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What Every Medical Services Professional Needs to Know About Patient Safety Organizations

Michael R. Callahan
Katten Muchin Rosenman LLP
+1.312.902.5634
michael.callahan@kattenlaw.com

Speaker Bio

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 is the immediate past 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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What Every Medical Services Professional Needs to Know about Patient Safety Organizations

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?

What Every Medical Services Professional Needs to Know about Patient Safety Organizations(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?

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

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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.

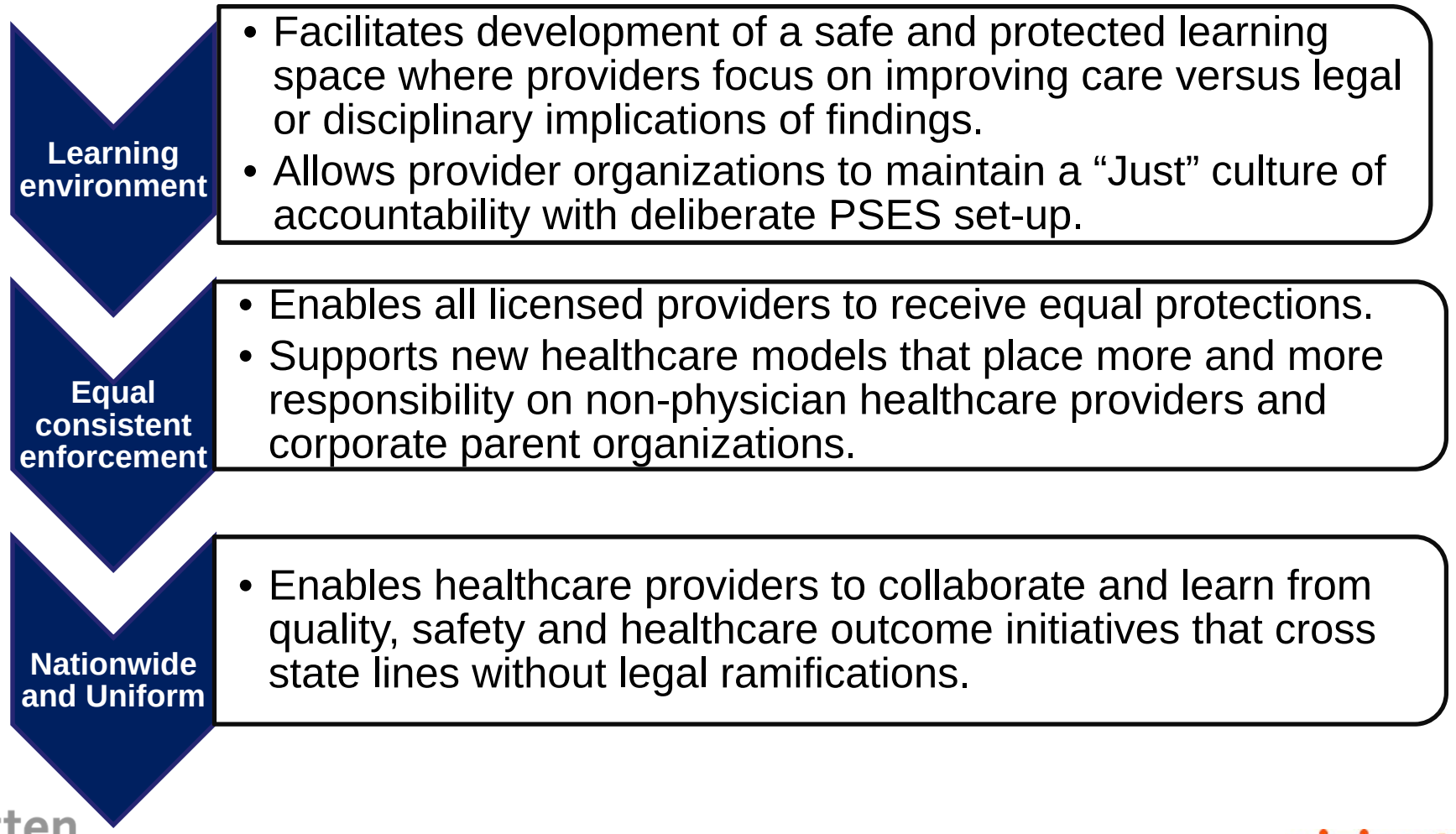
The Patient Safety and Quality Improvement Act of 2005

- 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



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Patient Safety Act

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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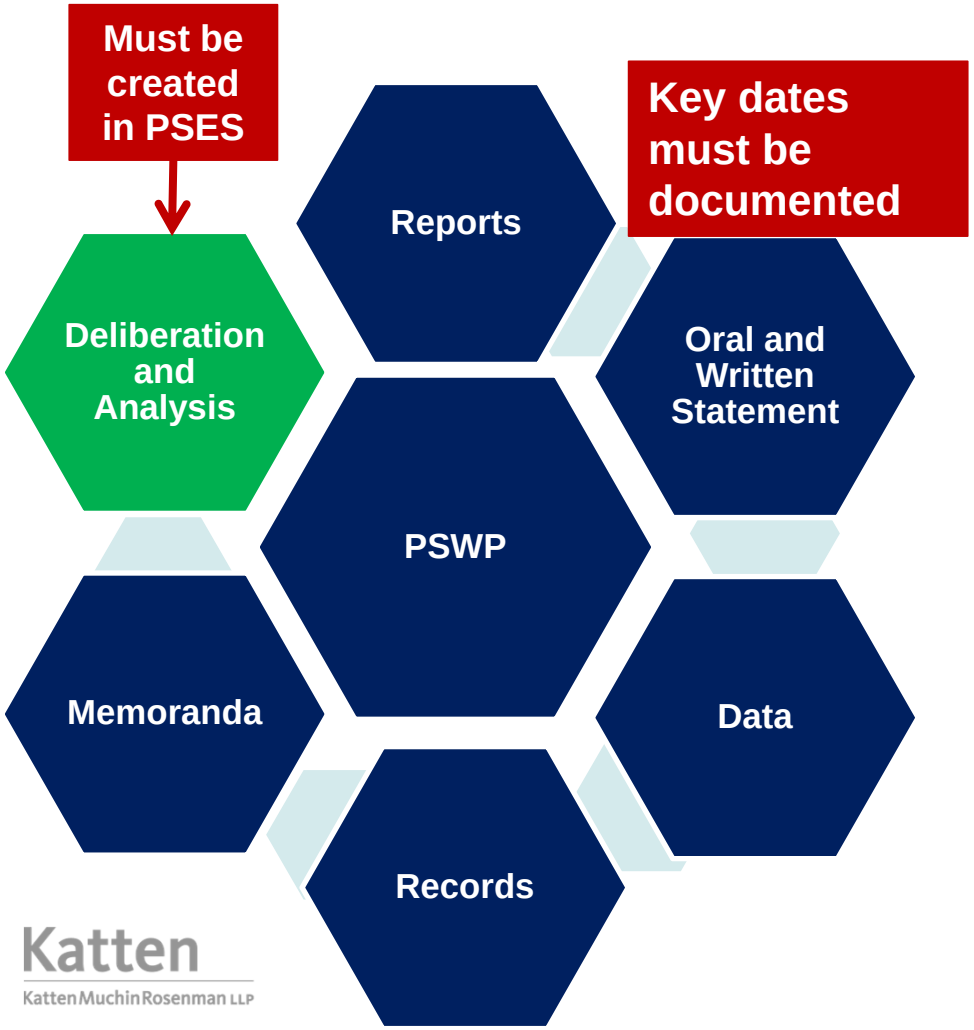
Patient Safety Activities

- 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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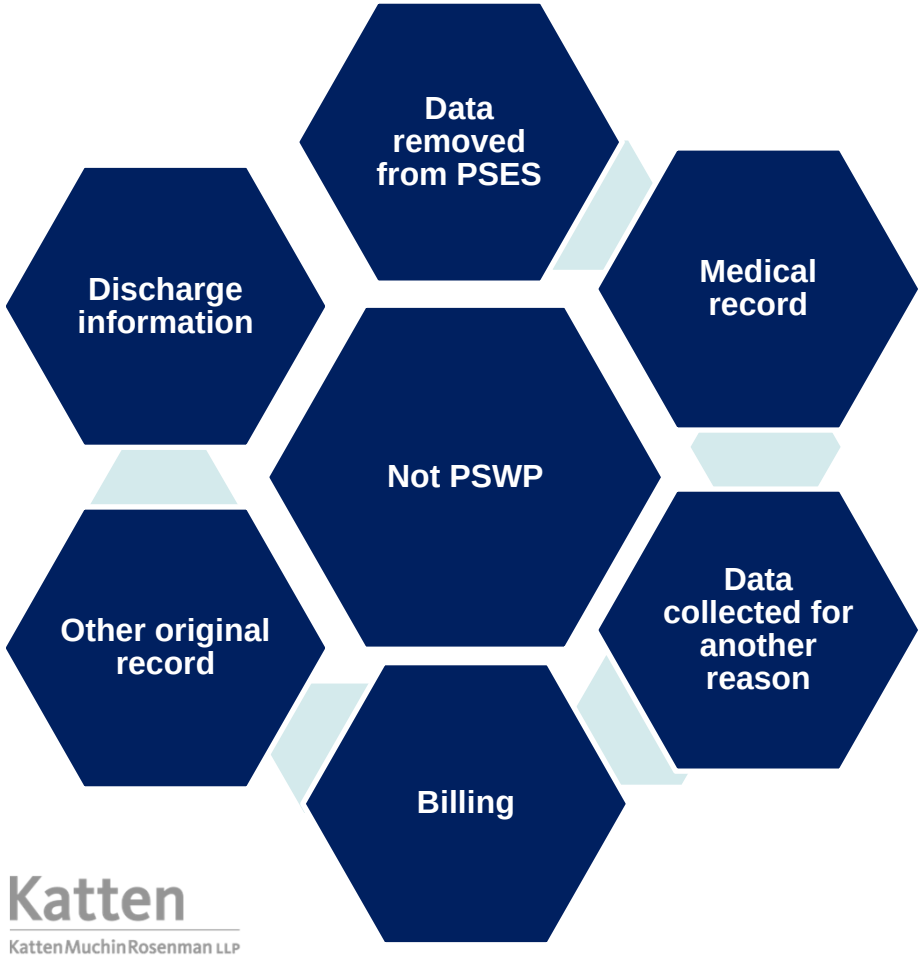
What is Not PSWP?



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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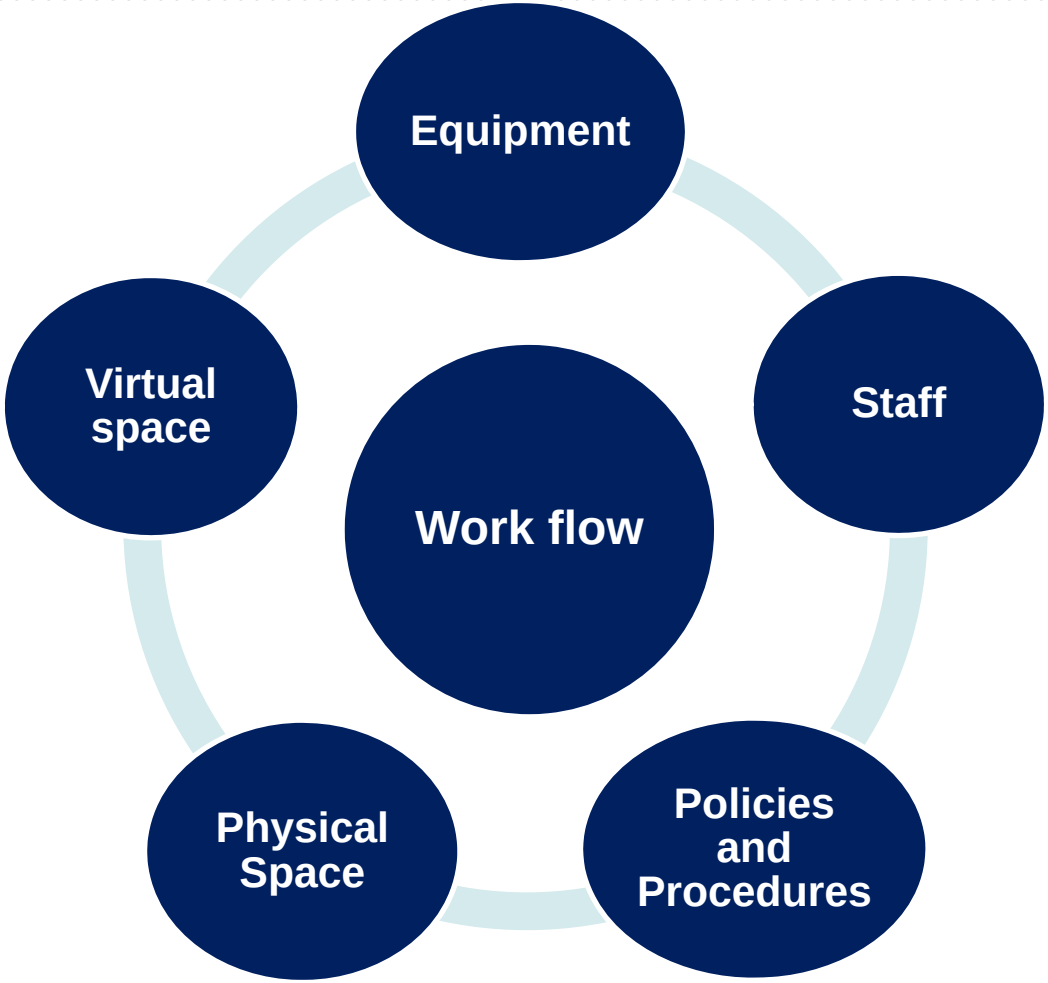
Patient Safety Evaluation System (PSES)

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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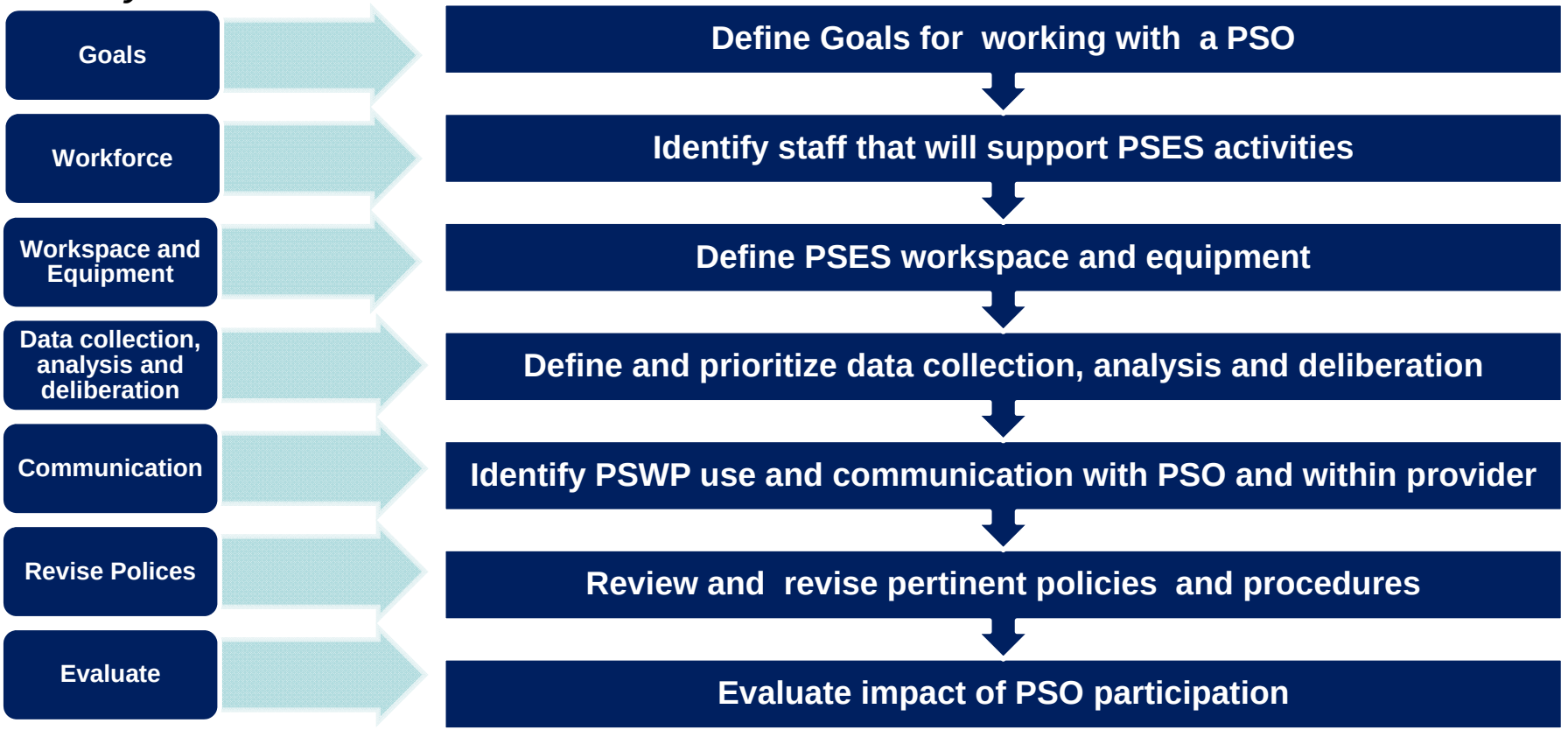
PSES Operations (cont'd)

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)

UHC Safety Intelligence Patient Safety Organization

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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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

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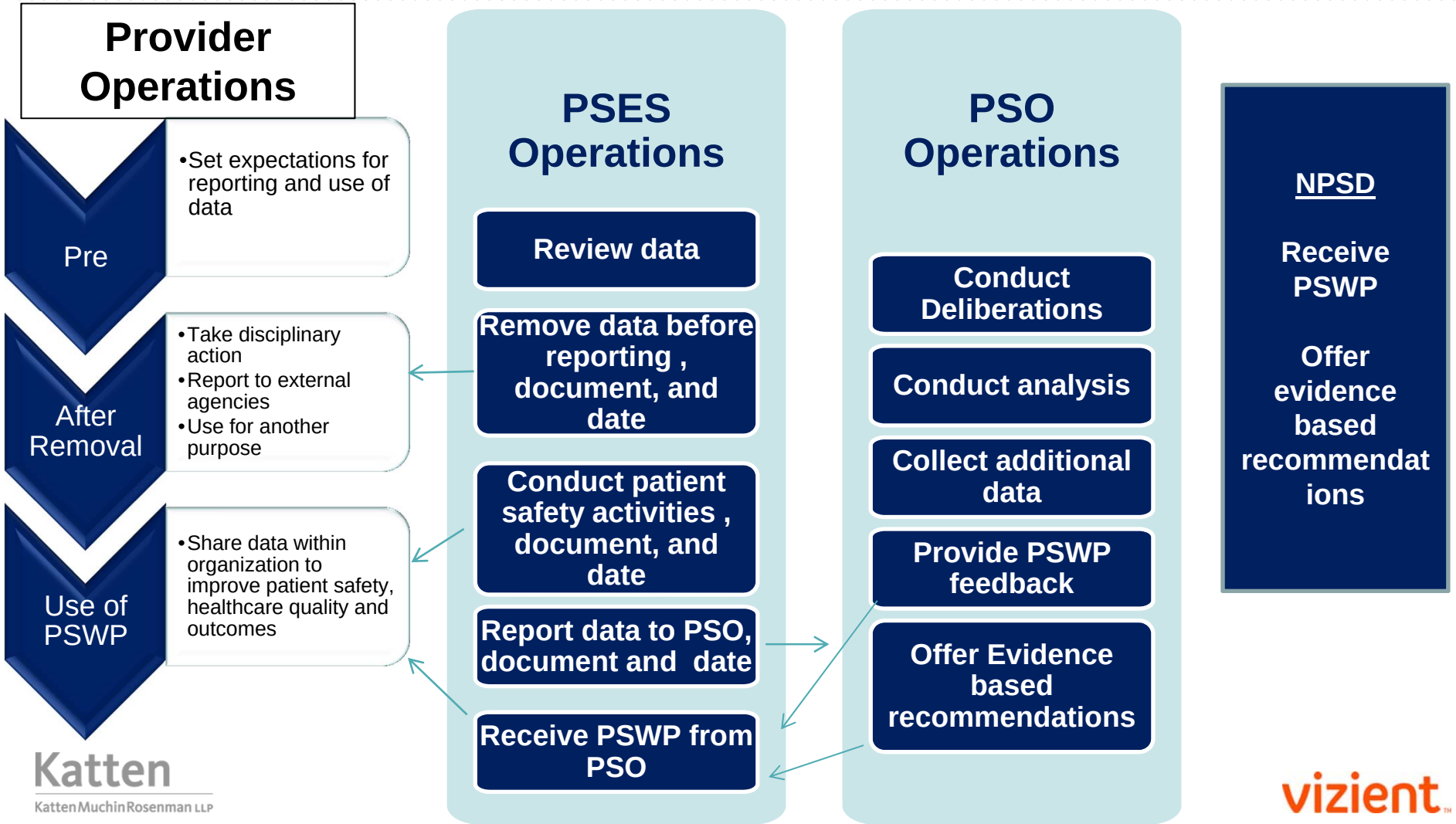
Drop-Out Provision

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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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

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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

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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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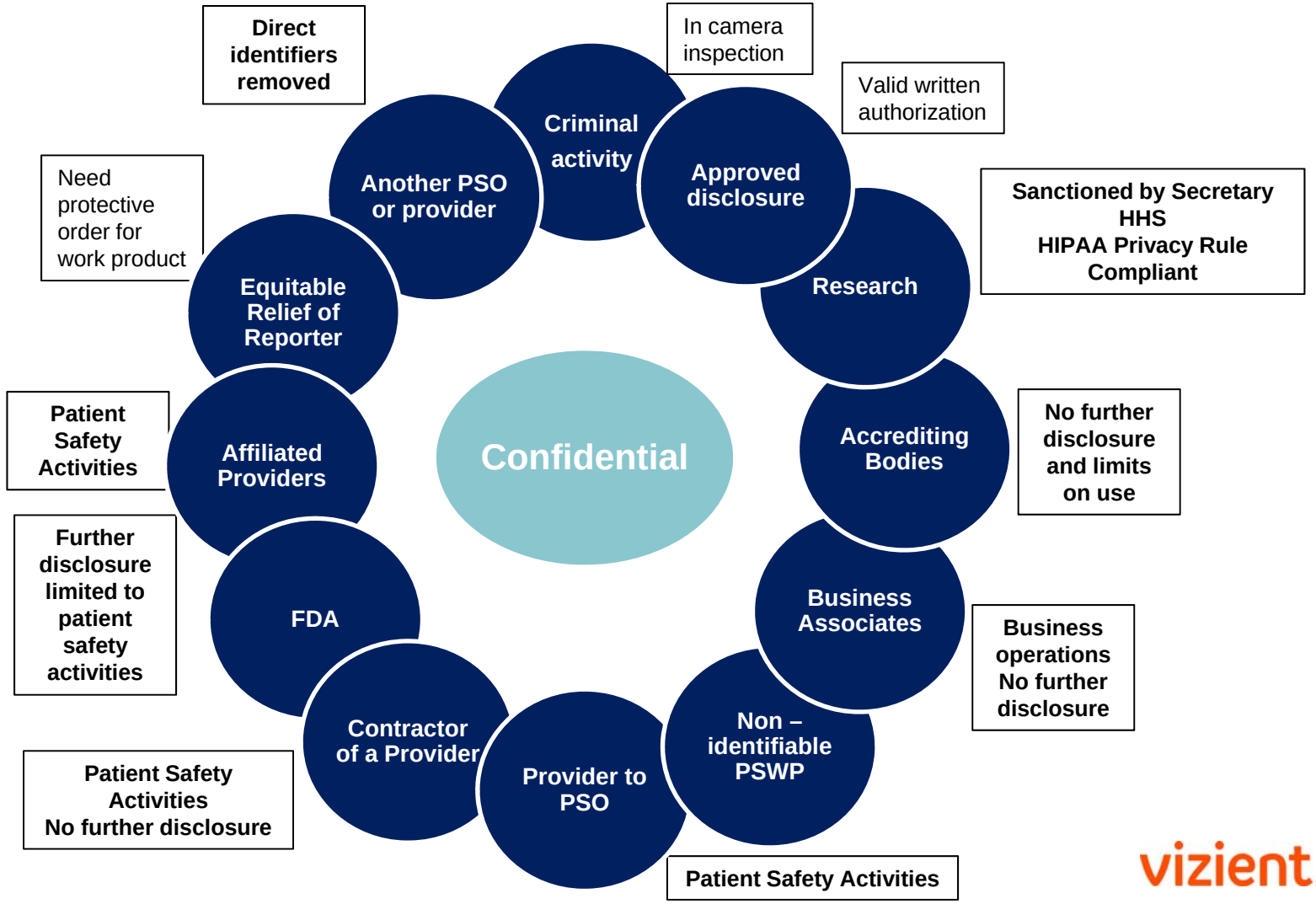
PSWP is confidential and not subject to disclosure with limited exceptions

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
- Mandated reports

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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)

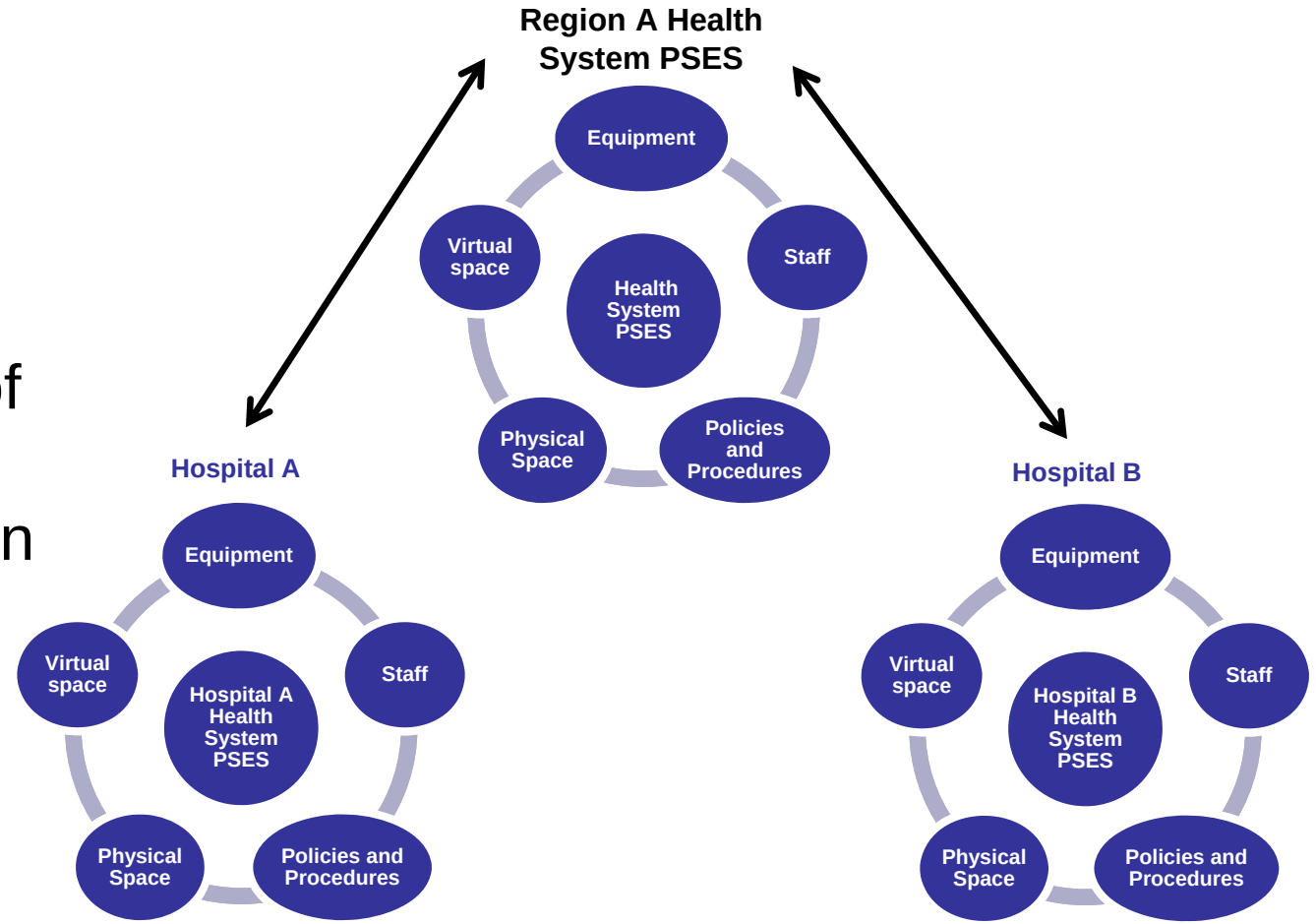
- Health System may require facilities and/or providers to report to a designated PSO.
- A patient safety event reporting requirement can be consistent with the statutory goal of encouraging organizational providers to develop a protected confidential sphere for examination of patient safety issues.

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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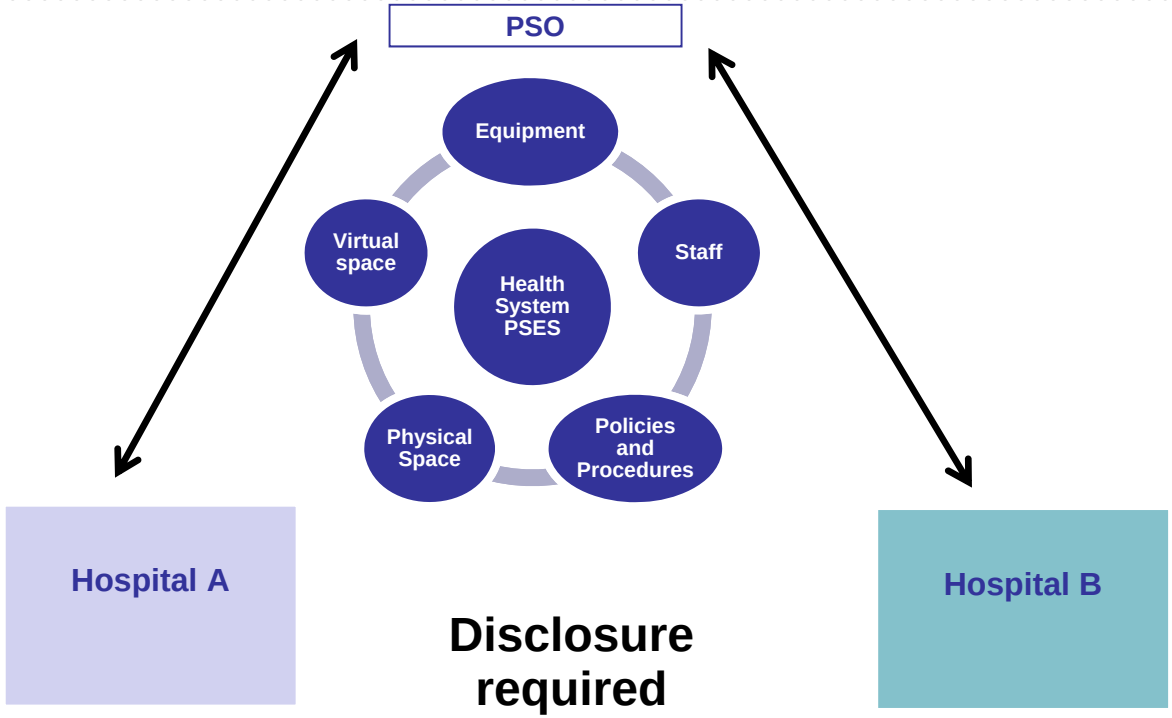
Patient Safety Evaluation System (PSES)

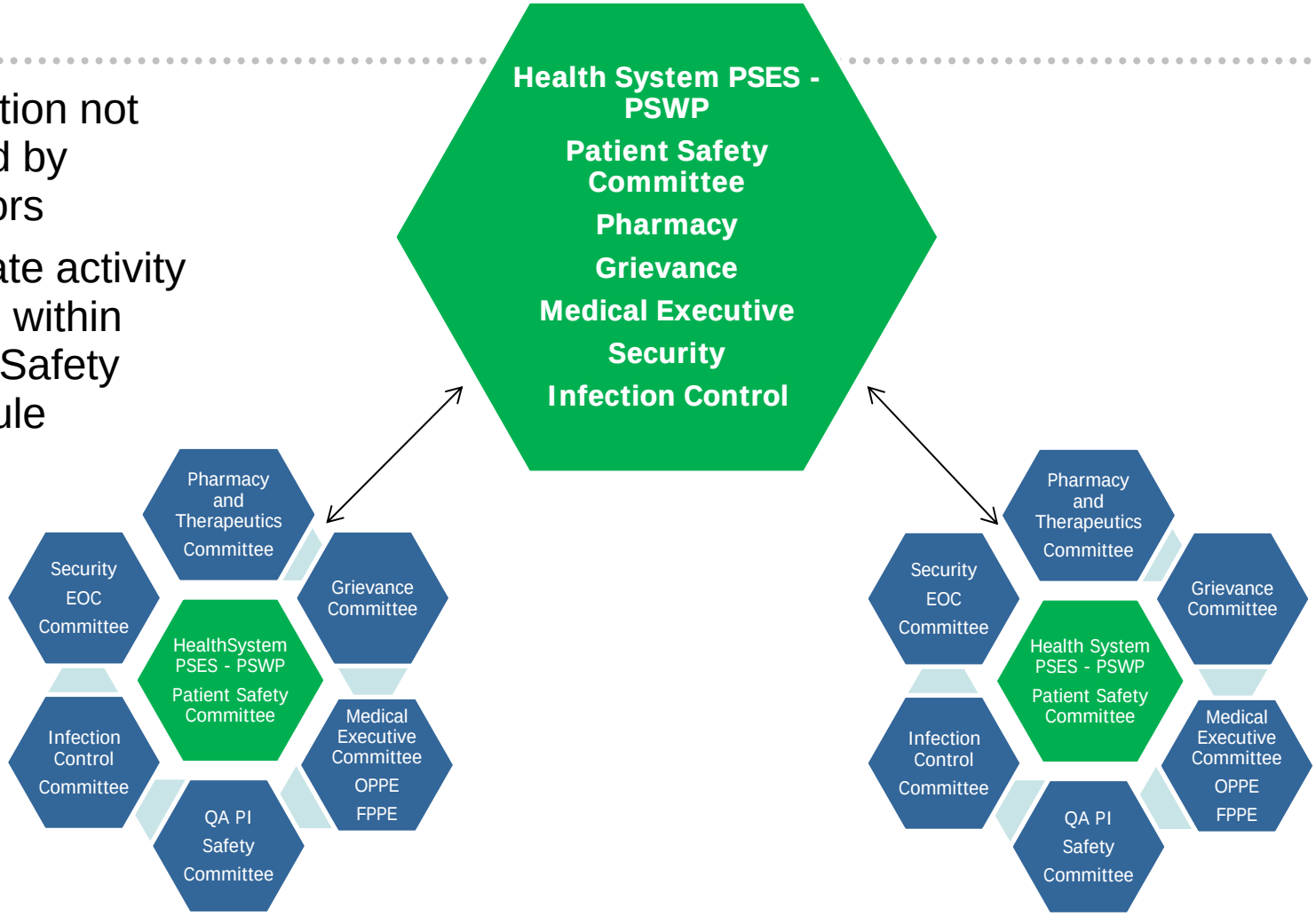
- Or permits the sharing of patient safety work product as a patient safety activity among affiliated providers.

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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QUESTIONS

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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

Katten Muchin Rosenman LLP Locations

AUSTIN
One Congress Plaza
111 Congress Avenue
Suite 1000
Austin, TX 78701-4073
+1.512.691.4000 tel
+1.512.691.4001 fax

CHARLOTTE
550 South Tryon Street
Suite 2900
Charlotte, NC 28202-4213
+1.704.444.2000 tel
+1.704.444.2050 fax

CHICAGO
525 West Monroe Street
Chicago, IL 60661-3693
+1.312.902.5200 tel
+1.312.902.1061 fax

HOUSTON
1301 McKinney Street
Suite 3000
Houston, TX 77010-3033
+1.713.270.3400 tel
+1.713.270.3401 fax

IRVING
545 East John Carpenter Freeway
Suite 300
Irving, TX 75062-3964
+1.972.587.4100 tel
+1.972.587.4109 fax

LONDON
125 Old Broad Street
London EC2N 1AR United Kingdom
+44.0.20.7776.7620 tel
+44.0.20.7776.7621 fax

LOS ANGELES – CENTURY CITY
2029 Century Park East
Suite 2600
Los Angeles, CA 90067-3012
+1.310.788.4400 tel
+1.310.788.4471 fax

LOS ANGELES – DOWNTOWN
515 South Flower Street
Suite 1000
Los Angeles, CA 90071-2212
+1.213.443.9000 tel
+1.213.443.9001 fax

NEW YORK
575 Madison Avenue
New York, NY 10022-2585
+1.212.940.8800 tel
+1.212.940.8776 fax

ORANGE COUNTY
100 Spectrum Center Drive
Suite 1050
Irvine, CA 92618-4960
+1.714.966.6819 tel
+1.714.966.6821 fax

SAN FRANCISCO BAY AREA
1999 Harrison Street
Suite 700
Oakland, CA 94612-4704
+1.415.293.5800 tel
+1.415.293.5801 fax

SHANGHAI
Suite 4906 Wheelock Square
1717 Nanjing Road West
Shanghai 200040 P.R. China
+86.21.6039.3222 tel
+86.21.6039.3223 fax

WASHINGTON, DC
2900 K Street NW
North Tower - Suite 200
Washington, DC 20007-5118
+1.202.625.3500 tel
+1.202.298.7570 fax

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www.kattenlaw.com