Illinois Health and Hospital Association

Midwest Alliance for Patient Safety

A federally certified Patient Safety Organization (PSO)

IHA and MAPS PSO Legal Webinar: PSO Case Law Updates, CANDOR and Expanding the PSES

September 22, 2025
10:55 am - 12:30 pm

Attendees are placed in listen-only mode

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PSO Case Law Updates, IL perspective on CANDOR and Expanding the PSES to include visitor and non-patient events

Welcome and Introductions	Carrie Pinasco, Senior Director, Midwest Alliance for Patient Safety PSO	10:55 to 11:00 pm
IHA and MAPS PSO Legal Webinar: PSO Case Law Updates, CANDOR and Expanding the PSES	Michael R. Callahan, JD, Senior Consultant, Hardenbergh Group	11:00 am to 12:20 pm
Questions & Answers	Crystal Lathen, MAPS PSO Consultant, Midwest Alliance for Patient Safety PSO	12:20 to 12:30 pm

Let's Get Started!

Today we will:

1. Summarize recent PSO litigation cases and lessons learned.
2. Discuss the impact of the Patient Safety Act on CANDOR Programs in consideration of Illinois laws.
3. Expanding Patient Safety Evaluation System (PSES) policies to include visitor and staff events as part of Patient Safety Work Product (PSWP.)

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

Hardenbergh Group

Midwest Alliance for Patient Safety

September 22, 2025

IHA and MAPS PSO Legal Webinar:
PSO Case Law Updates, CANDOR and Expanding the PSES

Presented by:
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Hardenbergh Group

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Michael R. Callahan
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Michael R. Callahan brings an unparalleled level of healthcare consulting experience. Formerly a healthcare attorney for over 40 years, he provides consultative services, educational programs and thought leadership in his role as Senior Consultant.

His areas of focus include hospital/physician relations, medical staff bylaws and policies, peer review policies and investigations, privileging and credentialing issues, National Practitioner Data Bank guidelines and reporting standards, EMTALA standards, accreditation compliance, medical staff integration and hospital/medical staff disputes.

In addition, he is recognized as a national expert involving all aspects of the federal Patient Safety and Quality Improvement Act of 2005.

In Re: BayCare Medical Group

Factual Background

- Surgeon filed an employment discrimination lawsuit in federal court after being terminated by BayCare Medical Group and St. Joseph's Hospital in Tampa, Florida.
- Termination was based on alleged commission of several surgical errors.
- During discovery, surgeon sought to require that BayCare disclose "internal documents about the performance of other doctors who were not fired despite also committing errors."
- Surgeon also demanded production of "referral logs" which identified patient and other complaints brought against other physicians.
- BayCare argued that all of the requested documents (collectively referred to as "quality files') were privileged under the PSQIA and therefore not subject to discovery.

(In Re): Baycare Medical Group 101 F. 4th 1287

Federal District Court Decision

- BayCare had established that the quality files were collected within its PSES.
- Trial court ruled, however, that the PSQIA privilege protections do not apply if the quality files had a "dual purpose" as opposed to being collected for the "sole purpose" of reporting to a PSO.
- Because the quality files were also used for internal safety analysis and peer review, BayCare did not satisfy the "sole purpose standard."
- BayCare subsequently filed a writ of mandamus requesting that the 11th Circuit Court of Appeals vacate the district court's order compelling disclosure of the quality files.

11th Circuit Court of Appeals Decision

In reversing the trial court's decision, the Court of Appeals made the following findings:

- The plain text of the PSQIA does not require that privileged information be "kept solely for the provision to a [PSO]."
- The Court noted that the PSQIA protections also apply to PSWP which "identif[ies] or constitue[s] the deliberations or analysis of, or identifies the fact of reporting pursuant to a [PSES], citing to 42, USC Section 299b-21(7)(A).
- BayCare "may use [PSWP] for any purpose within [its] legal entity" (72 Fed. Reg. 70732-01 at 70779 (Nov. 21, 2008)(Preamble to the Final Patient Safety Rule).
- "Nothing prohibit[s] the disclosure of [PSWP] among physicians and other health care professionals, particularly for educational purposes or for preventing or ameliorating harm." Id. At 70778.
- The Court again quoted from the Preamble in noting: "The regulation is clear - [U]ses of a [PSWP] within a legal entity are not regulated and thus, [PSWP] may be used within an entity for any purpose, including "credentialing, disciplinary, peer review purposes". Id at 70779.
- Court ruled that the trial court abused its discretion in applying the wrong legal standard and was instructed to vacate is prior order and to reconsider BayCare's privilege argument.

Burke v. The Ingalls Memorial Hospital

Factual Background

- Plaintiff in this medical malpractice action was a 76-year-old patient who was admitted to the inpatient rehab unit at Ingalls after a 3-week hospital stay for cancer treatment
- Precautions were taken because he was identified as a fall risk
- Despite precaution efforts, he had an unwitnessed fall and was taken to the ICU after sustaining a head injury
- A nurse created an occurrence report the same day and reported it to Clarity PSO via the Ingalls Healthcare Safety Zone portal
- The report triggered a patient safety investigation which resulted in a nursing peer review process.
- All of the materials which were generated by the review were reported to the PSO

Burke v. Ingalls 2023-L-006063, Ill., Cook Cty

Factual Background

- During the discovery process the hospital provided an updated privilege log which identified the 13 pages at issue as PSWP under the PSQIA.
- The log also cited to the Daley Appellate Court decision along with two affidavits, one from the VP for Clinical Performance Excellence who was responsible for Risk and Patient Safety Quality Performance Improvement.
- The second affidavit was from the Executive Director of Clarity PSO.
- Plaintiff argued in its Motion to Compel that Ingalls had not met the "sole purpose standard" allegedly required under Daley.
- Plaintiff further argued that the materials should be treated as documents prepared in the Hospital's "ordinary course of business" and therefore not privileged under the PSQIA.

Trial Court’s Decision

- Citing to the 11th Circuit Court of Appeals decision in BayCare, Ingalls argued that there is no "sole purpose" requirement under the PSQIA even though the documents in dispute in fact had been reported to a PSO.
- The affidavit prepared by the Hospital included as attachments the Hospital's PSES policy, its event reporting policy and its Quality Plan.
- The affidavit submitted by Clarity PSO confirmed receipt of the reported materials and also described how the PSO reviews, analyses and prepares reports and feedback to Ingalls and all of its members to support their efforts to improve patient safety and reduce risk.
- In rejecting the plaintiff's "sole purpose" argument, the trial court observed that the Hospital’s legal arguments, affidavits and policies reviewed together "set forth a plethora of information as to the workings of the defendant hospital, its agreement with Clarity as its PSO, as well as the purposes and compliance with the requirements of the PSQIA.”

Trial Court’s Decision

- In response to plaintiff's "ordinary course of business" argument, the Hospital pointed out that there is no such exception under the PSQIA. Also, the mission of all hospitals through their myriad quality, performance improvement and peer review policies and practices is to improve patient safety and reduce risk. To rule that the work product produced by these efforts is not privileged would be to effectively gut the privilege protections under both the Illinois Medical Studies Act and the PSQIA.
- And even if there was such a common law or other standard to support an "ordinary course of business" exception, the PSQIA specifically pre-empts and should be any law or standard which provides less protections.
- Based on these arguments and the supporting affidavits and attachments, the court found that Ingalls had "satisfactorily established the elements of the privilege from disclosure, contained in the PSQIA."
- The court further ruled that the plaintiff's "sole purpose" and "ordinary course of business" arguments "are beyond those required by the statute."
- Plaintiff's motion to compel was therefore denied.

Two Other Notable Decisions

Shands Teaching Hospital and Clinics, Inc. v. Beylotte, No.1D22-1277, 357 So.3d 307 (2023)

- Court ruled that the PSQIA privilege protections applied to an incident in which an individual who was visiting a patient slipped and fell sustaining an injury
- Hospital had prepared an "investigation report" in response to the fall and reported it to its PSO
- Hospital contended that it uses all slip and fall reports and investigations to prevent such falls in patient-traversed corridors in order to improve patient safety.
- The Court noted that the PSQIA is not limited to patients and could apply to "any person - staff, patients and visitors alike."

Sunrise Hosp. & Med. Ctr., LLC v. Eight Jud. Dist. Ct., 544 P3rd 241 (Nev. 2024)

- Privilege protections under the PSQIA cannot be waived.

CANDOR/CRP Programs and the Patient Safety Act

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CANDOR/CRP Programs Background

Background

- Before the publication of the Institute of Medicine Report “To Err is Human,” which identified that over 100,000 deaths occurred from medical errors, Hospitals and physicians often used a “delay, defend and deny” approach, when unintended adverse patient events occurred.
- This approach largely was based on concerns about legal liability, loss of reputation, refusing to acknowledge error, reports to the Data Bank and licensing boards and similar implications.
- Over the years, however, it has been universally recognized by state and federal governments, accrediting bodies, health care associations and agencies such as the National Institute of Health and the Agency for Healthcare Research and Quality, that programs were needed to engage in honest and forthright discussions with patients and their families about these adverse events.

CANDOR/CRP Programs

- It is in this context that programs such as Communications and Optimal Resolution), and other Communications and Resolutions Programs were developed so as to address the following:
  - What happened and why?
  - Acceptance of responsibility for the adverse event
  - The provision of a true and honest apology
  - How the identified problem is going to be fixed going forward
  - How the patient and family will be actively engaged in this particular effort

Applying CRP Programs within a PSES Policy

Background

- All hospitals have events reporting systems and policies in place which identify the occurrence of an adverse event that could have been or was harmful to patients.
- Most hospitals participating in a PSO such as MAPS, collect adverse event reports in their PSES and either report them to the PSO or treat them as deliberators or analysis.
- Information which is reported to a PSO or treated as deliberations on analysis is privileged patient safety work product under the Patience Safety Act.
- Such Incident reports can be considered CANDOR/CRP reports which then typically trigger an internal investigation consistent with existing quality improvement/quality performance peer review investigations, committee reviews, reports, analyses, etc.

Applying CRP Programs within a PSES Policy

- If designed correctly, all such investigations and reviews can be privileged at a minimum under the Patient Safety Act and possibility under the Illinois Medical Studies Act.
- Under CANDOR/CRP programs, the communications with the patients and family members regarding the facts and cause of an adverse event along with the investigations can be kept privileged and confidential under the Patient Safety Act.
- The question is how much information does the hospital need to reveal to the patient and family that is considered PSWP, if any?
- Non-privileged information which can be disclosed and discussed include the following:
  - Any information in the medical record

Applying CRP Programs within a PSES Policy

- Any and all facts relating to the adverse event including the cause of the adverse event
- The results of any investigation, including a root cause analysis
- The actions the the hospital intends to avoid the occurrence of future adverse events such as the one affecting the patient
- Communications with the patient and family as to the outcome of remedial actions being taken by the hospital.

- Given the scope non-privileged information which can and should be disclosed to the patient and family it is probably not necessary to also disclose PSWP.

Applying CRP Programs within a PSES Policy

- In a rare event that the judgment is made to disclose PSWP, the hospital can exercise the written authorization disclosure exception under the Final Rule (Section 3.206(b)(3)) without protections waiving the privilege.

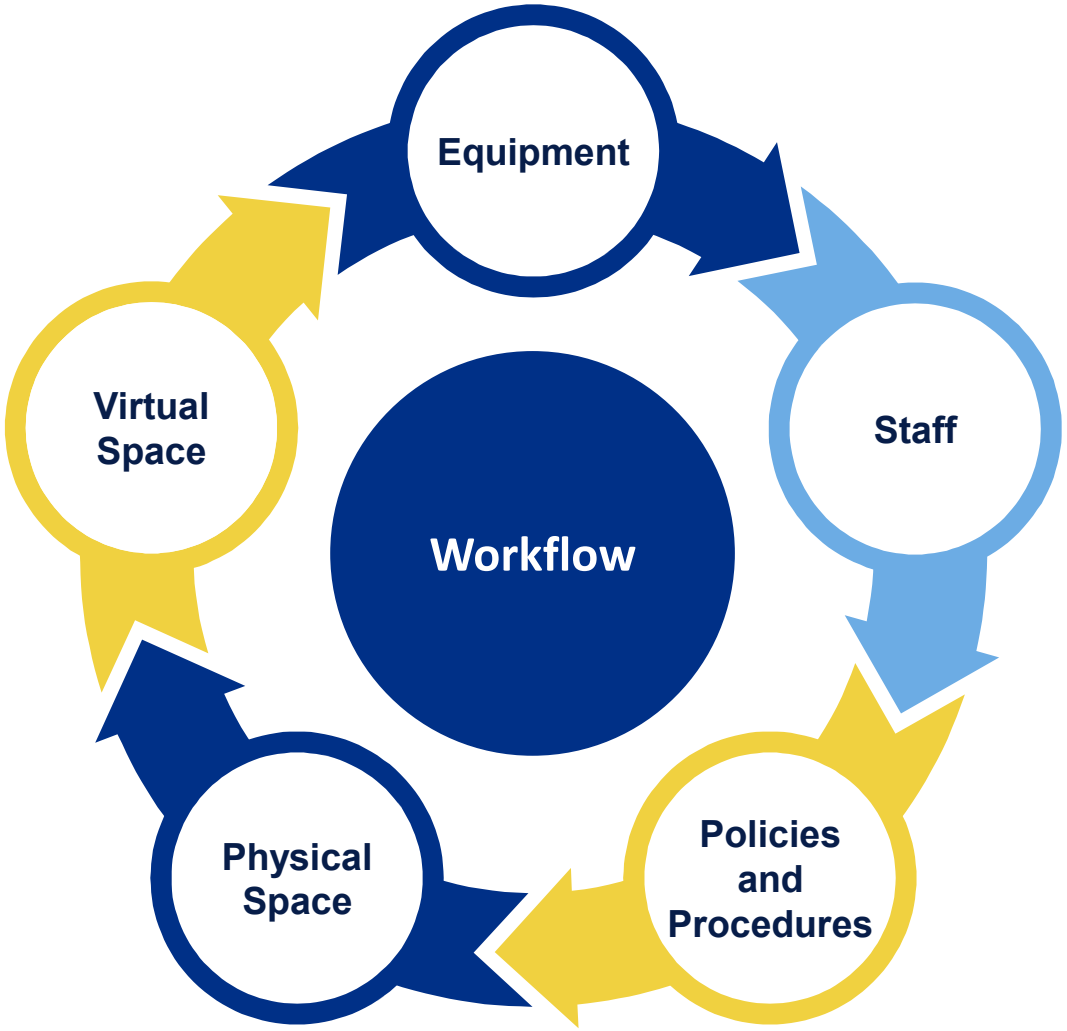
Recommendations

- Review your PSES Policy to determine whether the types of investigations and subsequent work product relating to adverse events is covered in order to be considered privileged under the Patient Safety Act.
- Add to the Policy a specific reference to CRP program including discussions with the family which are to be treated as PSWP to make sure that no PSWP is being disclosed to the family unless you are using the written disclosure exception under the Patient Safety Act.

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.

PSES Policy Development

- **Develop Both a Specific and Broadly Worded PSES policy**
  - ➢ One of the fundamental documents for internal educational purposes as well as to be introduced to a court in demonstrating that the materials in dispute are indeed PSWP is a provider's PSES policy.
  - ➢ The courts are not going to simply accept the word of the hospital or other provider that information qualifies as PSWP.
  - ➢ The provider should conduct an inventory of activities, its performance improvement, quality assurance, peer review and other related patient activities as well as the various committees, reports and other analyses being conducted within the organization.
  - ➢ This is the starting point when determining the scope of activities you wish to include within the PSES and therefore claim as privileged PSWP.
  - ➢ The details of these activities and the information to be protected should be reflected within the PSES.

PSES Policy Development

- When seeking to claim privilege protections over an incident report, committee minutes or other internal analysis, a provider can then cite to the specific reference within the PSES as evidence of the hospital's intent to treat this information as PSWP.
- The provider should also include the phrase "including but not limited to" a "catch all" to account for other privileged patient safety activities in the PSES policy.
- PSES Policy needs to be updated annually.
- May want to cross-reference to related policies.

- **Carefully Describe Your PSWP Pathway**
  - As reflected in the Appellate Court's decision in Daley, a provider can create PSWP via actual reporting, function reporting or through deliberations or analysis.
  - It is critical that your PSES policy distinguish which forms of information, incident reports, etc., are being actually reported to the PSO or scanned and downloaded and reported and what forms of information are being treated as deliberations or analysis.

PSES Policy Development

- As a practical matter, most patient safety activities can be characterized as deliberations or analysis.
- Information that is deliberations or analysis automatically becomes PSWP when collected within the PSES and does not need to be reported to the PSO although reporting is certainly an option.
- Most of the PSO appellate court decisions, including the Daley decision, involved actual reporting and not deliberations or analysis.
- Rumsey v. Guthrie Clinic is the first "deliberations or analysis" decision.
- Keep in mind too, that information which is being treated as deliberations or analysis cannot be "dropped out" and used for other purposes but can be shared if you meet one or more of the disclosure exceptions. These include disclosing to consultants, your attorney, and independent contractors that are assisting the hospital in patient safety activities and other disclosures permitted under the PSA.

Rumsey v. Guthrie Med. Grp., P.C. No. 4:18-CV-01605

Example Health System PSES

Example Health System PSES

What Comprises the System's Patient Safety Evaluation System (PSES)?

- A Patient Safety Evaluation System (PSES) is a structured process within a healthcare organization that is designed to collect, manage, and analyze information about patient safety events, incidents, near misses, and medical errors.

- The purpose of a PSES is to facilitate the collection of Patient Safety Work Product (PSWP) and to set guidelines for the management and analysis of information reported to or by a PSO.

Example Health System PSES

Key Components of a PSES:

- **Collection of Data**: This data can be gathered from various sources, such as incident reports or safety audits within the hospital.
- **Management of Patient Safety Work Product (PSWP):** Information collected through the PSES becomes PSWP if it is created for the purpose of improving patient safety.
  - ➢ PSWP includes data, reports, records, and analyses related to patient safety activities.
- **Internal Deliberation and Analysis:** Under the PSES, healthcare providers discuss and review events, identify root causes, and assess the effectiveness of existing safety protocols. These internal processes are protected from legal discovery under PSQIA.
- **Reporting to a PSO:** By reporting to a PSO, healthcare providers contribute to a broader effort to improve patient safety at a system-wide level.

Example Health System PSES

What is PSWP?

- Any data, reports, records, memoranda, analyses, communications in any form (including emails and text messages), or written or recorded statements created ***for the purpose of improving patient safety, quality, and clinical outcomes***
  - ➢ Copies of the above material are also PSWP

- Any deliberation or analysis ***conducted for the purpose of improving safety, quality, and clinical outcomes***

Example Health System PSES
Patient Safety Activities

- Patient Safety Activities may be conducted by any individual, committee or body that has assigned responsibility for any such activities. This includes faculty, staff, trainees, volunteers, and contractors who perform work under the direct control of the health system.

- Patient Safety Committees
- Center for Performance Improvement
- Medical Executive Committees
- Serious Safety Event (SSE) / Never Event (NE) Committees
- Peer Review Board

- Quality Improvement Committees
- Medication Safety Committees
- Bioethics Committees
- Network Performance Group
- Patient Experience Steering Committees
- Other committees with jurisdiction

Example Health System PSES

Examples of PSWP:

- Quality Reviews
- Peer review activities and documents
- Incident/adverse event reports
- RCAs
  - Investigation, notes, communication, emails, distributed materials, etc. surrounding review of RCA triggering event are PSWP
  - RCA document submitted to DOH is not PSWP
- Focused/Ongoing Professional Practice Evaluations (FPPE and OPPE)
- Risk Management activities not related to claims and litigation
- Communication (written, oral, or digital) and/or information developed or captured directly or in minutes by individuals or quality and/or patient safety committees
- Including emails and text messages
- Investigation around customer complaints and/or grievances related to quality and patient safety events

Example Health System PSES

What is Not PSWP:

- Medical Records
- Discharge Information
- Billing
- Patient Complaints and Grievances
  - Communication to Customer Service by the patient
  - Communication by Customer Service to the patient
  - Customer Service events unrelated to quality and patient safety concerns
- Information collected to comply with external obligations, such as:
  - State incident reporting requirements
  - Adverse drug event information reporting to the Food and Drug Administration (FDA)
  - Certification or licensing records for compliance with health oversight agency requirements
  - Reporting to the National Practitioner Data Bank of physician disciplinary actions

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Questions?

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Questions for our expert?

- Let's review chat
- Raise hands

Many Thanks to our Speaker:
Michael R. Callahan

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 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.

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 **Monday, September 29.**

https://www.surveymonkey.com/r/Sept22

A SPECIAL THANK YOU to YOU!

THANK YOU FOR SUPPORTING PATIENT SAFETY!

The Midwest Alliance for Patient Safety Team

For additional information or questions, please contact MAPSHelp@team-iha.org

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

Appendix of Cases

In re: Baycare Medical Group, 2024 WL 2150114 (11th Cir. 2024)

Burke v. Ingalls Memorial Hospital, No. 2023-L-006063 (Cir. Ct. of Cook County, Sept. 4, 2024) (Ruling on Motion to Compel)

Rumsey v. Guthrie Med. Group, No. 4:18-CV-01605 (M.D. Pa. Sept. 26, 2019) (Memorandum Opinion)

Shands Teaching Hosp. & Clinics, Inc. v. Beylotte, No. 1D22-1277 (Fla. 1st Dist. Ct. App. March 8, 2023)

Sunrise Hosp. & Med. Ctr. LLC v. Eighth Judicial Dist. Ct., No. 85844, 544 P3d 241 (Nev. 2024)