

IHA and MAPS Present Case Law Updates to Maximize Legal Protection for PSWP

Attendees will be placed in listen-only mode

Tuesday, February 28, 2023 - 12:00 pm- 1:00 pm

Help Line Phone: 630-276-5657

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

Agenda:

- Welcome
- Overview of MAPS PSO
- Review Educational Credits
- Meet our Presenter – **Robin Locke Nagele**
- Strategies to Better Understand PSO Case Law
- Question and Answer Session

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 and closing codes on the evaluation. *Note that there is a closing code at the end of today's presentation.***
- 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:

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

Who is Attending Today's Event?

- In-house legal counsel from IHA and MAPS Members
- External legal counsel for IHA and MAPS Members
- Directors of Risk Management
- Directors of Patient Safety and Quality
- MAPS PSO Coordinators

CE and Disclosure Information

CE Statement: As the sponsor of this didactic lecture with interactive exercises, the Illinois Health and Hospital Association 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.

Midwest Alliance for Patient Safety (MAPS) Representing A Diverse Membership

- **Non-Profit; founded in 2010, certified every year eligible**
- **Component of the Illinois Health and Hospital Association**
- **Offers protections, education, networking, shared learning**
- **Across the continuum focus on all safety events**
- **Simple and easy data mapping and collection**
- **Active national role**



100 MAPS Members and counting:

- Hospitals and Hospital Systems
- Critical Access Hospitals
- Physicians Groups
- Specialty Clinics
- Outpatient Facilities



Plan a Discussion with Your Teams

- You can distribute the electronic copy of this presentation to your core PSO and legal teams.
- You can review your PSES policies for any gaps or needed updates.
- If you do not have a PSES, you can begin writing your policy to add protection to your organization.
- You can print or distribute any of the legal cases to reinforce PSO training.
- The recording will be available and provided to attendees.

Today's Presenter



Robin Locke Nagele is a Principal and Co-Chair of the Firm's Health Care Practice Group at Post & Schell, P.C. She has a national health care litigation and consulting practice, in which she represents, in complex commercial, regulatory and antitrust matters, proprietary and not-for-profit health care providers, multi-hospital systems, integrated delivery systems, academic/teaching medical centers, and ancillary service providers, along with their medical, executive and corporate leadership.

Ms. Nagele is AV Preeminent peer review rated with Martindale-Hubbell, and she was recognized by *Best Lawyers in America*® in its 2020 and 2021 editions in the category of Health Care Law.

Case Law Update to Maximize Legal Protection for PSWP

Illinois Health and Hospital Association

February 28, 2023

Robin Locke Nagele

Senior Counsel, Post & Schell, P.C.

Federal PSQIA

Congressional Goal: *to remove barriers to improving safety and quality of care*

- **Confers:**

- *Confidentiality* and *Privilege* protection to report, collect and analyze safety and quality events so as to develop best practices leading to high quality patient care.

- **Facilitates:**

- Development of strategies to improve patient safety.
- Sharing of data and knowledge between providers.
- Collective analysis and learning from common safety challenges.

- **Protects:**

- *Patient Safety Work Product (PSWP)* developed within a...
- *Patient Safety Evaluation System (PSES)* of clinical providers who contract with ...
- *Patient Safety Organizations (PSOs)* to collect, aggregate, and analyze information to improve care.

Key Concepts of PSO Participation

PATIENT SAFETY EVALUATION SYSTEM (PSES)

- Collection, management or analysis of information for reporting to or by a PSO
- Promotes robust analysis and learning under federal privilege to improve patient safety, healthcare quality, and patient outcomes.

PATIENT SAFETY WORK PRODUCT (PSWP)

- Patient safety investigation & analysis within the PSES framework generates PSWP (data, reports, records, etc.)
- PSWP is *confidential and privileged*

PATIENT SAFETY ORGANIZATION (PSO)

- Entity certified by the federal Agency for Healthcare Research and Quality (AHRQ) to receive and analyze PSWP
- Feedback to providers for learning and improvement in patient care delivery

Patient Safety Work Product (PSWP)

<u>Reporting Pathway</u>	Patient safety data and information that is assembled or developed by a provider for reporting – and reported - to a PSO.	<ul style="list-style-type: none">• Event Reports• RCAs prepared for reporting to the PSO
<u>D&A Pathway</u>	Information that identifies or constitutes <u>deliberations or analysis</u> of a PSES.	<ul style="list-style-type: none">• RCAs conducted to improve quality and safety of the Provider• Patient Safety Meeting Minutes• Peer Review• Safe Tables
<u>PSO Pathway</u>	Patient safety data and information that is developed by a PSO for the conduct of patient safety activities.	<ul style="list-style-type: none">• Patient Safety Advisories• Feedback on specific patient safety events• Safe Tables

Patient Safety Work Product (PSWP)

What is excluded from PSWP definition?

Original patient and provider records	Medical chart, billing records, patient complaints.
Information collected, developed, maintained (or existing) separately from the PSES	<i>This will be defined by the Provider PSES</i> and could include, e.g., training records, videotapes, records of disciplinary actions, routine surveillance data, and information required for external agency reporting.
<i>The PSQIA does not limit providers' legal obligation to comply with legally mandated recordkeeping for public health & oversight purposes.</i>	<i>Providers must determine how to comply with regulatory obligations; this may be accomplished with PSWP, with provider consent and subject to continuing privilege protections.</i>

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, NPIN, 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	Consult counsel.
10.	PSWP may be produced pursuant to court order in certain criminal and equitable proceedings under very narrow circumstances.	Consult counsel.

Patient Safety Work Product (PSWP)

Special Rules on Disclosure of PSWP

Disclosure of <u>Non-Identifiable</u> PSWP negates the Privilege Protection	Comments
<p>If PSWP is rendered <u>non-identifiable</u>, then it can be disclosed without limitation, and is no longer considered PSWP.</p>	<p>Non-identifiability can be established through certification by a statistical expert or by removing all specified patient and provider identifiers from the PSWP.</p>
<u>Identifiable</u> PSWP Remains Privileged and Confidential Even if Disclosed.	Comments
<p>So long as PSWP is <u>identifiable</u>, then it continues to be privileged and confidential PSWP no matter who it is disclosed to, and <u>any recipient</u> to whom it is disclosed is subject to fines and penalties under the PSQIA for any further non-authorized disclosure.</p>	<p>PSQIA’s statutory privilege and confidentiality provisions are more stringent than HIPAA’s to the extent that they apply to <u>any recipient</u> of PSWP. Even PSWP disclosed impermissibly retains its privilege protection.</p>
Safe Harbor for Providers	Comments
<p>A <u>provider</u> may disclose PSWP so long as it does not (i) assess the quality of care of an identified provider, or (ii) describe or pertain to actions or failures by an identified provider.</p>	<p>The Safe Harbor provides flexibility to Providers to voluntarily share PSWP learnings both within and outside of their organizations.</p>

- Positive trends
 - Illinois (visitor fall case)
 - Florida
 - Virginia

- Concerning trends
 - Federal prison suicide cases

Fredericks v Edward-Elmhurst Health, 18th Judicial Circuit Court of DuPage County, Ill (2021)

Issue: Is a PSER of a Visitor Injury PSWP?

Facts:

- Patient Visitor in ER put her foot under a hydraulic bed. Nurse lowered bed and woman was injured (a premises liability case).
- Event report was reported in the PSES/dated and marked as PSWP and reported to the PSO (all documented in an affidavit).
- Hospital argued the definition of PSWP focuses on patient safety and quality improvement, including risks and hazards in specific settings for the delivery of care or in specialty care settings. See Fed. Reg. 8114 (Feb. 12, 2008).
- Plaintiff wanted to limit the definition to patient harm medical errors involving actual patients.

Holding:

- Court order agreed with Hospital - visitor PSERs are PSWP.

AQIPS Industry Definition

Patient safety or quality related event is an event that occurred, or is identified as a potential hazard or risk, during the delivery of a healthcare service or simulation of care or environment in which care is provided, that resulted in harm, or could have resulted in harm, to a patient, healthcare provider, or visitor, whether or not the patient, healthcare provider, or visitor is physically present. The term also encompasses an error of omission or commission, mistake, or malfunction in a patient-care process, including any related to professional behavior. It may also involve an input to such a process (such as a drug or device) or the environment in which such a process occurs. Patient safety or quality related events include near-miss events and events that result because of systems or workflow failures. This concept is applicable in any setting in which healthcare is delivered—a healthcare facility that is mobile (e.g., ambulance), fixed and free-standing (e.g., hospital), attached to another entity, as well as a patient's home or workplace.

Fla. Health. Sci. Ctr v. Azar (MD Fla. 2019) vacated (11th Cir., 2/11/2021)

Issue: Does Florida's Amendment 7 preempt the federal PSQIA's privilege protections for PSWP?

Holding:

- *No, Am. 7 does not preempt* the federal PSQIA's privilege protection for PSWP.
- *The decision was vacated but can be cited for is persuasive authority.*

Rationale:

- Express and unambiguous statutory text.
- Preemptive privilege protection is essential to promote the fundamental purposes of the act – patient safety analysis leading to improved care for patients.

Hacking v. United States (S.D. Fla. Discovery Order 4.28.21)

At Issue:

- 3 Patient Safety Analyses, 2 of which had been reported to the PSO.

Trial Court review:

- Court reviewed affidavits, deposition testimony and the documents *in camera*.
 - The Director of Patient Safety averred that the documents were created “solely” for purposes of the PSES and not used for Florida recordkeeping or reporting requirements.
 - At deposition, the Director did not recognize the terminology “Patient Safety Evaluation System.”

Holding:

- **All three documents were privileged PSWP:**
 - PSA 2017-32822 and PSA 2017-33824 were developed within the PSES for reporting and reported to the PSO.
 - SEA 2017-32822, internal RCA **not** submitted to PSO.
 - “PSQIA protects RCA that “identify or constitute the deliberations or analysis of a PSES.”
 - It was protected even though not reported to the PSO.

Hacking v. United States (S.D. Fla. Discovery Order 4.28.21)

Important Takeaways:

- **The PSWP was protected:**
 - Even though Patient Safety Director did not recognize the terminology “PSES.”
 - *The court applied a functional, not a formalistic, analysis.*
 - Even though the data could be used for statutory reporting or recordkeeping requirements.
 - *The court rejected the plaintiff’s argument as too speculative in light of the Director’s direct averment that it had not been used for reporting or recordkeeping.*
- **The court accepted the uncontradicted averments of Hospital staff, not the conjectures of plaintiff’s counsel.**

Tallahassee Memorial Healthcare, Inc. v. Wiles, No. 1D21-1503 (Fla. 1st DCA Nov. 14, 2022)

Issue: Does an Event Report created 12 days after the birth of a child who had meconium staining and respiratory difficulties at birth, that was prepared for reporting, and reported, to a PSO qualify as PSWP?

Facts:

- 39-wk pregnant patient gave birth via c-section to a newborn who had meconium staining and respiratory difficulties, requiring resuscitation and ventilation.
- 12 days later, a staff member created a Patient Safety Event Report, prepared solely for submission to a PSO and which was submitted to the PSO.
- Long after the event, the Wiles child was diagnosed with cerebral palsy, and the family sued.
- Plaintiff moved to compel production of the PSER, and the trial court, without explanation, ordered it to be produced.

Tallahassee Memorial v. Wiles (cont.)

Appeals Court Decision: Event Report was privileged PSWP.

Rationale:

- PSQIA provides a broad and preemptive federal privilege.
- PSQIA does not protect information that is required by law to be documented and reported externally.
 - Charles held that “adverse incident” reports required by law to be reported externally and never submitted to a PSO could not qualify as PSWP. Such documents, created for a “dual purpose,” could not be PSWP.
 - Charles also held that the PSQIA did not preempt Florida’s Amendment 7, even though it had already found that the documents in question were not PSWP.
- Wiles is distinguishable from Charles.

Tallahassee Memorial v. Wiles (cont.)

Appeals Court Rationale (cont.):

- The PSER qualifies as PSWP based on the evidence that it was prepared for reporting and submitted to the Hospital's PSO.
- The PSER does not qualify as an "adverse incident" that must be reported to the Agency for Healthcare Administration.
 - A reportable "adverse incident" is "an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which the intervention occurred," and which results in death, brain, or spinal damage, and other severe injuries (and other occurrences not relevant here).
- The corporate representative's testimony that the PSER was created in part to meet mandated "recordkeeping" responsibilities does not mean it was not "solely" created for reporting to the PSO.
- The federal PSQIA is preemptive, and the Charles holding to the contrary does not control the outcome in this case.
- Florida's Amendment 7 is preempted by the PSQIA. The PSWP is privileged.

Tallahassee Memorial v. Wiles (cont.)

Important takeaways:

- The Wiles decision not only confirms PSQIA's preemptive authority but strongly endorses the application of the privilege based on the Hospital's sworn statements and testimony.
- A concurring Opinion also attacks the unwarranted expansion of Am. 7 by Florida trial courts to virtually eliminate protection for internal hospital patient safety analysis.
- The Florida Supreme Court has accepted the plaintiffs' Petition for Review.
- AQIPS will be filing an Amicus Brief supporting the Hospital's position.
- We are cautiously optimistic that this case will present a vehicle by which the Florida Charles decision may be overruled or limited in scope.

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

Issue: Does an event report of a visitor fall in the hospital qualify as PSWP?

Facts:

- 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. Kimberly Beylotte (cont.)

- **Shands' Arguments on Writ of Certiorari**

- 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 does 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. Kimberly Beylotte (cont.)

- **AQIPS Amicus Brief**

- Visitor Events are encompassed within the PSQIA’s broad PSWP reporting framework.
 - ▶ PSWP encompasses “near miss” information that could result in improved patient safety, quality or healthcare outcomes.
 - ▶ AHRQ’s “common formats” for reporting “incidents, near misses and unsafe conditions” illustrate the breadth of information deemed relevant and useful.
 - ▶ Eliminating “unsafe conditions” requires analyzing threats of all kinds in all facilities where care is provided and to all categories of individuals.
 - ▶ In *Fredericks v. Edward-Elmhurst Health*, No. 2019L001238 (Cir. Ct. Du Page County, Ill. Jun. 17, 2021), the court ruled a visitor event report was PSWP.
- Charles was a deeply flawed decision that should not be expanded.
 - ▶ Its preemption analysis has been refuted by other courts and HHS itself.
 - ▶ It has been deeply damaging to patient safety analysis and should be limited strictly to its holding – i.e., mandated reporting info is not PSWP.

***Swenson v. Centra Health* (Va. Cir. Ct., Sept. 28, 2021)**

Holding: Plaintiff cannot discover “facts” contained in PSWP.

Background:

- Negligence case alleging fall by plaintiff in Centra’s ER bathroom.
- Plaintiff moved to compel PSWP in the form of interview and meeting notes and action plan prepared by the Serious Event Review Team.
- Plaintiff argued she was entitled to extract factual data from the PSWP

Rationale:

- Plaintiff is entitled to discovery underlying factual information through other means but not to extract it from the PSWP.
- PSQIA created a forum in which providers can “discuss the facts and share information openly, without worrying about their analysis being read back to them in court.”
- PSQIA did not create a “vacuum to suck up undesirable facts.”
- Plaintiff can take discovery to confirm that the documents qualify as PSWP.

Federal Prison Suicide Cases

- Significant trend of federal cases denying PSQIA protection for M&M reports in the context of prison suicides.
 - *Garcia v. Bd. of Cty. Comm'rs* (D. NM, Jan. 3, 2023); *Schiavone v. Luzerne Cty.* (MD Pa, Jan. 3, 2023); *Dence v. Wellpath* (D. Or. Nov. 29, 2022), *recon. den.* (Jan. 10, 2023); *Hultman v. Ventura* (C.D. CA 2022); *Louzi v. Ft. Bend* (S.D. TX 2021); *Penman v. Correct Care* (WD Ky. 2021); *Herriges v. Macomb Cnty.* (E.D. Mich. 2020).
- **Common elements**
 - Health care contractor for county prison system prepares M&M within its PSES, reports to PSO, and often copy goes to the county.
 - State law regulatory or contractual requirements to conduct the M&M and/or share it with the county.
 - Cases cite each other and 2016 HHS Guidance.

Federal Prison Cases (cont.)

Counter-Arguments

- Wrongly decided
 - ▶ No “sole purpose” test
 - ▶ HHS Guidance has been misinterpreted and disavowed by HHS.
- Distinguishable
 - ▶ County government contractor.
 - ▶ External reporting obligations (regulatory and/or contractual requirements to share report with the government client).
 - ▶ In some case, failure to establish through sworn testimony the key requirement that PSWP be “prepared within the PSES for reporting and reported to the PSO.”

Maximizing Privilege Protection

- Maintain a comprehensive and clear PSES Policy that accurately and completely defines your PSWP and explicitly incorporates the privilege protections, including the “continuing privilege” provisions of the statute and regulations. 42 USC 299b-22(d); 42 CFR 3.208.
- Work closely with malpractice defense counsel to strongly defend a Motion to Compel or support a Motion to Quash.
 - Assert appropriate and timely objections supported by a detailed Privilege Log.
 - Timely oppose an MTC or support an MTQ with supporting comprehensive Affidavits.
 - Attach your PSES Policy if it fully supports your legal position.
 - Thoroughly brief the PSQIA issues, anticipating and countering Plaintiff’s arguments.
 - Rely on the statutory text, regulations and formal rulemaking – be prepared to counter plaintiff’s reliance on the 2016 HHS Guidance.
 - Be prepared to produce your privileged PSWP in court for *in camera* inspection if necessary.
 - You can do so pursuant to the Consent Disclosure Permission at 42 CFR 3.206(b)(3);
 - Note that the continuing protection provisions are binding on the trial judge who reviews *in camera*.
 - Be prepared to file an immediate appeal of an adverse trial court decision.

Questions

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THANK YOU!
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Questions?

Please complete the survey that will follow to obtain your CE certificate.

**For attorneys seeking IL CLE –
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