IHA and MAPS PSO Present: Basic Law Protections for Healthcare Organizations Under the Patient Safety Act and Updated PSO Case Law

Please use the “call me” feature to join by phone
Attendees will be placed in listen-only mode

Thursday, Sept. 16, 2021 - 12:00 pm- 1:30 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 CLE requirements. **For attorneys seeking IL CLE – *You will need to submit opening code on the evaluation. *Note that there is a closing code at the end of today's presentation.***
- Educational credits will be emailed within 4-6 weeks of the event. *Note that CLE's and CE's will be granted to Illinois attorneys and healthcare providers only.*

Key Benefits for Joining this Event:

- 90-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
- Illinois Association of Healthcare Attorneys (IAHA)
- Directors of Risk Management
- Directors of Patient Safety and Quality
- MAPS PSO Coordinators

Welcome from Karen Harris, Senior Vice President and General Counsel, IHA and IAHA's Executive Director

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
1.25 hours of nurse continuing education credit for this program.

By attending "Illinois Health and Hospital Association Presents Basic Law Protections for Healthcare Organizations under the Patient Safety Act and Illinois Medical Studies Act – Part 1" offered by the Illinois Health and Hospital Association, participants may earn up to **1.25 ACHE Qualified Education Hours** toward initial certification or recertification of the Fellow of the American College of Healthcare Executives (FACHE) designation.

This course is approved for **1 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.

- **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**

104 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.

Post & Schell P.C.
ATTORNEYS AT LAW

Basic Law Protections for Healthcare Organizations under the Patient Safety Act and Updated PSO Case Law

Illinois Health and Hospital Association
September 16, 2021

Robin Locke Nagele
Co-Chair, Health Care Practice Group
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 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)

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

Patient Safety Work Product (PSWP)

Reporting Pathway	Patient safety data and information that is assembled or developed by a provider for reporting – and reported - to a PSO.	• Event Reports • RCAs prepared for reporting to the PSO
D&A Pathway	Information that identifies or constitutes *deliberations or analysis* of a PSES.	• RCAs conducted to improve quality and safety of the Provider • Patient Safety Meeting Minutes • Peer Review • Safe Tables
PSO Pathway	Patient safety data and information that is developed by a PSO for the conduct of patient safety activities.	• 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	***This will be defined by the Provider PSES*** and could include, e.g., training records, videotapes, records of disciplinary actions, routine surveillance data, and information required for external agency reporting.
The PSQIA does not limit providers' legal obligation to comply with legally mandated recordkeeping for public health & oversight purposes.	***Providers must determine how to comply with regulatory obligations; this may be accomplished with PSWP, with provider consent and subject to continuing privilege protections.***

When and how can PSWP be shared?

	Types of Use and Disclosure	Comments
1.	PSWP may be *used* 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 ***consent*** of all identified providers.	A valid consent form: •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.

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, biometic 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.

Special Rules on Disclosure of PSWP

Disclosure of Non-Identifiable PSWP negates the Privilege Protection	Comments
If PSWP is rendered non-identifiable, then it can be disclosed without limitation, and is no longer considered PSWP.	Non-identifiability can be established through certification by a statistical expert that the risk is very small that the information could be used, alone or in combination with other available information by an anticipated recipient to identify a provider (or a patient (HIPAA)). Alternatively, it may be anonymized by removing all specified identifiers.
Identifiable PSWP Remains Privileged and Confidential Even if Disclosed.	**Comments**
So long as PSWP is identifiable, then it continues to be privileged and confidential PSWP no matter who it is disclosed to, and any recipient to whom it is disclosed becomes a "responsible person" subject to fines and penalties under the PSQIA for any further non-authorized disclosure.	PSQIA's statutory privilege and confidentiality provisions are more extensive than HIPAA's to the extent that they apply to any recipient of PSWP. **Even PSWP disclosed *impermissibly* retains its privilege protection.**

CASE LAW DISCUSSION

Rumsey v. Guthrie (MD Pa. 2019)

- PSQIA extends privilege protection to:
  - Deliberations and analysis conducted within a PSES.
    - The proceedings and minutes of Infection Control Meetings conducted within a PSES.
  - PSO work product shared with the Provider.
    - Infection control and prevention materials received from PSO.
- PSQIA does not protect:
  - "General" infection control policies
    - E.g, policies disseminated throughout the hospital that guide clinical decision-making.
  - Infection rate data shared with external agencies.

Practice Pointers:

- The PSES can encompass the deliberations of a quality committee.
- Analysis does not need to be reported to be PSWP.
- Helpful to define what quality control activities are within the PSES and what quality control policies may be in general circulation and not PSWP.

Rice v. St. Louis University (ED Mo. 2020)

- PSQIA did not extend privilege protection where:
  - Provider had a PSO contract,
  - Provider alleged that its peer review process doubled as its PSQIA investigation process, but…
  - Provider did not clearly establish how its peer review system functioned within its PSES.

Practice Pointers:

- Peer review can be conducted within a PSES as part of the "just culture" safety system.
- PSES should clearly document how peer review relates to the learning system as a whole.
- Helpful to define what, if any, peer review activities are conducted separately from the PSES (e.g., formal corrective action and fair hearing process).

CCS cases: Penman (W.D. Ky. 2020), *Herriges (*ED Mich. 2020) *Louzi v. Ft. Bend* (SD Tex 2021)

- PSQIA ***did not*** extend privilege protection where:
  1. Provider *collected and reported* PSWP to its PSO, but also sent to Dept. of Corrections
  2. Provider did not clearly articulate the basis of its claim of protection for ***each*** of 8 different M&M reports prepared over a period of nine years.
- PSQIA ***did*** extend privilege protection where:
  1. There was no evidence of external disclosure external to the PSES.

Practice Pointers:

- Defense counsel must continue to push back hard on the erroneous "sole purpose" test.
- Educate the courts to distinguish between how PSWP is *created* and how it is *used*.
- Once information becomes PSWP it retains its character and privilege through the confidentiality and continuing protection provisions regardless of its subsequent use or disclosure.

Hite v. Mary Immaculate Hosp. (Va. Cir. Ct. 2020)

- Court found PSQIA extended privilege protection to:
  - The analysis portion of an incident report, where the hospital did not claim PSWP privilege for the entire report, but only for those components that constituted analysis.
- Court did not recognize privilege protection for:
  - Those portions of the incident report that, while claimed as PSWP by the hospital, were determined, based on *in camera* inspection, to be "more factual than deliberative."

Practice Pointers:

- If a provider designs its evaluation system such that (i) original incident reports are collected and maintained separately from the PSES, but (ii) subsequent analysis will be performed within the PSES for PSO reporting purposes, it is helpful to clearly define and distinguish in the PSES Policy/Plan between the original, non-privileged component of the reports and the privileged PSWP.

Thompson v. United States (S.D. Ill. 2020)

- PSQIA extends privilege protection to:
  - Information collected for reporting and reported to a PSO.
  - Information drawn from a non-protected external source, such as a risk management report, that is then incorporated into PSWP within the PSES.

Practice Pointers:

- Helpful to distinguish between factual information that is collected and maintained separately from the PSES (in this case, risk management reports), and PSWP that is created and analyzed within the PSES.
- Based on the *Thompson* analysis, the risk management information, while discoverable from its original external source, is non-discoverable once integrated into the PSWP documents.

Crook v. Dart (N.D. Ill. 2019)

- PSQIA held not to extend privilege protection to:
  - Information that is "related" to information collected within a hospital's electronic incident reporting system (eMERS), where the hospital alleges that the eMERS information "could" be reported to the PSO but does not allege that the eMERS information *was* generated or assembled for purpose of reporting to a PSO.

Practice Pointers:

- Helpful to delineate how information becomes PSWP within the PSES, and how it may intersect with the provider's PSO reporting system.

Ungurian v. Beyzman (Pa. Super. 2020)

- PSQIA held not to extend privilege protection to:
  - An Event Report that was collected for reporting and reported to a PSO, where the provider did not specify that it was developed "for the purpose of reporting" to the PSO and where the Event Report was also used to improve quality at the hospital.
  - An RCA that was collected and reported to a PSO, where the provider did not specify that it was developed "for the purpose of reporting" to the PSO, and where substantive information from the RCA was disclosed to the patient's health insurer.

Practice Pointers:

- Helpful to clearly specify that information developed through the reporting or analysis pathways may also be used for other purposes within the organization and disclosed externally without losing its status as privileged PSWP.
- Defense strategy: aggressive privilege litigation, grounded in statutory text.

McCue v. Integra (D. Mont. March 15, 2021)

Hospital failed to meet its burden under the "reporting pathway" of demonstrating that its entire quality file was developed "for reporting" to its PSO.

- Court refused to apply the "deliberations and analysis" prong because the Hospital had not adequately developed that argument.
- The court said it "strained credulity" that the Hospital's entire quality file was developed "for reporting" to its PSO.
- Court acknowledged the strong preemptive power of the PSQIA and its non-waiver provisions.

Practice Pointers:

•Courts are open to the "deliberations and analysis" pathway when properly presented.
•The PSES Plan should clearly identify what "D&A" the Provider performs within its PSES.
•Defense counsel must establish the factual and legal basis of the "D&A" privilege through Affidavits and briefing in opposition to Motions to Compel.

Tampa General v. HHS (MD Fla 2019) *vac.* (11th Cir., 2/11/21) *Shands v. Morgan (ND Fla. 2020), aff'd* (11th Cir., 5/13/21)

- Both cases sought relief in the federal courts from the Florida Supreme Court's ruling in *Charles* that eviscerates PSQIA protection for event reports developed and reported to a PSO.
  - *Tampa General:* district court ruling is strongly supportive of the PSQIA privilege protection and its strong, *preemptive* impact on contrary state law such as Florida's Am. 7; although vacated, can still be cited for "persuasive power."
  - *Shands*: dismissed for lack of jurisdiction, and dismissal was affirmed.

Practice Pointer:

Cite *Tampa General* case for the "persuasive power" of the District Court's preemption discussion.

The PSES Plan/P&P are an important roadmap --

- Clearly delineate <u>all</u> of your activities within the PSES
  - Collecting, analyzing and reporting in the "reporting" pathway.
  - Analysis and deliberations to improve patient safety/quality.
  - Receipt of feedback from the PSO to improve patient safety/quality.
  - Use within your organization (for *any* purpose).
  - Disclosure external to your organization.
- Emphasize the confidentiality and continuing privilege protections
  - <u>*Any*</u> recipient of PSWP becomes a "responsible person" under the Act and regulations.
  - PSWP <u>*retains*</u> its privilege protection even when disclosed permissibly or impermissibly.
  - Develop "consent" provisions and disclosure agreements that emphasize the continuing privilege.
- Regular review and update to ensure continuing accuracy as the PSES evolves.
  - Make sure it conforms to actual practice.
  - Do not be too prescriptive or bright line.
- Make sure your defense counsel use it as a foundation for their legal arguments.

Many "wins" stay under the radar. . .

- *Plaintiffs' counsel will withdraw or settle cases to avoid "unfavorable" PSQIA rulings*.

  Plaintiff sought RCA of the alleged malpractice event, presented at the defendant hospital's Patient Safety Meeting.

  - We prepared lengthy Affidavit describing/defining the Provider's PSES, its reporting relationship to the PSO, and how the RCA and Patient Safety Committee fit within the overall structure of that system.
  - Argued "reporting" and "D&A" pathway privilege protection.
  - Also argued "redundant" state law privilege protection under PA's "Act 13."
  - Plaintiff "conceded" the PSQIA issues and withdrew the Motion to Compel.

- *Some privilege wins involve client-sensitive subject matter*.

  Plaintiff sought an RCA performed in close collaboration with its PSO after a negative news article.

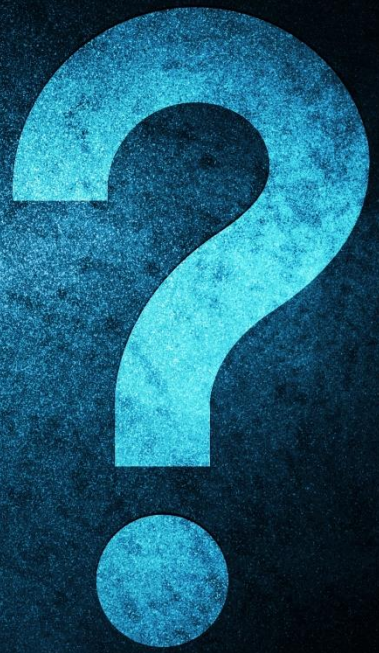
  - Court recognized the spectrum of PSQIA privileges under the three pathways and refused to order discovery of the RCA.

Under the Radar….

- *PSWP Continues to Be Privileged and Confidential upon Disclosure*

  Provider *voluntarily* discloses PSWP (usually RCA marked PSWP to government/Board of Medicine for regulatory oversight purpose)
  - Plaintiff FOIAs or subpoenas PSWP from government
  - Government *impermissibly* produces/discloses PSWP.
  - Providers argued that the Privilege is unwaivable and the PSWP remains confidential per 42 CFR 3.208.
- Court finds information *is PSWP* and therefore
  - *Privileged* (*cannot be used as evidence*) and
  - *Confidential* (*cannot be used in depositions of patients*).

Questions



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