

IHA and MAPS PSO Legal Webinar: PSO Case Law Updates CANDOR/CRP and the Patient Safety Act

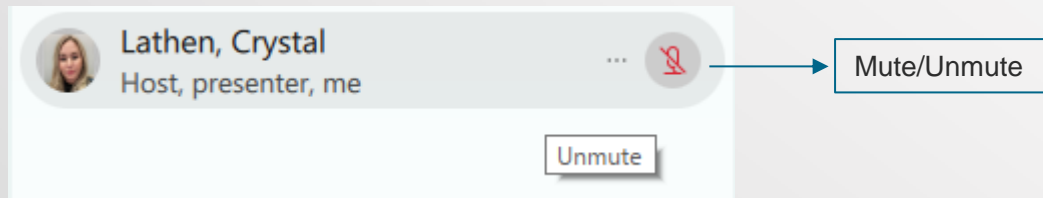
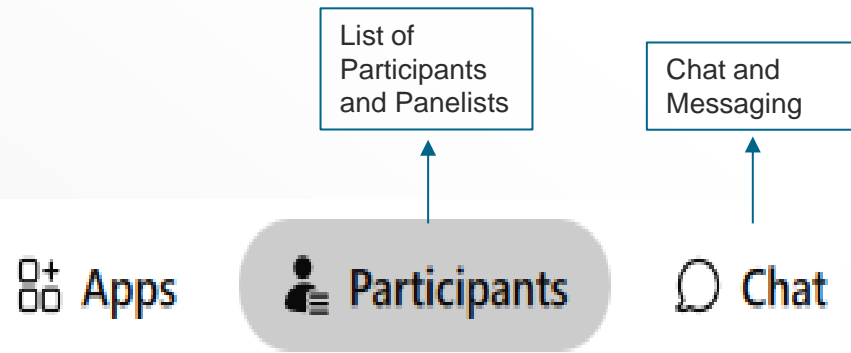
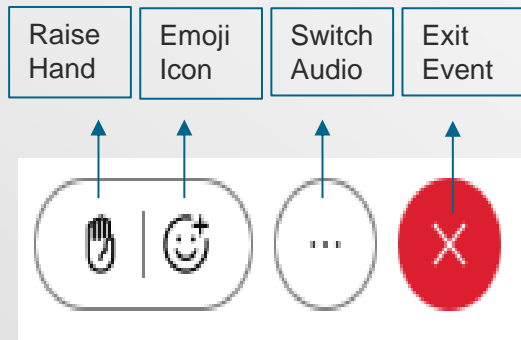
**Wednesday, January 22, 2025
12:55 - 2:30 pm**

Attendees are placed in listen-only mode

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- Continuing education credits are only available for attending the "live event."

PSO Case Law Updates CANDOR/CRP and the Patient Safety Act

Welcome and Introductions	Crystal Lathen, Consultant, Midwest Alliance for Patient Safety PSO	12:55 to 1:00 pm
PSO Case Law Updates CANDOR/CRP Programs and the Patient Safety Act	Robin Locke Nagele, Senior Counsel Post & Schell, P.C.	1:00 to 2:15 pm
Questions, Answers and Wrap-up	Carrie Pinasco, Senior Director, Midwest Alliance for Patient Safety PSO	2:15 to 2:30 pm

Let's Get Started!

Today we will:

Summarize recent Patient Safety Organization (PSO) litigation cases and lessons learned.

Discuss the impact of the Patient Safety Act on Communication and Optimal Resolution (CANDOR) and Communication and Resolution Program (CRPs.)

Review their Patient Safety Evaluation System (PSES Policies) to ensure Patient Safety Quality Improvement Act (PSQIA) protections for all relevant patient safety activities.



Robin Locke Nagele is Senior Counsel with the Health Care Practice Group of Post & Schell, P.C. She has a national health care litigation and consulting practice, in which she represents not-for-profit and proprietary health care providers, multi-hospital systems, physician practices and ancillary service providers, along with their medical, executive and corporate leadership in complex commercial, regulatory and antitrust matters.

Ms. Nagele counsels and represents federally listed Patient Safety Organizations (PSOs) and participating providers with regard to legal compliance and privilege protection under the federal Patient Safety Quality Improvement Act (PSQIA).

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PSO Case Law Updates
CANDOR/CRP Programs & Patient Safety Act
January 22, 2025**

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Case Law Update

Sunrise Hosp. & Med. Ctr. v. Eighth Judicial Dist., 544 P.3d 241 (Nev., March 7, 2024).

- Medical malpractice case alleging permanent brain damage to premature infant arising out of hypoxic event.
- The event was reported into and analyzed within the Hospital's PSES and reported to its PSO.
- At deposition, the Hospital's CMO discussed the Hospital's PSES and gave some information about the event, but other questions were objected to based on PSQIA privilege.
- Lower court ruled that, by testifying at deposition about the case, the CMO had waived the PSQIA privilege.
- Nevada Supreme Court reversed and issued a writ of prohibition.

Sunrise Hosp. & Med. Ctr. (cont.)

- The high court found that the lower court had misconstrued 42 USC 3.208 (which states that even PSWP disclosed *impermissibly* retains its privilege) as establishing the inverse proposition that any PSWP disclosed *permissibly* is not privileged.
 - The high court noted that the PSQIA regs have explicit, narrow exceptions to an otherwise broad privilege protection – which was negated by the lower court’s interpretation.
- “We determine that the PSQIA privilege is absolute.”
- The PSQIA “privilege cannot be waived.”
- A party may “inadvertently disclose [PSWP] . . . but the privilege continues to exist.”

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

- 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 produced.

In re: Baycare Med. Grp. (cont.)

- 11th Circuit issued a writ of mandamus reversing 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.”

In re: Baycare Med. Grp. (cont.)

- Key Takeaways from the 11th Circuit ruling:
 - Debunks the 2016 HHS Guidance as authority for the “sole purpose” test
 - There is only a “brief reference” to sole purpose in that guidance, contained in an illustrative chart.
 - That guidance document is not law (citing Kisor).
 - Explains why the exceptions to the PSWP definition do not create a “sole purpose” test.
 - Distinguishes between state mandates to maintain information internally (which may be privileged) from state mandates for external reporting.
 - Distinguishes *Charles* on the basis that that case dealt with external state law obligations.
 - Holds that *mandamus* is appropriate because of the “importance of privileged information, the seriousness of the injury when disclosed during discovery, and the lack of effective review after disclosure.”

Whistleblower Cases – Statutory Basis

- **Statutory Reporter Protection – 42 USC 299b-22(e)**

- Prohibition against adverse employment action against an individual based upon the fact that the individual in good faith reported information (i) to the provider for reporting to a PSO, or (ii) to a PSO.

Adverse employment action

- Loss of employment, failure to promote, failure to provide any other employment-related benefit to which the individual would otherwise be entitled,
- Adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual.

- **Remedies – 42 USC 299b-22(f)(4)**

- Civil lawsuit by aggrieved individual for equitable relief, including injunction, reinstatement, back pay, restoration of benefits and “other appropriate relief.”

Dailey v. Alliance Phys., Inc., (S.D. Ohio, Feb. 12, 2024)

- Dailey was a Hospitalist and Nocturnist employed by Alliance Physicians, Inc. from February 2019 until his resignation July 21, 2021.
- Alleges he repeatedly expressed concerns re: patient safety.
 - “Forced to intervene” when patients’ “lives were in peril.”
 - Made multiple complaints orally and by email to other physicians.
 - Filed MIDAS incident reports regarding dereliction of duty by fellow physicians “with the intent that these reports be forwarded to a PSO.”
- Alleges management retaliated with bad assignments and the patient safety issues continued.
- Claims under PSQIA that he was “constructively discharged” for reporting patient safety events with the intent that they be reported to a PSO.

Dailey v. Alliance Phys., Inc.

- Hospital claims on Motion to Dismiss:
 - “Constructive discharge” is not actionable under PSQIA.
 - Dailey failed to adequately plead “constructive discharge.”
 - Dailey failed to adequately plead that he reported patient safety issues to Alliance with intent that they be reported to a PSO.
- Court assumed without deciding that PSQIA whistleblower provisions encompass “constructive discharge,” i.e.,
 - Deliberately creating intolerable working conditions as perceived by a reasonable person with
 - Specific intent to force the employee to quit.

Dailey v. Alliance Phys. Inc.

- However, Dailey had not alleged sufficient facts to give rise to a plausible claim of constructive discharge.
 - Dailey’s fear that he would be implicated in malpractice cases due to “poor standards of care and refusal to address his concerns” was insufficient.
 - There were no facts to suggest that management’s failure to respond to his patient safety concerns was motivated by a desire to force him to quit.
 - An isolated allegation that the Medical Co-Director had called him a “liar” was insufficient to support his intent argument.
 - His general allegation that he received retaliatory assignments, unsupported by specific facts, was likewise insufficient.
 - In short, plaintiff could not rely on his own subjective beliefs to make out the claim.
- The Court did not reach the question of whether Dailey’s allegation that he made the patient safety reports with intent that they be reported to a PSO was sufficient to withstand Motion to Dismiss.

Manazer v. Adena Hlth. Sys., (S.D. Ohio, June 12, 2024)

- Manazer was a vascular surgeon who started Adena's program in 2006 and in 2013 became Chief of Surgery, overseeing quality & conduct.
- In 2022, another physician, Dr. Betz, started performing TAVR before he was fully credentialed to do so.
- A year later, the Ohio Medical Board contacted Manazer, and Manazer told the Board that allowing a physician to perform TAVR without proper credentialing posed a patient safety risk.
- Manazer alleges he also gave similar information to directly to Dr. Betz and to Adena "*with the intent of having the information forwarded to a PSO.*"

Manazer v. Adena Hlth. Sys.

- The situation escalated when Manazer allegedly gave damaging information about the TAVR procedures to a local news station and made damaging Facebook posts.
- Adena terminated Manazer’s employment for engaging in “social media attacks, posts, threats, misinformation, and malicious behavior.”
- Manazer sued Adena, *inter alia*, under the PSQIA whistleblower provision.
- Hospital’s Claims on Motion to Dismiss:
 - Manazer failed to allege he reported “PSWP” as defined by PSQIA.
 - Manazer failed to allege that he reported directly to a PSO or to a provider with intent to report to a PSO.

Manazer v. Adena Hlth. Sys.

- Court dismissed the case based on failure to adequately plead Manazer’s intent to report to PSO:
 - The Complaint does not allege a direct report to a PSO.
 - Neither Adena nor the Ohio Board is a certified PSO.
 - The Complaint does allege that Manazer reported the safety concerns “with the intention of having the information forwarded to” a PSO, but
 - He offers no specific facts in support of that claim, and
 - The mere conclusory allegation, standing alone, is insufficient under federal pleading standards (*Twombly*).
- Court did not reach the alternate argument that he failed to adequately allege that the information was PSWP.

CMS Patient Safety Structural Measures CANDOR/CRP Programs and the Patient Safety Act

CMS Patient Safety Structural Measures

- **Domain 4: Accountability and Transparency**
 - Confidential safety reporting system
 - Participation in PSO Patient Safety Activities
 - Safety Metrics tracked and reported to all staff
 - **Defined Communication and Resolution Program following harm (e.g., CANDOR):**
 - Harm identification
 - Open and ongoing communication with patients/families
 - Event investigation, prevention, learning
 - Care-for-the-caregiver
 - Financial and non-financial resolution
 - Patient/family engagement and ongoing support
 - Inclusion of CRP in ongoing performance monitoring and reporting to Board.

CMS Patient Safety Structural Measures

- **Domain 5: Patient and Family Engagement**
 - Patient and Family Advisory Council with diverse representation
 - Comprehensive patient access to medical records, clinical notes
 - Incorporation of patient and caregiver input on safety events, issues
 - Promoting family/caregiver engagement as part of the care team.
- **What fits well within PSQIA structure?**
 - Patient/Family participation in event analysis within PSES.
 - Patient/Family/Caregiver support within PSES.
 - Patient/Family Advisory Council participation within PSES.
- **What does not fit well within PSQIA structure?**
 - Real-time patient/family communication while providing care.
 - Litigation/claims resolution process.

Patient Communication mandated by PSSM

- **Real-Time Communication in the Provision of Care:**
 - Provider-patient/family communication in the course of providing care.
 - Comprehensive patient access to medical records, clinical notes
 - Real-time incorporation of patient and caregiver input on safety events and issues
 - Promoting family/caregiver engagement as part of the care team.
- **After-the-Fact Communication and Resolution of Patient Safety Events (CRP):**
 - Provider-patient/family communication of root cause analysis and corrective actions (note that some states provide immunity protection for “apologies” but not Illinois).
 - Patient/family participation in root cause analysis and corrective actions.
 - Patient/family support following adverse event.
 - Financial and/or non-financial resolution of issues/claims.
- **CRP has two components: Communication and Resolution.**
 - Communication: information sharing and opportunity for learning.
 - Resolution: attempt to resolve issues/claims outside of litigation.

Use of PSQIA Protections for CRP Communication

- **Benefits**

- Provides consistent federal protections so that patients can receive the same quality and quantity of information across the country.
- Permits greater transparency to the patient/family and support to workforce. Sharing the root cause and corrective actions with the patient/family may promote more in-depth analysis – which can improve quality.

- **Structure**

- CRP Communication may take place within a PSES, which provides a protected space within which providers and patients/families can meet to candidly share, listen and learn from adverse events.
 - Sharing of results after the RCA has occurred (requires formal consent of all identified providers).
 - Inviting patient/family into the RCA process as workforce (requires agreement of all participants).
- Family members as temporary PSES workforce
 - Requires education/training and confidentiality agreements.
- All PSES interactions generate strictly privileged PSWP.
- The PSQIA non-waiver provisions prevent subsequent disclosure/use of PSWP communications in downstream litigation.

Confidentiality Agreements for CRP Resolution

- **Benefits of CRP Resolution**

- Can bring closure, healing and allow the hospital and patient/family to continue to work together constructively in the future.
- Can be cost-effective and limit liability exposure by avoiding large verdicts and costs of defense.

- **Structure**

- Not suitable for PSES because dispute resolution is not a patient safety activity.
- Requires state law privilege protection AND/OR a confidentiality agreement.
- A signed Confidentiality Agreement will protect all parties and prevent subsequent disclosure/use of information shared within the resolution process from subsequent disclosure/use in downstream litigation.
- PSWP may be disclosed/used in the mediation with the consent of all identified providers, with the following express limitations:
 - It is limited to use during the mediation and may not be used/disclosed for any other purpose.
 - It is protected by the continuing protection provisions of the PSQIA and the Confidentiality Agreement governing the mediation.

Why is Confidentiality Essential? - CRP Case Law

- **Castillo v. Rex (Tenn. October 2023)**

- Parties attempted CRP but it was not successful.
- During the CRP, the Hospital shared particulars of the case that had been generated during a Quality Improvement Committee (QIC) meeting (which ordinarily is privileged under TN law).
- Patient then sued providers and sought to use the QIC information against the Hospital.
- Hospital argued QIC privilege, but court noted that the QIC information was shared with the family in a non-QIC context, which is outside the scope of the QIC privilege protection under TN law.
- The court examined a Colorado statute governing CRP programs and noted that Colorado requires: (i) up front disclosure to the family that information shared during CRP is confidential/privileged, and (ii) the signing of a Confidentiality Agreement.
- TN did not have such a statute and, even if it did, no such disclosures were made and no Confidentiality Agreement was signed.
- Privilege protection was denied.
- **Takeaway:** providers can't presume privilege protection is available and a signed Confidentiality Agreement is essential for either Disclosure or attempted Resolution.

Patient Disclosure using the Patient Safety Act

- **Discussions Protected upon Disclosure:** PSWP information disclosed to the patient/family is protected as the discussion occurs within the PSES and does not need to be reported to the PSO (42 U.S.C. 299b-21(7)(a)(ii); *In Re: BayCare*).
- **Disclosure Permission:** Can use “all providers agree as a condition of employment/privileges” disclosure permission and a confidentiality agreement to preserve the privilege.
- **Encourage reporting the causal information and learnings to the PSO to share learnings across the continuum and develop disclosure best practices.** (Note the Patient Safety Events are already reported.)
 - CRP measures – what disclosures are the most effective
 - Causal analysis and best practices
- Many PSOs are collecting patient disclosure information.

Use of PSOs in CRP Programs

- PSOs and PSO tools used in the CRP can be helpful in improving quality of patient care and the disclosure process - for example:
 - Patient disclosure Policies and Procedures and template confidentiality agreement.
 - Safe-tables for all the participants in a patient disclosure program, including on RCAs and best practices to improve the quality of patient care.
 - PSO committee to review RCA/action plans to ensure the RCA has actually uncovered the root causes and the action items will resolve the problem or make it harder for the event to be repeated. PSO committees also review RCAs to develop best practices for hospitals.
 - Care for the Caregiver Policies and Procedures – This allows the healthcare provider who was involved in a patient safety event to talk about the event without fear of the support caregiver being deposed.

Updating the PSES Policy

- Providers that opt to conduct CRP/CANDOR discussions under PSQIA protections should make sure their PSES Policies reflect this approach.
- Review and Update as Needed:
 - Description of Patient Safety Activities conducted within the PSES to include anticipated CRP Patient/Family communications, e.g.
 - Patient/Family/Caregiver and/or Patient Advisory Council Safe Tables.
 - Patient/Family Disclosure of RCA Results.
 - Patient/Family/Caregiver Support Programs.
 - Provide procedures for securing required Confidentiality Agreements & Disclosure Permissions.
 - Ensure that your PSWP Definitions encompass the work product generated as a result of CRP communications
 - Deliberations and Analysis
 - Information Developed for Reporting and Reported to the PSO.
 - Ensure that your P&Ps related to maintenance, storage, access, security, disclosure and reporting of PSWP encompass the PSWP generated as a result of CRP communications and all anticipated uses.

Thank you!

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Are You Struggling with Transparency and Discussing Safety?

Benefits of transparency in discussing events:

Improved patient safety:

- Openly discussing errors leads to improved identification of root causes and implementation of preventative measures to avoid future errors.

Enhanced trust among staff and patients:

- When patients feel that healthcare providers are honest about mistakes, it builds trust and strengthens relationships.
- Programs such as CANDOR (Communication and Optimal Resolution) can be protected under PSO policies.



Are You Struggling with Transparency and Discussing Safety?

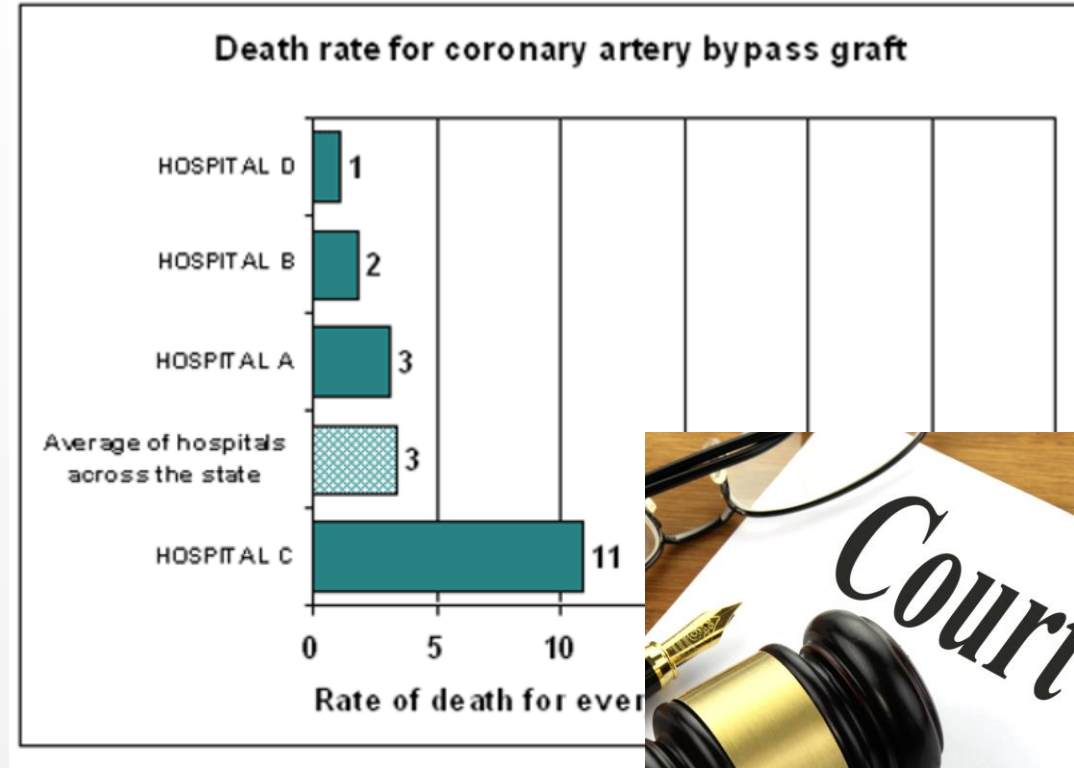
Benefits of transparency in discussing events:

Learning and improvement:

- By analyzing reported events, healthcare organizations can learn from mistakes and implement quality/safety improvement strategies.

Reduced legal risk:

- Studies indicate that open disclosure of adverse events within and organization can potentially reduce the likelihood of lawsuits.



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, and patients? 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? 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 About the Value of a PSO?

- 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.
- PSWP cannot be discovered or admitted into evidence in connection with any state, federal or local disciplinary proceedings, or proceedings of professional bodies created by state law.
- A provider cannot be compelled to produce PSWP in the discovery process of a lawsuit. PSWP can be disclosed voluntarily, as long as, the manner of disclosure meets the confidentiality requirements.



Next Steps and Closing Remarks

- PSO membership is key to defending challenges to your patient safety investigations, internal event details and verbal discussions.
- 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.

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.
- Prioritize having a PSES in place if you have your own internal PSO.
- Review your PSES policies.
- Share the legal cases to reinforce PSO knowledge with staff and legal counsel.

The recording will be available and provided to all attendees.

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.

Questions?

Please complete the survey to give MAPS feedback on your experience today.

Remember to record your CE/MCLE credit requests in the evaluation.

CE requests are due February 5

MCLE requests are due January 29

<https://www.surveymonkey.com/r/cslaw>

Reminders:

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Interested in learning more about MAPS?

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Thank you!