

# Katten



## **Patient Safety Act Fundamentals and Policies**

### **2024 LONL Annual Meeting New Orleans, LA**

**Michael R. Callahan, Senior Counsel**  
Katten Muchin Rosenman LLP  
312.902.5634  
[michael.callahan@katten.com](mailto:michael.callahan@katten.com)  
<https://katten.com/Michael-Callahan>

March 28, 2024

The background is a solid blue color with a faint, semi-transparent image of a white lab coat and a stethoscope. Overlaid on this are several hexagonal icons representing various medical concepts: a microscope, a camera, a water drop, a pill, a stethoscope, a globe, a virus, a wheelchair, a cross, and a molecular structure. The word "MEDICAL" is repeated in a light blue font within several of these hexagons.

# Purpose of the PSQIA

# PSQIA Purpose

- The Patient Safety Act focuses on creating a voluntary program through which health care providers can share information relating to patient safety events with PSOs with the aim of improving patient safety and quality of care nationwide.
- The Statute attaches privileged and confidentiality protections to this information without fear of liability, and creates PSOs to receive this protected information and analyze patient safety events.
- These protections will enable all health care 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 providers.
- Protections apply in all state and federal proceedings.

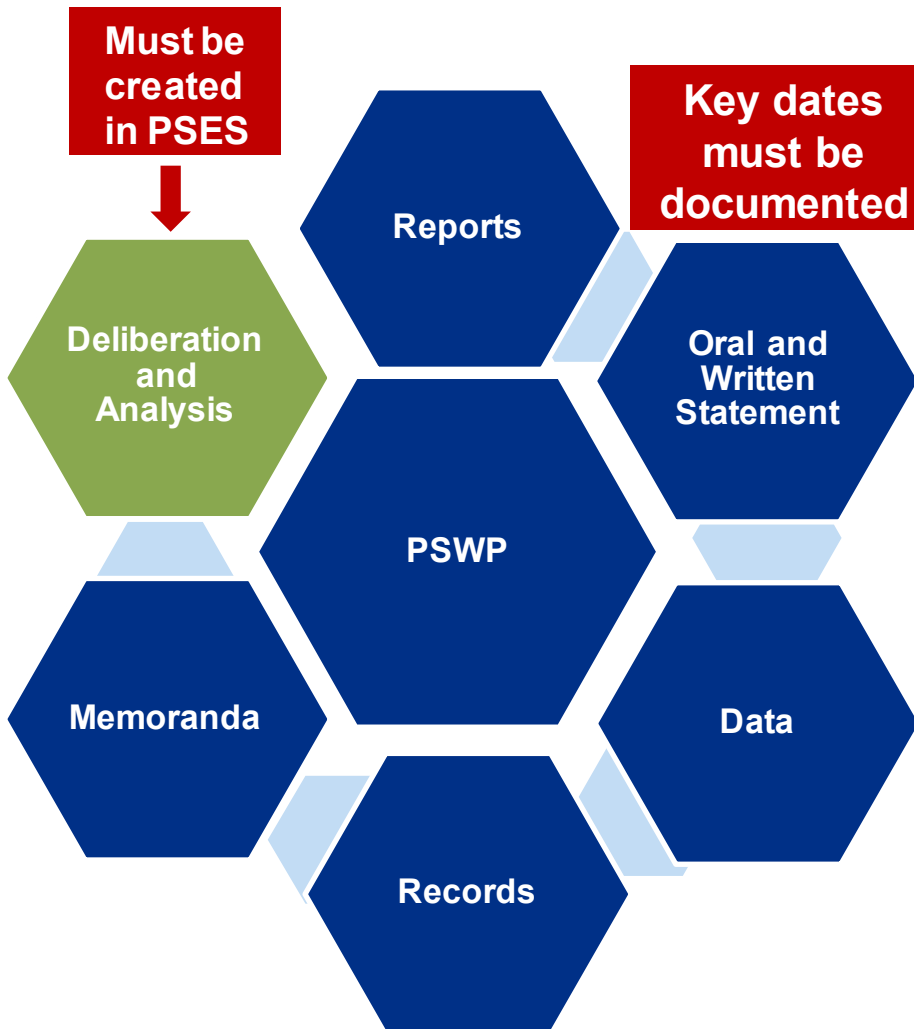


# PSQIA Overview

# Patient Safety Work Product

- Privileged Patient Safety Work Product
  - Any data, reports, records, memoranda, analyses (such as Root Cause Analyses (RCA)), or written or oral statements (or copies of any of this material) which could improve patient safety, health care quality, or health care outcomes;
- And that:
  - Are assembled or developed by a provider for reporting to a PSO and are reported to a Patient Safety Organization (PSO), which includes information that is documented as within a patient safety evaluation system (PSES) for reporting to a PSO, and such documentation includes the date the information entered the PSES; or
  - Are developed by a PSO for the conduct of patient safety activities; or
  - Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES.

# 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

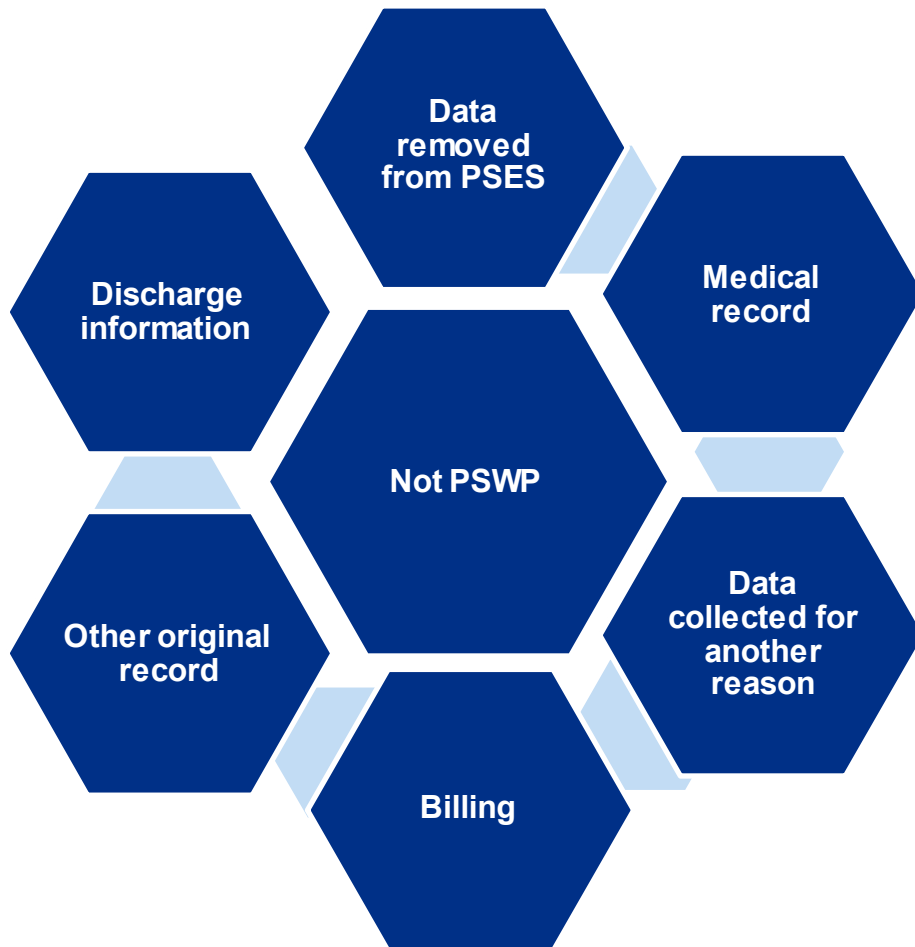
Analysis and deliberations conducted within a PSES

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

# What Is Not PSWP?

- What is not PSWP?
  - Patient's medical record, billing and discharge information, or any other original patient or provider information
  - Information that is collected, maintained, or developed separately, or exists separately, from a PSES. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered PSWP
  - PSWP assembled or developed by a provider for reporting to a PSO but removed from a PSES is no longer considered PSWP if:
    - Information has not yet been reported to a PSO; and
    - Provider documents the act and date of removal of such information from the PSES
  - Reports that are the subject of mandatory or federal reporting or which must be collected and maintained pursuant to state or federal laws should not be treated as PSWP

# What Is Not PSWP?



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

Mandated reports



# Provider Entities That Are Covered Under The Act

- All entities or individuals licensed under state law to provide health care services or which the state otherwise permits to provide such services, i.e., hospitals, SNFs, physicians, physician groups, labs, pharmacies, home health agencies, etc.
- A non-licensed corporate entity that owns, controls, manages or has veto authority over a licensed provider is considered a provider.



# Patient Safety Activities

- Patient safety activities mean the following activities carried out by or on behalf of a PSO or a provider:
  - 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.
  - The maintenance of procedures to preserve confidentiality with respect to patient safety work product.

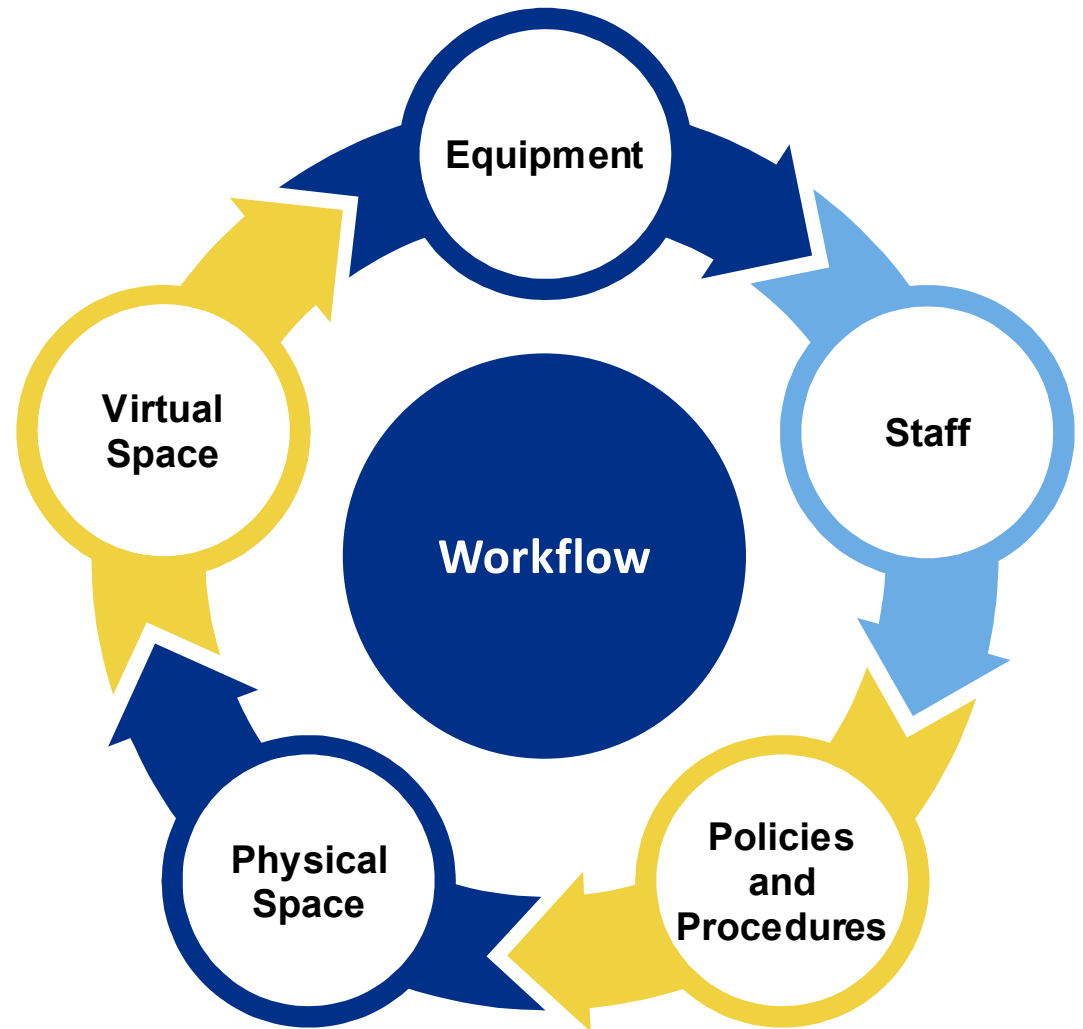
# Patient Safety Activities

- The provision of appropriate security measures with respect to patient safety work product.
- The utilization of quality staff.
- 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.



# 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.



# PSES Operations

## **Establish and Implement a PSES to:**

- Inventory all reports, analyses, committees, etc., involved in any and all patient safety activities as a PSES starting point
- Collect data to improve patient safety, healthcare quality and health care outcomes – must document date of collection
- Review data and take action when needed to mitigate harm or improve care
- Analyze data and make recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes
- Conduct proactive risk assessments, in-depth reviews, and aggregate medication errors
- Determine which data will/will not be reported to the PSO and what will be treated as deliberations or analysis
- Report to PSO – must document date of report
- Conduct auditing procedures, adopt security measurements and enforce confidentiality policies

# Example PSES Patient Safety Activities

- What types of information can be considered for inclusion in the PSES for collection and reporting to the PSO if used to promote patient safety and quality and treated as PSWP?
  - Medical error or proactive risk assessments, root cause analysis
  - Risk Management — Not all activities will qualify such as claims and litigation management, but incident reports, investigation notes, interview notes, RCA notes, etc., tied to activities within the PSES can be protected
  - Outcome/Quality—may be practitioner specific
  - Peer review
  - Relevant portions of Committee minutes for activities included in the PSES relating to improving patient quality and reducing risks
  - Deliberations or analysis
  - Incident/adverse event reports

# Affiliated Provider

- Affiliated provider means, with respect to a provider means:
  - A legally separate provider that is the parent organization of the provider.
  - Is under common ownership, management, or control with the provider.
  - Or is owned, managed or controlled by the provider.



# Patient Safety Act Privilege and Confidentiality Protections Prevail Over State Law Protections

## State Peer Review

- Limited in scope of covered activities and in scope of covered entities
- State law protections do not apply to federal claims
- State laws usually do not protect information when shared outside the institution – considered waived
- Statutes require that privileged information be generated by a defined peer review committee

## 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 healthcare system
- PSES can include non-provider corporate parent
- Protections not limited to peer review committee activity

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



# Disclosure

- Disclosure means the release, transfer, provision of access to or divulging in any other manner of patient safety work product by:
  - An entity or natural person holding the PSWP to another legally separate entity or natural person, other than a work force member of, or a health care provider holding privileges, with the entity holding PSWP or
  - A component PSO to another entity or natural person outside the component PSO and within the legal entity of which the component PSO is a part.



# Use

- The use and distribution or sharing of PSWP within a single entity or a health care provider holding privileges with the entity holding the PSWP for any legitimate business or other purpose



# PSES Policy Development

- **Develop Both a Specific and Broadly Worded PSES policy**
  - One of the fundamental documents for internal educational purposes as well as to be introduced to a court in demonstrating that the materials in dispute are indeed PSWP is a provider's PSES policy.
  - The courts are not going to simply accept the word of the hospital or other provider that information qualifies as PSWP.
  - The provider should conduct an inventory of all of its performance improvement, quality assurance, peer review and other related patient activities as well as the various committees, reports and other analyses being conducted within the organization.
  - This is the starting point when determining the scope of activities you wish to include within the PSES and therefore claim as privileged PSWP.
  - The details of these activities and the information to be protected should be reflected within the PSES.

# PSES Policy Development

- When seeking to claim privilege protections over an incident report, committee minutes or other internal analysis, a provider can then cite to the specific reference within the PSES as evidence of the hospital's intent to treat this information as PSWP.
- The provider should also include the phrase “including but not limited to” a “catch all” to account for other privileged patient safety activities in the PSES policy.
- PSES Policy needs to be updated annually.
- May want to cross-reference to related policies.
- **Carefully Describe Your PSWP Pathway**
  - A provider can create PSWP via actual reporting, functional reporting or through deliberations or analysis.
  - It is critical that your PSES policy distinguish which forms of information, incident reports, etc., are being actually reported to the PSO or scanned and downloaded and reported and what forms of information are being treated as deliberations or analysis.

# PSES Policy Development

- As a practical matter, most patient safety activities can be characterized as deliberations or analysis.
- Information that is deliberations or analysis automatically becomes PSWP when collected within the PSES and does not need to be reported to the PSO although reporting is certainly an option.
- Rumsey v. Guthrie is the first “deliberations or analysis” decision.
- Keep in mind too, that information which is being treated as deliberations or analysis cannot be “dropped out” and used for other purposes but can be shared if you meet one or more of the disclosure exceptions. These include disclosing to consultants, your attorney, and independent contractors that are assisting the hospital in patient safety activities and other disclosures permitted under the PSA.

# Example Health System PSES

## What Comprises the System's Patient Safety Evaluation System (PSES)?

- The PSES includes the collection, management and/or analysis of Patient Safety Concern information recorded in the System's Event Reporting System (ERS) for reporting to a PSO. **It includes information documented in the ERS and also deliberation and analysis of a Patient Safety Concern.**

—A Patient Safety Concern includes:

- A patient safety event that reached the patient, whether or not there was harm;
- A near miss or close call - a patient safety event that did not reach the patient; or
- An unsafe condition - circumstances that increase the probability of a patient safety event.

# Example Health System PSES

— It may also include all activities, communications and information reported to or developed by individuals or committees, such as data analyses, Root Cause Analyses, outcome reports and minutes, for the purpose of improving patient safety and/or healthcare quality

## Creation of PSWP

- PSWP is created automatically upon filing an event report in the ERS that involves a Patient Safety Concern. All Patient Safety Concern information is collected and/or developed with the intent to report to the PSO.
- If so designated by Authorized Staff, PSWP may encompass the data collection efforts leading up to making the Event report. The date of entry into the PSWP is the date these activities occur.

# Example Health System PSES

- **PSWP is created when deliberations and analysis (D or A) related to a Patient Safety Concern is conducted.** The date of entry into the PSES is the date these activities occur. **PSWP protections will apply immediately. Deliberations and analysis cannot be de-designated as PSWP. Documents included in this category include but are not limited to:**
  - Failure Mode Effects Analysis (FMEA)
  - Root Cause Analysis (RCA) not otherwise reported in the ERS
  - Data analysis reports & comparative outcomes
  - Patient Safety Committee minutes
  - Quality Improvement Committee minutes



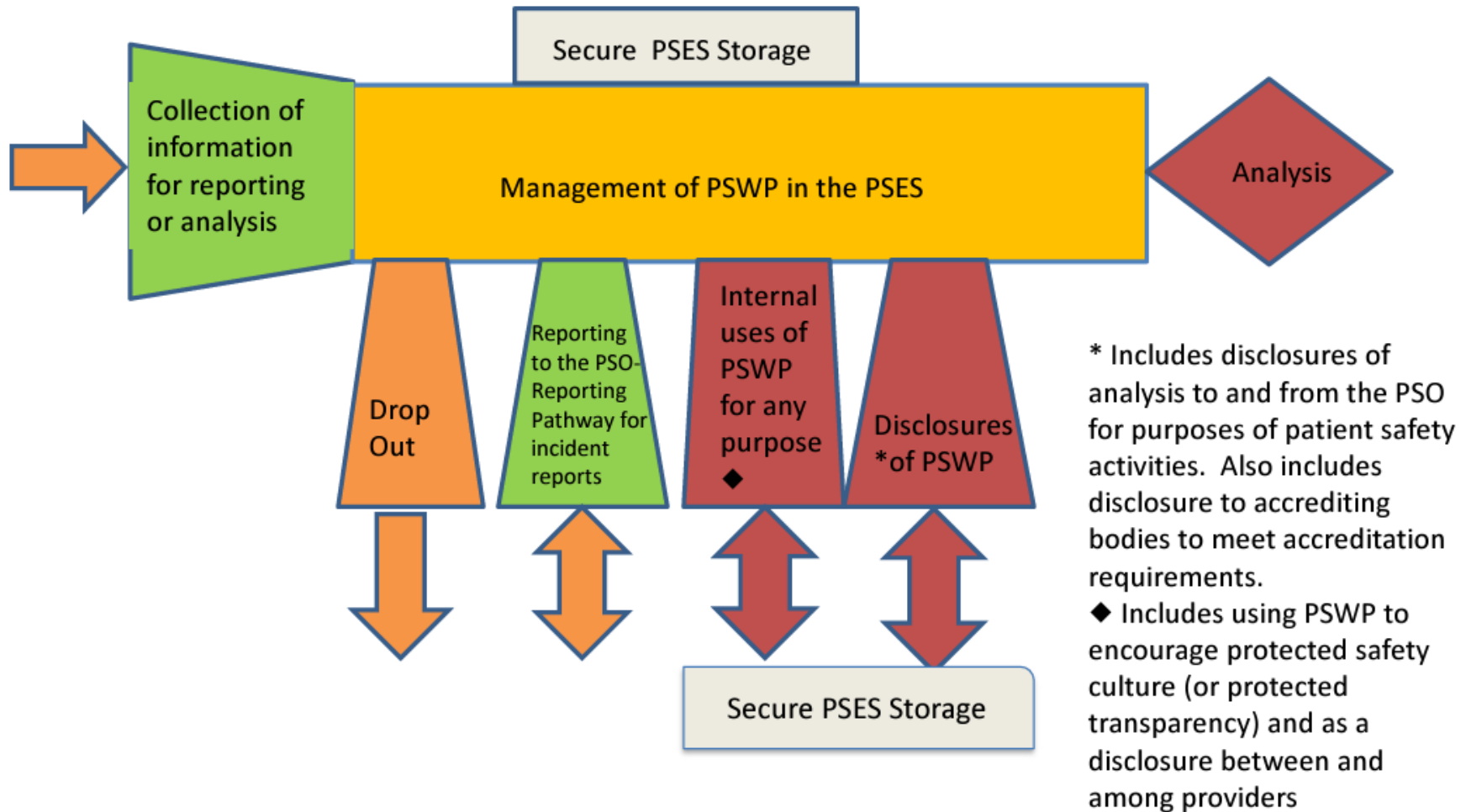
# Example Health System PSES

- Patient Safety Activities

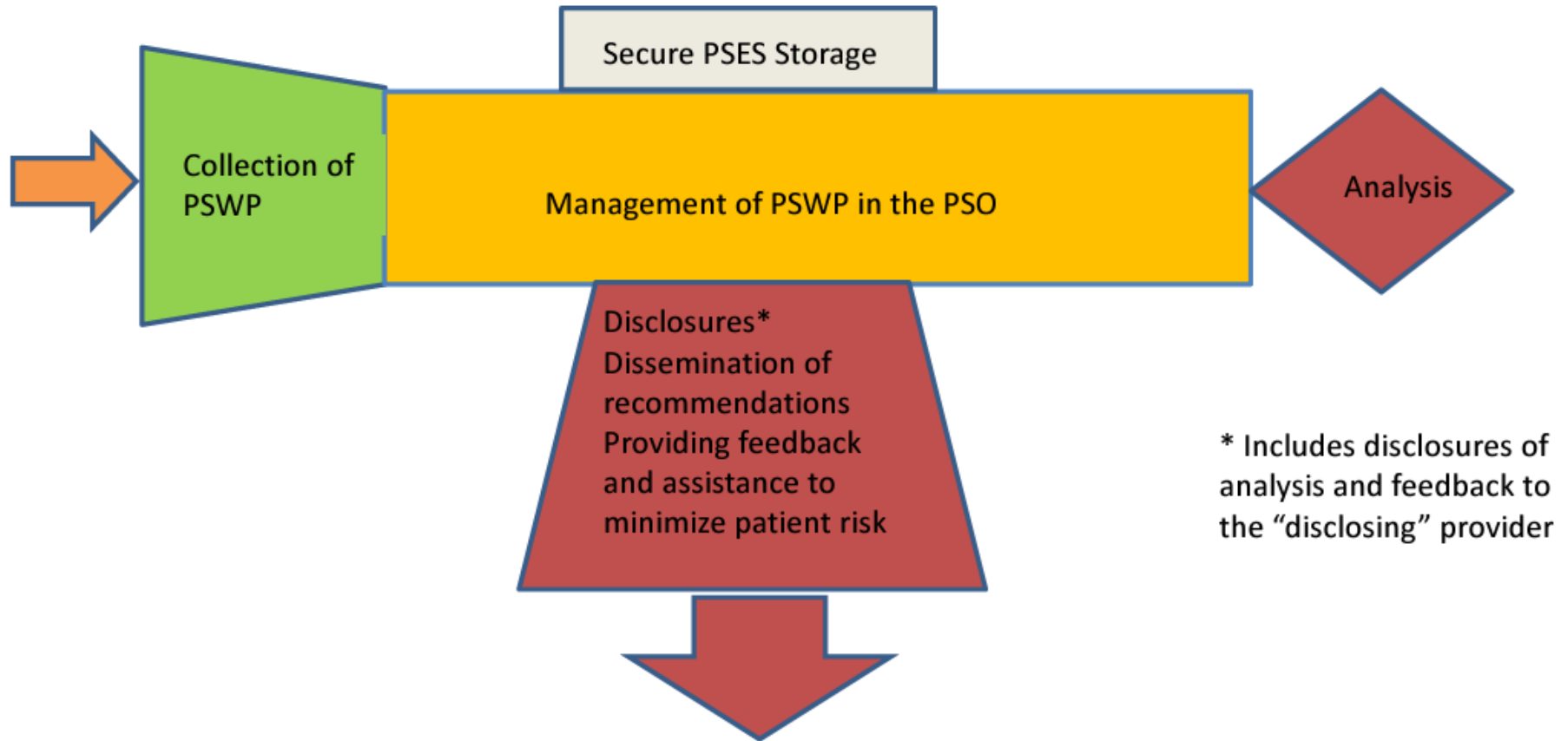
—Patient Safety Activities may be conducted by any individual, committee or body that has assigned responsibility for any such activities. The workforce includes faculty, staff, trainees, volunteers, and contractors who perform work under the direct control of the health system. Committees include but are not limited to:

- Patient Safety Committees
- Clinical Performance Improvement Committees
- Risk Management Committees
- Chief Medical Officers/Chief Nursing Officers
- OP Risk Services and/or Committees
- Audits and Compliances Committee
- Quality Improvement Committees
- Medication Safety Committees
- Health System Services Committee
- Center for Healthcare Quality Innovation
- OP Data Management System
- Other committees with jurisdiction

# Provider PSES



# PSO PSES



# What is “Peer Review”?

- Efforts to improve patient care and reduce morbidity or mortality
- Tracking, investigating and managing unacceptable behavior identified in Code of Conduct - Disruptive Behavior Policies
- Physician wellness evaluations and activities
- Evaluating healthcare providers regarding performance, skill, technique, competence, utilization and compliance with hospital and medical staff bylaws, rules, regulations and policies
- Review and establishment of standards of care
- Analyses undertaken for the purpose of reducing the risk of harm
- Peer review investigations and hearings

# What is “Peer Review”?

- All of the discussions, analyses and work product produced by these patient safety activities
- Nursing Peer Review
- OPPE/FPPE
- “Just Culture” efforts

# Use of PSWP in Peer Review Disciplinary Matters

- Under a “just culture” approach, the goal is to move away from the “blame game” and instead use other remedial measures to help the physician, advanced practice nurse and other healthcare providers to “get back on track” in order to improve the future delivery of patient care services.
  - Examples include use of an FPPE plan, concurrent/retrospective review of cases, collegial intervention, monitoring, proctoring and reeducation
- At some point, if all of these efforts fail, the hospital and medical staff may have no other alternative but to consider the use of disciplinary action which, if approved by the Board of Directors, may result or require a report to the National Practitioner Data Bank or to the state.
- But can peer review PSWP be used for disciplinary actions?

# Use of PSWP in Peer Review Disciplinary Matters

- The short answer is Yes. The Preamble to the Patient Safety Act specifically points out that PSWP can be used for this purpose.
- But
  - Is this “use” consistent with Just Culture?
  - If anticipating that the healthcare provider will sue if the recommended disciplinary action is upheld, you must keep in mind that PSWP cannot be introduced into any state or federal proceedings in order to defend the hospital’s actions.
  - The inability to introduce PSWP can both benefit the hospital, in the sense that the provider cannot discover or introduce PSWP into evidence to prove up a breach of contract, malicious interference, defamation or a discrimination action, but neither can the hospital introduce this privileged information—double-edged sword.

# Use of PSWP in Peer Review Disciplinary Matters

- But if not using PSWP in a disciplinary hearing, how does the hospital make a sufficient “evidentiary” record to support the disciplinary action? What are the options?
  - Repeat the internal, external reviews and other PSWP on which the disciplinary action was based outside of the PSES.
  - Rely on the “facts” and medical record and non-privileged information to support the adverse decision.
  - If the information supporting the disciplinary action utilized the reporting method of creating PSWP, hold onto the information and drop it out for use in disciplinary hearings and possible litigation.
  - Keep in mind that a state peer review privilege may apply which has the same consequences concerning non-discovery or non-admissibility into evidence.



# Use of PSWP for HR and Risk Management Purposes

- Remember the distinction between a “use” and a “disclosure”
  - PSWP can be used/shared for all internal purposes consistent with PSES and confidentiality requirements
  - An example of a permitted use is sharing PSWP with attorneys and accountants
  - PSWP, however, also can be used “outside of the PSES” but you should be able to document why such use is necessary in order to fulfill a business or related purpose
  - A “disclosure” is sharing PSWP to an unrelated third party which meets one of the permissible disclosure exceptions, i.e.:
    - Independent contractors
    - Accrediting bodies
    - Affiliated entities
    - From one PSO to another PSO

# Use of PSWP for HR and Risk Management Purposes

- PSWP which is disclosed under one or more of the permissible disclosure exceptions remains PSWP—the privilege is not waived
- Sharing PSWP with HR and risk management is considered a use and not a disclosure
- Important considerations
  - Must be able to establish that any PSWP which is shared with HR and/or risk management was developed for the purpose of improving patient care and not for employment or claims and litigation management purposes
  - Does HR and risk management really need access to PSWP whether identifiable or non-identifiable?
  - PSWP should not be placed in the employees HR File because
    - Employees are legally entitled to access all file materials

# Use of PSWP for HR and Risk Management Purposes

- PSWP is not subject to discovery or admissibility into evidence by any party. At some point therefore, hospitals cannot disclose PSWP when defending against a state (breach of contract) or federal (discrimination) claim
- HR needs to create its own non-privileged investigation record, notes, interviews, etc., which are then placed in the HR file and can be used in the event of litigation
- Risk management also can access PSWP but like HR, must create its own forms, reports, etc., for claims and litigation management which generally are discoverable
- For this other information, other privileges which could be available include attorney-client work product and communications, and the insured/insurer privilege

# PSWP Questions and Answers

- What should be included or referenced in minutes/documentation in order to access the privilege?
  - Make sure the committees or activities producing the minutes are reflected in the PSES
  - Determine whether the minutes/reports are going to be actually reported to the PSO and are reported with the date on which they are reported or are being treated as deliberations or analysis – clarify which method is being utilized for the information in the PSES
  - The language “Privileged and Confidential under the Patient Safety and Quality Improvement Act of 2005 [and the \_\_\_\_\_ Act]” for those portions of the minutes you are treating as privileged
  - Some hospitals have an email system which includes this or similar language of privileged emails

# PSWP Questions and Answers

- Remember, it is not fatal if this language is not inserted. It is more important that the minutes be identified in the PSES
- Who can review PSWP minutes/documentation?
  - Workforce members who have been identified by the provider – these are the individuals who prepare or need to access PSWP as part of their job responsibilities
- What PSWP can be shared from the Peer Review process and who can see it?
  - Workforce members
  - Hospital identifiable PSWP can be shared with affiliated entities, including the parent corporation and their workforce members, who are members of the PSO and are in a single system PSES

# PSWP Questions and Answers

- PSWP can be shared/disclosed if utilizing a permissible disclosure exception, i.e. attorneys, accountants, business associates, accreditation bodies, etc. (See Section 3.206 of the Final Rule)
- Is any report, analysis, study, etc., prepared by a PSO considered PSWP?
  - Yes
- If CMS or other government agency demands PSWP, must it be turned over to them?
  - No – HHS in its May, 2016 Guidance for Patient Safety Rule stated that government agencies cannot require providers to turn over PSWP, but must otherwise demonstrate compliance

# PSWP Questions and Answers

- Sharing physician identifiable PSWP generated within a hospital is considered a use and not a disclosure and therefore can be shared with the hospital's workforce members
- In order to share physician identifiable PSWP generated in the hospital with outside entities, including affiliated providers, the physician must sign a written authorization permitting the disclosure of this information
  - Authorization can be included in a separate form or in the appointment/reappointment application, or an employment agreement.



# Questions & Answers



# Firm Bio



## Michael R. Callahan

**Senior Counsel**  
Health Care

Chicago Office  
+1.312.902.5634

[michael.callahan@katten.com](mailto:michael.callahan@katten.com)  
<https://katten.com/michael-callahan>

A nationally recognized advisor to health care providers across the country, Michael Callahan provides deeply informed business and legal counseling in all areas of hospital-physician relations and health care regulatory compliance and governmental investigations, including the Emergency Medical Treatment and Active Labor Act (EMTALA), the Health Insurance Portability and Accountability Act (HIPAA), Medicare Conditions of Participation (CoPs), hospital licensure and accreditation standards. He is widely respected for his leading work on the Patient Safety Act from a regulatory compliance, policy and litigation standpoint, including the development of patient safety organizations (PSOs).

### The knowledge to identify efficient and practical solutions

Health systems, hospitals and physician groups large and small across the country come to Michael for practical, real-world guidance and answers to challenging legal and operational issues, which he can provide quickly because of his many years of experience. He understands the reality of hospital quality, peer review, risk management and related operational legal and regulatory complexities and can rely on a large client base in order to provide better and comparative solutions.

He also is sought out by many of the largest health systems around the country for his understanding and interpretation of the Patient Safety Act. In a case of first impression, he advised a national pharmacy that became the first provider to successfully assert an evidentiary privilege under the Patient Safety Act. Since that case, he has represented or advised many hospitals, physician groups and other licensed providers in creating or contracting with federally certified PSOs and has been directly involved in most of the major state appellate and federal court decisions interpreting the Patient Safety Act.



## Community Involvements

- American Bar Association
- American Health Law Association (AHLA), Fellows Coordinating Council, former Chair of the Medical Staff, Credentialing and Peer Review Practice Group
- DePaul College of Law, Mary and Michael Jaharis Health Law Institute Advisory Board
- Illinois Association of Healthcare Attorneys
- Illinois Association Medical Staff Services
- Massachusetts Association of Medical Staff Services
- National Association Medical Staff Services, former Public Member, Board of Directors
- New York State Association for Medical Staff Services
- Northlight Theatre, former President and Member, Board of Directors
- National Practitioner Data Bank, former Member, Executive Committee



## Recognitions

*Recognized or listed in the following:*

- American Health Lawyers Association
  - Fellow, 2019
- AV Preeminent Peer Review Rating by LexisNexis Martindale-Hubbell
- *Best Lawyers in America*
  - Health Care Law, 1991–2024
- *Chambers USA*
  - Healthcare, 2005–2023
- Illinois Association Medical Staff Services
  - Leadership Award, 1995
- LAF Katten José de Diego Legal Clinic
  - Volunteer of the Year, 2017
- Massachusetts Association of Medical Staff Services
  - Honorary Lifetime Member
- National Association Medical Staff Services
  - ICON Award, 2020
- New York State Association for Medical Staff Services
  - Honorary Lifetime Member
- *Super Lawyers*
  - Illinois, 2005–2020

# Katten Locations

## **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

## **DALLAS**

2121 North Pearl Street  
Suite 1100  
Dallas, TX 75201-2591  
+1.214.765.3600 tel  
+1.214.765.3602 fax

## **LONDON**

Patemoster House  
65 St Paul's Churchyard  
London EC4M 8AB  
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 4150  
Los Angeles, CA 90071-2212  
+1.213.443.9000 tel  
+1.213.443.9001 fax

## **NEW YORK**

50 Rockefeller Plaza  
New York, NY 10020-1605  
+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

## **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**

1919 Pennsylvania Avenue NW  
Suite 800  
Washington, DC 20006-3404  
+1.202.625.3500 tel  
+1.202.298.7570 fax

Katten refers to Katten Muchin Rosenman LLP and the affiliated partnership as explained at [katten.com/disclaimer](http://katten.com/disclaimer).

Attorney advertising. Published as a source of information only. The material contained herein is not to be construed as legal advice or opinion.