Illinois Health and Hospital Association

Midwest Alliance for Patient Safety

A federally certified Patient Safety Organization (PSO)

IHA and MAPS PSO Legal Webinar: Understanding the Patient Safety Act to Maximize Protections for Your PSES

Wednesday, February 11, 2026
1:00 pm - 2:05 pm

Attendees are placed in listen-only mode

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- **For attorneys seeking IL MCLE – *You will need to submit the opening code on the evaluation. *Note that there is also a closing code at the end of today's presentation.***
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Important Survey Tips:

- **Have your nursing license number and/or ARDC# ready to complete the evaluation.**
- **Note your time-in and time-out of the webinar. This will be asked in the evaluation.**
- **Attorneys will need to submit the opening code and closing code in the evaluation.**
- **Continuing education credits are only available for attending the "live event."**

Webinar Agenda

Welcome and Introductions	Crystal Lathen, MAPS PSO Consultant, Midwest Alliance for Patient Safety PSO	1:00 to 1:05 pm
IHA and MAPS PSO Legal Webinar: Understanding the Patient Safety Act to Maximize Protections for Your PSES	Beth Anne Jackson, Esq., Principal, Health Care Practice Group, Post & Schell, P.C.	1:05 am to 1:50 pm
Questions, Answers and Wrap-up	Carrie Pinasco, Senior Director, Midwest Alliance for Patient Safety PSO	1:50 to 2:05 pm

Let's Get Started!

Today's Objectives:

1. Participants will understand how state law privilege protections and the Patient Safety Quality Improvement Act (PSQIA) privilege protections protect patient safety activities (and how they don't).
2. Participants will understand key features of relevant case law and how to conform practices and policies to maximize privilege protections for Patient Safety Work Product (PSWP).
3. Participants will understand how to leverage the Patient Safety Act to protect and enhance patient safety activities in the outpatient context.

Post event: Meeting materials and the recording will be sent to all program participants.

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Midwest Alliance for Patient Safety, PSO Presents: Understanding the Patient Safety Act to Maximize Protections for Your PSES

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Conflict of Interest Disclosure

Beth Anne Jackson, Esq. reported no relevant financial relationships or relationships she has with ineligible companies of any amount during the past 24 months.

Presenter

Beth Anne Jackson is a Principal in the firm's Health Care Practice Group and has focused her career on advising providers on the transactional, compliance, and operational aspects of health care law. She counsels health care providers on the development and implementation of contracts, transactions, policies, and procedures to comply with and preserve available privilege protections under federal and state health care regulations. This encompasses the PSQIA, peer review/HCQIA, HIPAA, the Stark Law, the Anti-Kickback Statute, EMTALA, and the corporate practice of medicine.

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Patient Safety and Quality Improvement Act

Understanding Essential Terms

Patient Safety Evaluation System ("PSES")

- Definition:
  - "the collection, management or analysis of information for reporting to or by a PSO"
- PSES policy *not* required, but recommended
  - Makes an abstract concept concrete for the uninitiated (judges, plaintiffs' attorneys)
  - Sets clear parameters for participants in the PSES
  - Defines what patient safety activities the PSES will engage in
  - Designates your PSO
  - Aligns Patient Safety Act rules with your internal practices
  - Specifies what routine activities occur within your PSES
  - Defines PSWP (include names of reports you routinely create)

Provider Patient Safety Work Product (PSWP)

Reporting Pathway

- Purpose: Patient safety data and information that is assembled by a provider for the purpose of reporting to a federally listed Patient Safety Organization (PSO); AND
- Reporting: Is actually reported to a PSO
- Examples: Event Reports, RCAs

Deliberations & Analysis Pathway

- Information that identifies or constitutes deliberations or analysis of a PSES
  - Does not have to be reported to gain privilege protection as PSWP
  - May be reported to PSO
- Examples:
  - Root cause analysis conducted to improve quality and safety of the Provider
  - Patient Safety Meeting minutes

Provider Patient Safety Work Product: Reporting Pathway

- **Prerequisite**:
  - Only applies to data, reports, memoranda, analyses, or written or oral statements "**which could improve patient safety, health care quality, or health care outcomes**"
  - This requirement prevents (perceived) abuse of PSWP privilege to hide "bad facts" to limit liability

What is NOT PSWP?

- Original patient and provider records
  - Medical chart
  - Billing records
  - Patient complaints
- Information collected, developed, maintained (or existing) separately from the PSES (define in PSES policy)

PSWP is protected

- **Privilege:**
  - Preemptive: “Notwithstanding any other provision of Federal, State, local, or Tribal law” – but subject to certain very limited exceptions – PSWP is privileged

- **Scope of privilege**: PSWP shall not be:
  - Subject to subpoena or order
  - Subject to discovery
  - Subject to a FOIA request
  - Admitted as evidence
  - Admitted in a professional disciplinary proceeding of a professional disciplinary body authorized under State law

PSWP is protected

- **Confidentiality: PSWP is confidential and may not be disclosed except as permitted by the Patient Safety Act rules**
  - Limited disclosure in criminal proceedings when PSWP contains evidence of a criminal act
  - Limited disclosure to permit equitable relief for reporters (protective order required)
  - Disclosure authorized by identified providers (entities and individuals)
  - Disclosures for patient safety activities (conditions)
  - Disclosure of nonidentifiable PSWP
  - Disclosure for research sanctioned by HHS Secretary (AHRQ)
  - Disclosure to FDA and entities required to report to FDA
  - Voluntary disclosure to an accrediting body
  - Disclosure for business operations (attorney/accountant)
  - Disclosure to law enforcement (limited; consult attorney)
  - Penalties for unauthorized disclosure (enforced by OCR)

Illinois Medical Studies Act

- Information, interviews, reports, statements, memoranda, recommendations, letters of reference, or other third party confidential assessments of a health care practitioner's professional competence, and other data (can be waived)
  - Must be data of a committee of a licensed or accredited hospital or their medical staff
  - Must be created "for the purpose of reducing morbidity or mortality, or for improving patient care"
  - Use limited to the evaluation and improvement of quality care, or granting, limiting, or revoking staff privileges

Scope of Illinois Medical Studies Act protection – case law

- *Nielsen v. Swedish American Hosp.* (IL App.2d, 2017):
  - At issue: Quality control reports prepared by committee's designees pursuant to **standing request** for information whenever a defined "medical occurrence" takes place
  - Reports held not to be privileged because the reports *began* a process but not an investigation
  - Reports made by nurses to committee member
  - Decision to investigate was made only after completed reports were forwarded to other personnel
  - Reports used for dual purpose of QA and risk management
- *Ardisana v. Northwest Comm. Hosp.* 795 NE 2d 964 (IL App. 3d, 2003):
  - At issue: Minutes from two committees, which court said constituted "investigative and deliberative materials generated by a hospital committee in formulating its recommendations" and were privileged
  - QM/QI worksheets based on committee minute contents were authored for use of peer review committee.
  - Letter from department chair, on behalf of a committee, for additional info for use by committee was privileged "by its own terms"

Scope of Illinois Medical Studies Act protection

- *Ritter v. 2014 Health, LLC* (IL App. 1st, 2020)
  - At issue: Sentinel Event Report and Investigation Summary not authored at the direction of a peer review committee
  - Documents drafted "as a matter of course" after patient death
  - Genesis of document's creation must be a committee
  - Committee – not hospital – directs the investigation to commence
  - Documents not privileged
- *Eid v. Loyola Univ. Med. Ctr.*, 772 N.E. 3d 851 (IL App. 1st, 2017)
  - At issue: investigative information
  - Hospital risk manager, member of peer review committee, instructed people to preserve records after patient death
  - Paged chair of committee, who instructed her to investigate the incident on the committee's behalf from a quality perspective
  - Entire committee did not have to convene first
  - Only documents generated after chair issued directive to investigate were privileged

Comparison of Illinois Medical Studies Act and Patient Safety Act

Medical Studies Act

- Covers hospital committees only
- Outpatient providers not covered
- Committee or authorized member thereof (chair) must initiate investigation – can direct a "designee" to commence the investigation on the committee's behalf
- Documents created as a matter of course at the committee's direction or pursuant to a standing request may not be protected
- Does not cover externally reported data (mandatory reporting) – waived if reported

Patient Safety Act

- Covers PSES of "provider," which includes outpatient/ambulatory care
- Investigations within the provider PSES are protected as "deliberations and analysis"
- Routine collection of data that has the ability to improve patient safety or health care quality can be PSWP if generated within the PSES for reporting or for use in the deliberations and analysis of PSES
- Not limited to specific committees – PSES policy defines what committees are acting within the PSES (ideally)
- Information created for external reporting is not PSWP

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Using case law as a guide to conform practices and policies to maximize privilege protections for PSWP.

PSQIA CASE LAW

In re: BayCare Med. Grp., 101 F. 4th 1287 (11th Cir. 2024)

- **Background**
  - Plaintiff Loux brought an employment discrimination case against BayCare Medical Group
  - In discovery, Loux sought "quality files and referral logs" claimed as PSWP
  - BayCare described its PSQIA process as follows:
    - Patient Safety referrals are tracked in referral logs which are stored in RL Datix
    - RL Datix generates a quality file for each referred complaint, which contains the Patient Safety Coordinator's investigation, analysis and rectifying actions
    - Serious safety concerns are forwarded to Risk which (i) sends a report to the PSO, and (ii) develops new safety protocols
    - The RL Datix quality files are available to multiple teams for risk management, quality assurance, peer review and RCAs
    - BayCare maintains separate files for state record-keeping and external reporting
    - Although a magistrate found the documents were PSWP, the District Court, based on a "dual purpose" test, ordered the documents to be produced

In re: BayCare Med. Grp., 101 F. 4th 1287 (11th Cir. 2024)

- **Appeals Court *reversed* the District Court, ruling**
  - District court erred in applying a "dual" or "sole" purpose test to determine the quality files and referral logs were not PSWP
  - The Patient Safety Act does not have a "dual" or "sole" purpose test
  - The Act only requires BayCare to establish that the files (i) identify or constitute the deliberations or analysis of a patient safety evaluation system, and (ii) are not collected, maintained or developed separately, or exist separately, from a PSES
  - The Act does not require PSWP to be kept "solely for provision to a PSO" but rather, protects deliberations and analysis regardless of whether it is reported to a PSO
  - Cites HHS Rulemaking that:
    - A provider "may use PSWP for any purpose within [its] legal entity"
    - Nothing "prohibit[s] the disclosure of patient safety work product among physicians and other health care professionals, particularly for education purposes or for preventing or ameliorating harm"

Shands Teaching Hospital and Clinics d/b/a Shands at the University of Florida v. Kimberly Beylotte, Case No. 1D22-1277 (Fla. 1st DCA, Mar. 8, 2023)

- **Holding**: An event report of a visitor fall in the hospital can qualify as PSWP.
- **Background:**
  - Kimberly Beylotte allegedly slipped and fell on liquid in front of the Nurse's Station at Shands Teaching Hospital.
  - An Event Report was prepared within Shands' PSES and submitted to Shands' PSO as PSWP. It did not exist separately and was never removed from the PSES.
  - Plaintiff filed a Motion to Compel the Event Report, arguing it could not qualify as PSWP because it did not pertain to a patient.
  - Trial court ruled that a visitor fall Event Report could not qualify as PSWP and "should not have been placed in the PSES."

Shands Teaching Hospital and Clinics d/b/a Shands at the University of Florida v. Kimberly Beylotte, Case No. 1D22-1277 (Fla. 1st DCA, Mar. 8, 2023)

Appeal Court *reversed.*

- The Hospital's uncontradicted affidavit established that the PSER was (i) prepared solely for submission to a PSO, (ii) placed in a PSES, (iii) submitted to the PSO, and (iv) not a medical record, billing or discharge information, or an original patient or provider record.
- It was clearly created in the PSQIA-privileged "reporting pathway"
- Moreover, the Hospital's affidavit established that it was a report that "could improve patient safety, health care quality, or health care outcomes"
  - Specifically, the court pointed out that improving potential slip-and-fall conditions in patient-traversed corridors is necessarily related to improved patient safety
  - PSWP is not limited to patients: "Any person – staff, patients, and visitors alike – face similar slip-and-fall risks in a hospital's common areas"
- ***The court quashed the order requiring production of the PSER***

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Using case law to strengthen your PSES

APPLYING CASE LAW

BayCare – they did it right!

- **Clear procedures**
  - How information enters the PSES (referral logs through RL Datix)
  - How information flows (RL Datix generates quality file for each referred complaint)
  - How information is used in the PSES
    - Serious complaints forwarded to Risk, which (a) sends report to PSO, and (b) develops new safety protocols
    - Quality files available for use by risk management, QA, peer review, and RCAs
  - Addresses how external mandates are handled: separate files for state record-keeping and external reporting

Elements of a PSES Policy

Who

- Leads the PSES
- Operates within the PSES sphere

Where

- In organizational chart
- Physical space for operations
- Separate/secure electronic space
- Documentation of event reports (NOT in EMR)

What

- Committees/entities (local and/or system-wide)
- Patient safety activities undertaken

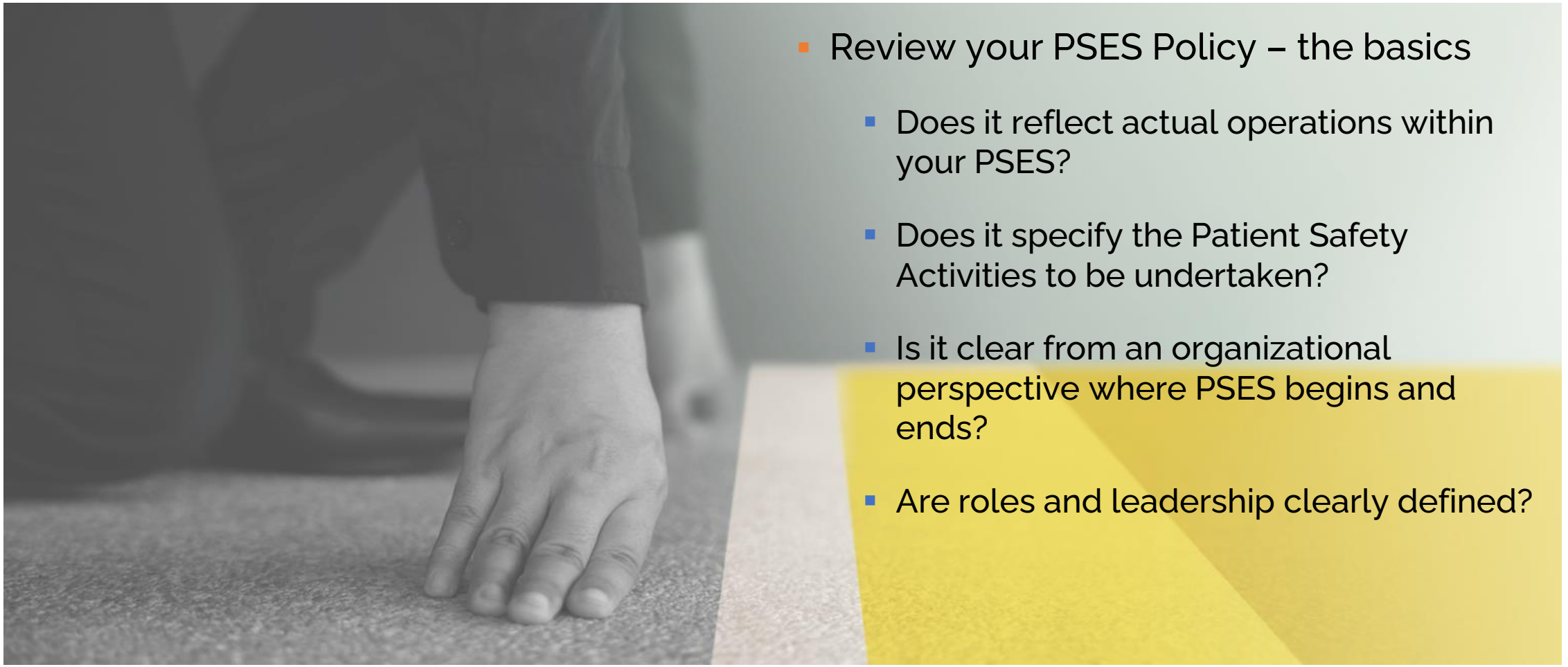
How

- Reporting to PSO
- Meetings/mechanisms for communication
- Use and sharing of PSWP within single legal entity

Why

- Patient safety reporting
- Feedback from PSO
- Dissemination of learnings

Start at the Beginning



- Review your PSES Policy – the basics
  - Does it reflect actual operations within your PSES?
  - Does it specify the Patient Safety Activities to be undertaken?
  - Is it clear from an organizational perspective where PSES begins and ends?
  - Are roles and leadership clearly defined?

Strengthen Your PSES: Mandatory Reports

- Specify how external reporting is accomplished *outside/separately* from the PSES (silo) OR provide for obtaining consent to allow disclosure of PSWP to state authorities (HHS does not want PSWP)
- Describe how external reports can be used within the PSES to facilitate analysis without becoming PSWP

ASK: Is it clear in your policy how external reporting occurs?

Strengthen Your PSES: All Safety Events Can Lead to Creation of PSWP

- Define what is within the scope of the PSES to review – be broad! Ensure any incident that *could* affect patient safety is within the scope of the PSES (near misses, visitor incidents, staff incidents, simulations, workplace violence, slip and fall risks)
- Adopt the broad AQIPs definition of Patient Safety Event

ASK: Does your reporting format adequately allow for the types of information that you are seeking to collect?

Strengthen Your PSES: PSWP Is Meant To Be Used!

- Distinguish purpose of creating
  - Reporting
  - Deliberations and analysis
- From subsequent uses
  - Identify organizational needs for use and disclosure (broadly) and specify them as permitted
  - Emphasize ongoing privileged nature of identifiable PSWP

ASK: Does the PSES Policy address all potential uses of PSWP?

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PSWP CAN BE CREATED IN OUTPATIENT SETTINGS

LEVERAGE THE PATIENT SAFETY ACT IN AMBULATORY CARE

AMBULATORY CARE

- Bulk of U.S. health care spending goes to ambulatory care (Feb. 14 2025 JAMA and JAMA Health Forum)
  - $1 Trillion on ambulatory care in 2019
  - $578 Billion on inpatient care
  - $331 Billion on pharmaceuticals
- Outpatient encounters vastly outnumber inpatient encounters, but peer review focuses almost exclusively on inpatient
  - Required organized medical staff – protected peer review activities
  - Stricter hospital licensure requirements/quality measurements

AMBULATORY CARE: MORE STATS

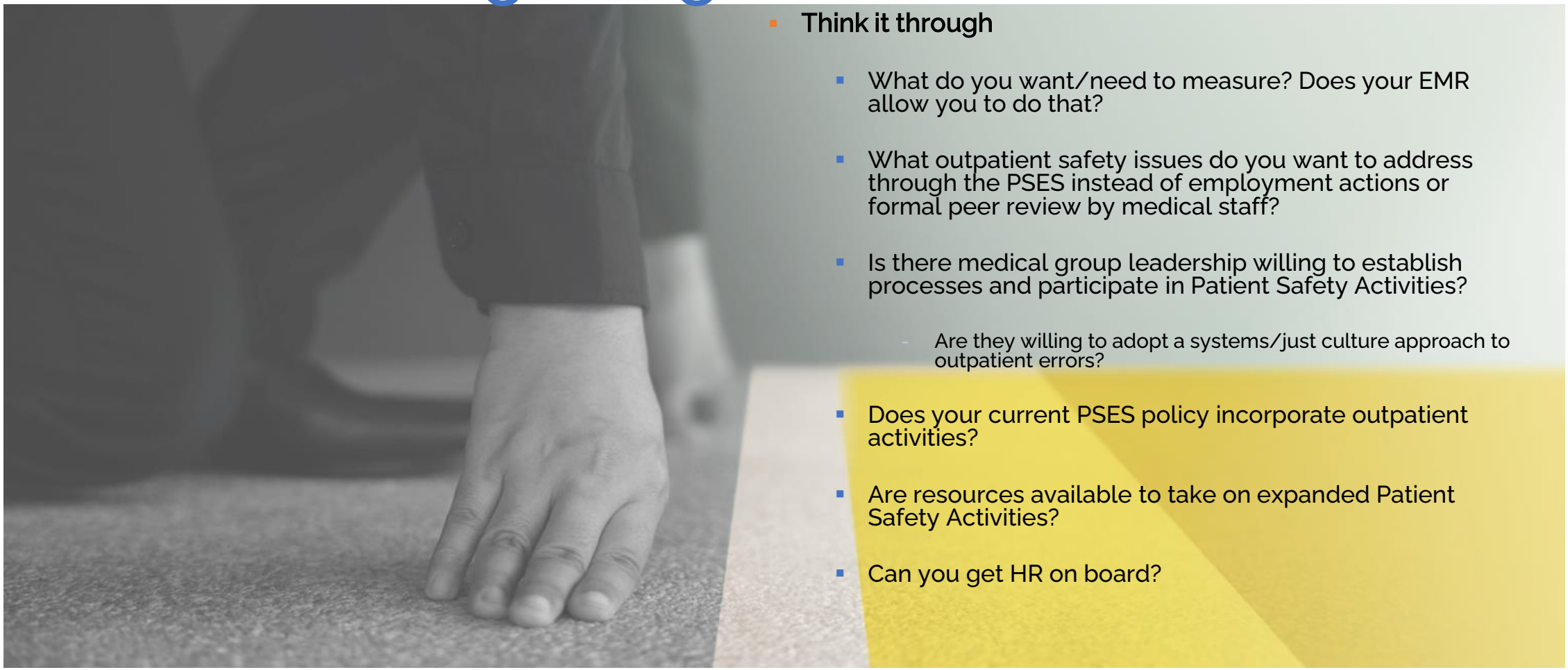
- 2024 Study "The Safety of Outpatient Health Care"*
  - 7% of patients experienced at least one adverse event
  - 17.4% of adverse events identified were considered serious in nature; 2.1% were life-threatening; none were fatal
  - 10.4% of Black or African American patients and 13.1% of patients over the age of 85 experienced an adverse event
  - 64% of adverse events identified were medication-related
  - Variation in adverse event rates across the 11 study sites ranged from 1.8% to 23.6% of patients who received care
  - Study likely undercounted the true number of adverse events

*Annals of Internal Medicine, Volume 177, Number 6 https://doi.org/10.7326/M23-2063

PSQIA makes peer review of ambulatory care privileged

- Definition of “provider” is expansive – “an individual or entity licensed or otherwise authorized under State law to provide health care services” including:
  - Hospitals
  - Nursing facilities
  - CORF
  - Home health
  - Hospice
  - Dialysis facility
  - Ambulatory surgery facility
  - Pharmacy
  - **Physician or health care practitioner’s office, including a group practice**
  - Clinic laboratory
  - Individual health care practitioners

Implementing PSQIA in the Outpatient Setting: Start at the Beginning



- **Think it through**
  - What do you want/need to measure? Does your EMR allow you to do that?
  - What outpatient safety issues do you want to address through the PSES instead of employment actions or formal peer review by medical staff?
  - Is there medical group leadership willing to establish processes and participate in Patient Safety Activities?
    - Are they willing to adopt a systems/just culture approach to outpatient errors?
  - Does your current PSES policy incorporate outpatient activities?
  - Are resources available to take on expanded Patient Safety Activities?
  - Can you get HR on board?

Outpatient harms that can be analyzed in the PSES

- Medication errors/adverse med events (including dispensing errors in pharmacies)
- Diagnostic errors (delayed/missed diagnoses)
- Communication failures/miscommunications
- Healthcare-associated infections
- Outpatient surgical procedures – adverse events
- Patient care adverse events
- Perinatal/maternal care adverse events

Review and Update Your PSES Policy

- Who/What –
  - Committees/leaders/qualified analysts will carry out outpatient safety analysis and formulate improvement plans
  - Specific patient safety activities to be undertaken
- Where
  - Source of documentation will often be the EMR, but analysis must not reside in your EMR
  - How outpatient care fits into your PSES organizational chart
- How
  - What will you report to PSO? Will you conduct deliberations and analysis?
  - How will you use and share this new PSWP within your organization?
  - Dissemination of learnings

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Questions for our expert?

- Let's review chat
- Raise hands

Many Thanks to our Speaker:
Beth Anne Jackson

Maximizing Privilege Protection in the PSES Policy

Establish the purpose of creating the PSWP at the time it was created.

- Describe the reporting system and broadly define the type of information that is collected and reported within it.
- Does it extend to near misses, visitors, staff and patients? Does the reporting format adequately allow for the types of information that you are seeking to collect?
- Describe the various types and settings for deliberations and analysis conducted within the Patient Safety Evaluation System (PSES) framework. Does it extend to committee meetings? Board reports? Safe tables? Peer evaluation?
- Identify key personnel and committees that conduct patient safety activities within the PSES framework, who can use and disclose, and to whom.

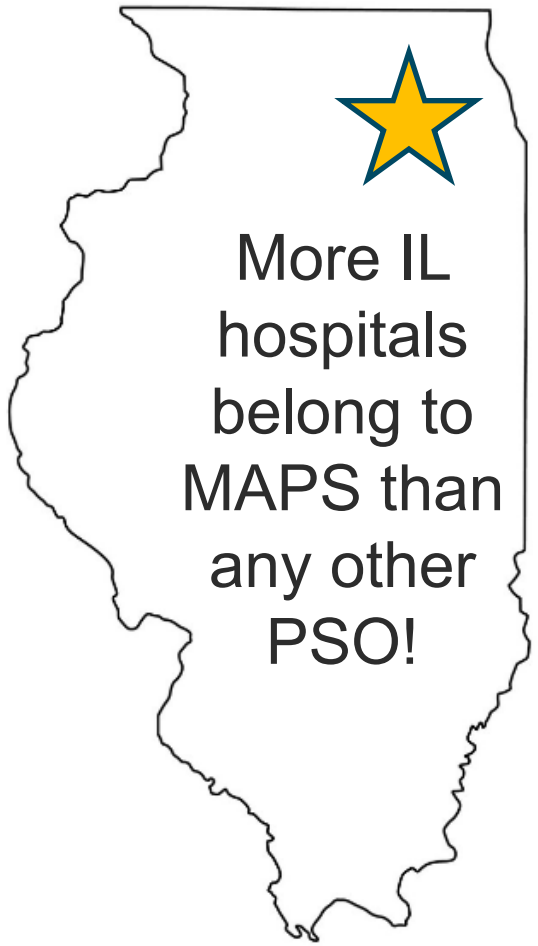
What Did You Learn?

- Patient Safety Work Product (PSWP) is not admissible as evidence in federal or state courts in civil, criminal or administrative hearings.
- It is not discoverable as evidence in civil and administrative matters, or in virtually all criminal matters, with one minor exception.
- Documentation and Policy details will prevent your organization from potentially turning over documentation and investigations.
- A provider cannot be compelled to produce PSWP in the discovery process of a lawsuit. Organizations should include internal and external legal council in the review process of the Patient Safety Evaluation System (PSES.)

Next Steps and Closing Remarks

- PSO membership is key to defending challenges to your patient safety investigations, internal event details and verbal discussions. Note that the CMS Patient Safety Structural Measures support PSO membership in Domain 4: Accountability & Transparency
- Including internal and external legal counsel in PSO education is crucial to understanding privileged patient safety work product (PSWP.)
- MAPS PSO membership provides the strongest legal protections along with collaborative learning opportunities among participating healthcare organizations.
- If you do not have a PSES, MAPS membership provides a template to begin writing your policy to add protection to your organization.

Getting to Know MAPS



We are one of 102 AHRQ PSO's in good standing.

We are the only PSO to offer de-identified comparative Illinois data reports on key data points, geographic regions and hospital/healthcare type.

We are only one of 35 PSO's collecting all event information across the care continuum.

MAPS has a focus on Illinois and Midwest patient safety and improved community health.

MAPS is member-directed and member-focused by listening to a board and advisory council composed of its organizations.

Final Prep for Credits

1. Please complete the survey to give MAPS feedback on your experience today.
2. Remember to record your CE/MCLE credit requests in the evaluation.
3. Put the opening and closing codes on your evaluation.
4. Complete this by Tuesday, February 17.

https://www.surveymonkey.com/r/PSES26

Reminders

Interested in learning more about MAPS?
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