

**Katten**

# **2024 THA PSO Spring Summit**

## **Patient Safety Act Caselaw, CANDOR, and National Patient Safety Initiatives**

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# Agenda

# **Recent Patient Safety Act Case Law Updates**

# Veltri v. AMITA Health Alexian Brothers Medical Center, 2023 IL App (1<sup>st</sup>) 230073-U (Sept. 29, 2023)

## Background

- This case involves a medical malpractice lawsuit in which the patient alleges that she suffered a fractured left distal femur during a surgical procedure by physicians acting as agents of the hospital.
- Plaintiff filed a Motion to Compel the discovery of three documents which the hospital claimed were privileged under both the Illinois Medical Studies Act (IMSA) and the Patient Safety Act (PSA).
  - Patient Safety Event Report (Veltri's RL Datix Report)
  - Acesis Peer Review Committee Case Write Up
  - SERT Event Review Team Case Notes

# Veltri v. AMITA Health Alexian Brothers Medical Center, 2023 IL App (1<sup>st</sup>) 230073-U (Sept. 29, 2023)

- Plaintiff argued that IMSA did not apply because the hospital failed to establish that the documents “were used, requested, or generated by any peer review committee, or its designee, in the course of an internal peer review process.”
- Regarding the PSA, the plaintiff argued that the hospital “had not asserted that the documents were generated strictly for submission to an approved” PSO.
- The privilege log actually implies “the documents were used for internal quality control and review separate and distinct from any PSO reporting.”
- The log also failed to “state that the documents ... were in fact submitted to a PSO” as the PSA requires.

# Veltri v. AMITA Health Alexian Brothers Medical Center, 2023 IL App (1<sup>st</sup>) 230073-U (Sept. 29, 2023)

- The trial court judge, which was the same judge in the *Daley* case, granted the plaintiffs Motion to Compel because the affidavit submitted in support of both privileges was “insufficient” and further: “It is the burden of the defendant in these cases to indicate or to prove when the Committees met and when they ended ... [and] that’s not found here in the Affidavit. So, therefore I’m finding that these documents which were prepared prior to any Review Committee Meeting were made in the ordinary course of business.”
- The court denied the hospital’s Motion for Reconsideration.
- Upon the hospital’s refusal to produce the documents, it was held in civil contempt. The hospital subsequently appealed.

# Veltri v. AMITA Health Alexian Brothers Medical Center, 2023 IL App (1<sup>st</sup>) 230073-U (Sept. 29, 2023)

## Appellate Court Decision

- The only document which the hospital claimed was patient safety work product (PSWP) under the PSA was Veltri's RL Datix Report under the "reporting pathway".
- Because the trial court did not make any findings of fact regarding this Report and whether it did or did not meet the PSA requirements, the appellate court addressed this question de novo.
- The Report was submitted both to the trial court and on appeal for in camera inspection.
- The court relied on the *Daley* decision in determining whether the report was "created for the purpose of reporting to a patient safety organization" and noted that the affidavit in that case stated that the documents in dispute were created "solely" for submission to the PSO.

# Veltri v. AMITA Health Alexian Brothers Medical Center, 2023 IL App (1<sup>st</sup>) 230073-U (Sept. 29, 2023)

- The appellate court ruled that the hospital had failed to meet its burden of establishing that the report was PSWP for the following reasons:
  - The affidavit submitted “is silent as to whether such reports are generated specifically for the purpose of submission to the [Ascension Health PSO] AHPSO.
  - The affidavit states only that the hospital “used the RL Datix electronic reporting system within its designated [PSES] and provides RL Datix reports to [the AHPSO]”
  - The affidavit actually suggests that “referral to the AHPSO is not the only use, as the patient safety specialist analyzed it for referral to the SERT Committee and MSQOC”



# **Veltri v. AMITA Health Alexian Brothers Medical Center, 2023 IL App (1<sup>st</sup>) 230073-U (Sept. 29, 2023)**

- The hospital's contention that these committees are subparts of AHP SO and/or that the reports were created only for reporting for AHP SO is not supported by the affidavit or the record which was established during the trial court.
- As a result, the hospital's argument that the report was privileged under the PSA was rejected.

# Franco v. Yale New Haven Hospital, Inc., Docket No. CV-20-6103795-S (New Haven Judicial District) (March 31, 2023)

## Background

- The plaintiff in this lawsuit was accidentally injured when resisting efforts by the hospital's protective services officers to address his threatening and aggressive behavior when attempting to remove a woman from the emergency room.
- The lawsuit against the hospital alleged assault and battery, negligence, negligent training and supervision and unlawful forceable detention leading to false arrest.
- During discovery, the plaintiff deposed the hospital's Patient Safety Coordinator and requested that she produce "any and all records, (including any written reports, videos, email communications, interoffice memos concerning the incident, etc.) ... wherein [Plaintiff] was injured and subsequently arrested."

# Franco v. Yale New Haven Hospital, Inc., Docket No. CV-20-6103795-S (New Haven Judicial District) (March 31, 2023)

- In response, the hospital argued that the materials requested were created within its PSES as part of the investigation into the incident. Because they were reported to its contracted PSO, they therefore were privileged under the Patient Safety Act and Connecticut statutes.

## Trial Court's Decision

- The trial court relied heavily on the Illinois Appellate Court decision in *Daley*, and also on the unrebutted representation in the Patient Safety Coordinator's affidavit, which included the following:
  - As Patient Safety Coordinator, she conducted an investigation of the incident within the hospital's PSES.
  - She was one of the “designated leaders responsible for collecting, analyzing and managing [PSWP] for the purpose of submitting to a PSO.

# **Franco v. Yale New Haven Hospital, Inc., Docket No. CV-20-6103795-S (New Haven Judicial District) (March 31, 2023)**

- The investigation notes she prepared were reported to the PSO and were not prepared, maintained or distributed outside of its PSES.
- The hospital contracted with an AHRQ certified PSO during the time of the incident.
- The Coordinator participated in a safety huddle with other employees to discuss the incident and interviewed an emergency nurse who witnessed the event.
- The purpose of the huddle and interview was to obtain information to report to the PSO in order to improve the quality and safety of patient care.
- “The results of the investigation and interview led to the creation of a subcommittee to work on an alert process designed to manage incoming aggressive behavior in patients in order to better manage the care and safety of these patients.”

# **Franco v. Yale New Haven Hospital, Inc., Docket No. CV-20-6103795-S (New Haven Judicial District) (March 31, 2023)**

- “The affidavit ... establishes that the documents were assembled and prepared by her solely for submission to the [PSO] ... and were reported to the [PSO].”
- The court further concluded that “the documents had the ability to improve patient safety and quality healthcare, and ... were submitted to the PSO.”
- Trial court rejected the plaintiff’s argument that the Patient Safety Act and Connecticut statutes only apply to medical malpractice cases.
- It noted that there was no specific provisions in the Patient Safety Act or Connecticut statutes to limit the protections to med mal cases.

# Franco v. Yale New Haven Hospital, Inc., Docket No. CV-20-6103795-S (New Haven Judicial District) (March 31, 2023)

- The court also cited to *Tinal v. Norton Healthcare, Inc.* involving an alleged employee discrimination under the American with Disabilities Act in which the court extended the privilege protections in that non-medical malpractice case.
- The *Tinal* court concluded that “an absence of any explicit exception to the plain language of [the PSQIA] for civil rights actions, it is clear to the Court that the privilege created for patient safety work product is intended to apply across the board to all other types of claims.”

# Payton v. Columbia St. Mary's Hospital, Case No. 20CV1108, Wisconsin Circuit Court (July 8, 2022)

## Background

- Plaintiff brought a negligence action against the hospital after being beaten and stabbed in the hospital's parking garage.
- During discovery, the plaintiff requested "all documents, communication or correspondence as it relates to [Hospital's] "Serious Event Review Team(s)" (SERT) which were generated over a specific period of time.
- The plaintiff filed a motion to compel after the hospital refused to produce any materials arguing that they were privileged under the Patient Safety Act and Wisconsin statutes.
- Through affidavits and the hospital's memorandum in support of its motion for a protective order, it established the following:

# Payton v. Columbia St. Mary's Hospital, Case No. 20CV1108, Wisconsin Circuit Court (July 8, 2022)

- The minutes were entered into the hospital's event reporting system (ERS) and were discussed at the SERT meetings.
- SERT and ERS are both components of the hospital's PSES policy which describes a process of collecting, utilizing, sharing and reporting PSWP or treating PSWP as deliberations or analysis.
- It was the hospital's routine practice during the relevant time frame that event reports were "prepared by and submitted to SERT for review and were reported to the hospital's PSO.
- Both the date on which the minutes entered into the PSES and were reported to the PSO were included.
- The minutes related to the medical care provided to the plaintiff.



# Payton v. Columbia St. Mary's Hospital, Case No. 20CV1108, Wisconsin Circuit Court (July 8, 2022)

## Trial Court's Decision

- After quoting from the definition of PSWP in the Patient Safety Act, the court determined that the minutes were “assembled or developed by a provider for the purpose of reporting to a PSO and are actually provided” as demonstrated through the affidavits.
- The court further held that the minutes were privileged because they “identify the discussions and analyses conducted by SERT ... meetings”
- The minutes were privileged under both the reporting pathway and the deliberations or analysis pathway, and therefore, were privileged from discovery under the Patient Safety Act.

# Payton v. Columbia St. Mary's Hospital, Case No. 20CV1108, Wisconsin Circuit Court (July 8, 2022)

- The court rejected the plaintiff's arguments that the minutes were created separately from the hospital's PSES.
- The court further determined that the minutes were privileged under the Wisconsin peer review statute.

# Shands Teaching Hospital and Clinics v. Beylotte, Fla. 1<sup>st</sup> District Court of Appeals (March 8, 2023)

## Background

- Plaintiff filed a negligence suit against the hospital while visiting a patient when she slipped and fell claiming she was injured on some clear liquid while walking through a hallway.
- During discovery she sought “an investigation report that was prepared by the hospital as a result of her fall.”
- In response to the plaintiff’s motion to compel, the hospital argued that the report was placed in the hospital’s PSES and “prepared solely for submission to [a] patient safety organization” and in fact was submitted and therefore was PSWP under the Patient Safety Act.
- The trial court ruled against the hospital, concluding that the Patient Safety Act only applies to patients and not incidents involving staff or visitors.

# Shands Teaching Hospital and Clinics v. Beylotte, Fla. 1<sup>st</sup> District Court of Appeals (March 8, 2023)

- The hospital's *petition for certiorari* was granted by the Florida First District Court of Appeals.

## Appellate Court's Decision

- In reversing the trial court's decision, the appellate court pointed to an "uncontracted affidavit" from the hospital "certifying that the subject report was assembled for reporting to a patient safety act organization under the Act and that the report was in fact submitted" utilizing the confidential reporting pathways set forth under the Patient Safety Act.
- The court agreed with the hospital's arguments that efforts to improve conditions that would have caused slip and fall injuries meets the requirement under the Act that the report "could result in improved patient safety, health care quality or health care outcomes."

# Shands Teaching Hospital and Clinics v. Beylotte, Fla. 1<sup>st</sup> District Court of Appeals (March 8, 2023)

- Because these safety efforts apply to all persons, including patients, visitors and employees, the court stated that it did not matter that the plaintiff was not a patient at the time.
- Because the Patient Safety Act was not limited to reports which only involved patients, the court held that the disputed report was privileged and that the trial court's order requiring a disclosure of the report be quashed.

# Lessons Learned and Recommendations

- Consider revising PSES policies to extend to employees and visitors as long as the identified patient safety activities and reviews can also cover patients.
- The Patient Safety Act privilege and state peer review privileges are not mutually exclusive. Both can apply, depending on the documents which the hospital or health care provider are seeking to protect.
- The decisions emphasize the importance of introducing affidavits, relevant PSES policies and legal memorandums in support of a motion for protective order or effort to quash a subpoena.
- Supporting affidavits should specifically describe the following:
  - The process by which the PSWP was collected or generated in the PSES and the date on which this occurred.

# Lessons Learned and Recommendations

- How it was shared, reviewed and utilized to improve patient care and/or reduce patient, employee or visitor risk.
- If utilizing the reporting pathway, state that the PSWP was collected for the purpose of reporting to a PSO and when it was reported.
- If relying on the deliberations or analysis pathway, establish how and when the PSWP was being deliberated and analyzed within the context of the PSES.
- The affidavit should specifically cite to the relevant provisions in the PSES to support compliance with the Patient Safety Act.
- That the PSWP was not created outside of the PSES.
- That the PSWP was created for the purpose of improving patient care and reducing risk.

# Lessons Learned and Recommendations

- PSES policy should specifically identify which PSWP is being actually reported to the PSO and which is being treated as deliberation or analysis.
- As a best practice, the PSES policy should identify the names of reports, analyses, committees, minutes and other work product utilized or created through identified quality assurance, quality improvement, peer review or other patient safety activities.
- In order to further support privilege arguments, be prepared to turn documents over for an *in camera* inspection which can be accomplished under the permissible disclosure exception under Section 3.206(b)(3) of a Final Patient Safety Rule which allows a provider to disclose its own PSWP.



# Lessons Learned and Recommendations

- If appealing an adverse discovery ruling, make sure that the record on appeal, including supporting affidavits, policies, legal arguments, etc., are included.
- Red Herring Arguments
  - PSWP was not prepared for the “sole purpose” of reporting to a PSO.
  - PSWP was shared outside of the PSES.
  - Claimed PSWP only included factual information.
  - Claimed PSWP was created in the normal course of business.
  - Privilege was waived because it was improperly shared or disclosed.

# **Options for Sharing PSWP Within a Hospital/Healthcare System**

# Sharing PSWP Within a Hospital

- The Patient Safety Act allows a PSO participating provider to share PSWP within a hospital or participating provider entity for any “use”. There are no limitations.
- That said, PSWP should only be shared and used by workforce members or others who need access to PSWP in order to carry out their identified responsibilities.
- PSWP, like HIPAA, must be kept privileged and confidential and not inappropriately shared with outside or other parties who do not need access to PSWP to carry out any legal or other responsibilities.
- HR and risk managers can access PSWP in order to carry out their employment and claims and litigation management responsibilities but should not place PSWP in files unrelated to a patient safety activity.

# Sharing PSWP Within a Hospital

- Instead, HR and risk should create separate forms and, if necessary, separate interviews outside of the PSES which can then be used for appropriate employment, claims and litigation management purposes.
- This information, created outside of the PSES, will not qualify as PSWP or for the privilege protections under the Illinois Medical Studies Act.
- Because this information is not privileged, it can be used in defending against employment claims or introduced into evidence in the defense of the med mal or other litigation if not otherwise privileged under, for example, attorney client work product or insurer-insured privileges.

# Sharing PSWP Within a Healthcare System

- The Patient Safety Act has a number of exceptions which would permit the disclosure of PSWP, including a “disclosure among affiliated providers (Section 3.206)(b)(4)(iii) and disclosure authorized by identified providers under Section 3.206(b)(3).
- The disclosure among affiliated providers’ exceptions will allow all participating healthcare providers which are owned, controlled, or managed by a parent organization to share identifiable PSWP among, for example, the hospitals within the healthcare system.
- In other words, if there are three hospitals within a healthcare system, that are controlled affiliates of a parent organization, each of the hospitals can share identifiable PSWP amongst themselves, as well as with the parent organization.

# Sharing PSWP Within a Healthcare System

- Such disclosures do not waive any of the privilege protections and would be important in terms of tracking trends, outcomes, the results of other patient safety activities which can be used by the system for the purpose of improving patient care and reducing risk.
- The disclosure authorization for identified providers is important in the context of being able to track physicians and other healthcare providers which serve as members of multiple hospitals or provider entities within the system.
- In other words, assume Dr. Callahan is a member of the medical staff of three affiliated hospitals within a healthcare system.

# Sharing PSWP Within a Healthcare System

- It is important that Dr. Callahan's quality, behavior and other activities affecting patient care be tracked and shared by the three medical staffs and hospitals consistent with privacy and confidentiality requirements.
- However, under the Medical Studies Act and the Patient Safety Act, Dr. Callahan would have to authorize the disclosure and sharing of identifiable peer review and PSWP by and among the hospitals and medical staffs.
- This typically is achieved by including the written authorization in Dr. Callahan's appointment and reappointment application and/or employment agreement, keeping in mind that the disclosure authorization should be very specific in citing to the Medical Studies Act and to the Patient Safety Act as well as describing the purpose for which the authorization is being requested/required.

# **CANDOR/CRP Programs and the Patient Safety Act**



# 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 Patient 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.

# Recent National Patient Safety Efforts

## A Transformational Effort on Patient Safety

- In September 2023, the President’s Council of Advisors on Science and Technology issued a Report to the President – A Transformational Effort on Patient Safety
- The Report made the following recommendations:
  - Establish and maintain federal leadership for the improvement of patient safety as a national priority
  - Ensure that patients receive evidence-based practices for preventing harm and addressing risks.
    - This will require that appropriate federal agencies develop a list of high-priority harms, evidence-based practices, and system-level mitigation strategies to eliminate preventable harms including “never events” that should never occur in healthcare.

# Recent National Patient Safety Efforts

- Partner with patients and reduce disparities and medical errors and adverse outcomes.
- Accelerate research and deployment practices, technologies and exemplar systems of safe care.
- The Report also contains the following:
  - “To ensure standards for timely communication to patients and families of harm events and immediate root cause analysis of the harm – with dissemination of the findings internally and with appropriate medical bodies, CMS should require within five years that hospitals demonstrate their efforts to communicate with families and appropriate medical bodies after future adverse events occur as a Condition of Participation. Hospitals should consider, as a model, prior efforts aimed at communication and resolution, including a communication and optimal resolution program (CANDOR) and communication resolution program (CRP).



# Recent National Patient Safety Efforts

- Another example in carrying out the recommendations includes the following:
  - “Building upon existing work by AHRQ to collect data from Patient Safety Organizations (PSOs), HHS, DoD, and VA could establish mandatory reporting to a national repository for patient safety events data which could support access to and interoperability of healthcare data as well as enable disparity stratification efforts.”

# Executive Order on the Safe, Secure and Trustworthy Development and Use of Artificial Intelligence (Executive Order)

- The President's Executive Order was issued on October 30, 2023.
- The Executive Order requires HHS to establish an "HHS AI Task Force" by January 28, 2024.
- The Task Force has 365 days to develop a regulatory action plan for predictive and generative AI-enabled technologies in healthcare that include:
  - The organization and implementation of an AI Safety program by September 30, 2024.
    - In partnership with federally listed Patient Safety Organizations, the program will be tasked with creating a common framework that organizations can use to monitor and track clinical errors resulting from AI use in healthcare settings.

# **Executive Order on the Safe, Secure and Trustworthy Development and Use of Artificial Intelligence (Executive Order)**

- The Program also will create a central tracking repository to track complaints from patients and caregivers who report discrimination and bias related to the use of AI.

# Use of PSWP for HR and Risk Management Purposes

- Remember the distinction between a “use” and a “disclosure”
  - PSWP can be used/shared for all internal purposes consistent with PSES and confidentiality requirements
  - An example of a permitted use is sharing PSWP with attorneys and accountants
  - PSWP, however, also can be used “outside of the PSES” but you should be able to document why such use is necessary in order to fulfill a business or related purpose
  - A “disclosure” is sharing PSWP to an unrelated third party which meets one of the permissible disclosure exceptions, i.e.:
    - Independent contractors
    - Accrediting bodies
    - Affiliated entities
    - From one PSO to another PSO

# Use of PSWP for HR and Risk Management Purposes

- PSWP which is disclosed under one or more of the permissible disclosure exceptions remains PSWP—the privilege is not waived
- Sharing PSWP with HR and risk management is considered a use and not a disclosure
- Important considerations
  - Must be able to establish that any PSWP which is shared with HR and/or risk management was developed for the purpose of improving patient care and not for employment or claims and litigation management purposes
  - Does HR and risk management really need access to PSWP whether identifiable or non-identifiable?
  - PSWP should not be placed in the employees HR File because
    - Employees are legally entitled to access all file materials

# Use of PSWP for HR and Risk Management Purposes

- PSWP is not subject to discovery or admissibility into evidence by any party. At some point therefore, hospitals cannot disclose PSWP when defending against a state (breach of contract) or federal (discrimination) claim
- HR needs to create its own non-privileged investigation record, notes, interviews, etc., which are then placed in the HR file and can be used in the event of litigation
- Risk management also can access PSWP but like HR, must create its own forms, reports, etc., for claims and litigation management which generally are discoverable
- For this other information, other privileges which could be available include attorney-client work product and communications, and the insured/insurer privilege

# PSWP Questions and Answers

- What should be included or referenced in minutes/documentation in order to access the privilege?
  - Make sure the committees or activities producing the minutes are reflected in the PSES
  - Determine whether the minutes/reports are going to be actually reported to the PSO and are reported with the date on which they are reported or are being treated as deliberations or analysis – clarify which method is being utilized for the information in the PSES
  - The language “Privileged and Confidential under the Patient Safety and Quality Improvement Act of 2005 [and the \_\_\_\_\_ Act]” for those portions of the minutes you are treating as privileged
  - Some hospitals have an email system which includes this or similar language of privileged emails

# PSWP Questions and Answers

- Remember, it is not fatal if this language is not inserted. It is more important that the minutes be identified in the PSES
- Who can review PWSW minutes/documentation?
  - Workforce members who have been identified by the provider – these are the individuals who prepare or need to access PSWP as part of their job responsibilities
- What PSWP can be shared from the Peer Review process and who can see it?
  - Workforce members
  - Hospital identifiable PSWP can be shared with affiliated entities, including the parent corporation and their workforce members, who are members of the PSO and are in a single system PSES



# PSWP Questions and Answers

- PSWP can be shared/disclosed if utilizing a permissible disclosure exception, i.e. attorneys, accountants, business associates, accreditation bodies, etc. (See Section 3.206 of the Final Rule)
- Is any report, analysis, study, etc., prepared by a PSO considered PSWP?
  - Yes
- If CMS or other government agency demands PSWP, must it be turned over to them?
  - No – HHS in its May, 2016 Guidance for Patient Safety Rule stated that government agencies cannot require providers to turn over PSWP, but must otherwise demonstrate compliance

# PSWP Questions and Answers

- Sharing physician identifiable PSWP generated within a hospital is considered a use and not a disclosure and therefore can be shared with the hospital's workforce members
- In order to share physician identifiable PSWP generated in the hospital with outside entities, including affiliated providers, the physician must sign a written authorization permitting the disclosure of this information
  - Authorization can be included in a separate form or in the appointment/reappointment application, or an employment agreement.

# Questions & Answers

# Firm Bio



## Michael R. Callahan

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A nationally recognized advisor to health care providers across the country, Michael Callahan provides deeply informed business and legal counseling in all areas of hospital-physician relations and health care regulatory compliance and governmental investigations, including the Emergency Medical Treatment and Active Labor Act (EMTALA), the Health Insurance Portability and Accountability Act (HIPAA), Medicare Conditions of Participation (CoPs), hospital licensure and accreditation standards. He is widely respected for his leading work on the Patient Safety Act from a regulatory compliance, policy and litigation standpoint, including the development of patient safety organizations (PSOs).

### **The knowledge to identify efficient and practical solutions**

Health systems, hospitals and physician groups large and small across the country come to Michael for practical, real-world guidance and answers to challenging legal and operational issues, which he can provide quickly because of his many years of experience. He understands the reality of hospital quality, peer review, risk management and related operational legal and regulatory complexities and can rely on a large client base in order to provide better and comparative solutions.

He also is sought out by many of the largest health systems around the country for his understanding and interpretation of the Patient Safety Act. In a case of first impression, he advised a national pharmacy that became the first provider to successfully assert an evidentiary privilege under the Patient Safety Act. Since that case, he has represented or advised many hospitals, physician groups and other licensed providers in creating or contracting with federally certified PSOs and has been directly involved in most of the major state appellate and federal court decisions interpreting the Patient Safety Act.



## Community Involvements

- American Bar Association
- American Health Law Association (AHLA), Fellows Coordinating Council, former Chair of the Medical Staff, Credentialing and Peer Review Practice Group
- DePaul College of Law, Mary and Michael Jaharis Health Law Institute Advisory Board
- Illinois Association of Healthcare Attorneys
- Illinois Association Medical Staff Services
- Massachusetts Association of Medical Staff Services
- National Association Medical Staff Services, former Public Member, Board of Directors
- New York State Association for Medical Staff Services
- Northlight Theatre, former President and Member, Board of Directors
- National Practitioner Data Bank, former Member, Executive Committee



## Recognitions

*Recognized or listed in the following:*

- American Health Lawyers Association
  - Fellow, 2019
- AV Preeminent Peer Review Rating by LexisNexis Martindale-Hubbell
- *Best Lawyers in America*
  - Health Care Law, 1991–2024
- *Chambers USA*
  - Healthcare, 2005–2023
- Illinois Association Medical Staff Services
  - Leadership Award, 1995
- LAF Katten José de Diego Legal Clinic
  - Volunteer of the Year, 2017
- Massachusetts Association of Medical Staff Services
  - Honorary Lifetime Member
- National Association Medical Staff Services
  - ICON Award, 2020
- New York State Association for Medical Staff Services
  - Honorary Lifetime Member
- *Super Lawyers*
  - Illinois, 2005–2020

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