

IHA and MAPS Present Case Law Update to Maximize Legal Protections

Attendees will be placed in listen-only mode

Monday, September 9, 2024 - 1:00 pm- 2:00 pm

Help Line Phone: 630-276-5657

Email: MAPSHelp@team-iha.org | web: www.alliance4ptsafety.org

Agenda:

- Welcome
- Meet our Presenter – Beth Anne Jackson
- Question and Answer Session

This event is being recorded, if you do not wish to be recorded, we ask that you leave the event.

Today's Housekeeping:

- The webinar is being recorded and available via a link along with the PowerPoint presentation pdf. We cannot grant any credits for listening to the recording. CE's and CLE's will only be granted for live attendance.
- Lines will be muted until the Question/Answers portion which is at end of all presentations.
- Feel free to use the chat feature throughout the webinar.
- You must complete the evaluation survey to fulfill CE and MCLE requirements. **For attorneys seeking IL MCLE – *You will need to submit opening code xx on the evaluation. *Note that there is a closing code at the end of today's presentation.***
- You must attend the live event to receive CE or MCLE credits. Listening to the recording does not provide eligibility for earning credits.
- Educational credits will be emailed within 4 weeks following the event. *Note that MCLE's and CE's will be granted to Illinois attorneys and healthcare providers only.*

Key Benefits for Joining this Event:

- 60-minute overview of important operational needs for PSO and non-PSO members including: Patient Safety Evaluation System Policy, internal team structure, organizing internal documentation and understanding legal protections.
- Gain better understanding of state and federal laws regarding privileges
- Collaboration with other legal professionals on healthcare law challenges

Today's Objectives

At the end of this presentation, the participants will be able to:

- Discuss the Patient Safety Act and its role in preventing discovery of Patient Safety Work Product within a PSO.
- Summarize recent litigation cases brought to court and lessons learned.
- Identify what healthcare organizations need to include in their PSES policy to protect investigative materials from discovery.

CE and Disclosure Information

CE Statement: The Illinois Health and Hospital Association (IHA) is authorized by the State of Illinois Department of Financial and Professional Regulation (license number 236.000109) to award up to 1.0 hours of nurse continuing education credit for this program.

This course is approved for **.75 Illinois MCLE general credit hours.**

Completion of the survey will be required to obtain CE credits.

Disclosure

No one involved in the planning or presentation of this activity has disclosed any relevant conflict of interest with any commercial entity.

Illinois Health and Hospital Association Presents: Case Law Updates to Maximize Legal Protections

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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.



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

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)

- *The PSQIA does not limit a provider's legal obligation to comply with legally mandated recordkeeping for public health and oversight purposes:*
- *State serious event reporting*
- *CMS QAPI for hospitals*
- *HAI reporting*

Sharing PSWP: Use v. Disclosure

Use (internal)

- May use PSWP for any purpose within a single legal entity
 - Patient safety
 - Business decisions
 - Risk management
 - Feedback
- Minimize identifiable information (patients, providers) as best practice

Disclosures

- Third party:
 - Affiliated providers
 - Third parties

When and how can PSWP be shared?

	Types of Use and Disclosure	Comments
1.	PSWP may be <i>used</i> for any purpose within a single legal entity	PSWP retains its character as privileged PSWP no matter how it is used, and the government does not regulate internal uses.
2.	PSWP may be disclosed among affiliated providers for patient safety purposes.	Members authorize sharing PSWP among affiliated providers under PSQIA privilege protection.
3.	PSWP may be disclosed to and from a PSO for patient safety purposes.	Members share PSWP with one or more contracted PSOs.
4.	PSWP may be disclosed to contractors of a provider or PSES for patient safety purposes.	Subject matter expertise can be obtained through contractor agreements.
5.	PSWP may be disclosed with the <u>consent</u> of all identified providers.	A valid consent form: <ul style="list-style-type: none">• Is in writing and signed by the identified provider(s).• Describes the scope of the disclosure.• Is maintained for at least 6 years from the date of final disclosure.

Patient Safety Work Product (PSWP)

When and how can PSWP be shared?

	Types of Use and Disclosure	Comments
6.	PSWP may be disclosed for business operations (e.g., to attorneys or accountants).	No specific agreement is required, but it is recommended that the recipient acknowledge in writing their duty of confidentiality.
7.	PSWP may be disclosed for patient safety activities to another PSO or to a provider that reports to a PSO with identifiers removed.	Remove: names, postal info., telephone, fax, email, SSN, TPN, NPI, DEA, License, URLs, IP addresses, biometric and full face IDs of all providers, parents, affiliates (and HIPAA info).
8.	PSWP may be disclosed for research, to the FDA, and to accrediting agencies under certain circumstances.	Each category has separate requirements which should be reviewed on a case-specific basis.
9.	PSWP may be disclosed to law enforcement if related to a crime or criminal investigation	Legal analysis required.
10.	PSWP may be produced pursuant to court order in certain criminal and equitable proceedings under very narrow circumstances.	Legal analysis required.

Patient Safety Work Product

Special Rules on Disclosure

- Disclosure of Non-Identifiable PSWP negates the PSWP Privilege
- Identifiable PSWP retains privileged status even if disclosed, even if disclosed impermissibly.
- Provider safe harbor: A provider may disclose PSWP if it does not:
 - Assess the quality of care of an identified provider, or
 - Describe or pertain to actions or failures by an identified provider

Illinois Medical Studies Act

- What it protects:
 - 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.

Illinois Medical Studies Act

- From the following entities:
 - Committees of licensed or accredited hospitals or their medical staffs, including Patient Care Audit Committees, Medical Care Evaluation Committees, Utilization Review Committees, Credential Committees, and Executive Committees, or their designees
- For the following purpose:
 - 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

PSQIA's Relationship to Medical Studies Act

Scope	PSQIA	Medical Studies Act
Who does it protect?	Protects <u>all</u> healthcare providers and parents that have a contract with a PSO and have established a PSES.	Protects committees of licensed hospital, HMOs, other listed entities.
What does it protect?	<u>All</u> Identifiable PSWP.	Committee information, data, reports, etc.
What does it <u>not</u> protect?	Original source data, external reporting data, info maintained separately from PSES.	Original source data and documents prepared outside of the Committees processes or for purposes other than internal quality control or improving patient care.
Strength of protections.	Federal, preemptive, strict, with very limited exceptions.	State, strong but narrowly defined.
Statutory penalties for violation.	Fines/penalties up to \$11,000 per violation.	None.

Peer Review Under the Provider PSES

- Routine peer review (OPPE) can be conducted within the PSES if your policy/structure permit
- If incident report reveals that formal corrective action may be indicated, incident must be referred to Medical Staff
 - Disclosure of incident to Medical Staff is protected
 - ▶ Disclosure for any reason within single entity is permitted
 - ▶ Disclosure for patient safety purposes to an affiliated entity permitted
 - Medical Staff must conduct its own investigation under the Medical Staff Bylaws because documents regarding a peer review investigation must be shared with the physician if it proceeds to a fair hearing
 - Parallel process but *outside* of the PSES

Illustrative Scenario:

- CRNA suspects patient (there for an elective surgery) consumed illicit drugs, even though patient denies (ASC staffed only by CRNAs)
- CRNA attempts to cancel surgery; surgeon (an ASC owner) refuses and demands that surgery proceed; patient experiences severe respiratory depression and must be transferred to hospital, where patient later expires
- RCA concludes:
 - System issues: CRNAs not recognized as having authority to cancel a surgery; no drug testing/screening immediately available
 - Physician recklessly proceeded with a surgery after CRNA expressed concerns
- Next step: referral of incident to Medical Staff; RCA in PSES can proceed separately

Case Law Learnings

Sunrise Hospital & Med. Ctr., LLC v. Eighth Jud. Dist. Ct., 2024 Nev. LEXIS 7.

- At Issue:
 - The hospital objected to Plaintiff's questions in physician's deposition regarding what information the Patient Safety Committee examined in its investigation.
 - Plaintiff claimed the hospital waived PSWP privilege by allowing a physician to be deposed on privileged topics.
- Trial Court review:
 - The hospital had allowed physician and other employees to testify about privileged topics.
 - Privilege waived by disclosure; court granted Plaintiff's motion to compel.

Sunrise Hospital (cont.)

Analysis:

First consideration: Can PSQIA privilege be waived?

- Two categories of PSWP
 - Identifiable PSWP
 - Non-identifiable PSWP
- Identifiable
 - Exceptions to privilege (certain criminal proceedings, civil actions brought by a good-faith reporter, or when authorized by all providers identified in the PSWP) do not apply
 - PSWP remains privileged even when disclosed impermissibly (42 CFR 3.208(a))
- Must look at statute as a whole: voluntary disclosure makes non-identifiable PSWP lose its privileged status (otherwise superfluous)

Sunrise Hospital (cont.)

Analysis:

Second consideration: is the information sought PSWP?

- Two-prong test for determining whether identifiable PSWP is privileged:
 - Whether the materials were created for the purpose of reporting to a Patient Safety Organization
 - Whether they were so reported
- If privileged, then consider if exception applies (certain criminal proceedings, civil actions brought by a good-faith reporter, or when authorized by all providers identified in the PSWP)
- Court ignored deliberations and analysis pathway

Takeaways:

- PSQIA privilege is absolute and not waivable for identifiable PSWP
- Disclosure does not defeat privilege
- Exceptions may apply as set forth in statute and regulations

***In re Baycare Medical Group, Inc.* , ___ F.4th ___ (11th Cir. 2024)**

Context: Employment discrimination suit. Physician sought comparator information re surgical errors, which employer claimed was PSWP.

Trial Court: Information not created “solely” for reporting to a PSO, so not PSWP.

Appeals Court: There is no “sole purpose” requirement in the PSQIA.

Test: Baycare must establish that the disputed documents “identify or constitute the deliberations or analysis of” [its] process of “collect[ing], manag[ing], or analyz[ing] information for reporting to or by a patient safety organization.” [D&A pathway + definition of PSES]

Veltri v. Amita Health Alexian Bros. Med. Ctr., 2023

II. App (1st) 230073-U; III App. Unpub. LEXIS 1584

Holding: Defendant failed to show the RL Datix report was created solely for reporting to the PSO.

Requirements to establish privilege:

- Information developed by provider for purpose of reporting to PSO.
- Information must have the ability to improve patient safety.
- Information must be reported to the PSO.
- Information must contain the date it was entered into the PSES.

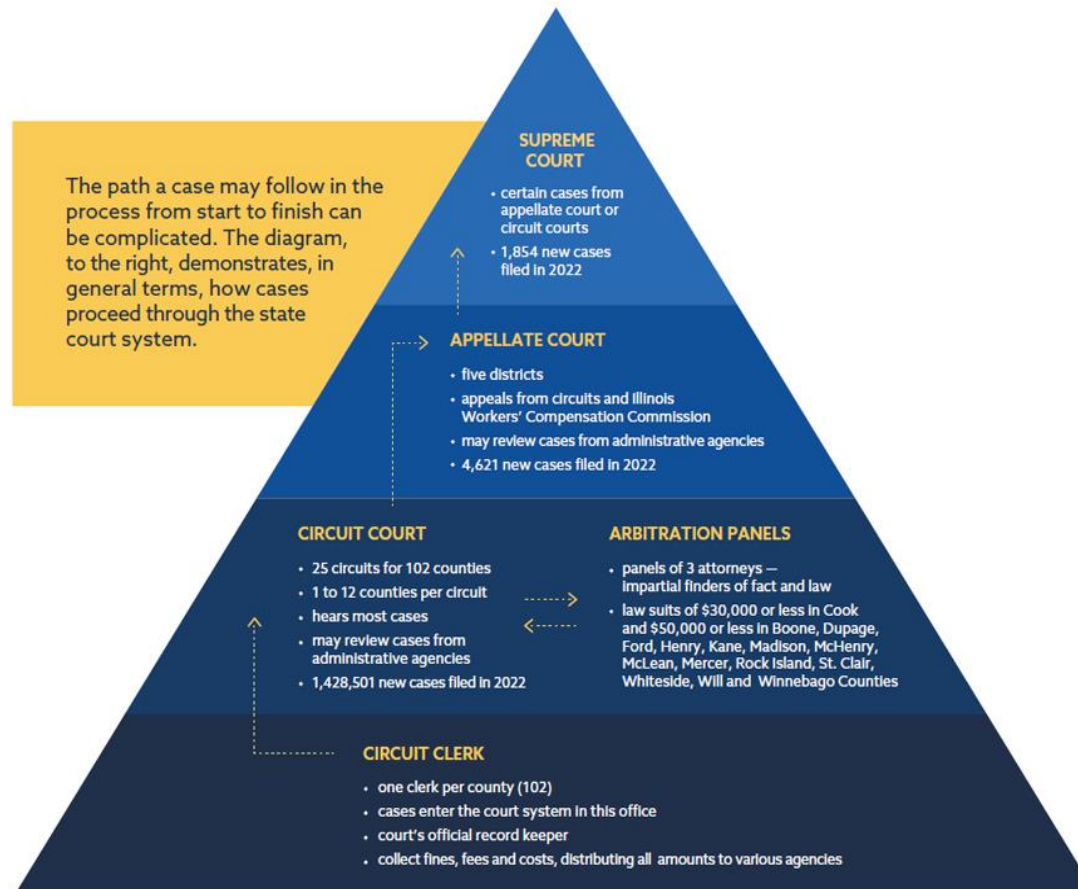
Rationale:

- Report on its face did not indicate that it was generated specifically for submission to the PSO.
- Affidavit did not aver that reporting was the sole purpose.
- Affidavit suggested that reporting was not the sole purpose as the patient safety specialist analyzed it for referral to committees under the PSES.

Veltri (cont.)

Takeaways:

- Know the tests in your jurisdiction - this is an Illinois case, but there are 5 appellate court districts.
- Address each element of the test in the affidavit.
- Maintain a comprehensive and clear PSES policy and describe in affidavit.
- Demonstrates continuing need to educate the courts on the PSQIA and your PSES:
 - PSWP can be used by provider internally for any purpose.
 - Provider's use does not negate privilege.
 - PSWP privilege cannot be not waived.



Source: 2022 Annual Report of the Supreme Court of Illinois

Franco v. YNH Hospital, Ct. Super., CV:20-6103795-S **(Mar. 31, 2023)**

Holding: PSWP privilege upheld as to investigative materials prepared solely for submission to the PSO and to improve patient safety/quality.

Background:

- Plaintiff was a hospital visitor who became aggressive in the ED, was injured during the altercation, and ultimately arrested.
- The Patient Safety Coordinator conducted an investigation, creating notes of an interview and a safety huddle, which were submitted to the Hospital's PSO.
- The Plaintiff noticed the PSC's deposition, asking for all of the investigative materials.
- The Hospital moved to preclude the deposition and all investigative materials.
- The PSC averred that the investigation and notes were part of the Hospital's PSES and not distributed or maintained outside the PSES.
- The Court granted the protective order as to the deposition and the investigative materials.

Franco v. YNH Hospital (cont.)

Rationale:

- It is undisputed that Hospital is a “provider” that submits information to a “PSO.”
- The question is whether the investigative materials qualify as “PSWP.”
- PSWP can be created through the reporting, D&A or PSO pathway.
- There are four specific requirements under the reporting pathway:
 - The information was developed for the purpose of reporting to the PSO.
 - The information has the ability to improve patient safety and quality.
 - The information is reported to the PSO.
 - The information contains the date it was entered into the PSES.
- The Hospital’s affidavit testimony established that these requirements were met.
- Court mentioned subsequent use, but did not directly address that such use did not change the outcome of the “purpose” test.

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 v. Beylotte (cont.)

The Hospital appealed. It argued:

- The PSQIA protects information developed within a PSES for reporting and reported to a PSO – including this visitor Event Report.
- The visitor Event Report was not mandated by Florida recordkeeping or reporting requirements and therefore did not fall within the Charles exclusion.
- There is no limitation or exclusion in the PSQIA for visitor Event Reports – they are precisely the type of “near miss” information that providers are encouraged to report under the PSQIA privilege protections.
- The PSQIA provides broad protection to encourage robust reporting.
- The AQIPS industry definition of “patient safety or quality related event” is one that has harmed, or could have harmed, “a patient, healthcare provider or visitor, whether or not a patient, healthcare provider or visitor is physically present. . .”

Shands v. Beylotte (cont.)

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 appeals court cited and followed the recent *TMH v. Wiles* decision.
- **The court quashed the order requiring production of the PSER.**

***Nelms v. Wellpath*, 2023 U.S. Dist. LEXIS 57292 (E.D. Mich. Mar. 31, 2023)**

Holding: M&M Review of death in county jail prepared by health care provider for PSO reporting, and which was reported to the PSO, was PSQIA-privileged PSWP.

Background:

- Wellpath provides health care services to county jail, where prisoner suffered a heart attack and died.
- M&M Review prepared following the death had three parts:
 - Part I – Patient Information Report;
 - Part II – List of attendees at the M&M review;
 - Part III – Report and Recommendations.

Nelms v. Wellpath (cont.)

- The Patient Safety Officer's sworn affidavit established:
 - Wellpath has a contractual relationship with a PSO.
 - The relationship is for PSQIA purposes, including the exchange of patient and quality information in the conduct of patient safety activities.
 - Wellpath maintains a PSES to collect, manage and analyze information that may be reported to the PSO, including documents such as its M&M Reviews.
 - Wellpath conducted an M&M Review within the PSES; Part III was done with the exclusive intent to report it to the PSO, it was reported to the PSO, and not used to fulfill external obligations.

Nelms v. Wellpath (cont.)

Rationale:

- Wellpath met the two prongs for PSWP through Affidavit testimony:
 - The document was created for the purpose of reporting to a PSO, and
 - It was so reported.
- The Affidavit was corroborated by Wellpath's PSES Policy.
 - The Policy includes M&M reviews in its definition of PSWP.
 - The Policy defines PSWP as being produced for the purpose of reporting to the PSO.

Plaintiff's Arguments Rejected:

- Affidavit didn't establish personal knowledge of facts or PSO reporting methods.
- Requirement that the information "could result in improved patient safety, healthcare quality, or health care outcomes" not met because of (i) 13-month delay in reporting, and/or (ii) failure to include the main personnel in charge of the patient's care in the M&M review.
- M&M Review created for "dual purposes" (e.g., state or federal agency reporting, recordkeeping or other maintenance obligation).
- M&M Review exists separately from the PSES.

Liability for Attorney Fees in Motion to Compel

Allen v. Clinton HMA, LLC, 2024 U.S. Dist. LEXIS 40954

- Liable for Attorney Fees
 - Hospital failed to present evidence that the Review Document was prepared for reporting to a PSO. Rather, document appeared on its face to have been prepared for other purposes.
 - Privilege log stating only “Patient Safety Work Product Patient Safety and Quality Improvement Act, 42 C.F.R. Part 3” was insufficient.
 - No affidavit produced.

Garcia v. Bd. Of Cnty Commrs. for Cnty. Of Dona Ana, 2023 U.S. Dist. LEXIS 146

- Not Liable for Attorney Fees
 - Lack of definitive law in the jurisdiction
 - Defendant submitted adequate privilege log that detailed the mortality review’s authors, recipients, dates of creation and specific privilege claimed.
 - Defendant submitted affidavit that identified the purpose of the mortality review as “reporting to PSO.”

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, simulations? Does it include videos? 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 PSES framework. Does it extend to committee meetings? Safe tables? Peer evaluation?

Distinguish between purpose of creating and subsequent uses.

- Describe the disclosure permissions and continuing protections set forth in the statute so that it is clear that internal use and external disclosure are within the specific parameters of the privilege protections that the statute confers.
- Identify key personnel and committees that conduct patient safety activities within the PSES framework, who can use and disclose, and to whom.

Maximizing Privilege Protection in Discovery Disputes

- **Assert privilege in response to discovery request.**
 - Ensure your med mal attorney understands your PSES and asserts the PSWP privilege
 - Produce a detailed privilege log – burden is on party claiming the privilege.
 - Accompany privilege log with comprehensive affidavit that supports the purpose of creating disputed document (reporting pathway or deliberation & analysis).
 - ▶ Attach your PSES Policy if it fully supports your legal position.
- **In motion to quash or in response to motion to compel, thoroughly brief the PSQIA issues, anticipating and countering Plaintiff’s arguments.**
 - If a subsequent use or disclosure is used to question the purpose, included a detailed analysis of the statute as a whole:
 - ▶ Emphasize purpose at time of creation (reporting or deliberation & analysis).
 - ▶ Discuss permitted uses and disclosure: PSWP was meant to be *used* to improve safety and can be used within the provider for *any* purpose.
 - ▶ Address non-waiver.
 - Rely on the statutory text, regulations and formal rulemaking – be prepared to counter plaintiff’s reliance on the subregulatory and outdated 2016 HHS Guidance and 2023 CMS QAPI guidance.

QUESTIONS?

USE CHAT OR ASK TO BE UNMUTED!

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ATTORNEYS AT LAW

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Plan a Discussion with Your Teams

MAPS Members

- Distribute the electronic copy of this presentation to your core PSO and legal teams.
- Review your PSES policies for any gaps or needed updates.
- No PSES? Begin writing your policy to add protections.
- Print or distribute any of the legal cases to reinforce PSO training.

Non-MAPS Members

- Contact MAPS to learn more about the advantages of federal protections.
- You have your own internal PSO, review your PSES policies.
- Always prioritize having a PSES.
- Share the legal cases to reinforce PSO knowledge.

The recording will be available and provided to all attendees.

Reminders

Please complete the survey that will follow to obtain your CE certificate. For attorneys seeking IL CLE – *Attendees will need to submit 2 codes on the evaluation. The codes are xx and xx.*
<https://www.surveymonkey.com> link to come.

Interested in learning more about MAPS? Contact: Carrie Pinasco, Senior Director, Quality, Safety and Health Policy at cpinasco@team-iha.org.