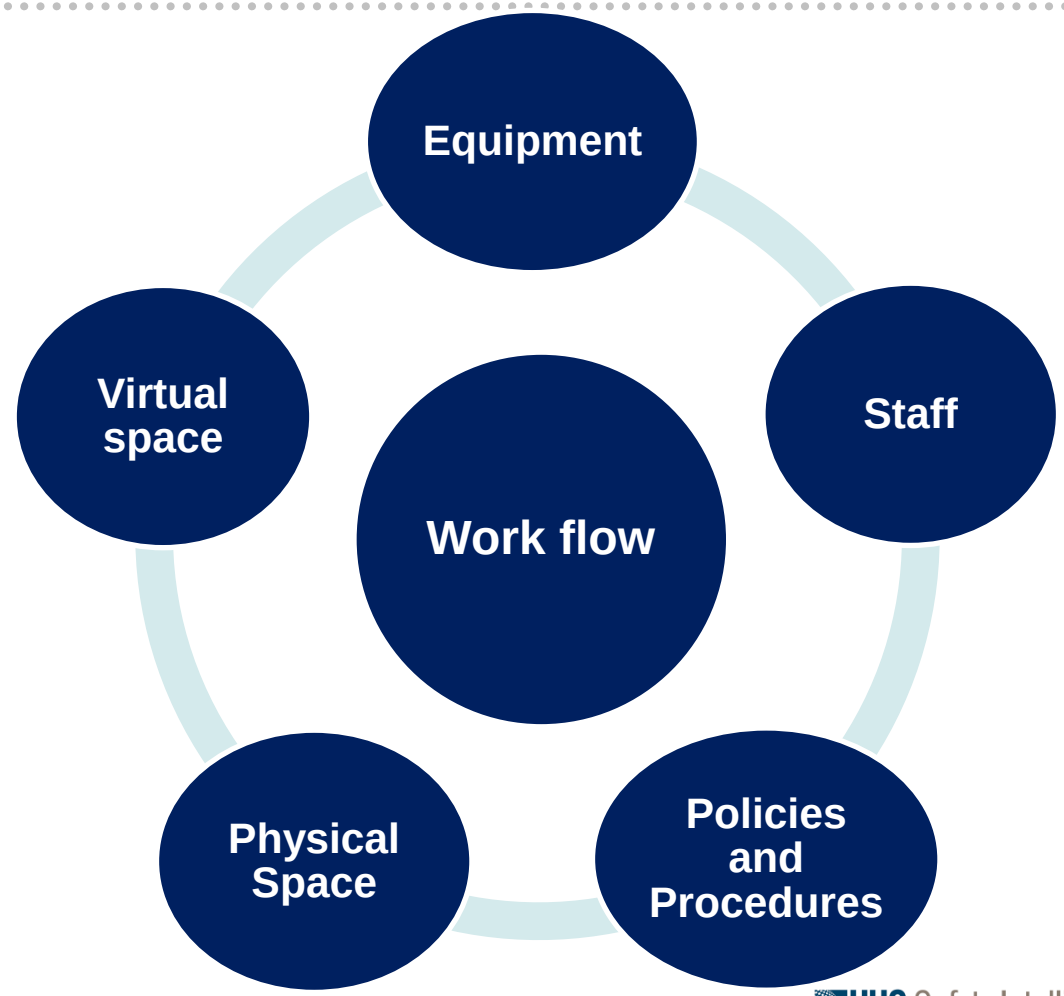
Patient Safety Evaluation System (PSES)

The collection, management, or analysis of information for reporting to or by a PSO. A provider's PSES is an important determinant of what can, and cannot, become patient safety work product.



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PSES Operations

Establish and Implement Your PSES to:

- **Collect** data to improve patient safety, healthcare quality and healthcare outcomes
- **Review** data and takes action when needed to mitigate harm or improve care
- **Analyze** data and makes recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes
- Conduct RCAs, Proactive Risk Assessments, in-depth reviews, and aggregate RCAs
- Determine which data will/will not be reported to the PSO
- Report to PSO
- Conduct auditing procedures

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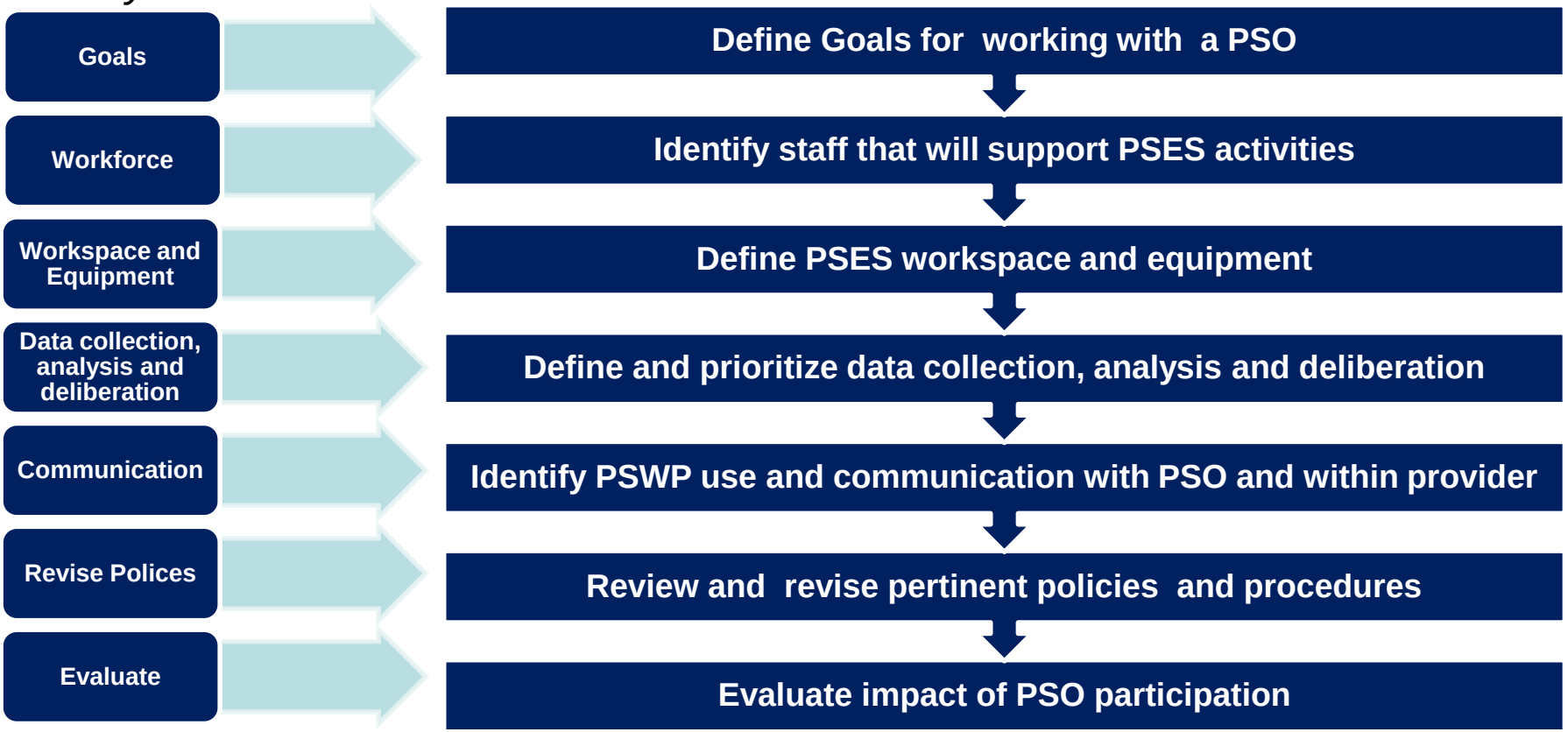
PSES Operations (cont'd)

Examples in PSES for collecting and reporting to a PSO:

- Medical Error investigations, FMEA or Proactive Risk Assessments, Root Cause Analysis
- Risk Management - incident reports, investigation notes, interview notes, RCA notes, notes from risk recommendations via phone calls or conversations, notes from PS rounds which relate to identified patient safety activities
- Outcome/Quality - may be practitioner specific, sedation, complications, blood utilization etc.
- Peer Review
- Committee minutes – Those portions of Safety, Quality, Quality and Safety Committee of the Board, Medication, Blood, Physician Peer Review relating to identified patient safety activities

Steps to documenting a provider PSES

PSES means the collection, management, or analysis of information for reporting to or by a PSO



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PSES Consideration Checklist

PSES participation decisions – preparing to assert privilege and confidentiality protections generates from consistency in practice

- Internal communication
  - Involving other clinical departments
- External communication
  - Involving your defense counsel
- How to assert a claim of privilege and confidentiality
- Handout available

Documenting Your Organization's Patient Safety Evaluation System (PSES)

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PSES Documentation Considerations	Completed
• Develop PSES organizational chart (includes health system coordination)	☐
Workforce	
• Develop grid with job titles, responsibilities and level of access to PSWP and purpose	☐
• Identify 2 key contact roles for PSO	☐
Description of the following:	☐
• PSES Workforce training plan	
• Non-PSES workforce employees and providers training plan	☐
• Who can enter SI event reports into the PSES	☐
• Who can conduct additional investigations within PSES	☐
• Who conducts proactive risk assessments within PSES	☐
• Who collect any data outside of SI or conducts deliberation, analysis and documents date	☐
• Who reviews data after it enters PSES	☐
• Who can remove data from PSES before reporting to PSO and record date	☐
• Who can report to the PSO and record date reported	☐
• Who can functionally report to PSO and record date	☐
• Who has access to the functionally reported drive (PSO and internal)	☐
• Who can conduct analyses/deliberations within PSES	☐
• Who disseminates non-identifiable PSWP	☐
• Who determines non-identifiable SPWP	☐
• Who may disclose PSWP	☐
Equipment/software	
• Safety intelligence software environment –define what is PSWP and what is not	☐
• Secure functional reported drive within PSES and who has access	☐
• Secure PSES drive and who has access	☐
PSWP	
• Describe how PSWP can be shared across health system and disclosed amongst affiliate providers if applicable	☐
• Describe how PSWP is maintained within PSES	☐
• Describe data collected (consider data inventory)	☐
• Describe who can access PSWP for operation of PSES and/or interactions of PSES	☐
PSES Operations	
• Describe patient safety activities conducted	☐
• Describe how additional deliberation and analysis may occur within PSES	☐
• Describe how a copy of other data may be reported to PSO	☐
• Describe how data may be used internally	☐
Disclosure	
• Describe how, when and by whom PSWP may be disclosed, disclosure form used, and record retention (minimum 6 years for provider disclosure)	☐
• Describe what and how PSWP may be disclosed amongst affiliate providers	☐
Functional reporting	
• Describe agreement and how PSO has access	☐
Physical space (if any)	
• Describe dedicated office space	☐
• Describe any physical storage files	☐
Pertinent policies and other documents that might benefit from review	
• Incident report	☐
• Disclosure	☐
• Confidentiality	☐
• Record retention	☐
• Discipline	☐
• Possibly peer review	☐
• Training	☐
• Manager investigation	☐
• RCA	☐
• Privacy and Security policy	☐
• Confidentiality	☐
• Risk Management Policies	☐

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Prioritizing Data for PSO Reporting

High = subjective or judgmental information, event contributing factors, recommendations for improvement

Medium = additional facts that clarify understanding about the event

Low = basic facts that may be available in the medical record (original not PSWP)

Data	Main Purpose	Other Uses	Priority for Reporting	Type	Report to PSO
System peer review	Patient safety, healthcare quality and outcomes	None	High	PSWP	Yes - original
System patient safety committee	Patient safety	None	High	PSWP	Yes - original
Completed actions	Patient safety	Patient safety	Medium	Not PSWP	Yes - copy
RCA conducted within PSES	Patient safety	None	High	PSWP	Yes - original
Hospital OPPE	Reappoint physicians	Patient safety	Medium	Not PSWP	Yes - copy

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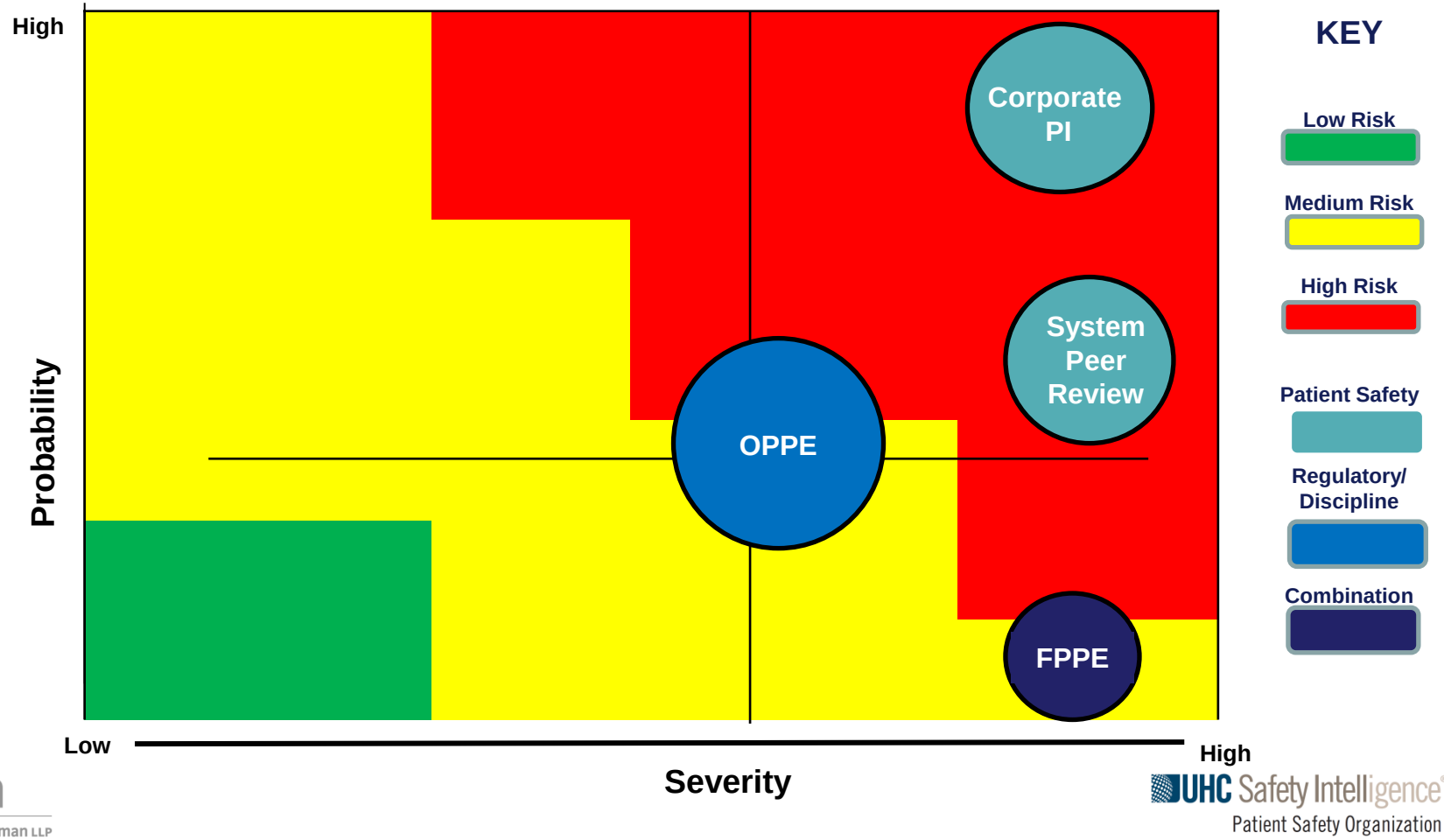
Prioritizing PSO Submission Activities

This graph displays one way to prioritize those activities that will be reported to a PSO. This grid should created based upon results of data inventory. The x axis shows data that may be problem prone, the y axis displays the probability this data would be discoverable without the PSO privilege and confidentiality protections or ineligible for protections.. The color identifies the primary purpose and the size of the bubble identifies the frequency of the activity.



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Functional reporting

What is it?

Reporting of information to a PSO for the purposes of creating patient safety work product may include authorizing PSO access, pursuant to a contract or equivalent agreement between a provider and a PSO, to specific information in a patient safety evaluation system and authority to process and analyze that information, e.g., comparable to the authority a PSO would have if the information were physically transmitted to the PSO.

Considerations:

- How is it maintained by Provider within PSES
- How can the PSO retain the same responsibilities for privacy and security

Functional reporting (cont'd)

- What type of Functional Reporting agreement with PSO is necessary that describes how PSO will access to the data and utilize the data to identify quality, patient safety and healthcare outcome improvements
- Must decide how and when functional reporting has taken place and must document same

If PSWP Is Functionally Reported, PSO Must Have Access

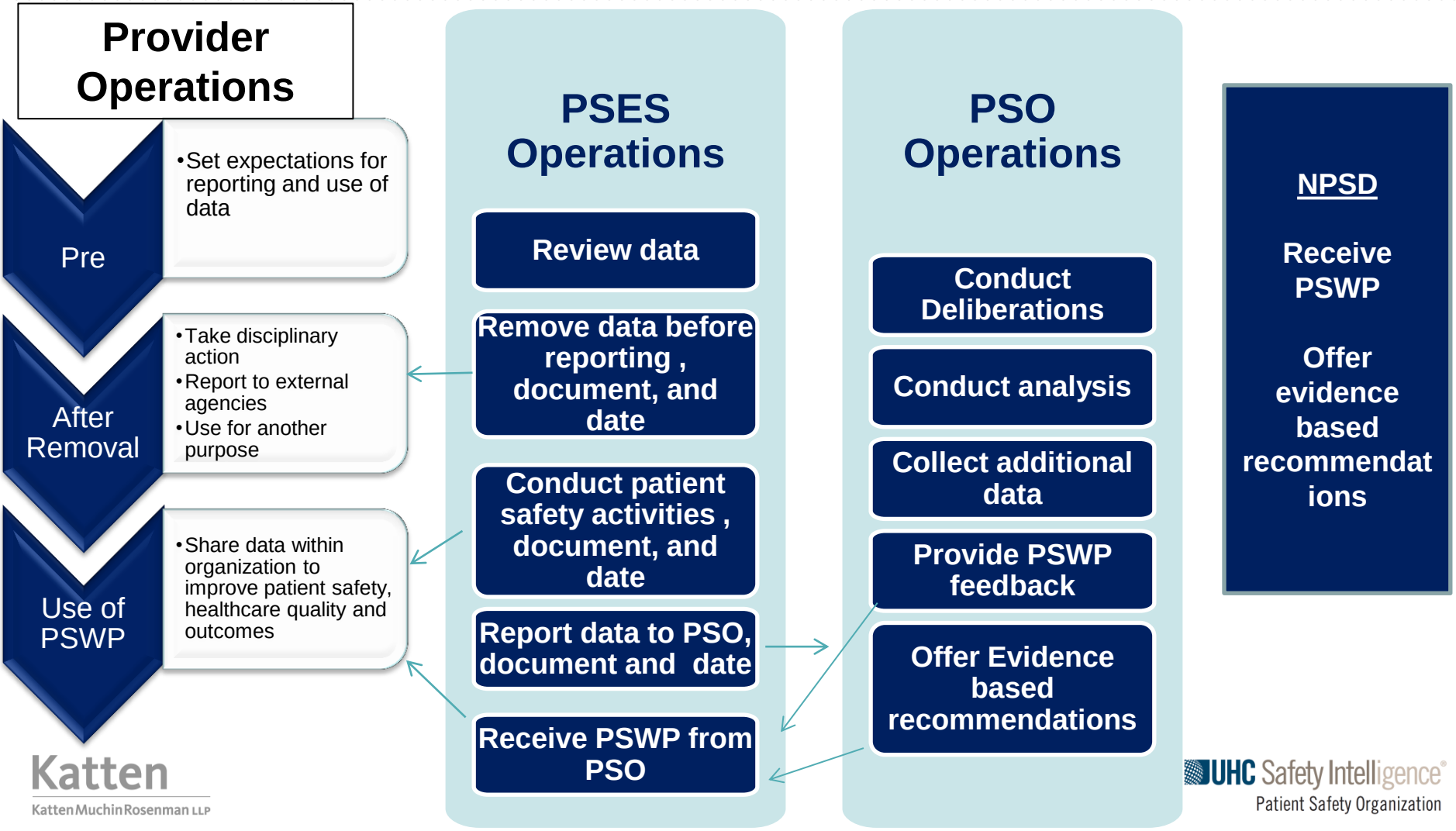
Drop-Out Provision

The Patient Safety Rule provides a limited opportunity for a provider to remove PSWP protections from information that the provider entered into its PSES for reporting to a PSO.

The drop-out provision can be used for any reason, provided the information that the provider had placed in its PSES has not been reported to a PSO and the provider documents the action and its date.

Upon removal, the information is no longer protected. The drop-out provision cannot be used if the information has been reported to a PSO and it does not apply to information that describes or constitutes the deliberations or analyses of a PSES.

Maintain JUST Culture when Removing Data From PSES Before Reporting to PSO



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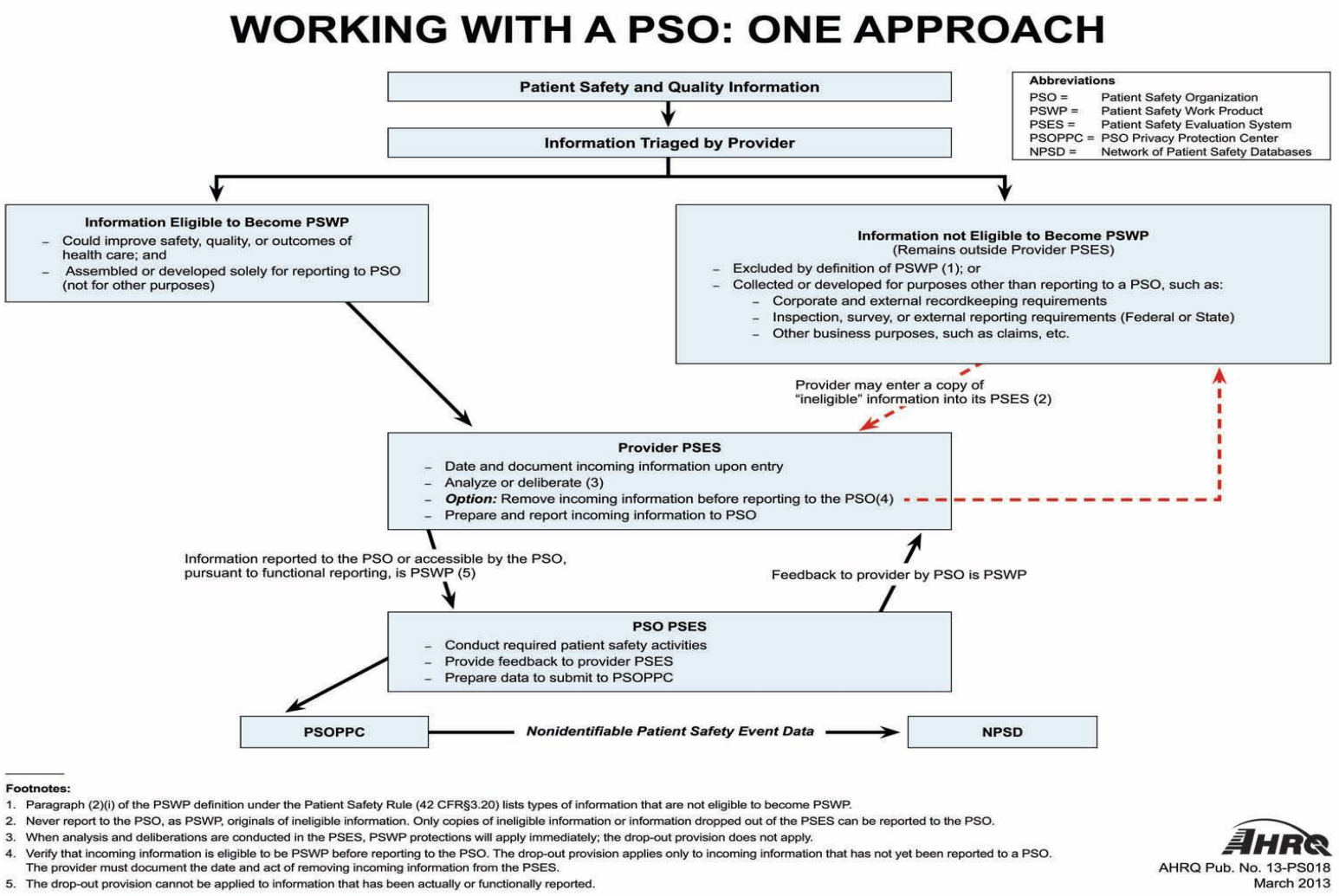
PSO Participation Schematic



Footnotes:

1. Paragraph (2)(i) of the PSWP definition under the Patient Safety Rule (42 CFR§3.20) lists types of information that are not eligible to become PSWP.
2. Never report to the PSO, as PSWP, originals of ineligible information. Only copies of ineligible information or information dropped out of the PSES can be reported to the PSO.
3. When analysis and deliberations are conducted in the PSES, PSWP protections will apply immediately; the drop-out provision does not apply.
4. Verify that incoming information is eligible to be PSWP before reporting to the PSO. The drop-out provision applies only to incoming information that has not yet been reported to a PSO. The provider must document the date and act of removing incoming information from the PSES.
5. The drop-out provision cannot be applied to information that has been actually or functionally reported.

AHRQ Pub. No. 13-PS018
March 2013

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PSWP is Privileged :

Not Subject to:

- subpoenas or court order
- discovery
- FOIA or other similar law
- requests from accrediting bodies or CMS

Not Admissible in:

- any state, federal or other legal proceeding
- state licensure proceedings
- hospital peer review disciplinary proceedings

Patient Safety Act Privilege and Confidentiality Prevail Over State Law Protections

The privileged and confidentiality protections and restriction of disciplinary activity supports development of a Just Learning Culture

State Peer Review

- Limited in scope of covered activities and in scope of covered entities
- State law protections do not apply in federal claims
- State laws usually do not protect information when shared outside the institution – considered waived

Patient Safety Act

- Consistent national standard
- Applies in all state and federal proceedings
- Scope of covered activities and providers is broader
- Protections can never be waived
- PSWP can be more freely shared throughout a health care system
- PSES can include non-provider corporate parent

Working with a PSO must be implemented in a way that facilitates a Just Learning Environment while taking advantage of privilege and confidentiality protections.

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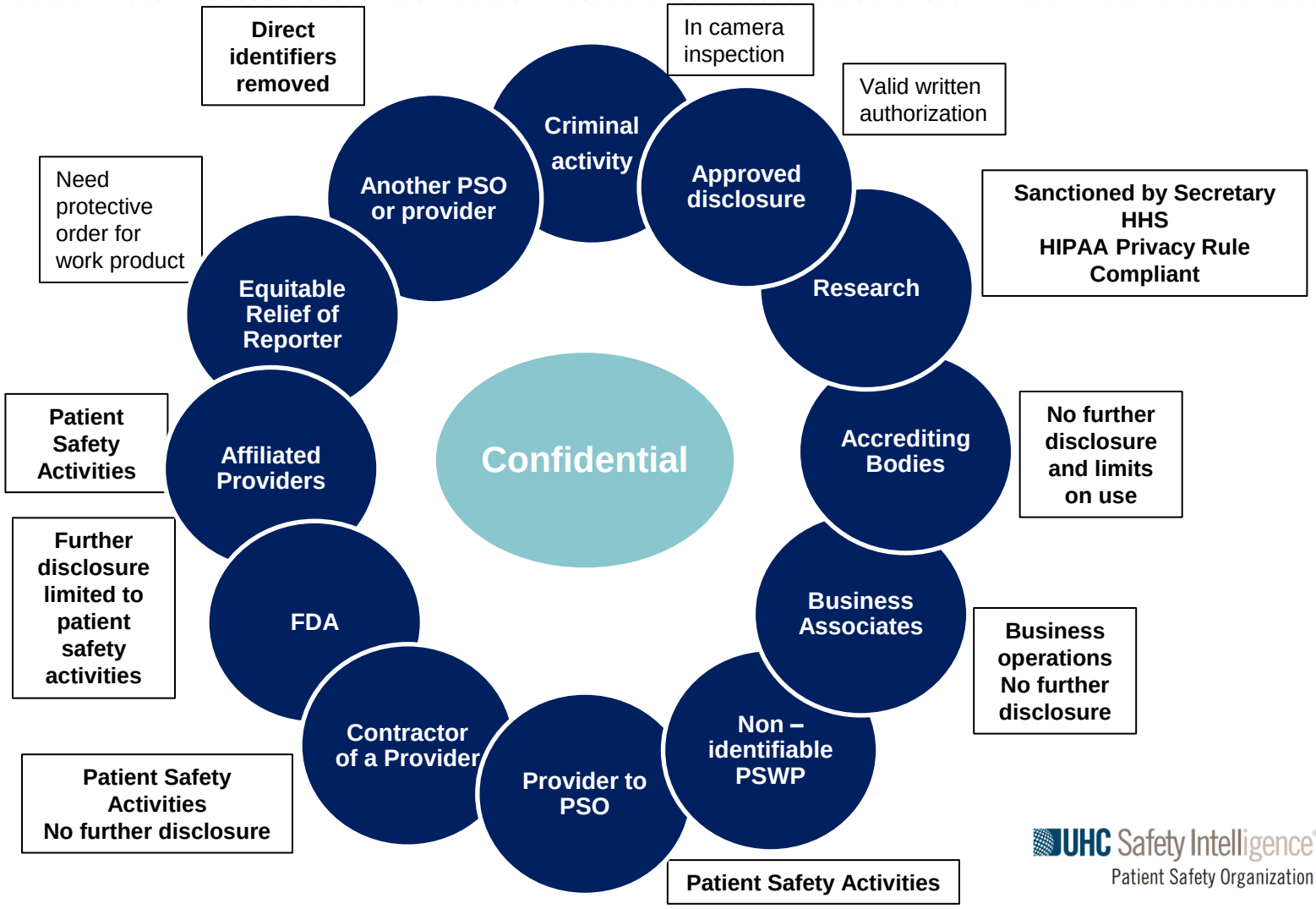
PSWP is confidential and not subject to disclosure with limited exceptions

Please see Patient Safety Final Rule



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Centralized PSES Model

PSES Role-PSWP
- Deliberations
- Analysis
- Recommendations
- Additional data collection

Regulatory Committee- not PSWP
- Completed actions
- Review of factual data
- Review of state, CMS and TJC required data

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Decentralized PSES Model

Information Eligible to Become PSWP

- Data aggregation, deliberations and analysis of PSWP and non-PSWP
- Review of specific actual and near miss event reports developed solely for reporting to PSO
- Activities initiated with the goal of learning, improving and enhancing patient safety and quality of care

Information NOT Eligible to Become PSWP

Collected/developed for purposes other than for reporting to PSO

- Claims, medical records
- Accreditation/ regulatory survey information
- State regulatory record keeping requirements

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Healthcare Systems Data Sharing

- 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)

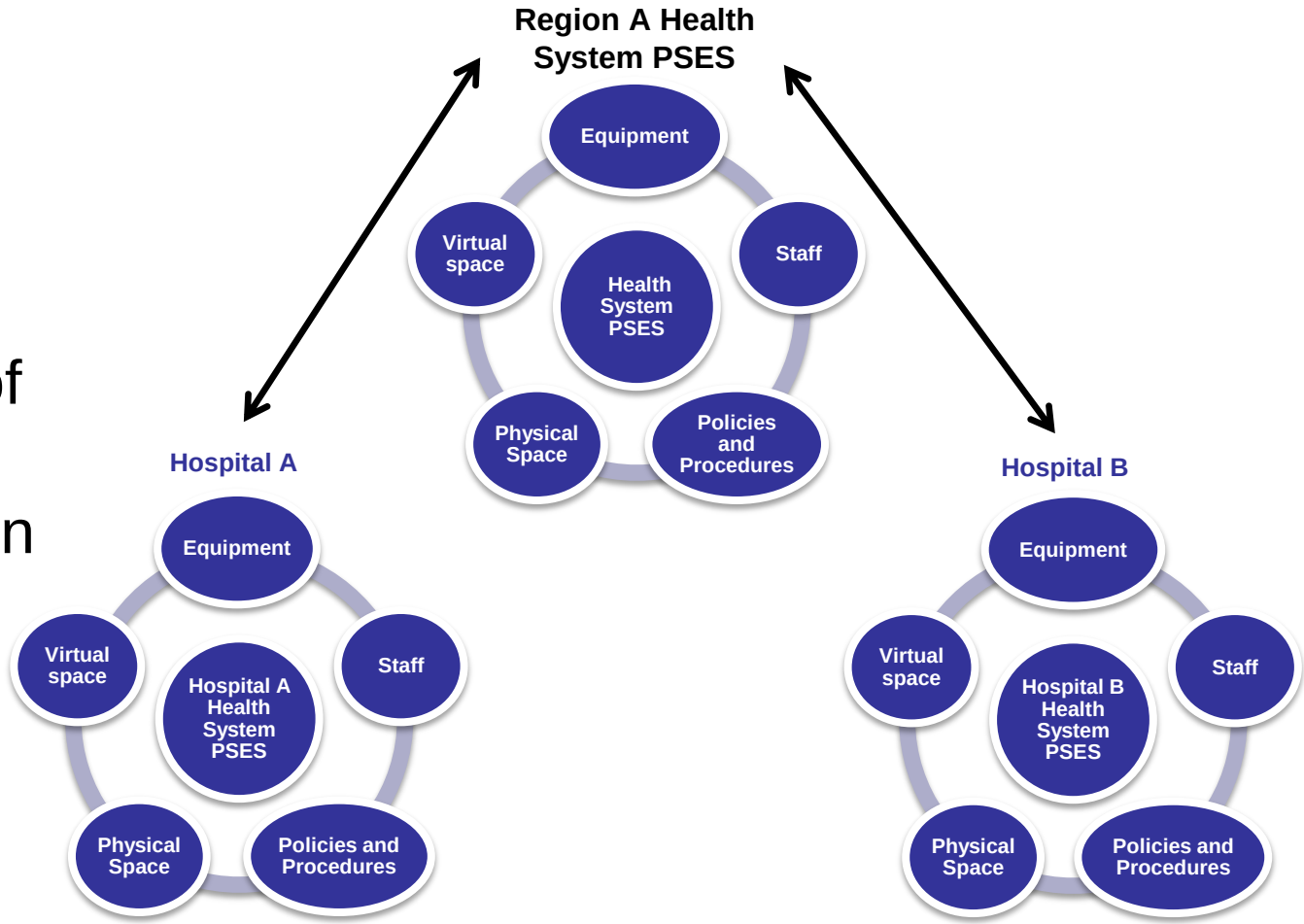
- Health System may require facilities and/or providers to report to a designated PSO.
- A patient safety event reporting requirement can be consistent with the statutory goal of encouraging organizational providers to develop a protected confidential sphere for examination of patient safety issues.

Healthcare Systems Data Sharing (cont'd)

- 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.

Patient Safety Evaluation System (PSES)

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



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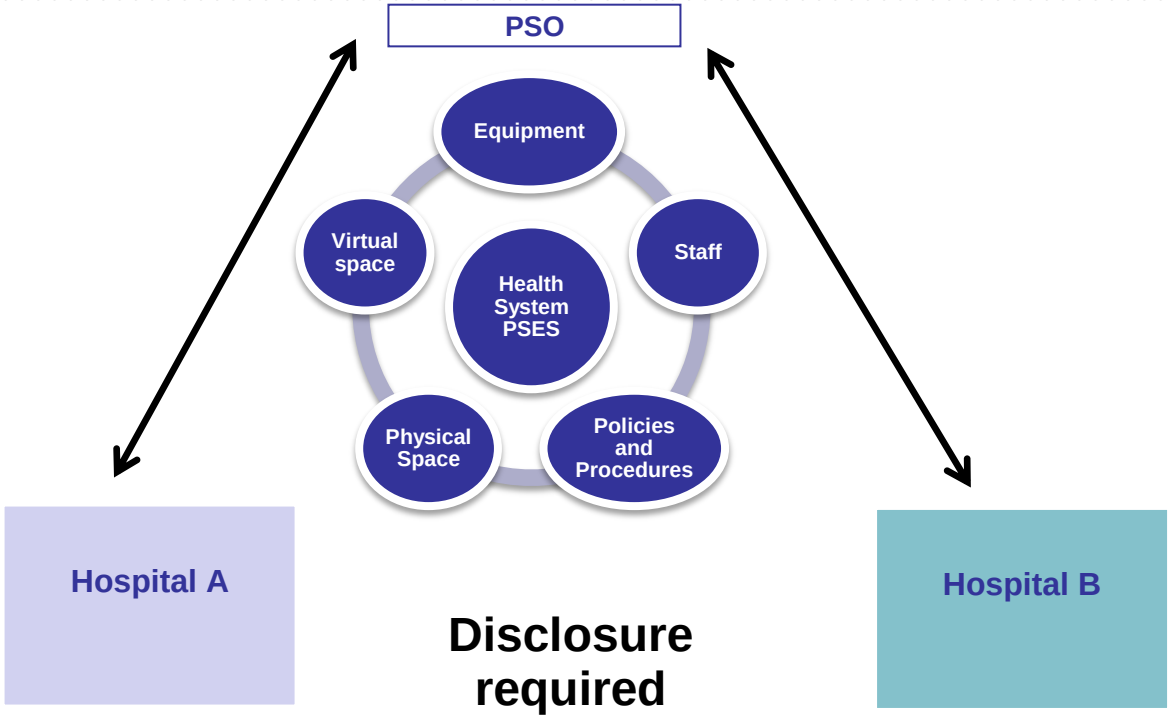
Patient Safety Evaluation System (PSES)

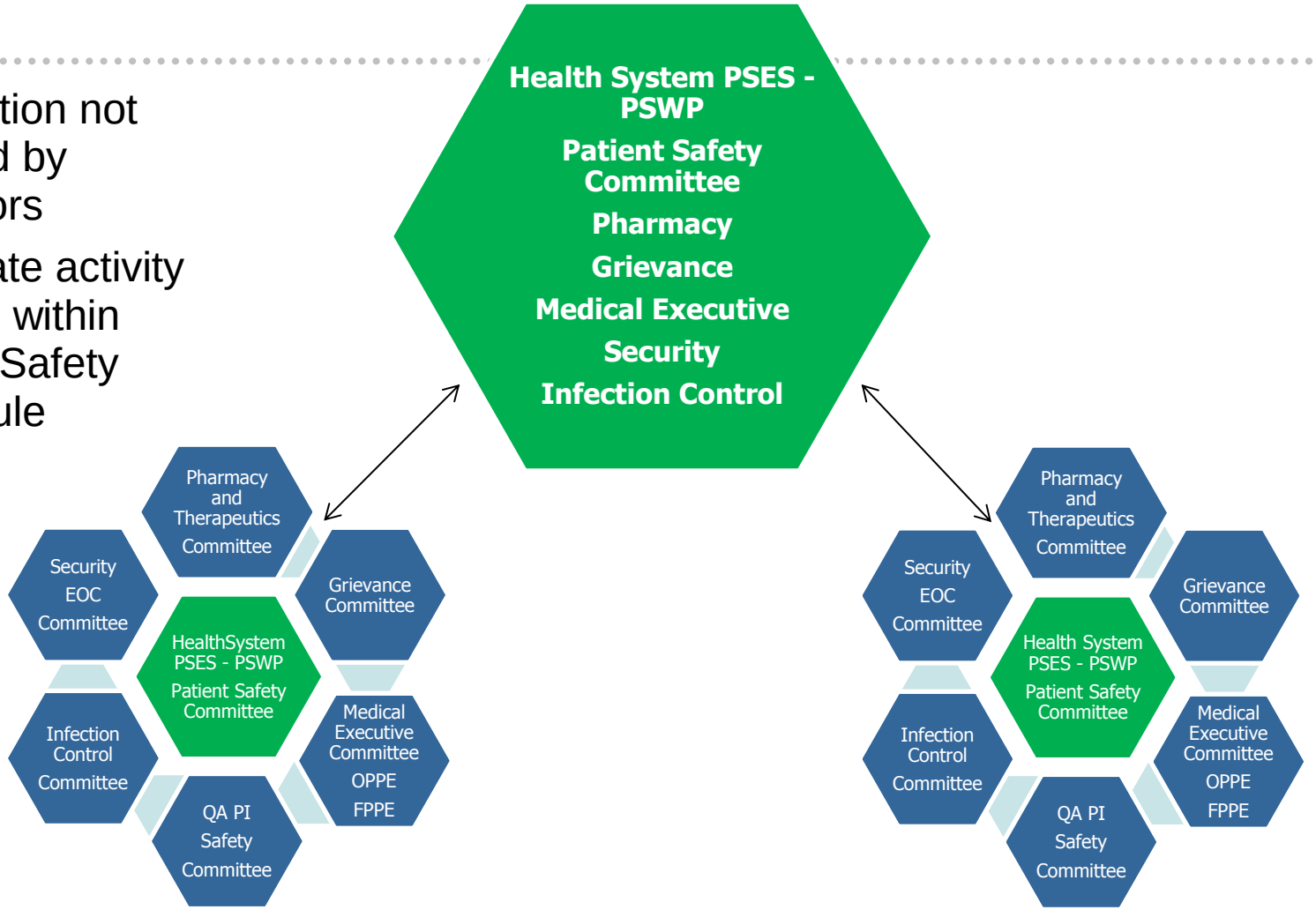
- Or permits the sharing of patient safety work product as a patient safety activity among affiliated providers.

Will Sharing PSWP across affiliated providers inhibit learning culture?



Centralized PSES Model

- Information not required by regulators
- Corporate activity may fall within Patient Safety Final Rule



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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

Key Steps, Terms and Requirements

- 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)

- 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)

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)

- 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."

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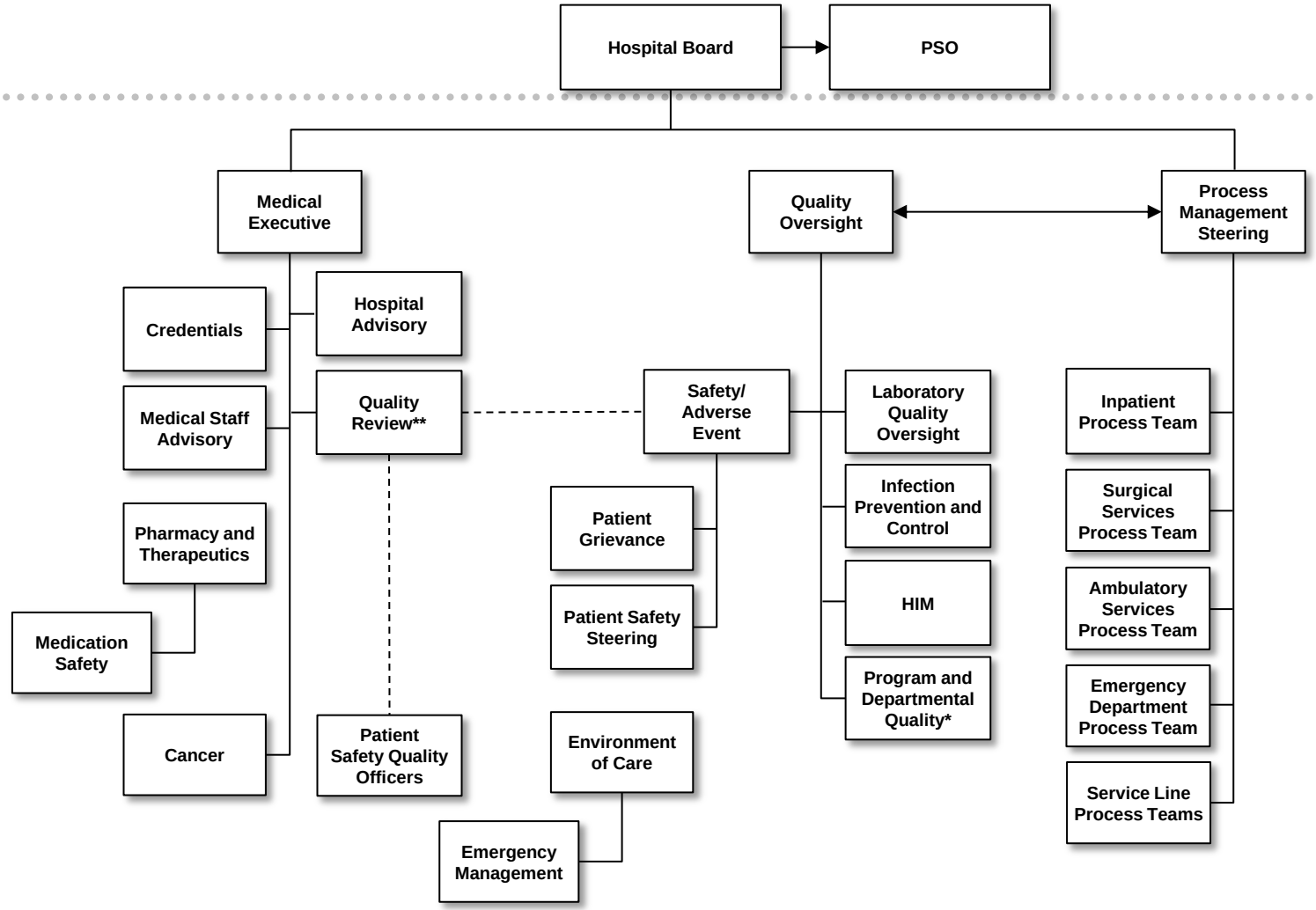
Key Steps, Terms and Requirements (cont'd)

- 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.

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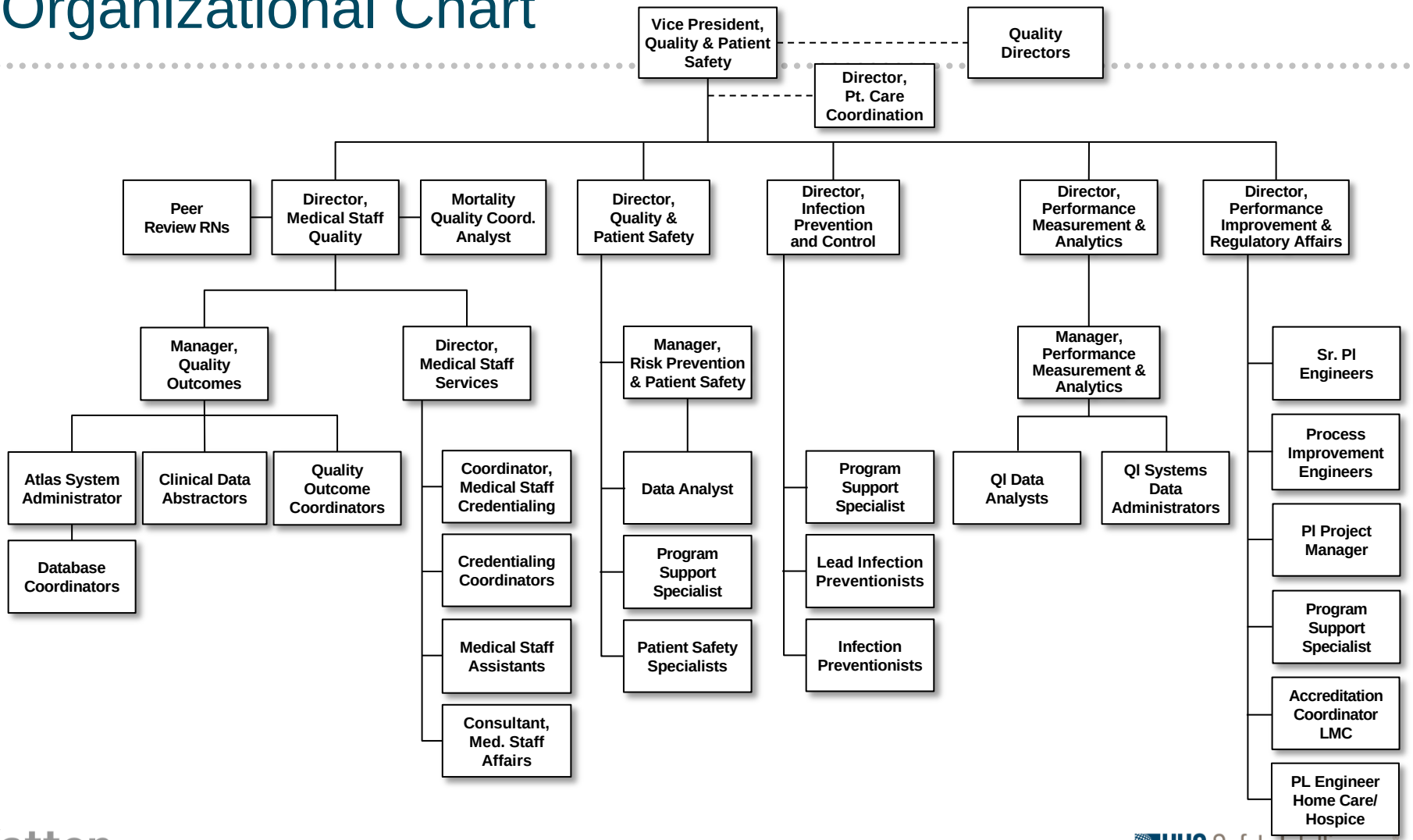
QUALITY AND PATIENT SAFETY

Organizational Chart



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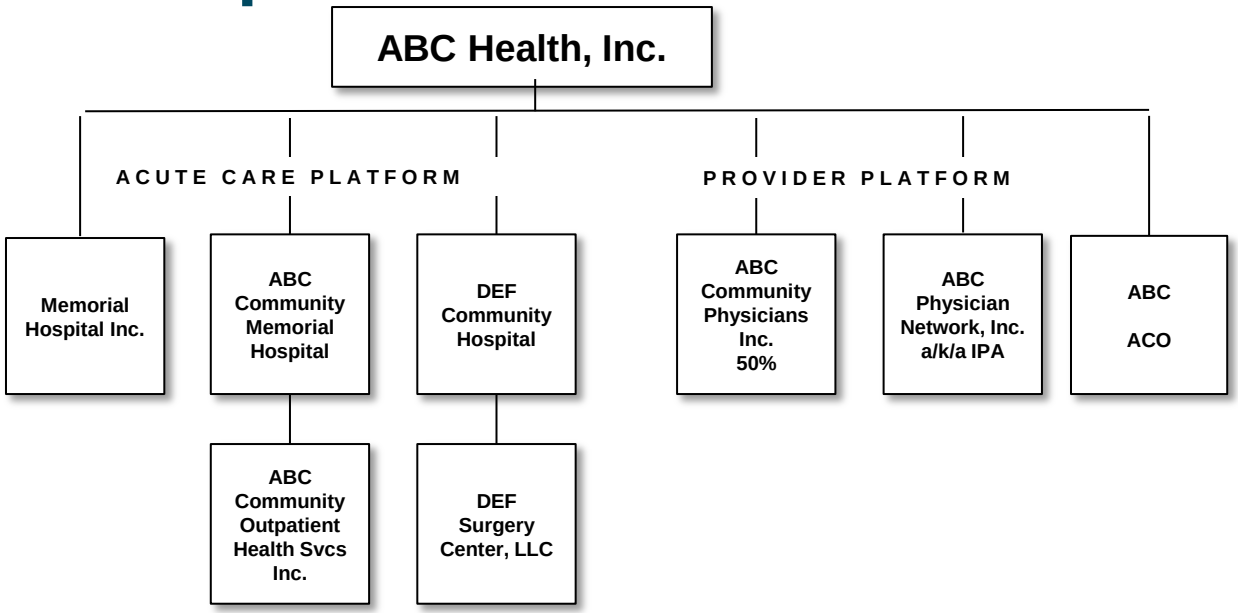
Health System Corporate Structure



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%

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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

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Key Take Aways

- 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)

- 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)

- 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 thirty party

QUESTIONS

Katten's Health Care Practice

- 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

- 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 PSOs and members via Safe Tables, in person meetings, and webinars
- Click here to view the PSES Checklist

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