



Sentact Center for Clinical Excellence PSO



How to Create a Safe and Privileged Space for Learning and Improving Patient Outcomes through a Patient Safety Evaluation System (PSES)

April 8, 2026



Michael R. Callahan, JD
Senior Consultant

Ellen Flynn RN, MBA, JD
SVP | General Manager, PSO Services
Sentact Center for Clinical Excellence

Disclosure Slide

- Michael R. Callahan and Ellen Flynn have no conflicts to report.

Disclaimer

- The opinions expressed in this presentation do not reflect the official position of the Agency for Healthcare Research and Quality (AHRQ) or Sentact Center for Clinical Excellence.
- This information is not being offered as legal or medical advice.
- Seek competent legal counsel for specific guidance.
- Every organization should review the PSQIA and new guidance, review external obligations, and determine what is eligible to be PSWP based on your risk tolerance.

Presenters



Michael R. Callahan, JD
Senior Consultant
Sentact

mcallahan@sentact.com
312-720-3197

Michael brings an unparalleled level of healthcare consulting experience. Formerly a healthcare attorney for over 40 years, he provides consultative services, educational programs and thought leadership in his role as Senior Consultant.

His areas of focus include hospital/physician relations, medical staff bylaws and policies, peer review policies and investigations, privileging and credentialing issues, National Practitioner Data Bank guidelines and reporting standards, EMTALA standards, accreditation compliance, medical staff integration and hospital/medical staff disputes.

Michael is recognized as a national expert involving all aspects of the federal Patient Safety and Quality Improvement Act of 2005. He was the former Chair of the AHLA Medical Staff Credentialing and Peer Review Practice Group, a current AHLA Fellow, and former member of the Fellows Coordinating Committee.

Presenters



**Ellen Flynn, RN, MBA, JD
SVP | General Manager
PSO Services**

Sentact Center for Clinical Excellence

**eflynn@sentact.com
734-743-8939**

Ellen serves as Senior Vice President and General Manager of Patient Safety Organization (PSO) Services at the Sentact Center for Clinical Excellence. In this role, she leads efforts to advance patient safety, healthcare quality, and clinical outcomes across customer organizations.

Prior to joining Sentact, Ellen led the Vizient PSO for more than a decade, where she supported members in strengthening their cultures of safety through initiatives focused on Just Culture, High Reliability, Human Factors, and Safety Culture. She developed one of the first PSOs in the nation and has a deep understanding of how to help organizations operationalize patient safety strategies within a PSO.

Earlier in her career, she managed quality, safety, and regulatory compliance programs within large and complex health systems, including Rush System for Health, Children's Hospital of Wisconsin, and Universal Health Services.

Learning Objectives

- Describe how documenting your Patient Safety Evaluation System (PSES) creates a safe space for learning and improvement
- Define the key steps for documenting your PSES
- Explain how a PSES helps organizations distinguish voluntary patient safety activities from those required by regulation
- Describe how a well-documented and implemented PSES transforms “check-the-box” activities into meaningful learning and improvement
- Describe how a well-documented PSES will maximize the broad privilege protections under the Patient Safety Act.
- Understand the role that CMOs, Quality and Risk personnel and MSPs can and should play in developing and protecting privileged patient safety work product
- Explain how rounding data relating to quality and risk events should be added as privileged and protected information in your PSES
- Learn how the scope of your existing privileged information within the PSES can be greatly expanded so as to provide additional opportunity to improve patient safety and reduce risk

Environmental Overview Motivating Participation in PSOs

- Increased Liability Exposure
 - HIPAA/Privacy
 - COVID Litigation and Regulatory Compliance
 - EEOC/OSHA/DOL/EMTALA
 - HHS/CMS/Accreditation Compliance
 - State Regulators
 - Medical Malpractice and Negligent Credentialing
 - Discrimination and Employment Claims
 - Antitrust/False Claims/Anti-Kickback
 - Data Bank Reporting Lawsuits
 - Peer Review Disciplinary Lawsuits

Environmental Overview Motivating Participation in PSOs

- Reimbursement Based on the Quality Outcomes

- Value-Based Purchasing
- ACOs
- Merit-Based Incentive Payment Systems
- Hospital Readmission Penalties
- Managed Care Plans

- Government and Industry Quality Reports

- Hospital Quality Initiative Quality Reporting
- AHRQ National Score Card on Hospital-Required Conditions
- State-Sponsored Public Reporting
- HCAHPS
- Leapfrog Group
- U.S. News & World Report
- Hospital Safety Grade

- Increased Competition

- CMS Five Domains

Patient Safety and Quality Improvement Act of 2005

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.

Patient Safety Activities

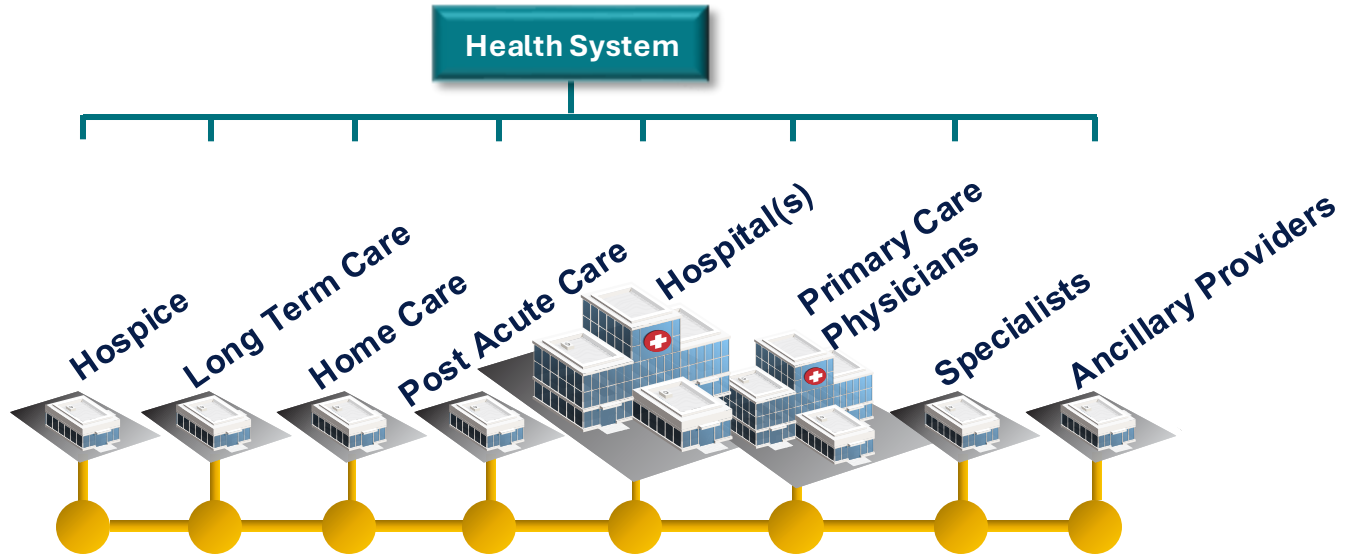
- Patient safety activities mean the following activities carried out by or on behalf of a PSO or a provider:
 - Efforts to improve patient safety and the quality of health care delivery.
 - The collection and analysis of patient safety work product.
 - The development and dissemination of information 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.



Example Health System



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.
- Deliberations or Analysis Pathway
 - Determine what information will not be reported to the PSO but instead is identified as D or A
 - Examples include:
 - Committee minutes and reports
 - QA and proactive risk assessments/analyses
 - Peer learning
 - Aggregate analyses
 - Recommendations to improve patient safety, healthcare quality and outcomes
 - Measure and evaluate implementation and impact of activities
 - Consider cross-referencing to system and affiliated hospital QAPI/Quality Plans
- Reporting Pathway – Report to PSO
 - Identify what information is being reported to the PSO, e.g., event reports, fact-finding
 - Must document the date when the PSWP was created/collected/generated and when it was reported to the PSO

Create a Data inventory of External Obligations and Voluntary Safety Activities

- **High** = subjective or judgmental information, 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	External obligation	Pathway	Priority	Original or Copy	Report to PSO

Example: Distinguishing Non-PSWP and PSWP in event reports

Medical record data – not PSWP

Start

- Who was affected by the event?
- Date of admission or ambulatory encounter

People affected by the event

- Type
- MRN
- Subtype
- Last, first name, middle initial
- Date of birth
- Sex

Event Location

- Site, primary location/service name
- Site, other location/service name
- Clinical service

Patient Safety Event Basics

- Patient safety event type
- Patient safety event discovery/occurrence date/time

Providers should consult with their Legal Counsel in determining which fields should or should not be labeled PSWP, taking into consideration State Reporting and CMS requirements.

Potential PSWP

Event Basics

- Patient safety event category, subcategory
- Was the event related to a handover/handoff?
- Was health information technology (HIT) implicated in this event?
- How did you learn about the event?

Event Detail

- Describe the event in your own words
- Describe any factors contributing to the event, lessons learned, and/or recommendations to prevent recurrence
- Extent of harm and harm score
- How long after the incident was harm assessed?
- Was any intervention attempted to prevent, reverse, or halt the progression of harm?

Miscellaneous Information

- Who was notified? (consider if this should be labeled “not PSWP”)
- Was anybody else involved in the event?

Reporter Information

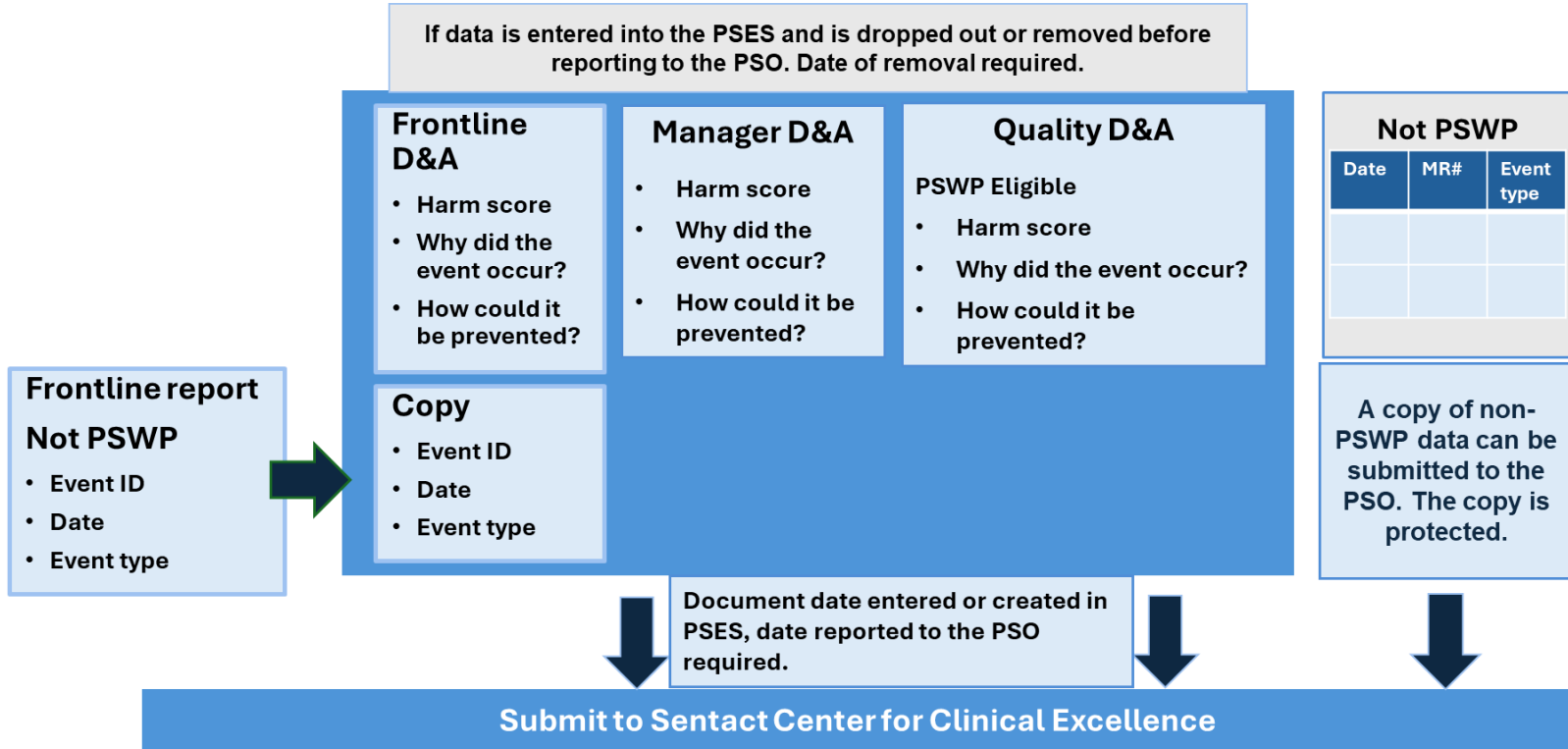
- Reporter role, name, contact phone number, email address

Event Specific Detail Questions

Manager Reviews

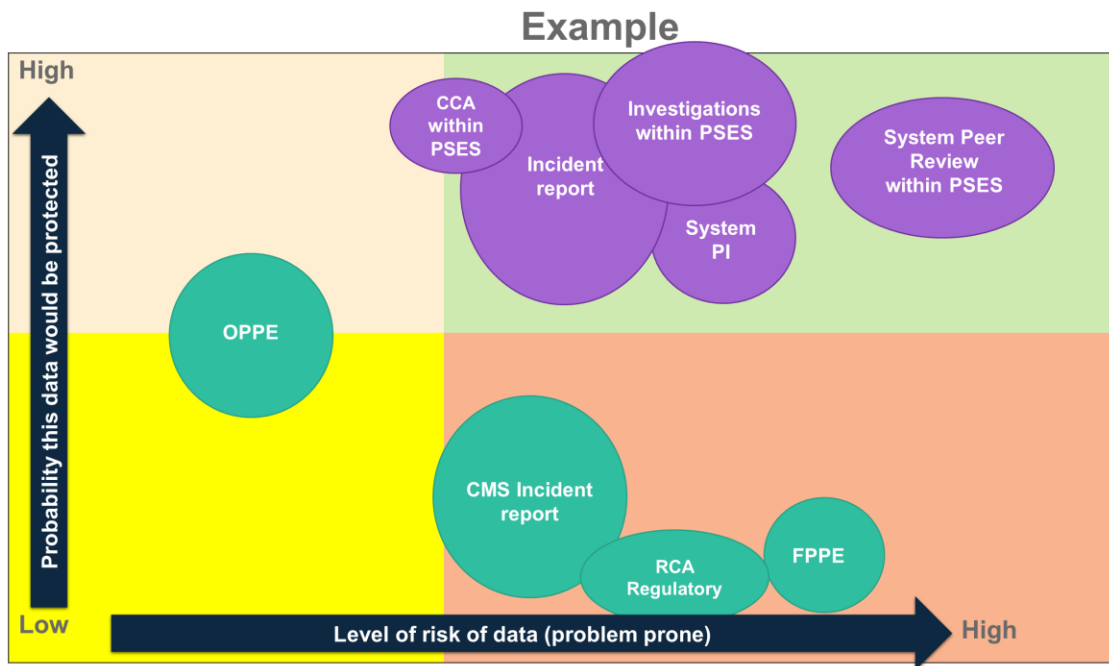
If deliberations and analysis, they must be created in PSES to be protected.

PSES Safety Activities



Prioritizing PSO submission activities:

This graph displays one way to prioritize those activities that will be reported to a PSO. This grid should be 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 and eligible for protections. The color identifies the primary purpose, and the size of the bubble identifies the frequency of the activity.



Each organization should revise and select items to report to the PSO based on their risk tolerance.

KEY

- High risk data (Likely PSWP eligible)
- Low risk data (Likely PSWP eligible)
- High risk data (most likely not PSWP eligible)
- Low risk data (most likely not PSWP eligible)

PSES Allows For A Safe Learning Space to Make Healthcare Better

Hospital regulatory/accreditation requirements

- OPPE – required for reappointment
- FPPE – required for reappointment

Licensed provider organization creates safe space for learning with voluntary OPPE

	Provider 1	Provider 2	Provider 3
Unplanned return to OR	2%	15%	2%
Readmission	10%	15%	10%
Wound infection	1%	12%	1%

PSWP

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 activities, 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.

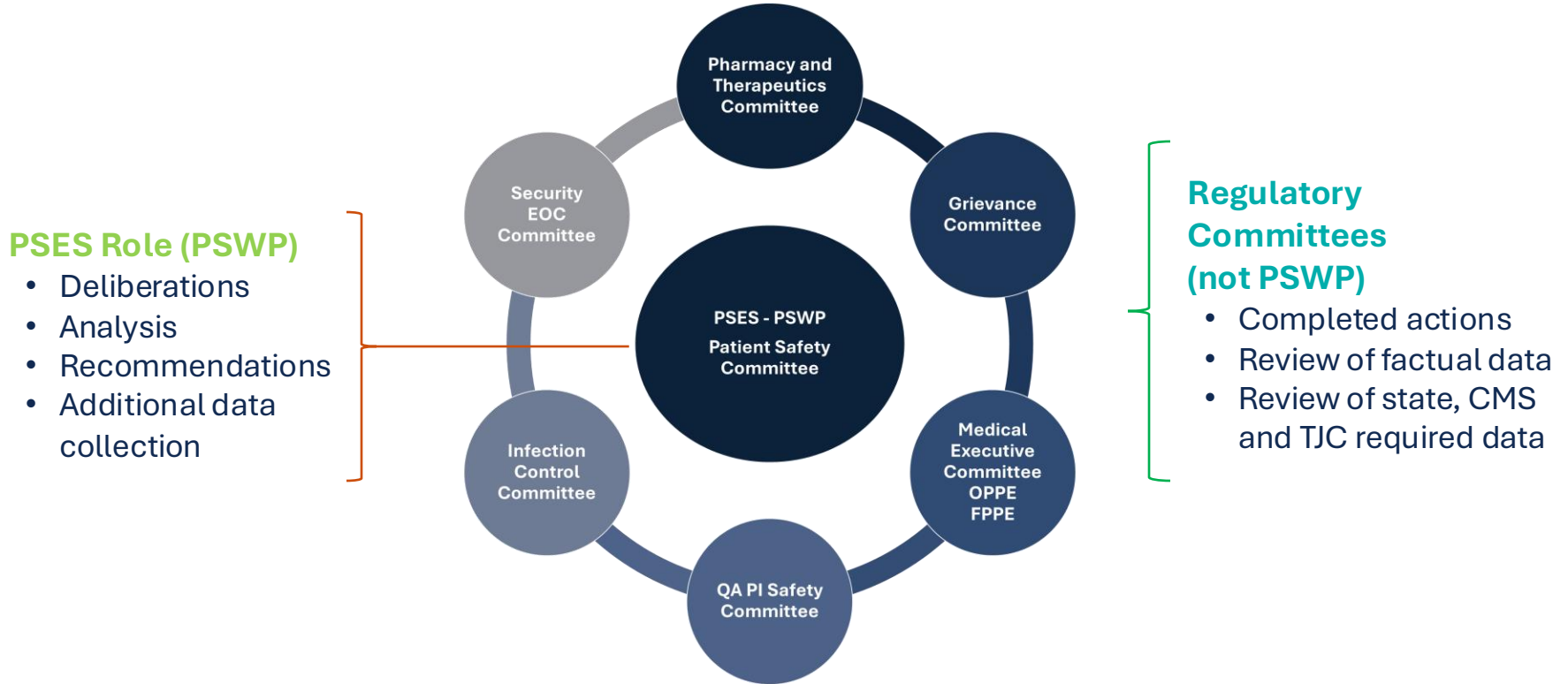
PSES Policy Development

- 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**
 - As reflected in the Appellate Court's decision in Daley, a provider can create PSWP via actual reporting, function 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

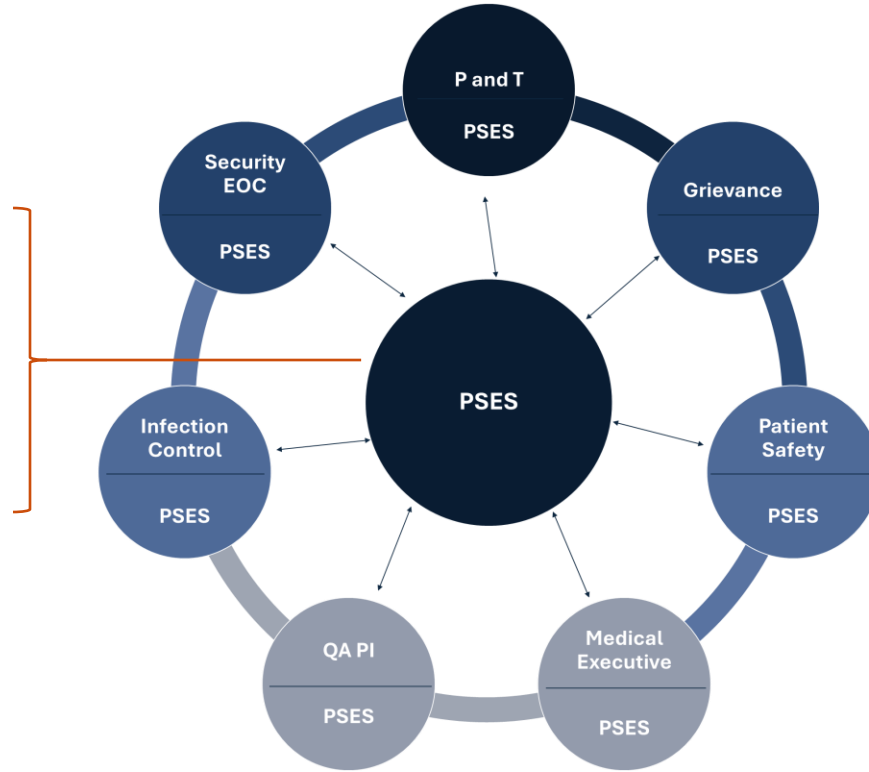
- As a practical matter, most patient safety activities can be characterized as deliberations or analysis.
- Information that is deliberations or analysis automatically becomes PSWP when collected within the PSES and does not need to be reported to the PSO although reporting is certainly an option.
- Most of the PSO appellate court decisions, including the Daley decision, involved actual reporting and not deliberations or analysis.
- Rumsey v. Guthrie Clinic 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.

Centralized PSES model



Decentralized PSES model

- PSES Role (PSWP)**
- Deliberations and analysis



Regulatory Committees (not PSWP)

- Meet accreditation, local, state and federal requirements

Example Health System PSES

Example Health System PSES

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

- A Patient Safety Evaluation System (PSES) is a structured process within a healthcare organization that is designed to collect, manage, and analyze information about patient safety events, incidents, near misses, and medical errors.
- The purpose of a PSES is to facilitate the collection of Patient Safety Work Product (PSWP) and to set guidelines for the management and analysis of information reported to or by a PSO.

Example Health System PSES

Key Components of a PSES:

- **Collection of Data:** This data can be gathered from various sources, such as incident reports or safety audits within the hospital.
- **Management of Patient Safety Work Product (PSWP):** Information collected through the PSES becomes PSWP if it is created for the purpose of improving patient safety.
 - PSWP includes data, reports, records, and analyses related to patient safety activities.
- **Internal Deliberation and Analysis:** Under the PSES, healthcare providers discuss and review events, identify root causes, and assess the effectiveness of existing safety protocols. These internal processes are protected from legal discovery under PSQIA.
- **Reporting to a PSO:** By reporting to a PSO, healthcare providers contribute to a broader effort to improve patient safety at a system-wide level.

Example Health System PSES

What is PSWP?

- Any data, reports, records, memoranda, analyses, communications in any form (including emails and text messages), or written or recorded statements created ***for the purpose of improving patient safety, quality, and clinical outcomes***
 - Copies of the above material are also PSWP
- Any deliberation or analysis ***conducted for the purpose of improving safety, quality, and clinical outcomes***

Example Health System PSES

What is Not PSWP:

- Medical Records
- Discharge Information
- Billing
- Patient Complaints and Grievances
 - Communication to Customer Service by the patient
 - Communication by Customer Service to the patient
 - Customer Service events unrelated to quality and patient safety concerns
- Information collected to comply with external obligations, such as:
 - State incident reporting requirements
 - Adverse drug event information reporting to the Food and Drug Administration (FDA)
 - Certification or licensing records for compliance with health oversight agency requirements
 - Reporting to the National Practitioner Data Bank of physician disciplinary actions

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. This includes faculty, staff, trainees, volunteers, and contractors who perform work under the direct control of the health system.

- Patient Safety Committees
 - Center for Performance Improvement
 - Medical Executive Committees
 - Serious Safety Event (SSE) / Never Event (NE) Committees
 - Peer Review Board
- Quality Improvement Committees
 - Medication Safety Committees
 - Bioethics Committees
 - Network Performance Group
 - Patient Experience Steering Committees
 - Other committees with jurisdiction

Example Health System PSES

Examples of PSWP:

- Quality Reviews
- Peer review activities and documents
- Incident/adverse event reports
- RCAs
 - Investigation, notes, communication, emails, distributed materials, etc. surrounding review of RCA triggering event are PSWP
 - RCA document submitted to DOH is not PSWP
- Focused/Ongoing Professional Practice Evaluations (FPPE and OPPE)
- Risk Management activities not related to claims and litigation
- Communication (written, oral, or digital) and/or information developed or captured directly or in minutes by individuals or quality and/or patient safety committees
- Including emails and text messages
- Investigation around customer complaints and/or grievances related to quality and patient safety events

Additional Example PSES Language

Deliberations or Analysis are any activities carried out or information used for the purpose of quality and patient safety improvement which are not reported to or generated by the PSO, including but not limited to:

- Quality assurance/improvement and patient safety activities, communication (written, oral, or digital), and/or information reported, developed, or captured directly in minutes by individuals or committees for activities relating to improving patient quality and reducing risks including but not limited to: 28 listed activities
- Data and documents that support quality assurance/improvement and patient safety activities that are created, derived from, and/or obtained during or for the above activities

Additional Example PSES Language

- The development and implementation of committees and programs to address quality and patient safety improvement, whether permanent or ad-hoc, and conducted at the department, division, group or hospital/system level. These committees and programs include but are not limited to: 55 listed committees
- Any committee not listed above but included in the system QAPI Policy and the QAPI Policy of any affiliated entity
- Ad-hoc committees formed in response to an identified need for improving the quality and safety of patient care and services provided within the system.

What is Peer Review?

What is Peer Review?

- The process of improving quality and safety in healthcare organizations
- Privileging and credentialing
- Performance of a medical or quality assurance review function
- Utilization review
- Concurrent and retrospective review of medical cases and adverse events
- Root cause analysis
- FPPE and OPPE

What is Peer Review? (cont'd)

- Collegial intervention
- Monitoring, proctoring, consultation requirements and similar remedial measures
- Medical research
- 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

What is Peer Review? (cont'd)

- 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
- All the discussions, analyses and work product produced by these patient safety activities

Consider conducting peer learning within a PSES

- **Peer learning within a PSES**

- Multidisciplinary reviews where the team focuses on how care could be better
- Nurse and physician OPPE where a provider could transparently compare his performance to others within the entity and identify ways to improve
- RCAs
- Medical and nursing peer review
- Grand rounds
- Morbidity and Mortality reviews

- **Regulatory requirements outside PSES**

- OPPE
- FPPE
- State required RCA/ Adverse Event reporting

Required activity can be brought within the PSES for additional deliberations and analysis

Reporting Deliberations and Analysis within a PSES to promote national learning

DE1	DE2	DE999069	DE999075	DE999070
Provider ID	Report ID	Event occurrence date	Peer Review D&A Date	Peer Review D&A Summary

Create a safe space (PSES) to explore provider billing data and make care better

- Billing or claims data base – not PSWP
- If this same data is aggregated and analyzed within a PSES, it may be PSWP

	Provider 1	Provider 2
O/E LOS	1.0	2
O/E Mortality	.8	1.7

Use of AI Resources within a PSES

- AI is defined as a tool used within the PSES to conduct initial deliberation and analysis (d and a)

“Yes—AI **does** perform internal *deliberation and analysis*, but with some important clarifications about **how** it works and **what you can or cannot access**.”

“*This content was generated by AI (OpenAI, 2025). The model may produce inaccuracies.*”

- AI reviews all mortalities within PSES
- AI prepares case summaries and questions for providers within PSES (d and a)
- Physicians review and respond to specific questions within the PSES (d and a)
- Case discussed with involved providers within PSES

Additional PSES Policy Considerations – Workforce & PSWP Confidentiality (1/2)

- **Define the PSO Workforce**

Clearly define who is included in the PSO workforce (employees, contractors, vendors, trainees) and their permitted roles related to PSWP.

- **Outline PSWP Privacy & Confidentiality Requirements**

Specify how PSWP must be created, handled, stored, accessed, disclosed, and destroyed in accordance with federal protections.

- **Workforce Confidentiality & Nondisclosure Agreements**

Require confidentiality and nondisclosure agreements for all PSO workforce members with access to PSWP, including acknowledgment of civil and disciplinary consequences for improper disclosure.

- **Establish Workforce Expectations & Behavioral Standards**

Set clear expectations aligned with a Just Culture framework, mutual respect, psychological safety, and peer support. Reinforce non-punitive reporting and learning-focused use of PSWP.

Additional PSES Policy Considerations – Workforce & PSWP Confidentiality (2/2)

- **Ongoing Workforce Reminders & Reinforcement**

Implement recurring reminders (e.g., annual attestations, role-based training, system banners, onboarding refreshers) reinforcing PSWP privilege, confidentiality, and appropriate use.

- **PSWP Disclaimers & Labeling Standards**

Standardize PSWP disclaimers and visual labeling (headers, footers, EHR flags where applicable) to clearly identify protected content and reduce risk of inadvertent disclosure



Questions?

Unified Industry Leaders...

2k+ Healthcare Facilities

800+ hospital partners

95%+



Credentialing, Privileging, Payor Enrollment, and Peer Review

sentact

Digital Rounding & HRO Workflows

PRE⁺ERITY

Clinical Quality & Patient Safety Analytics

vizient
PSO

Patient Safety Organization

Performance Health
PARTNERS™

Best in KLAS Incident Reporting



CommonSpirit

CHC
Community Hospital Corporation

Tenet
Health

RUSH UNIVERSITY
MEDICAL CENTER

Northwestern
Medicine

Banner Health

Yale
NewHaven
Health

HCA
Healthcare

Cedars
Sinai

Sentara

NewYork-
Presbyterian

THE UNIVERSITY OF
CHICAGO
MEDICINE

Trinity Health

KAISER
PERMANENTE

Advent Health

ThedaCare

Powering **Quality, Safety, and Experience** initiatives with industry leading **Analytics, Technology, and Services**



Quality Outcomes

OUR INSIGHTS:

Sentact analyzes over 100 billion patient outcomes data points from 40+ sources and across 73 specialties to create 200 nationally benchmarked clinical measures that identify provider risk, inform mitigation strategies, and prioritize interventions.

OUR SOLUTIONS:

- **Peer Review:**
 - External Peer Review
 - Digital Workflow Application
 - Provider Benchmarking Analytics
 - Change Management & Education
- **Credentialing, Privileging, & Enrollment:**
 - Pre-Credentialing Provider Risk Analytics & Benchmarking
 - Credentials Verification Organization (CVO)
 - Medical Services Professionals Staffing



Safer Care

OUR INSIGHTS:

Sentact builds tools, structures processes, and creates analytics to help organizations elevate safety to drive down hospital-acquired conditions including CAUTI, CLABSI, MRSA, C. diff, Pressure Injuries, and VAP.

OUR SOLUTIONS:

- **Harm Prevention:**
 - Patient Safety Organization (PSO)
 - Incident Reporting
 - Risk-Prioritized HAC Prevention Audits
- **High Reliability:**
 - Real-time Digital Rounding to Influence (RTI)
 - Automated Safety Huddles
 - Culture of Safety Surveys
- **Regulatory Readiness:**
 - Digital Tracers, Mock Surveys, & EOC Tours
 - Intracycle Monitoring
 - Automated Plan of Correction



Better Experiences

OUR INSIGHTS:

Optimize the patient journey. Sentact leverage reviews, CAHPS, PROs, and leading indicator data to predict future results and uncover improvement and service recovery opportunities

OUR SOLUTIONS:

- **Anticipating Needs:**
 - Patient, Caregiver, and Leader Digital Rounding
 - Self-Directed Feedback Surveys
 - Caregiver Recognition
- **Elevating Response:**
 - Digital Complaint and Grievance Management
 - Patient Reported Outcomes (PROs)
 - On-Demand Service Recovery



Michael R. Callahan, JD
Senior Consultant
Sentact

mcallahan@sentact.com
312-720-3197



Ellen Flynn, RN, MBA, JD
SVP | General Manager, PSO Services
Sentact Center for Clinical Excellence

eflynn@sentact.com
734-743-8939

Contact Info



SENTACT

**Thank
You!**

[SENTACT.COM](https://www.sentact.com)