Katten

The Patient Safety Act 14 Years Later: Lessons Learned and Mistakes to Avoid

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Agenda

Wednesday, October 19, 2022

PSQIA Overview

1. Environmental overview motivating PSO participation
2. Review PSQIA fundamentals including key terms, definitions and differences between the PSQIA and state peer review statutes
3. Hypothetical adverse event scenario comparing example state peer review statute with Patient Safety Act

Agenda

Wednesday, October 26, 2022

Designing More Effective PSES Policies

1. What patient safety activities to include in the PSES policy
2. Which PSWP to consider reporting to a PSO or to treat as privileged Deliberations or Analyses
3. Should peer review activities be included?
4. HR and risk management PSWP access do’s and don'ts

Agenda

Wednesday, November 2, 2022

Maximizing PSQIA and State Peer Review Protections

1. Review of key PSQIA court decisions and takeaways
2. Identify impact of court decisions on PSES policy development
3. Litigation lessons learned in defending against discovery demands for PSWP

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

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

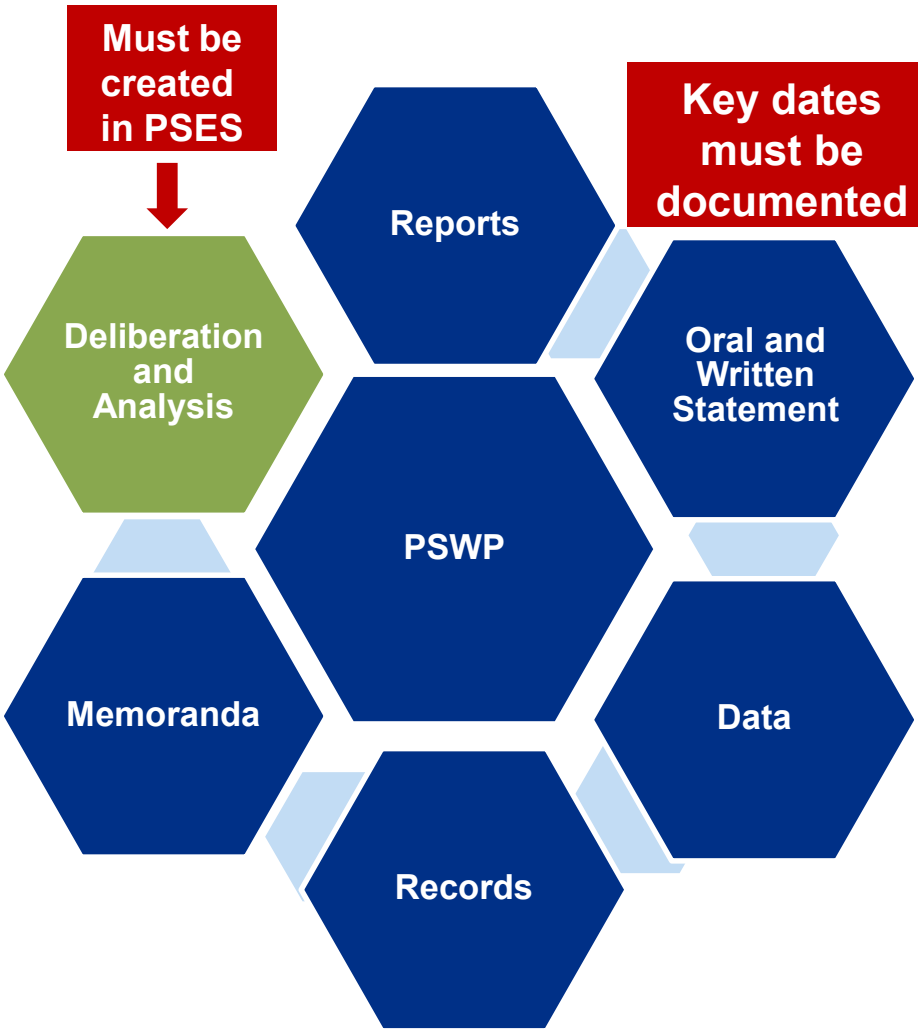
Environmental Overview Motivating Participation in PSOs

- 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

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**

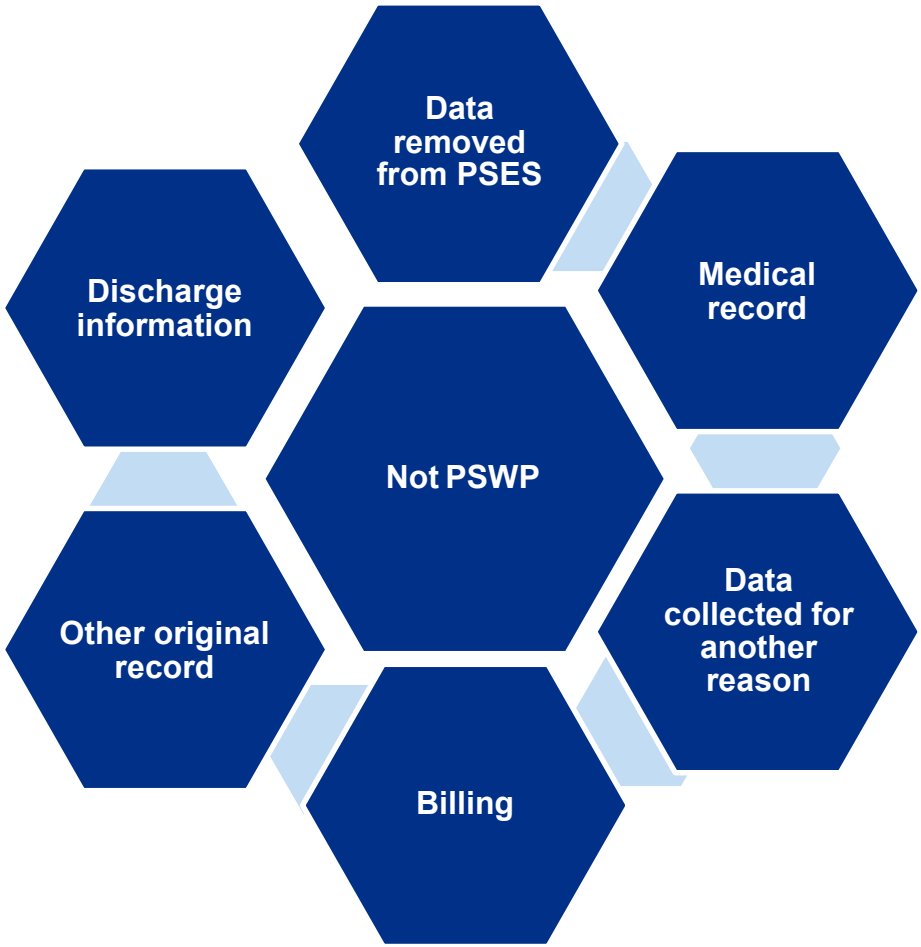
Analysis and deliberations conducted within a PSES

- **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 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

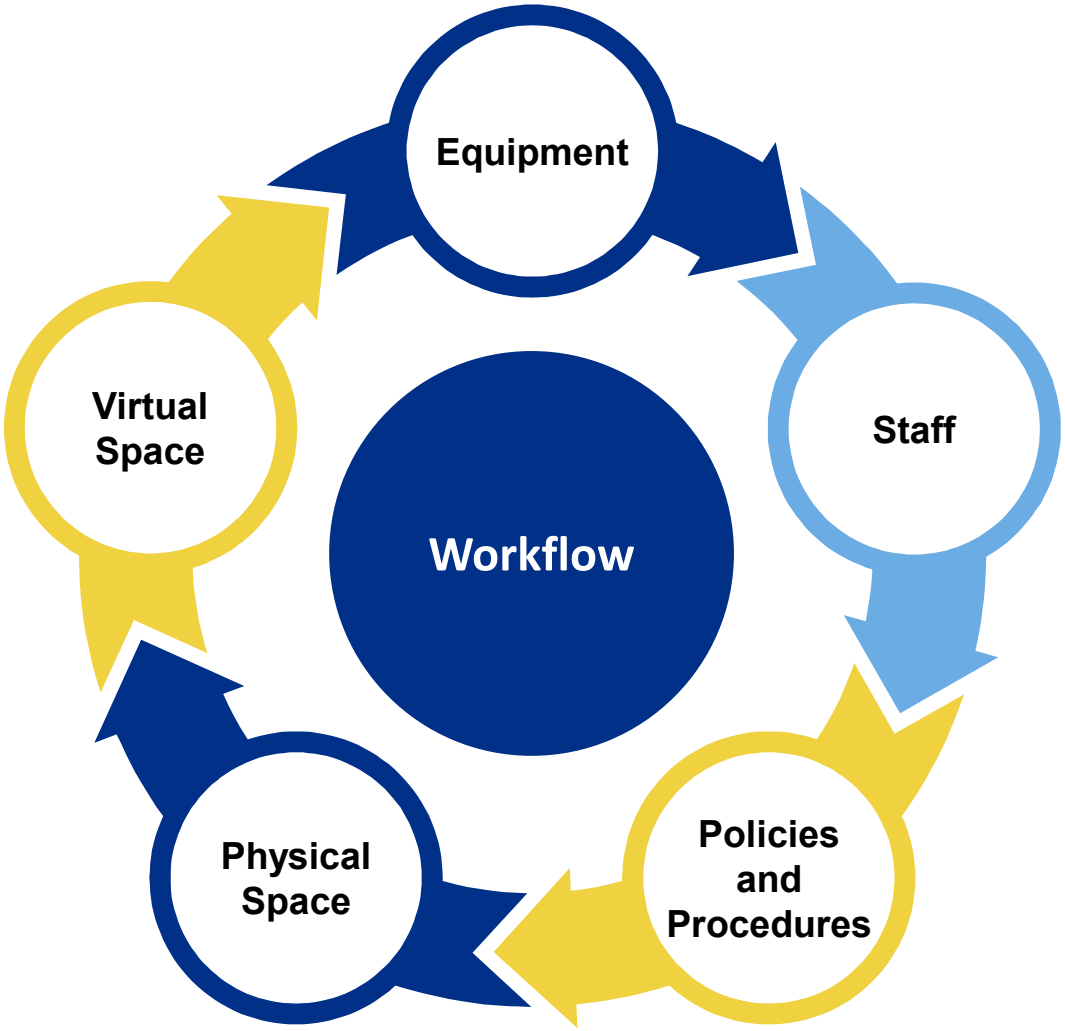
— The provision of appropriate security measures with respect to patient safety work product.

— 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

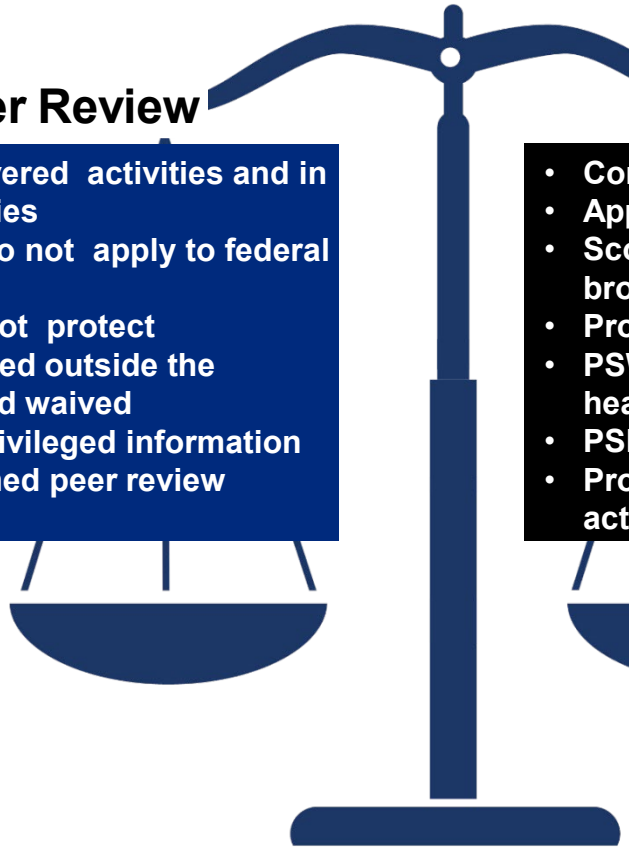
Establish and Implement a PSES to:

- 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

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.

Parent Organization

- Parent organization means an entity that:
  - — Owns a controlling interest or a majority interest in a component organization.
  - — Has the authority to control or manage agenda setting, project management, or day-to-day operations.
  - — Has the authority to review and override decisions of a component organization. The component organization may be a provider.

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.

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

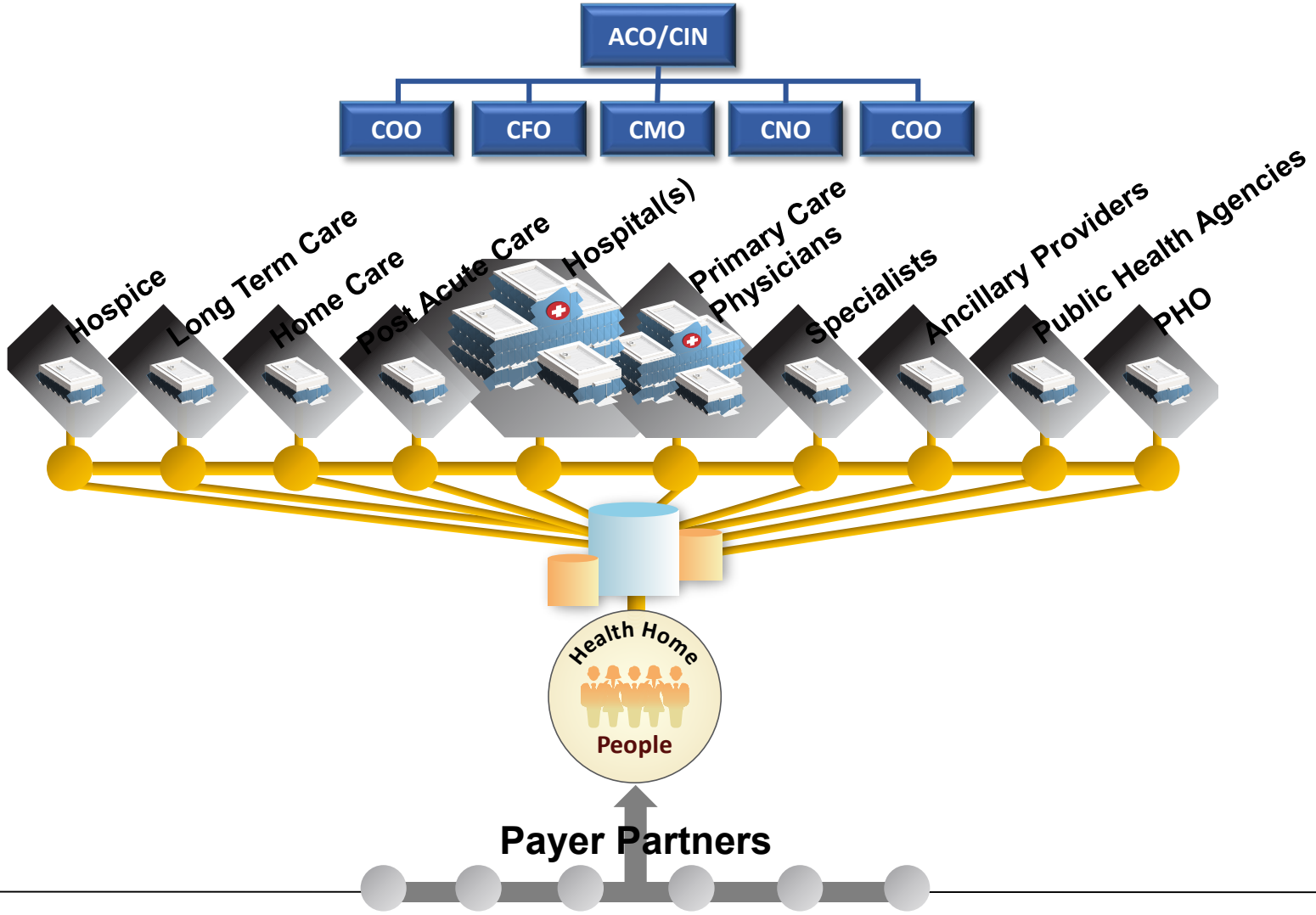
- The use and distribution or sharing of PSWP within a single entity or a health care provider holding privileges with the entity holding the PSWP for any legitimate business or other purpose

Adverse Event Hypothetical

Hypothetical

- You get a call from the CIN's Chief Medical Officer, Dr. Susan Carealot, who also Chairs the Health System's CIN Quality and Credentials Committee. She informed the risk manager and general counsel that the CIN's administrative offices have received a subpoena from a medical malpractice attorney requesting all CIN and Health System medical and other records and documents pertaining to the CIN's review of care provided to a Ms. Hada Bad-Outcome.
- Ms. Hada Bad-Outcome's family is suing the providers involved in her care for malpractice and negligent credentialing. All of her providers are CIN participants, including a PCP employed by Health System Physician Group, a cardiac surgeon who is a member of a participating independent physician group and member of the medical staff along with the CIN's hospital and an affiliated skilled nursing facility where she allegedly received negligent services.

Complete view of an operational ACO/CIN



Hypothetical

- Dr. Carealot tells you that Ms. Hada Bad-Outcome is a 40 year old CEO of a large, closely –held family company, who has 4 minor children and a stay-at-home husband, who experienced severe complications after her hypertension went undiagnosed by a Health System PCP. Ms. Bad-Outcome had seen the PCP because she was experiencing severe headaches, anxiety and nosebleeds. He believed she was stressed and dehydrated from travel, and prescribed Zoloft and regular exercise.
- Two weeks later she experienced a heart attack, and after a CABG procedure performed by the independent surgeon, developed post-surgical complications, and had a stroke. During her subsequent rehabilitation at a SNF, a medication error caused her to have another stroke, and she is now in a permanent vegetative state.

Hypothetical

- Dr. Carealot asks you the general counsel, for copies of the applicable peer review policies for the Health System, and the credentialing and quality review procedures of the CIN, the hospital, the SNF, and the physician group and to pull all of the responsive documents from the physician credentials and quality files and any other relevant information. In addition, she wants copies of any root cause analysis ("RCA") on other reviews that were generated by any of the provider entities involved in the patient's care. She then plans to have the general counsel analyze whether the medical records and peer review materials reviewed and created within the CIN are privileged from discovery.
- After reviewing the requested information, the CMO does not want to release the records because the CIN's Quality and Credentials Committee determined that the PCP, who had a history of noncompliance with care protocols and poor quality scores, had not followed standard procedures for assessing the patient for hypertension. She also tells the general counsel that the cardiac surgeon had a history of similar post-surgical complications, and that based on this data, they decided he should be terminated from participation in the ACO that was established by the CIN.

Summary and Analysis of Illinois Medical Studies Act

- Medical Studies Act
  - —735 ILCS 5/8-2101
    - All information, interviews, reports, statements, memoranda, recommendations, letters of reference or other third party confidential assessments of a health care practitioner's professional competence, or other data.
    - Allied medical societies, health maintenance organizations, medical organizations under contract with health maintenance organizations or with insurance or other health care delivery entities or facilities.
    - Their agents, committees of ambulatory surgical treatment centers or post-surgical recovery centers or their medical staffs, or committees of licensed or accredited hospitals or their medical staffs.

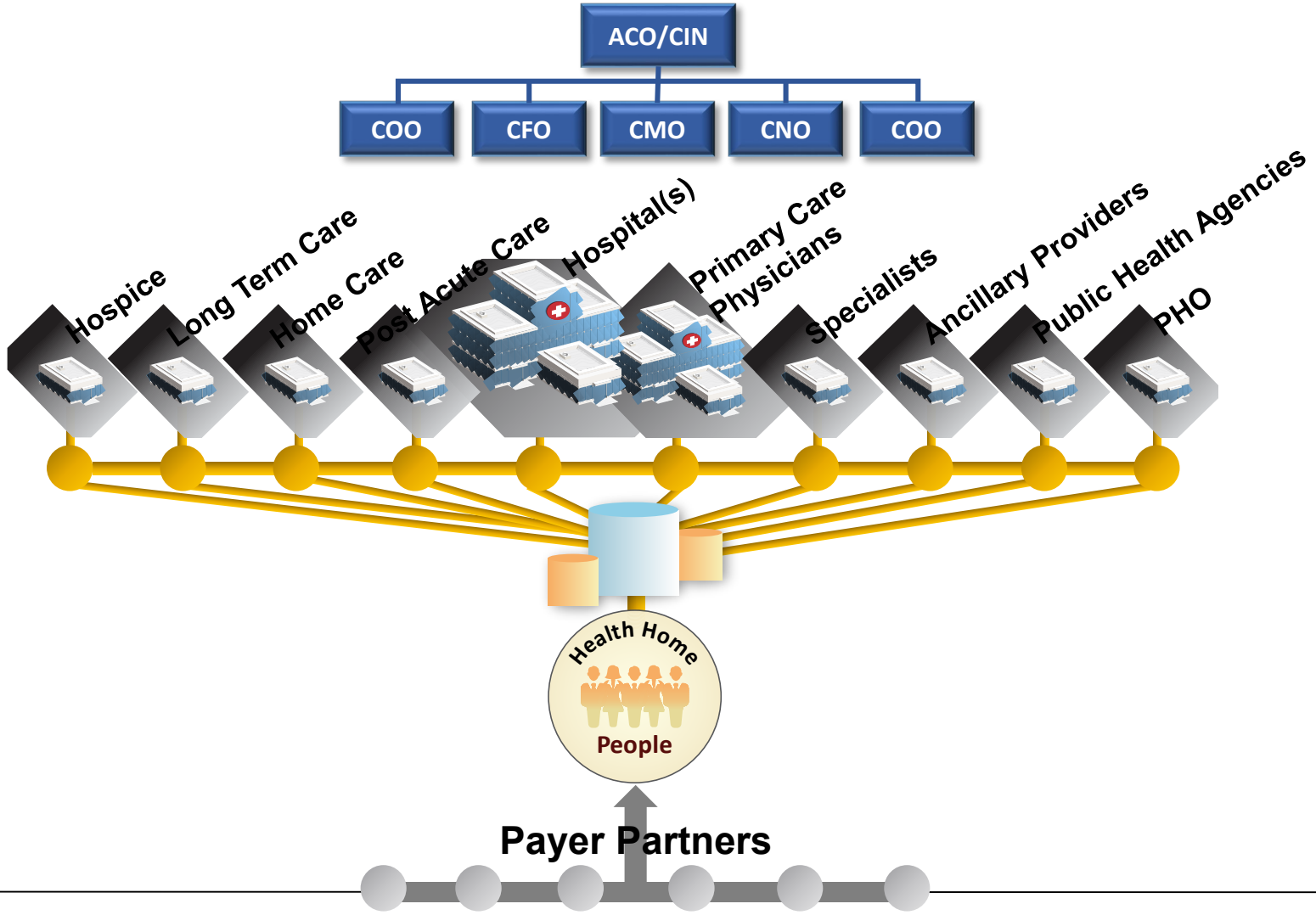
Summary and Analysis of Illinois Medical Studies Act

- Including Patient Care Audit Committees, Medical Care Evaluation Committees, Utilization Review committees, Credential Committees and Executive Committees, or their designees (but not the medical records pertaining to the patient), used in the course of internal quality control or of medical study for the purpose of reducing morbidity or mortality, or for improving patient care or increasing organ and tissue donations.
- Shall be privileged, strictly confidential and shall be used only for medical research, the evaluation and improvement of quality care, or granting, limiting or revoking staff privileges or agreements for services.
- Information can be used in disciplinary hearings and subsequent judicial review.
- Protections have been interpreted fairly broadly but information produced for a different purpose, i.e., risk management, is not protected even if used by a peer review committee.

Summary and Analysis of Illinois Medical Studies Act

- Although the Medical Studies Act references “medical organizations” under contract with HMOs or other healthcare delivery entities or facilities, surgicenters and hospitals, Appellate Courts have not extended protections to nursing homes or pharmacies.
- Recent 2nd District Appellate Court decisions have limited the application of the privilege protections to materials and discussions generated after an event or investigation has been initiated by an identified peer review committee and only if used exclusively for peer review/ quality activities.
- Protections cannot be waived if used for statutory purposes.
- Information arguably can be shared throughout the system among controlled affiliates as well as specific physician information if authorized.
- Protections do not apply to federal claims brought in federal court.

Complete view of an operational ACO/CIN



Summary and Analysis of Illinois Medical Studies Act

- Analysis
  - Does statute arguably protect requested records?
    - Medical records – No, never privileged.
    - Bylaws, policies and procedures – No. Question is whether documents support privilege argument
    - Peer review records and provider entities – Depends
      - Does CIN Quality and Credentials Committee qualify as a peer review committee? – probably, BUT
      - Is CIN a hospital, surgicenter, HMO, PHO or post-surgical recovery center? – No, therefore information is discoverable
      - If the hospital's physician group is conducting peer review through a medical review committee or through CIN Quality and Credential Committee are those activities protected? – No, therefore information is discoverable

Summary and Analysis of Illinois Medical Studies Act

- What about the SNF? – No, but is privileged under Long-Term Care Peer Review Act
- What about the PHO? – Probably
- Based on existing case law, any responsive documents are only privileged if created by a covered entity, i.e., hospital, after an investigation has been authorized by an appropriate committee or designee
- What about risk management documents? – No, therefore information is discoverable
- Protections arguably limited to committee activities

Summary and Analysis of Illinois Medical Studies Act

- Can privileged information be shared across CIN?
  - Under the hypothetical only peer review/quality information generated by a hospital or covered entity peer review committee or designee will be privileged.
  - Under the MSA the privilege cannot be waived unless used for activities unrelated to improving patient care or for reducing morbidity or mortality.
  - Privileged information arguably could be shared with the CIN affiliated entities although there is no case law on the subject.
- Does MSA privilege apply in federal proceedings? – No

Patient Safety Act Analysis

- Analysis
  - Do the protections apply to the requested documents?
    - Medical records – No
    - PSES policies and procedures – No
    - Records that must be reported (or collected and maintained) by a state or federal law – No
    - Committee reports, provider analyses, RCA
      - Yes, if collected and identified in a system-wide PSES or in the PSES of a provider which has collected the PSWP for reporting to a PSO and is reported or if it constitutes deliberation or analysis

Patient Safety Act Analysis

- Are all CIN entities covered?
  - All licensed providers, facilities and the physicians are covered if participating in a PSO
  - CIN is not covered unless it is a licensed provider and/or it owns, controls or manages licensed providers or has veto authority over decision making
  - If not, patient safety and peer review activities must be conducted in a licensed facility.
- What about the PHO? – No, it is not a licensed provider

Patient Safety Act Analysis

- Can PSWP be shared?
  - Identifiable PSWP can be shared by and between affiliated providers
  - Physicians and other licensed professionals need to authorize, in writing, the sharing of identifiable PSWP
- Can protections be waived?
  - There are disclosure exceptions but privilege protections are never waivable
- Do protections apply in all state and federal proceedings?
  - Yes

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

Questions & Answers

Speaker Bio

Michael R. Callahan - michael.callahan@katten.com

Michael R. Callahan assists hospital, health system and medical staff clients on a variety of health care legal issues related to accountable care organizations (ACOs), patient safety organizations (PSOs), health care antitrust issues, Health Insurance Portability and Accountability Act (HIPAA) and regulatory compliance, accreditation matters, general corporate transactions, medical staff credentialing and hospital/medical staff relations.

Michael's peers regard him as "one of the top guys […] for credentialing—he's got a wealth of experience" (Chambers USA). Additionally, his clients describe him as "always responsive and timely with assistance," and say he is "informed, professional and extremely helpful" and "would recommend him without reservation" (Chambers USA). Michael's clients also commend his versatility, and say "He is willing to put on the hat of an executive or entrepreneur while still giving legal advice," according to Chambers USA.

He is a frequent speaker on topics including ACOs, health care reform, PSOs, health care liability and peer review matters. He has presented around the country before organizations such as the American Health Lawyers Association, the American Medical Association, the American Hospital Association, the American Bar Association, the American College of Healthcare Executives, the National Association Medical Staff Services, the National Association for Healthcare Quality and the American Society for Healthcare Risk Management.

Michael was past chair of the Medical Staff Credentialing and Peer Review Practice Group of the American Health Lawyers Association and was recently named as an AHLA Fellows. 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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