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Illinois Health and Hospital Association
Midwest Alliance for Patient Safety

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What Every Healthcare Provider Needs to Know for Maximum PSO Protections

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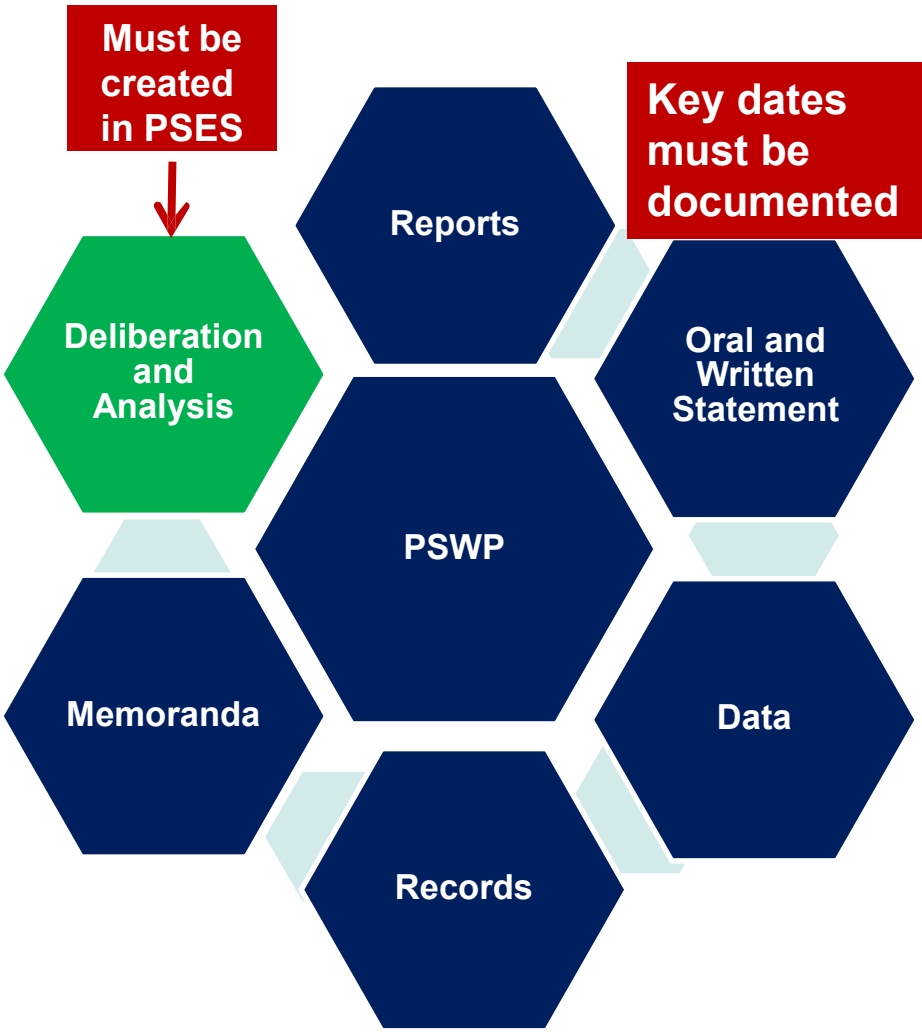
Patient Safety and Quality Improvement Act of 2005

- 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.

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

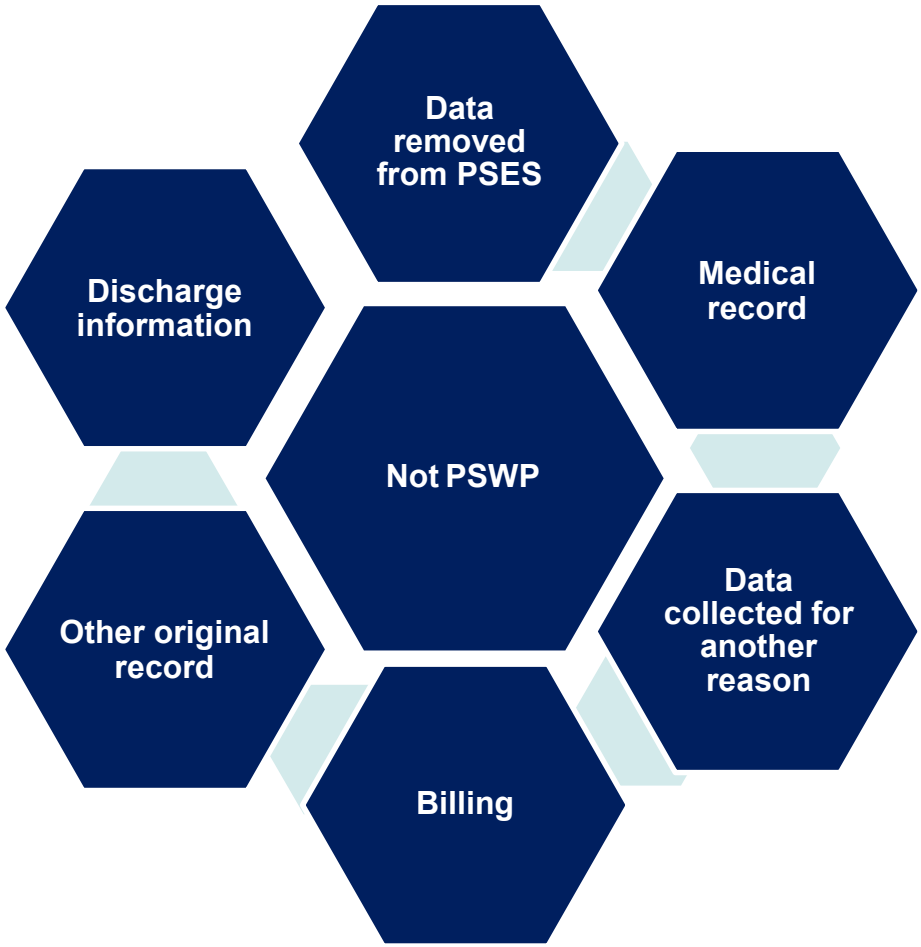
Analysis and deliberations conducted within a PSES

- 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 state or federal reporting or which may be collected and maintained pursuant to state or federal laws be treated as PSWP

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

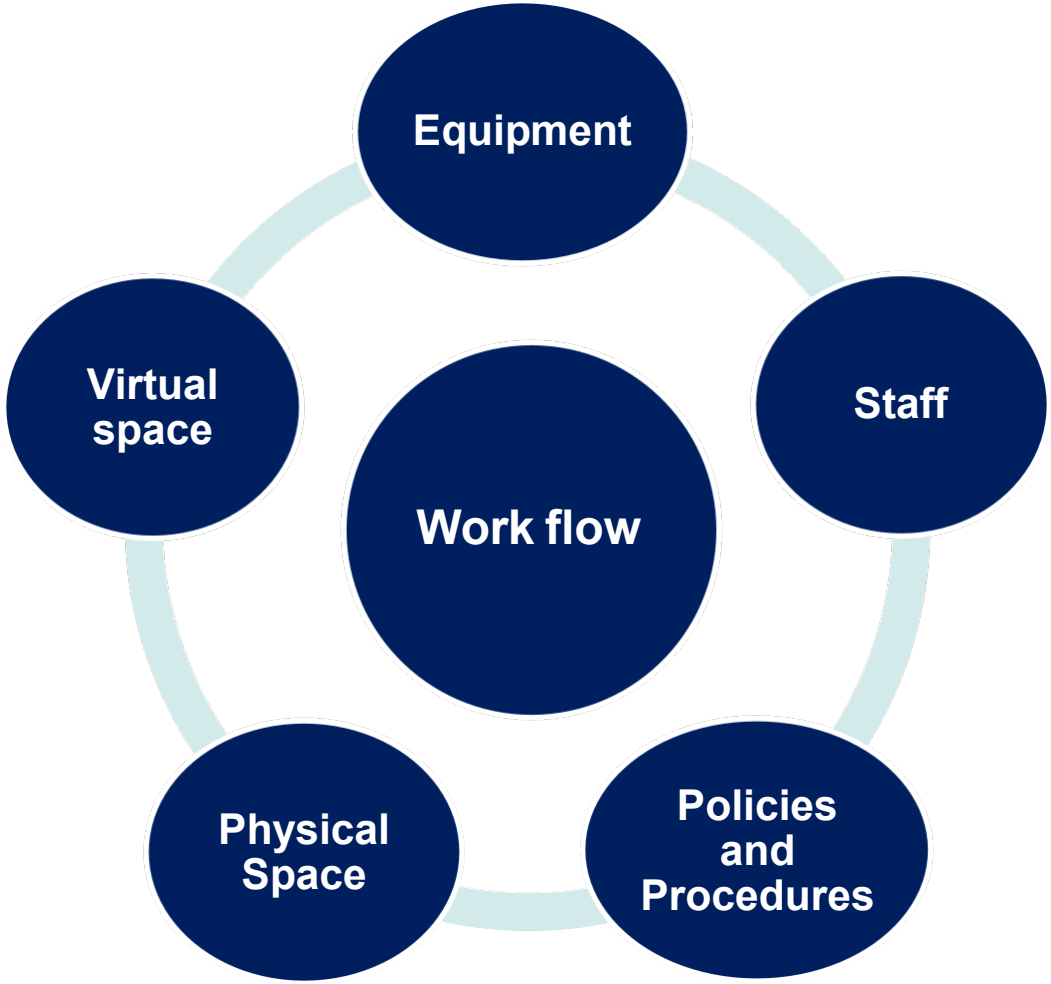
Data collected for another reason

What Entities 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 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:

- 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 Proactive Risk Assessments, in-depth reviews, and aggregate medication errors
- Determine which data will/will not be reported to the PSO
- Report to PSO
- Conduct auditing procedures

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?
  - Medical error or proactive risk assessments, root cause analysis
  - Risk Management — Not all activities will qualify such as claims 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

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 hospitals intent to treat this information as privileged.
- The provider should also include a “catch all” to account for other privileged patient safety activities that are not included in the PSES policy.

- **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.
- Ramsey 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, 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 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

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

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.

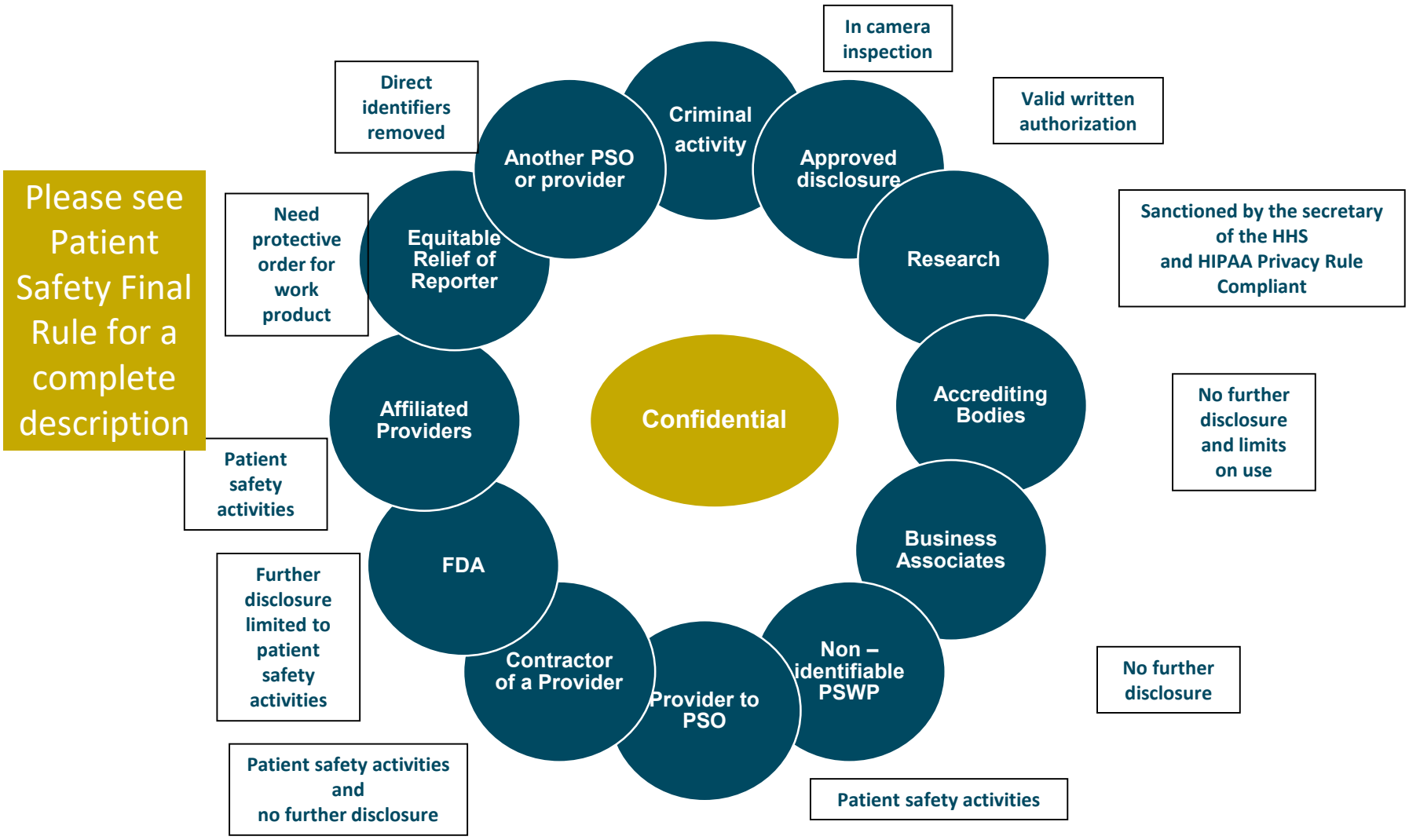
Comparison of Medical Studies Act to the Patient Safety Act

- Patient Safety Act
  - The confidentiality and privilege protections afforded under the PSA generally apply to reports, minutes, analyses, data, discussions, recommendations, etc., that relate to patient safety and quality if generated or managed, or analyzed within the PSES and collected for reporting to a PSO.
  - The scope of what patient safety activities can be protected, generally speaking, is broader than the activities and documents privileged under the MSA – not limited to committees.
  - The scope of what entities can seek protection is much broader.

Comparison of Medical Studies Act to the Patient Safety Act

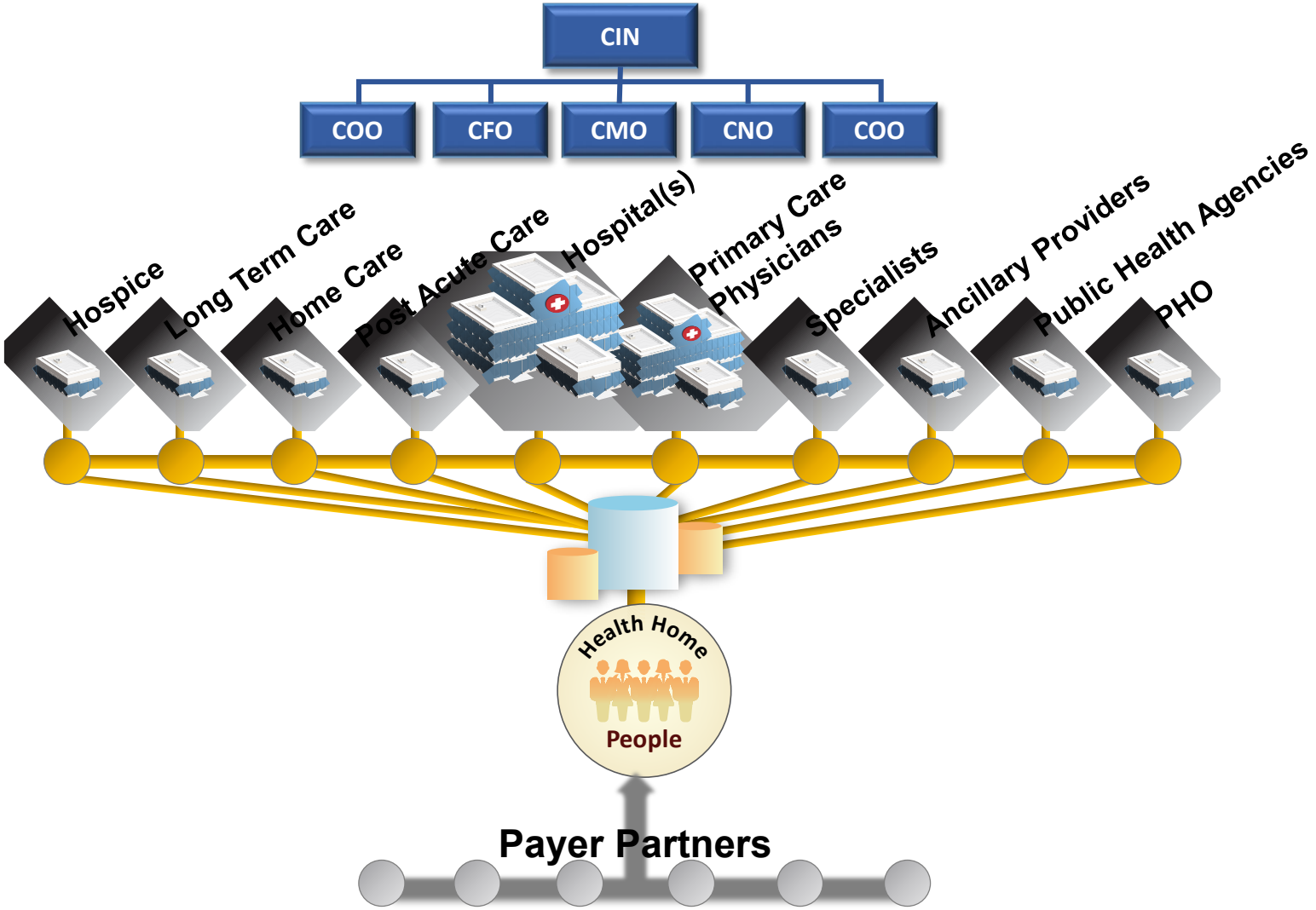
- The protections apply in both state and, for the first time, federal proceedings.
- The protections can never be waived under any circumstances.
- PSA pre-empts state law – Daley v. Ingalls Memorial Hospital.
- Non-provider corporate parent organization involved in patient safety activities as well as owned, controlled or managed provider affiliates can be included in a system-wide PSES and be protected.
- PSWP can be shared among affiliated providers.
- PSWP is not admissible into evidence nor is it subject to discovery.
- Key to these protections is the design of the provider's and PSO's patient safety evaluation system ("PSES").
- The MSA and PSA are not mutually exclusive. You can assert both depending on the documents you are seeking to protect

PSWP is Confidential and Not Subject to Disclosure with Limited Exceptions



Peer Review Protections For Physician Groups and Ancillary Providers

Complete View of an Operational CIN



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

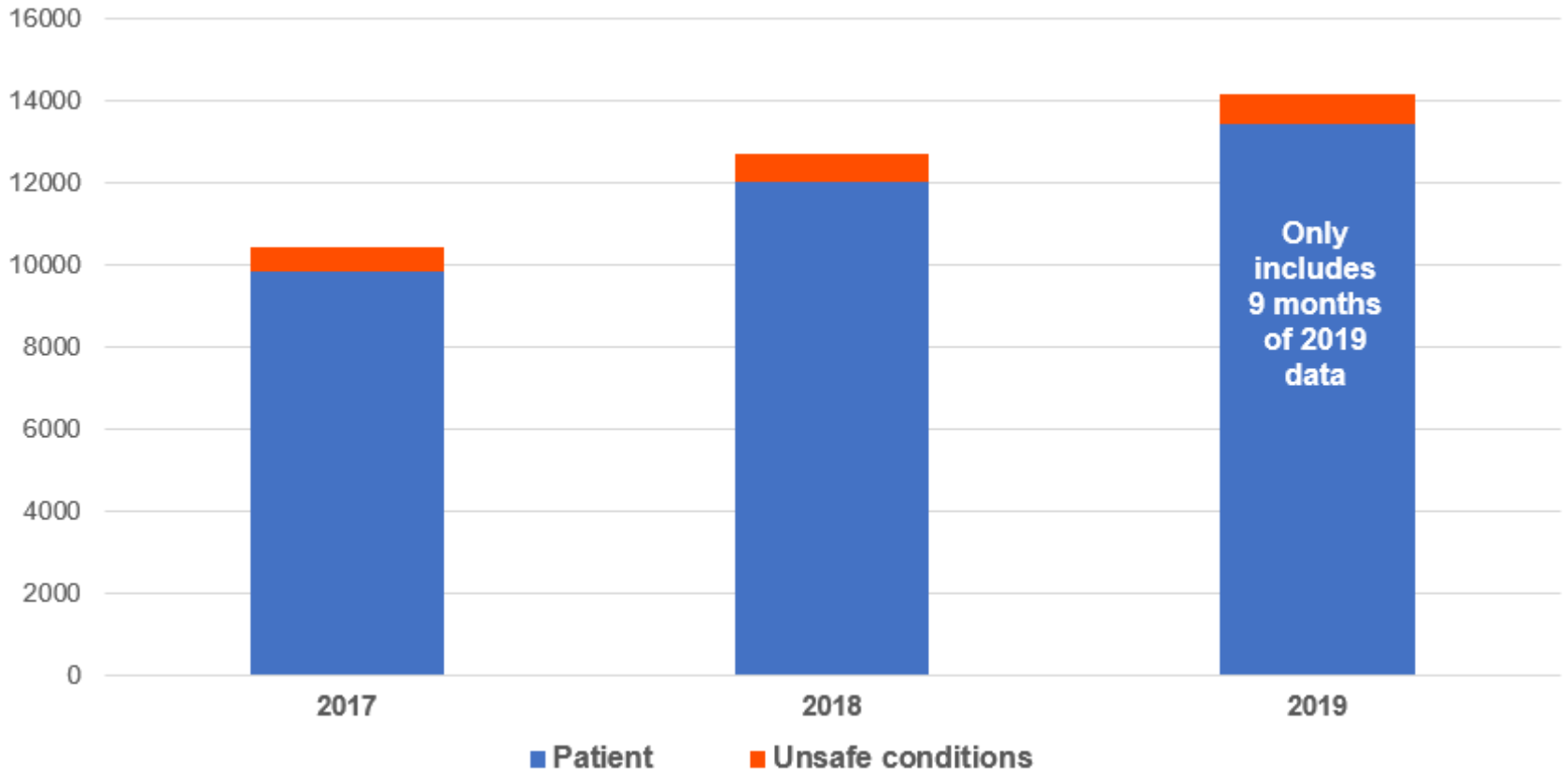
What is “Peer Review”?

- 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
- All of the discussions, analyses and work product produced by these activates

Ambulatory Adverse Patient Events

Increased Ambulatory Safety Events Reported to One AHRQ-Listed PSO

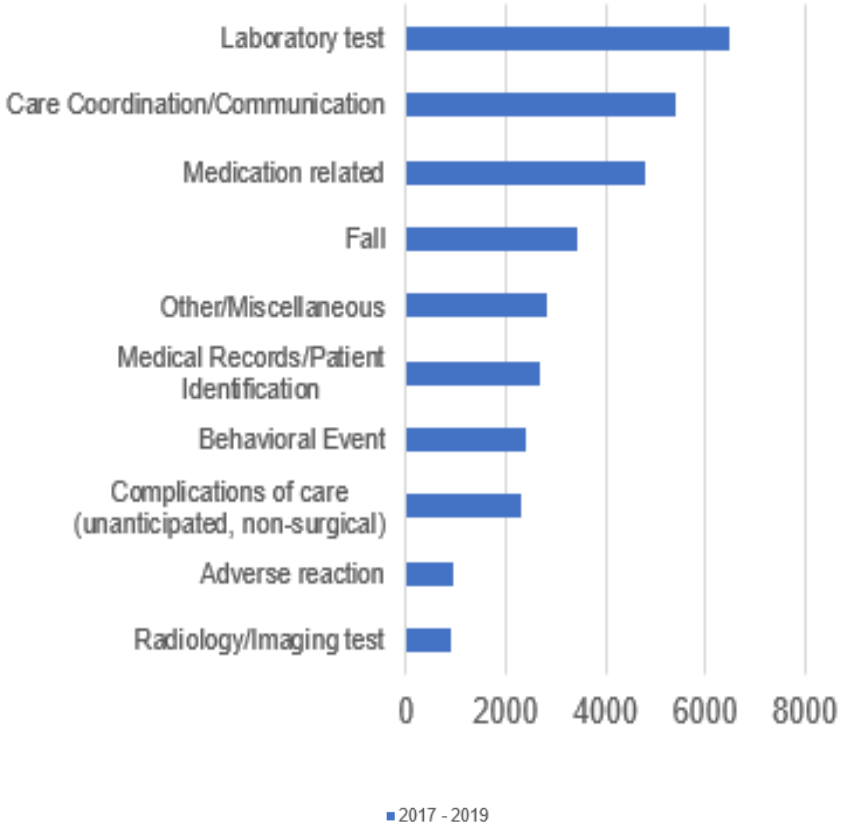
- **Ambulatory patient safety events reported to PSO**



PSO database Year:2017 - 2019

Findings from Ambulatory Care Safety Events Reported to One AHRQ-Listed PSO

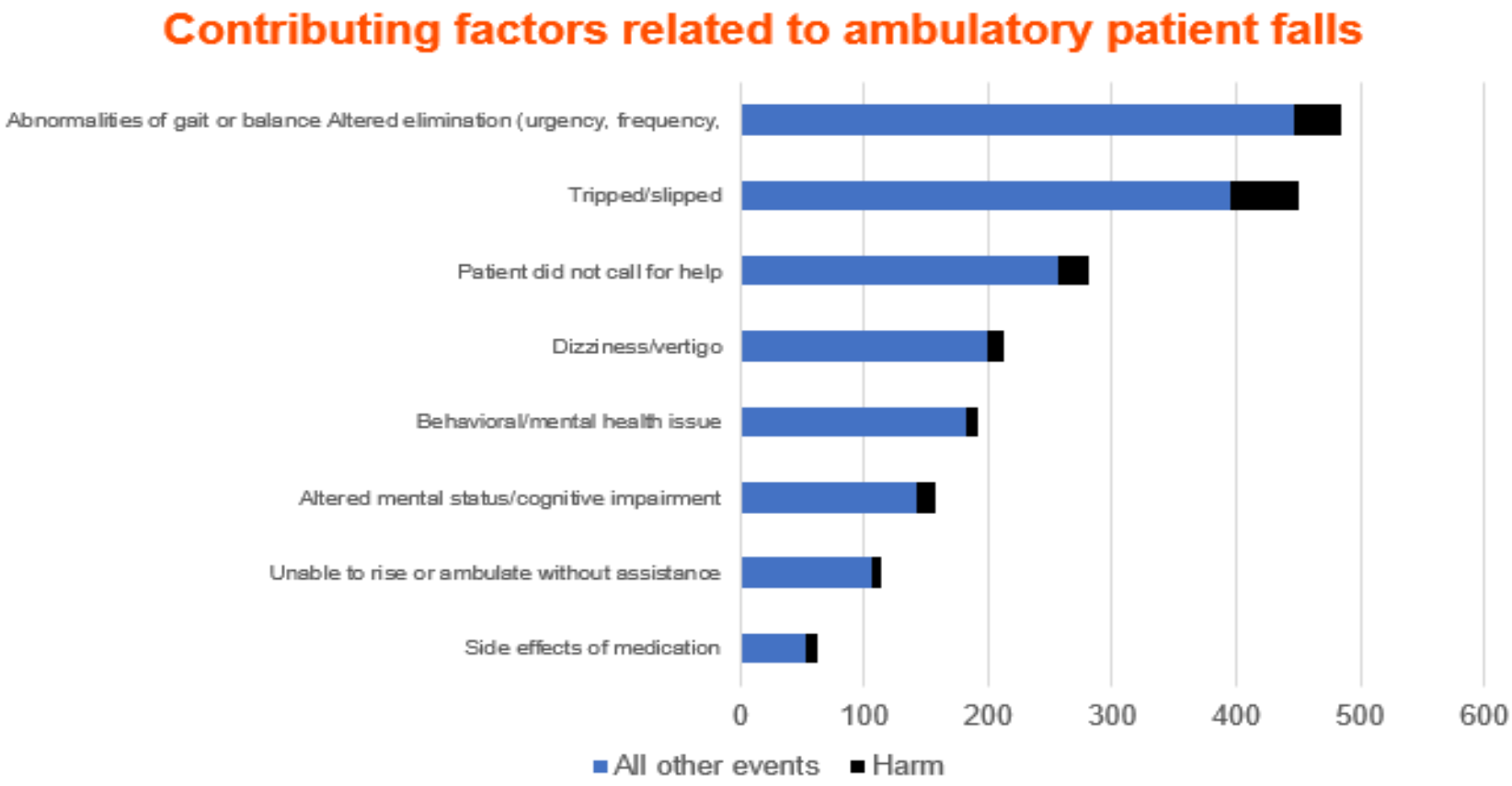
Top 10 ambulatory event types



Top 10 ambulatory event types (harm)

PSO database

Patient Safety Event Aggregation Enables PSOs to Detect Patterns and Trends that May Not be Visible in One Organization



PSO database Year: 2017 - 2019

MAPS Ambulatory Data Comparative 2020 thru 2021

Help Line Phone: 630-276-5657
Email: MAPSHelp@team-iha.org
web: www.alliance4ptsafety.org

Date: Jan. 2022

Ambulatory Focus Group Data Discussion on January 16, 2022

MAPS member highlights on AHRQ Common Format most reported event types including "other":

- Falls
- Infections/HAI
- Medications
- Diagnostic-error related
- Safety/Security/Patient Behavior
- Test Results
- Immunization
- HIPPA Violations

Questions?

Additional Resources

- NCPS Webinar presented by Michael Callahan June 2, 2021: Patient Safety Organizations: What Every Ambulatory Care Provider Needs to Know.
  - This webinar provides an overview of patient safety organizations (PSOs) and the federal laws and privilege protections afforded to providers who report patient safety information to federally listed PSOs, such as NCPS.
  - Using a hypothetical scenario, the presenter compares and contrasts the Nebraska state laws with the privilege and confidentiality protections afforded by participation in a PSO under federal law.
  - Available to NCPS members: https://www.nepatientsafety.org/members/member-login.html
- Davey, S., et al. (2002). A preliminary taxonomy of medical errors in family practice. Quality & Safety in Health Care; 11: 233-238. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1743626/pdf/v011p00233.pdf
- ECRI: DEEP DIVE -Safe Ambulatory Care. Strategies for Patient Safety & Risk Reduction. Available at: https://www.ecri.org/landing-ambulatory-care-deep-dive
- Kravet, S., et al. (2019). Prioritizing patient safety efforts in office practice settings. Journal of Patient Safety; 15(4): e98-e101.

Michael R. 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).

Practice focus

- Federal and state licensure and accreditation for hospitals and health systems
- Hospital-physician relations including contracts, bylaws, peer review investigation and hearings and related health care litigation
- PSOs and participating provider policies, compliance and litigation support
- Centers for Medicare and Medicaid Services (CMS) and state departments of health surveys and investigations
- Assisting health systems with medical staff integration and hospital/medical staff disputes

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.

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