

**DON'T
GET
IT
TWISTED!!**

The Contortion and Corrosion of the PSWP Privilege



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Educational Level

- **This session is being offered at a somewhat advanced level.**
- The material is designed for participants who have a detailed knowledge of the topic and specific experience applying or using this knowledge in a professional capacity over a period of at least 10 years.

Continuing Education Disclosure

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ATTENTION PARTICIPANTS

GOING TO MOVE VERY QUICKLY

NOT GOING TO BE COVERING ALL POINTS ON THE SLIDES – THE PPT INFO IS THERE AS A USEFUL TAKE-HOME RESOURCE

A LIST OF THE CASES (WITH CITATIONS) HAS BEEN PROVIDED WITH THE OTHER RESOURCE MATERIALS

FLORIDA INFO IS UNIQUE – WILL ALL BE AT THE END

EDUCATE YOUR COLLEAGUES AND RISK MANAGEMENT PEOPLE IMMEDIATELY BEGIN ADJUSTING YOUR POLICIES, PROCEDURES, PROTOCOLS, DOCUMENTS, AND INVOLVED STAFF ACCORDINGLY BEFORE YOU FORGET

DISCLAIMER: This is general information being provided to webinar participants for educational purposes, without knowledge of any participant's/organization's individual legal situation, and is not intended to, nor does it constitute specific legal advice to any participant or participant's organization.

Reminder

- The *Patient Safety and Quality Improvement Act of 2005 (PSQIA)* encourages reporting of patient safety and healthcare quality information to **patient safety organizations (PSO)** through a **patient safety evaluation system (PSES)** by providing **confidentiality** and **privilege** over that information, known as **patient safety work product (PSWP)**
- Any records assembled or developed by a provider for reporting to a PSO and are reported to a PSO or are developed by a PSO for the conduct of patient safety activities and which could result in improved safety, care, and outcomes, are protected as PSWP
- Those records that are not collected, maintained, or developed separately, or that do not exist separately from a PSES are not protected under the privilege

The “P Soup” of the PSQIA



42 USC 299b-21(7)

Patient safety work product

(A) In general. Except as provided in subparagraph (B), the term “**patient safety work product**” means **any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements:**

(i) which—

(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization;

or

(II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes;

or

(ii) which identify or constitute the **deliberations or analysis of, or **identify the fact of reporting pursuant to**, a patient safety evaluation system.**



The University of Kentucky v. Bunnell

October 20, 2017 KENTUCKY (state case)

- Considered the best and most statutorily correct analysis of the PSWP privilege provisions **MUST READ**
- Recognizes an express preemption clause over any contrary state law or Court order
- The *significant* body of law on the Federal Pre-emption Doctrine even supersedes state constitutional provisions where they conflict with the federal law

FOR EVERY DOCUMENT or PIECE OF INFORMATION, DETERMINE:

- **Does the document/information qualify for the privilege?**
 - What is it?
 - Why was it generated? **AND**
 - Might it improve overall patient safety or care?
- **Was it collected and protected inside the PSES?**
- **Was it collected solely for quality improvement or patient safety purposes?**
 - If deliberations among the designated patient safety/QI team took place to determine ***if it was for this sole purpose or for any other purpose as well, then the deliberations are still considered to be PSWP***

Does the Privilege Apply?

FACTS:

- The event was reported via the hospital's safety reporting system
- The patient safety event was reviewed by the hospital's Surgical Quality Improvement Committee
- You are asked to provide the RCA reports to opposing attorneys for the event in question. **Do you submit them?**
- You review the surgery schedules for the week during which the event occurred. **Is this protected?**



University of Kentucky v. Bunnell

Cont'd

- The **PSWP privilege *takes effect*** when information is solely intended for a PSO **AND** is collected / entered into the PSES
- Once submitted to the PSO, information is *presumed* to have been *intended* for QI/patient safety purposes and becomes “forever PSWP”

IMPORTANCE:

- Logically breaks the language of the statute into **two parts:**
 - 1) Intended for PSO and entered into the PSES, **AND**
 - 2) Sent to a PSO
- Provides a [rebuttable] presumption of statutorily compliant *intent regarding creation and collection of material*

University of Kentucky v. Bunnell

Cont'd

- If examining or deliberating to determine if the information is necessary to satisfy an external obligation is being held within the PSES, then the **organization should establish**:
 - (1) What information should be in the external report that the organization has not created **AND**
 - (2) Whether the information in the PSES also *exists outside* the PSES
 - *If it does exist outside* the PSES, then the information is not PSWP
 - *If it doesn't*, then the organization must use non-PSWP to complete the external obligation **OR** drop the information from the PSES

PSO vs External Reporting



Patient Safety Reporting:

- Equipment failures
- Patient death
- Acquired infections, illness
- Abnormal test results and actions taken to address situation
- Misaligned joint implants

External Reporting:

- FDA incident log
- Death related to restraints or other circumstances
- State-mandated infection, death, or incident reporting
- Documented care in the medical record
- Surgery case logs
- Cases to NPDB
- Contractually required reporting
- Accreditation entity required reporting



- **Courts**: privileges must be **strictly** construed as exceptions to the general duty to disclose (litigation discovery rules)
- **The burden of establishing that the PSWP privilege applies is on the healthcare organization (and its attorneys)**
- **Can establish this by:**
 - Submitting materials to judge for in-chambers review **OR**
 - Submitting **affidavits** showing ALL requirements are fully and properly met concerning the materials in question
 - **AND AFFIDAVITS ARE OFTEN THE PROBLEM.....**

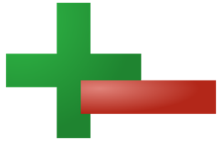
- Assemble **separate and original information** for purposes of meeting **external reporting** requirements
- **LATER**, create additional information intended *solely* for PSES and PSO
 - **DO NOT commingle information necessary to satisfy mandatory record keeping or external reporting obligations with PSO intended information**
- Recognizes **an express preemption clause** that supersedes any Court order or contrary state law

How Easy is it to Not Meet the Requirements?

- **Failing to include specific language reflecting the purpose of the document:** “The Mortality and Morbidity Report and Review is assembled and developed for the sole purpose of reporting to the Center for Patient Safety (PSO)”
- **Allowing another entity other than the contracted PSO to create and retain a document claiming to be PSWP**
- **Claiming cases are protected under PSWP without being fully compliant with PSQIA**
- **Creating a report for external organizational reporting and claiming PSWP privilege protection**
- **Sharing documents and reports outside the PSO/PSES closed loop**
- **Affiant/witness failing to be fully aware of all the specifics and particulars of the PSWP/PSO process**



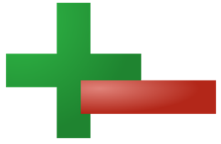
July 10, 2018 PENNSYLVANIA (state case)



Provides clear insight as to what to do, and not to do to affirm the privilege, specifically what may not work as information that was assembled or developed for the purpose of reporting to a patient safety organization:

- The *critical inquiry* is the purpose of creating the information
- Treatment narratives prepared by health care providers, and kept in the ordinary course of business **because they came from the EMR – do not count**
- Documents created for **entry into PSES (but not necessarily intended for submission to PSO at time of creation)** are **not privileged**
- Improper documents do not gain privilege status merely because it is reported to PSO





Grider v. Shawnee Mission Med. Ctr. August 14, 2018 KANSAS (federal case)

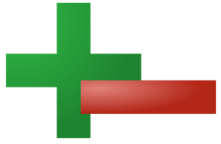


Supports PSWP privilege for data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements



- But NOT for information about:
 - whether a hearing of any kind was held
 - OR**
 - whether something actually exists or not

December 11, 2019 CALIFORNIA (federal case)



- Surveillance video, stills, and still photographs are not PSWP



- As long as other requirements are met, **deliberations and analysis** using information that is not PSWP:
 - Must be entered into the PSES
 - Covers deliberations about whether to even send to PSO
 - Still get PSWP protection whether or not sent to PSO because it is deliberations
 - Underlying information gets PSWP protection once sent to PSO (as long as it is not specifically excluded info like patient's medical record or billing info)

Per the Hyams Case: Consider This...

- **Hospital reviews a list of all near-misses reported in the past 30 days**
- **Intent is to determine whether to report part or all to PSO**
- If it meets the PSWP tests, is in the PSES, then analyses are fully protected whether reported to PSO or not
- The deliberation does not impact the list's status
- The list itself IS NOT protected until it is reported to PSO
- However, the deliberation and analyses of the near-miss cases are fully protected because they are logged in the PSES



Hyams v. CVS Health Corp.

Cont'd

- In this instance, the PSWP privilege is serving as a **“decisional / analysis privilege”** – things that are “pre-decisional”
 - Does not work the other way around:
 - **If a portion of a document contains protected deliberations or analysis it is not transformed completely into PSWP!**
 - Does not extend to deliberations / analyses outside of PSES

FOR COURT PURPOSES:

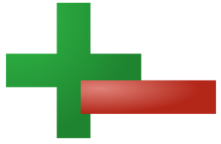


AFFIDAVITS and/or TESTIMONY:

1. **MUST** have been in **full compliance** with all requirements of **PSQIA and Court decisions** re: **PSWP** privilege throughout **entire** incident, investigation, and reporting process
2. **MUST** properly and fully assert **that it was and is** in full compliance with all statutory requirements at all times

AND

3. **MUST** properly and fully assert **that it was and is** in full compliance with all requirements of its **own internal policies** regarding **intending, designating, and protecting PSWP** at all times



Hite v. Mary Immaculate Hosp., Inc. April 20, 2020 VIRGINIA (state case)

Deals Specifically with Quantros Reports

(analogize to other analytic reports used for understanding, predicting, and improving healthcare performance / patient safety issues)

- **Redacted information** must identify or constitute deliberations or analyses of reporting to PSES and/or PSO

OR

- identify actual reporting to a PSES and/or PSO
 - **Must make the claim for EACH redaction**

Hite v. Mary Immaculate Hosp., Inc., Cont'd



- Information that is more factual than deliberative, does not constitute PSWP –
 - Factual information is generally considered to be information from patient charts, billing, and other material not covered as PSWP



- *Consistent with other cases – **BUT many things can be argued as “facts”***

EXAMPLE: *incident reports, near miss reports because they can contain nothing but facts, or information that can be construed as facts (opinions, witness observations which can be notoriously wrong)*

Example: Incident Report

- **Situation:** An alert patient on a ventilator developed pneumonia, transferred to intensive care and later died.
- During review of the medical record, it was noted that the patient was NPO (nothing by mouth). Patient had sudden change in respiratory status requiring transfer.
- A Notice of Intent was filed stating that when family was visiting patient, he was sipping water from a cup, so “staff must be allowing practice,” and citing negligence.
- During investigation, staff caring for the patient provided statements that patient was NPO, intake and output notes did not support claim of patient being provided fluids by mouth. A second statement noted a visitor to patient’s roommate provided a cup of water to patient because “he said he was thirsty”.



Hite v. Mary Immaculate Hosp., Inc., Cont'd

- It must be reported to the PSO to be covered
 - **CONTRADICTS** what was determined in Univ of KY v Bunnell (the PSWP privilege takes effect when information is solely intended for a PSO AND is collected / entered into the PSES) – takes **STRICT** interpretation of the statute that both parts must have occurred to get the privilege to attach
- +
- +
- Quantros [type] reports are not original patient or provider records
- **Quantros [type] reports** are a deliberative analyses of the incident at issue and **are PSWP**



Ungurian v. Beyzman, et al.

June 10, 2020 PENNSYLVANIA (state case)

- Plaintiff sought:
 - Event Report by physician concerning the hospital's medical services
 - Serious Safety Event Rating (SSER) Meeting Summary
 - Meeting Minutes from the Patient Safety Committee
 - Root Cause Analysis Report (RCA)
 - The hospital's Quality Improvement Staff Peer Review
- Hospital claimed *event report* and *RCA* were PSWP – (other documents were ordered by Court to be disclosed earlier)
- **The hospital submitted nothing but the (weak) affidavit of the Dir. Patient Safety Services in support of its claim**

THE COURT STATED:



- Hospitals and other healthcare providers **must be vigilant to adhere to the letter of relevant privilege standards** because, should they stray from strict compliance, the Court will *not enforce* those protections



- Hospital *through employee affidavit* **failed to allege** that it prepared the event report and RCA for reporting to a PSO and actually reported them to a PSO, therefore, it did not meet its burden to establish PSWP privilege



- Hospital **did not demonstrate** (allege, affirmatively state [preferably on each document]) that these documents were prepared for the *sole and singular purpose* of reporting to a PSO
 - Stating that the information **MAY** be reported to a PSO is **not in compliance with the PSQIA**

Ungurian v. Beyzman, et al., Cont'd



- The averments in the Affidavit only confirm **that the event report could have been developed for a purpose other than reporting to a PSO and still be managed within the PSES**
- PSQIA requires a document must be clearly developed for the purpose of reporting to a PSO to gain PSWP protection



- The Court found that Hospital admitted that **the information contained in the RCA was not contained solely in the PSES**, therefore existed outside the PSES and was not entitled to privilege
 - **An email between an administrator and a physician at the insurance carrier referencing parts of the RCA defeated the privilege**

Ungurian v. Beyzman, et al., Cont'd



- **ALSO OF NOTE: Under the PA state statute, several privilege protections were shot down because:**
 - **The person conducting the quality improvement peer review **had let their license lapse** – not a licensed individual as required**
 - **Some were **not healthcare providers** as required**
 - **Those who were **healthcare providers were not alleged and proven as such****
 - **The person conducting the peer review was actually a physician who was technically employed by a privately owned practice, not the hospital**

BE SAFE AND CHECK / STATE THESE THINGS EVEN UNDER PSQIA

Committee Structure

- Take a proactive approach
- Choose the right people for the roles
 - Hospital versus private/off-site practice
 - Provider versus administrative
 - Specialist versus generalist
- Review medical staff bylaws and HR guidelines – *edit as needed*
 - Medical staff HAVE to participate when asked
- Ensure licenses and certifications are current
- Follow ALL rules/requirements closely





Thompson v. United States

July 13, 2020 ILLINOIS (federal case)

Deals with Risk Management Worksheets PSO Encounter Entry Reports (and Privilege Logs)

- **Risk Management Worksheets** (*or similar documents*) are likely covered if created / generated for submission to PSO, and meet the *statutory requirements* of PSWP (*see Bunnell case for how to test*)
 - **Note:** statutory requirements state it has to be submitted to PSO as well
 - If not PSWP, likely covered under Attorney-Client Work Product if prepared in anticipation of litigation (because of severity rating of the underlying adverse event)

Thompson v. United States, Cont'd

- **PSO Encounter Entry Reports** are generated when something is specifically submitted to or from the PSO
 - Shows documents were specifically generated for
 - the purpose of reporting to/from their contracted PSO
 - AND
 - that the information was, in fact, submitted to that PSO
 - Hospital **submitted an affidavit** attesting that the documents were sent to the PSO along with providing the identity of the PSO, the title of the documents, and a description of them, which suggests they were created specifically for transmission to a PSO

Thompson v. United States, Cont'd

- **Same can apply for Privilege Logs**

- Make sure the Privilege Log and PSO Entry Report info is consistent with each other
- *Enter the PSO Entry Reports into the Privilege Log!!!*
- The privilege is not waived for a document generated specifically for reporting to a PSO merely because it references information generated elsewhere for other purposes (patient medical information, remote data entry information, etc).
 - Doesn't specifically address including such information, just referencing
 - *Generally consistent with other logically interpreted cases*

SAMPLE PRIVILEGE LOG FIELDS

Document Number (Sequential Log entry number)	Custodian (The custodian of a particular collection, assigned during review)
# Pages	Privilege Reviewer (Login ID)
Doc Title (Or subject line for email)	PSWP Privilege Verified (Date)
File Extension Type	PSES Entry by (Login ID)
Properly Marked as PSWP (Y/N – if not, note when corrected, by whom, on what date)	PSES Entered on (Date)
Created by (Individual(s), Dept or Team)	Family # (A unique ID number representing a document family. Ex: document and attachment, email, RCA, M&M Report, Peer Review)
Recipient(s) (addressee(s), CCs, BCCs, forwardees)	Sent to PSO on (Date)
Privilege Claimed (PSWP, A/C Privilege)	Sent to PSO by (Login ID)
Locus (Physically housed)	PSO Receipt Confirmed on (Date)



Penman v. Correct Care Solutions

July 24, 2020 KENTUCKY (federal case)

Deals with PROPERLY Asserting PSWP Privilege

- A Morbidity & Mortality (M/M) Report and Review was accidentally disclosed to plaintiff's counsel when medical and other records were subpoenaed
 - **WHY** was it anywhere near patient records such that someone could copy it?
 - **WHY** was the clear statement on each page ignored: **“Patient Safety Work Product — PSWP / This document is protected from further disclosure pursuant to 42 U.S.C. § 299b-22”**
- Sought Protective Order from Court after plaintiff's counsel used it at a deposition and read parts into the record, despite CCS and its counsel having informed them earlier that it was PSWP privileged material



Penman v. Correct Care Solutions

Cont'd

▪ Same can apply for Privilege Logs



- Make sure the Privilege Log and PSO Entry Report info is consistent with each other
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 - Doesn't specifically address including such information, just referencing
 - *Generally consistent with other logically interpreted cases*

APPARENTLY, NOBODY EVER READ THE BUNNELL CASE BECAUSE...

- In attempting to assert the PSWP privilege in Court, affidavits and testimony were required.

The Court held:

- **Merely stating** that the Mortality & Morbidity Report and Reviews *are assembled and developed for reporting to the Center for Patient Safety, a Patient Safety Organization* **was not good enough**
 - Not dealing with all documents, **dealing with this one in particular**

Penman v. Correct Care Solutions

Cont'd



- CQI Program Manager did not state in her affidavit that *this specific report was assembled and developed for reporting to a PSO* AND
- Did not state that the report was assembled and developed for the sole purpose of reporting to a PSO
- Her testimony has to be consistent with her affidavit – or everything becomes generally useless – no credibility

**Affidavit
Example
(in your
booklet)**

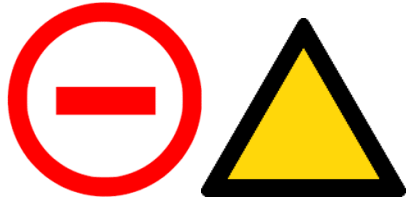
AFFIDAVIT OF
_____, [DNP, RN, MHA]

STATE OF _____)
) SS:
COUNTY OF _____)

I, _____ [DNP, RN, MHA], hereby swear and affirm the following as of the date noted below:

1. I am a resident of the State of _____.
2. I am an employee of _____ (hereafter, "_____").
3. I am employed by _____ as the _____.
4. In that capacity, I am hereby stating and confirming that _____, its corporate offices, and all satellite or otherwise affiliated work sites act as a Patient Safety and Quality Improvement Act ("PSQIA") provider, as that term is defined at 42 USC § 299b-21(8); 42 CFR 3.20.
5. I am hereby stating and confirming that _____ is contracted with a properly registered, Agency for Healthcare Research and Quality (AHRQ) compliant Patient Safety Organization ("PSO"), namely, _____ (hereafter, "_____").
6. [I am hereby stating and confirming that _____'s contract with its PSO contains a confidentiality agreement provision as a condition of membership.]
7. [I am hereby stating and confirming that XXXXXXX is an identified and recognized provider by _____, its PSO, and is recognized as being the new name for _____.]
8. [I am hereby stating and confirming that _____ (and its predecessor-in-interest _____) has maintained its PSO contract with _____ since 20____.]

9. I am hereby stating and confirming that all _____ clients, professional affiliates, and staff are notified of the relationship with the PSO via client/affiliate fact sheets and written policies and procedures, and staff are notified of same via staff fact sheets, written policies and procedures, and appropriate training regarding the requirements and protocols of the PSQIA and this organization.
10. I am hereby stating and confirming that _____ has a compliant Patient Safety Evaluation System ("PSES") in place with its established PSO.
11. I am hereby stating and confirming that _____'s PSES is separate, distinct, and resides alongside, but does not replace or comingle other information collection activities or systems.
12. I am hereby stating and confirming that _____'s PSES is a closed-loop system between _____ and its PSO, and appropriate and compliant security and confidentiality measures are maintained at all times, including ensuring that all staff involved in PSWP are trained in maintaining the required security and confidentiality measures.
13. I am hereby stating and confirming that in the course of providing healthcare services, _____ collects or generates data, reports, records, memoranda, analyses (such as root cause analyses [and related documents, notes, and reports], peer review worksheets and findings, proactive risk assessments, or continuous quality improvement [CQI] studies), deliberations (such as mortality and morbidity reviews, peer review findings (adverse event/near miss reporting/faulty device reporting and related analyses), or written or oral statements as information collected and developed for the sole and singular purpose of reporting to its PSO, and not to, for, or because it is required or needed by any other entity, organization, or governmental unit obligation.
14. [I am hereby stating and confirming that the purpose of _____'s peer review process is to collect, manage, or analyze healthcare professional/provider complaints to encourage a culture of safety as well as provide feedback and assistance to effectively minimize patient risk, and for reporting to its PSO to effectuate this purpose.]
15. I am hereby stating and confirming that any information that has been discussed, debated, or deliberated solely with regard to whether or not that information was needed to satisfy an external obligation as well as for submission to the PSO, or for any purpose other than submission to a patient safety organization (PSO), that such discussions, debates, or deliberations are also intended to be privileged as PSWP, without regard to the status of the underlying information being considered privileges PSWP, and have been kept secure and confidential as if PSWP protected.



Herriges v. County of Macomb

August 14, 2020 MICHIGAN (federal case)

Deals with Complying with the Law and
Asserting the PSWP Privilege

- This case is requiring **hyper-absolute compliance with the law, policy, process, and procedure**
- This entire case is characterized by this symbol:





The Court held:



- Organization has the burden of proving that the privilege applies and exists in that instance



- PSQIA/PSWP also applies in Section 1983 cases (federal civil rights and employment discrimination cases)



- Statute was not intended to provide a blanket protection for all information and communications generated for quality control purposes

Herriges v. County of Macomb, Cont'd



- PSWP is entitled to confidentiality and privilege if it is:
 - (1) created for the purpose of reporting to PSO **AND**
 - (2) is so reported – STRICT INTERPRETATION THAT BOTH ARE REQUIRED BEFORE GETS ANY PROTECTION
- **MUST show that:**
 - (1) The withheld documents contain patient safety information gathered as part of a PSES **AND**
 - (2) The withheld documents were reported by the provider to its PSO without being previously removed from the PSES or otherwise disclosed apart from the PSES
 - **Reported to PSO BEFORE the request for the documents was made AND before the affidavit was created and signed**



Herriges v. County of Macomb, Cont'd

- Patient cases or other matters occurring before the organization became FULLY compliant with PSQIA (*in every tiny detail*) do not get PSWP privilege protection
- Organization must prove its burden of establishing the information or document was reported to a PSO as required by the statute
- Affidavits executed before the date of any matter before the Court cannot be used as supporting evidence of those later PSWP or PSO events because did not have “personal knowledge” of them at the time of the execution of the affidavit
 - **If new issues or events come up with regard to PSWP, update the affidavit**



Herriges v. County of Macomb, Cont'd

- **Anyone attesting or testifying** to reports/documents as PSWP **MUST have:**
 - **First-hand, actual, and complete knowledge** that documents were collected properly
 - Were for covered purposes
 - Were never shared outside the PSES in any way **AND**
 - Were actually submitted to the PSO
 - **When that affidavit or testimony is made**

- **The person who may have to testify to submission of material to the PSO has to ACTUALLY be the one who submits it (not an admin person), and must be very familiar with the process for doing so**



Herriges v. County of Macomb, Cont'd

- **Comply to the letter with any requirements the PSO has for collecting, storing, and submitting documents to it, including file formats, file sizes, naming conventions, etc.**
 - **Example:** submission as doc file, but submitted as excel file

- **If the organization changes name for any reason:**
 - change it formally with the PSO
 - Sign an addendum to the contract **AND**
 - Get a formal acknowledgement that the relationship is continuing from old name to new name or privilege will not attach, especially for any cases that cross-over the name change time period



Herriges v. County of Macomb, Cont'd

- **Report to PSO as soon as able**
 - **Delayed reporting will kill the privilege**
 - Delay undermines purpose of using PSWP to improve quality and patient safety
- **DO NOT share with anyone before or after submitting to PSO**



MORE TAKEAWAYS:

- **Everything in documents submitted to PSO must be absolutely accurate** – no typos, no misspelling of names, no date inconsistencies - NO discrepancies!
- Making changes to anything already submitted creates a whole new can of compliance and PSWP applicability worms



Herriges v. County of Macomb, Cont'd



- **Make SURE** that all information contained in affidavits, attestations, and testimony are **100% accurate and match anything pled or written in legal documents by attorneys**, especially dates and document types/names



- **Make SURE** that **people** giving affidavits, attestations, and testimony **know**:
 - ALL of the information related to the case
 - Have read and understand every related document
 - Are aware of every particular that could be at issue



Herriges v. County of Macomb, Cont'd

- **Do not contradict in testimony what was provided in written documents** – get it right *before* testimony is given
 - Review the affidavit, attestation, record many times before giving testimony



Aligning Documentation with PSQIA



Rice v. St. Louis Univ.

October 21, 2020 MISSOURI (federal case)

**Deals with Peer Review Process and PSWP
Investigation Process in a Civil Rights/Employment
Discrimination Context**

- Physician was fired and alleges widespread harassment, bullying, discrimination, retaliation of residents at hospital
- Physician seeks records of many types that support her allegations of discrimination and retaliation for reporting patient safety concerns
- Hospital sought to protect various records including an internal investigation report that detailed widespread behavior of the type alleged by physician

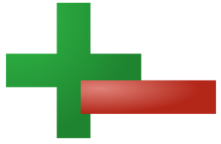


- Court recognizes that the PSWP privilege can apply in an employment civil rights legal context depending on the facts
- Hospital stated that its **peer review process doubled as its PSQIA investigation process**
- Hospital **did not ever assert or argue** that the purpose of its peer review process was to collect, manage, or analyze such complaints "for reporting to . . . a patient safety organization"
- Hospital made a **bare assertion that it participated in a PSO with no further detail**
- Hospital **did not ever assert** that the report and other records at issue were ever entered into a PSES or sent to the PSO

Achieving PSWP Privilege



**A Good Program + Good Affidavit and Testimony +
Knowledgeable Attorneys = SUCCESS**



Deals with Quality Committee Records in Wrongful Discharge Context

- The hospital's quality assurance committee recommended that the physician be fired
- Physician sought the quality committee's records, reports, correspondence, and other materials relevant to its recommendation to terminate
- Hospital claimed PSWP privilege

- Hospital submitted a privilege log and provided some of the relevant documents for the Court's review that included:



- **Email threads** between members of the quality committee **discussing physician's performance**
- **Email threads** between members of the quality committee and **outside management** discussing physician's peer review feedback
- **An email** containing the official recommendation of the quality committee
- Audio files of the committee's meetings
- Internal "talking points" memos prepared in advance of meetings with physician
- Physician's FPPE3 results
- Physician's peer review data
- The committee's meeting minutes





- The quality committee representative **never stated** that any of it was *actually submitted* to the PSO, let alone provided proof of same



- An email chain sent between members of the committee discussing aspects of the committee's data-collection procedures **is not communication or information "assembled or developed for reporting to a patient safety organization"**





- Although the Court could arguably disregard the privilege entirely on these bases the Court did not think this was the correct approach



- The confidentiality and privilege provisions originate with Congress and have been specifically restricted from judicial carveouts



- Regardless of hospital's failure to meet its persuasive burden, it was given another shot at preserving the privilege



- The quality committee representative could be deposed to determine exactly what documents and information were actually submitted to the PSO



- The Court did not agree that the PSQIA prevented plaintiff from deposing the various members of its quality committee



- During depositions, committee members **may only invoke the privilege to prevent testimony consistent with the scope of the PSQIA privilege** as described in the Court's order, which would **preclude questioning about the content of documents protected from discovery**



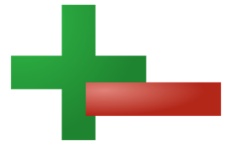
- Where necessary, the Court permitted the hospital and committee members to **protect/redact the names of comparator physicians in any documents that were not privileged, and in depositions** by referring to them as physician 1, physician 2, etc.



Louzi v. Fort Bend County, May 3, 2021 TEXAS (federal case)

Deals with Whether Documents Were Reported by the Provider to its PSO without Being Previously Removed from or Disclosed Outside of the PSES

- There was a **contractual obligation to divulge** any peer review info/documents to the County government
- Did not share report to County government though
- County government, therefore did not divulge to anyone either
- Proof of submission to PSO was provided to the court
- In-camera review showed report contained patient safety information
- **PSQIA applies**



Givens v St. Louis County, Dec 23, 2021 MISSOURI (federal case)

Deals with Excluding M/M Review Meeting Notes, Non-Federally Certified “PSO,” and Waiver of the PSWP Privilege

- Defendant county produced an M/M Review meeting report *with handwritten notes* to plaintiffs in response to a discovery request
- Defendant’s employee is the Accreditation Manager for the county’s Correction Medicine Program and took notes at MMR meeting for *accreditation audit purposes*. Defendant claims it is PSWP
- Defendant **did not argue** that the purpose of the MMR meeting notes was to improve patient safety, health care quality, or health care outcomes, or that it was related to a patient safety evaluation system.



Givens v St. Louis County, Cont'd

- Defendant asserts that the correctional medicine accreditation organization is a PSO - It is not on the AHRQ.gov approved PSO list



- Defendant did not argue that the MMR meeting notes were reported to any other AHRQ- listed PSO or collected for the purpose of reporting to a PSO
- Plaintiff argued Defendant waived any privilege objection because it



- **Failed to timely produce a privilege log containing the meeting notes** without a showing of good cause
- **Failed to raise the objection for** more than three years after the commencement of the action and **more than a year after “inadvertent” production of the notes**

Givens v St. Louis County, Cont'd



- **Failed to perform a reasonable inquiry into the existence of any MMR meeting notes, agenda, or action plans** before sending to plaintiff in the discovery response



- **Discovery responses were signed and certified** that to the best of the signer's knowledge, information, and belief formed after a reasonable inquiry, it is "complete and correct at the time it is made"
- Defendant says it never waived its assertion of privilege over the MMR meeting notes because counsel for Defendant was unaware of the existence of the M&M Review meeting notes, until employee's November 12, 2021, deposition

Givens v St. Louis County, Cont'd

- The following showed **lack of diligence on Defendant's part:**
 - **Failure to discover** the issue
 - **Failure to put the materials on a privilege log and provide to Plaintiff** without a showing of good cause
 - **Failure to timely object** to inadvertent production of the document
 - **Failure to properly certify discovery responses** for reasonable inquiry
- **PSWP Privilege was waived for lack of diligence, awareness, and care – work closely with attorneys on all discovery responses**



Mayotte v. Brattleboro Mem'l Hosp., April 11, 2022 VERMONT (state case)

Deals with an Internal Hospital Investigation PSQIA Report Analyzing Compliance with Regulations and Hospital Policies Concerning an Adverse Event

- Report noted **staff failed to complete an event report and conduct an RCA to investigate the incident** in accordance with the hospital's Incident Reporting policy
- It confirmed that an **event report should have been completed** but had not been done; that there had **not yet been an internal investigation** to identify any possible areas for improvement
- It lists various **recommendations for improving policies, procedures, and responses** to be in compliance with federal and state regulations, and **completion dates** for same

Mayotte v. Brattleboro Mem'l Hosp., Cont'd



- The report was on a **federal form** that **references PSQIA required compliance with regulations** for hospitals that receive Medicaid/Medicare federal funding to **measure, analyze, and track quality indicators**, including adverse patient events; tracking medical errors and adverse patient events, analyze their causes, implement preventive actions, and establish clear expectations for safety
- The report does not make any reference to negligence or liability for the underlying adverse event at issue in the case



- The Court held **it had no bearing on the question of negligence for the underlying medical malpractice case and would unnecessarily confuse the jury** and could prove to lead the jury to improper conclusions and cause **undue prejudice**



- **Not declared PSWP, but PSQIA compliance form was still not admissible for basically the same reasons – improving patient safety**



John Walker v. Ltach @ Riverside, LLC, April 14, 2022 VIRGINIA (state case)

Deals with Hospital Policies/Procedures and EMR Audit Trails/Logs

- Hospital **policies and procedures did not meet the definition of "patient safety work product"** they were not privileged
- **PSWP does not include a patient's medical record**, billing and discharge information, or any other original patient or provider record
 - It is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system
- **COURT HELD:** Although Plaintiff seeks audit trails for a time after she was transferred from the facility, **those audit trails are still part of her electronic medical record**
- **Plaintiff is entitled to receive the entirety of her medical record, electronic derivatives included**





Estate of Hultman v Ventura County, May 16, 2022 CALIFORNIA (federal case)

Deals with an M/M Report and Portion of a Psychological Autopsy of Decedent

▪ Synopsis of Facts/Circumstances

- Used to prepare the clinical mortality review
- Derived from non-PSWP info that was produced to plaintiff
- Submitted affidavit/declaration that does not state whether it was submitted to the PSO, and legal counsel confirmed it was not reported
- HELD: NOT PSWP under the reporting pathway
- IF NOT REPORTED TO PSO, then it is only PSWP if it is in PSES and identifies/constitutes the deliberations or analysis of, or identifies the fact of reporting to a PSES – did not meet this standard – facts and no deliberations/analysis



Estate of Hultman v Ventura County, Cont'd



- Information/data in a document that may be “used in” analysis or deliberations relating to some other document does not constitute PSWP

- HHS 2016 guidance states that “a provider should only place information in its PSES if it intends to report that information to the PSO”



- **Should be removed from PSES if not going to PSO – have procedure in place for doing so**

- HHS 2016 Guidance” at *32659 describing the “drop out” provision for removal of PSWP from a PSES

Estate of Hultman v Ventura County, Cont'd

- **M/M Report (Clinical Mortality Review)**
- Defendant **undertook a clinical mortality review that was internal** to its organization and stated it was done for the **sole purpose of reporting to the PSO, entered into the PSES, and was reported** properly to the PSO
- **Separately**, defendant **undertook the state-mandated “death review”** of decedent inmate that included persons from outside the organization
- **Wellpath’s own policies/procedures** show that information used in and resulting from the clinical mortality review (internal) is then used in the “death review” (external)
- Did not share written M/M with county, **but did tell them verbally**



Estate of Hultman v Ventura County, Cont'd



- **HELD**: the clinical mortality review (M/M Report) was prepared, at least in part, for reporting to the county at the “death review” – **not prepared solely for reporting to the PSO – dual purpose and externally released**
- **None of the information/documentation at issue was PSWP**



In re Admin. Subpoenas Duces Tecum, June 2, 2022 MISSOURI (federal case)

Deals with Law Enforcement Exception to PSWP

- A portion of **HIPAA**, codified at 18 U.S.C. § 3486, invests **DOJ with the authority to issue administrative subpoenas** in specified types of **criminal investigations**
- Section **3486 administrative subpoenas** may be issued only in investigations concerning the limited universe of federal criminal offenses identified in § 3486(a)(1)(A)
- Can be used to subpoena documents or to subpoena the testimony of document custodians but cannot be used to obtain testimony



In re Admin. Subpoenas Duces Tecum, Cont'd



- A federal agency's administrative subpoena should be enforced if
 - (1) the subpoena was issued pursuant to lawful authority,
 - (2) the subpoena was issued for a lawful purpose,
 - (3) the subpoena requests information that is relevant to the lawful purpose, and
 - (4) the disclosure sought is not unreasonable.



- An agency can investigate merely on the suspicion that the law is being violated, or even just because it wants assurance that it is not. So long as the material touches a matter under investigation, an administrative subpoena will survive a challenge that the material is not relevant."

In re Admin. Subpoenas Duces Tecum, Cont'd



42 U.S. Code § 299b–22 *Disclosure to law enforcement.*

(a) Privilege

Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be privileged and shall not be—



(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

...

In re Admin. Subpoenas Duces Tecum, Cont'd



(c)(2)(G) (42 CFR 3.206(b)(10(i)) Disclosure of patient safety work product to an appropriate law enforcement authority relating to an event that either constitutes the commission of a crime, or for which the disclosing person reasonably believes constitutes the commission of a crime, provided that the disclosing person believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

- **Law Enforcement exception to PSWP may permit compliance with HIPAA 3486 administrative subpoena - CONSULT LEGAL COUNSEL IMMEDIATELY**



- **Provide this case opinion – included in your resource booklet - Providing PSWP materials improperly could waive the privilege on some or all materials not provided**



McNamara v City of Philadelphia, June 30, 2022 PENNSYLVANIA (federal case)

Deals with Contract and Accreditation Organization Reporting Requirements and Affect on – “Preparation Solely for Submission to the PSO”

- Defendant Corizon asserted the statutory elements of the privilege, including that the documents were assembled for the purpose of reporting to a patient safety organization. The Court stated it has not done any more than recite the elements of the statute, and further held that Corizon's bare recitation is insufficient, because:
 - Corizon's **contract with the City** requires it to conduct the mortality review. Even if the PSO did not exist, Corizon would still be required to conduct the review and prepare the related documents, (and presumably submit a report of it).
 - Corizon admitted that its mortality review process is a key component of its **accreditation** by the National Commission on Correctional Health Care.





Dence v Wellpath, LLC, October 25, 2022 OREGON (federal case)

Deals with Extreme Delay in Submission to the PSO



- Wellpath Defendants fail to explain how the mortality report, which Wellpath Defendants submitted to a patient safety organization sixteen (16) months after Butterfield's death, was developed for the purpose of reporting to a patient safety organization
- The purpose of the PSQIA is to improve patient safety and quality. The Court found that there was obviously no interest in improving patient safety and quality if the report was not even presented to the PSO until 16 months after the inmates' death.
 - **NOTE: Courts are still noticing that purported PSWP is not being submitted timely and holding that it is not entitled to the privilege.**



Dence v Wellpath, LLC, November 29, 2022 OREGON (federal case)

Deals with Contract Reporting Requirements and Affect on – "Preparation Solely for Submission to the PSO"



- Defendant Wellpath is required to perform post-mortem reviews under its contract with Josephine County
- The quality Committee investigated and prepared an M&M report and shared same with the jail administrator **per the contract with the County**
 - Prepared for and used for dual purposes – not entitled to privilege under the PSQIA
- **SEE McNAMARA ABOVE – different state but decided 4 months after McNamara on similar facts.**



Garcia v Bd. of Cnty. Comm'rs for the Cnty. of Doña Ana, January 23, 2023 NEW MEXICO (federal case)

Deals with Contract Reporting Requirements and Affect on –"Preparation Solely for Submission to the PSO" AND Privilege Log Information Requirements

- Defendant Corizon is required to perform post-mortem reviews under its corrections medicine contract with Doña Ana County
- Defendant's obligations included "establishing a mortality review process" in the event of inmate fatality and remaining in compliance with the "standards, regulations, and recommendations of the National Commission on Correctional Health Care" ("NCCHC").

Garcia v Bd. of Cnty. Comm'rs for the Cnty. of Doña Ana, Cont'd

- Defendant conducted mortality reviews according to the procedure outlined in its internal policy for "an event involving death or serious injury.
- Use of its Sentinel Event Review policy and procedures in doing so facilitated the "accreditation of Defendant's facilities" and documented Defendant's compliance with agency regulators and third parties.
- Defendant had an independent contractual obligation with the County to conduct a mortality review that satisfied the NCCHC standards. **The Reviewer Affidavit was noticeably silent on the mortality review's relationship to the County's contract and whether the review could have been conducted for the dual purpose of satisfying that contract.**



Garcia v Bd. of Cnty. Comm'rs for the Cnty. of Doña Ana, Cont'd

- The Affidavit does not address whether Defendant could satisfy its NCCHC compliance obligation through any means other than the mortality review
- The Affidavit also does not say whether those duties include sharing the mortality review [document] with the County
- **HELD:** It follows that Defendant could have produced the mortality review not only for its PSES but also in the event that the County or NCCHC sought information. Defendant's declaration fails to acknowledge—let alone dispute—the plausibility of dual-purpose intent behind creating the review and it bears the burden to prove the privilege applies
- **SEE McNAMARA ABOVE – different state but decided 6 months after McNamara on similar issue. SEE Baker v. Corizon Health, LLC, February 3, 2023 NEW MEXICO (federal case), companion case to Garcia.**

Garcia v Bd. of Cnty. Comm'rs for the Cnty. of Doña Ana, **Cont'd**



▪ **Privilege Log Compliance:** Federal Rule of Civil Procedure 26 requires the following be stated for each document listed as being privileged and not subject to release/review in Privilege Logs:

- Date of creation
- Author(s)
- Recipient(s) – including addressees, CCs, BCCs, and forwardees
- The specific privilege intended to invoke



▪ **HELD:** Defendant's log adequately described the purpose and details of the document. As courts in this district routinely hold, such level of detail, especially coupled with an Affidavit, satisfies Rule 26's lenient standard



Franco v. Yale New Haven Hosp., Inc., March 31, 2023 CONNECTICUT (state case)

Deals with Privilege for Notes and Verbal Information Collected as Part of Investigation Activities

- As stated in her Affidavit, Patient Safety Coordinator conducted an investigation concerning the foregoing incident as part of YNHH's PSES. She was also responsible for collecting, analyzing and managing PSWP for the purpose of submitting that information to a PSO
- She created notes regarding her investigation that were submitted to the PSO – they were prepared and maintained for the PSES and PSO, and were not released outside that closed loop system
- All of her knowledge regarding the incident was obtained through her patient safety activities within YNHH's PSES

Franco v. Yale New Haven Hosp., Inc., Cont'd

- Plaintiff noticed a deposition regarding her knowledge and investigation and requested all related notes, documents, etc. Defendant sought a Protective Order because all her knowledge was obtained through the investigation and was therefore privileged as PSWP



- **HELD:**
 - The information was developed by the Patient Safety Coordinator for the purpose of reporting to a PSO
 - That information had the ability to improve patient safety and the quality of health care
 - That information was reported to the patient safety organization
 - The information contained the date it was entered into the PSES
- **DISCLOSURE PRECLUDED**



Nelms v. Wellpath, LLC, March 31, 2023 MICHIGAN (federal case)

Deals with Personal Knowledge of Affiant as to Privilege of Contested Portion of an M&M Review, **AND** Delay in Submission to PSO

- Parts 1 and 2 of the M&M report bear no claim of PSWP privilege by Defendant Wellpath. Part 3 which contained the investigation and patient safety and quality improvement portions was claimed as PSWP
- It was created solely for submission to the PSO, and was submitted timely to the PSO
- The information collected and procedure for collecting was completely within the PSES
- A detailed Affidavit was submitted by the Patient Safety Officer
- Plaintiff argues that the Affidavit is silent as to both personal knowledge of the facts asserted or even personal knowledge of the process and method of data reporting to the PSO

Nelms v. Wellpath, LLC, Cont'd

- The Court acknowledged his role as Patient Safety Officer indicated he would have knowledge of these facts
- **The Court interpreted the Affiant's statement that he "under penalty of perjury and having been duly sworn, hereby swear[s] and affirm[s] the following" as affirmation of personal knowledge of the facts therein" as knowledge of personal facts (SEE, *Herriges v. County of Macomb ABOVE*)**
- The Court distinguished *Herriges* because in that case the Patient Safety Officer's purported lack of personal knowledge of certain facts was based on *his testimony at an evidentiary hearing*, and not on the Affidavit submitted
 - The Court neither had testimony that contradicted his assertion of personal knowledge in his Affidavit nor a request by either party for an evidentiary hearing

Nelms v. Wellpath, LLC, Cont'd

- Defendant conducted mortality reviews according to the procedure outlined in its internal policy for "an event involving death or serious injury"
- Plaintiff argued that **Part 3 was not submitted to the PSO until almost 13 months later, and thus was not really completed for patient safety and quality improvement purposes (SEE *Herriges*)**
- The Court again distinguished the present case from *Herriges*, stating the prior case was a more extreme case than the one at issue, and **the delay in producing the information to PSO did not change whether such information was included in the review and could serve its purpose of improving care eventually**



Nelms v. Wellpath, LLC, Cont'd

- Plaintiff argued the analyses in Part 3 were conducted without interviewing the main personnel in charge of Decedent's care, which undermined whether the review could actually result in improved patient safety
- The Court concluded that although Defendant may not be using best practices or at least, the practices that Plaintiff would find adequate, but the PSQIA does not contain such rigid requirements. And it is possible that Part 3 includes recommendations that could improve patient safety, even though the providers themselves were not part of the morbidity and mortality review meeting. Failure to include them in the meeting does not mean that the resulting analysis was devoid of information that could be used to improve healthcare outcomes. **The law simply does not require the best or most-informed analyses for the privilege to apply**





Nelms v. Wellpath, LLC, March 31, 2023 MICHIGAN (federal case)

Deals with Motions to Seal Internal Policies and PSO Contract

- **Separate opinion on same case as above**
- As part of the briefing on the above case's issues, each party filed documents that, per Defendants' confidentiality designations under the parties' protective order, were to be filed under seal.
- Defendant moved to have the Wellpath **policies** (Patient Death, Morbidity, Critical Clinical Events, CQI, and Patient Safety Organization), and the **PSO contract sealed** because each policy is related to Wellpath's continuous quality improvement program, as the "CQI" policy sets out.

Nelms v. Wellpath, LLC, Cont'd

- Thus, because the policies would reveal Wellpath's strategy for improving patient safety, which affects its competitive position, it has shown a compelling reason to justify sealing based on competitive disadvantage
- Wellpath's contract with the Center for Patient Safety includes details about each organization's responsibilities in furtherance of improved patient safety and healthcare quality
- **HELD:** Defendants have sustained their burden of showing that the relevant Wellpath policies and its PSO contract should be sealed. But Defendants have not made a sufficient showing as to the Licensed Practical Nurse (LPN) job description and the staffing matrix.



ONE LAST SNEAKY THING....

THE PSQIA states:

- PSWP may not be provided in response to any subpoena or other order in any federal, state, local, or tribal civil, criminal or administrative proceeding, including but not limited to a disciplinary proceeding against any healthcare provider
- IN MICHIGAN in September 2021, the Attorney General's Office sought to use a search warrant signed by a sympathetic judge to obtain PSWP (M/M Report) created in another state (at the head office of a Michigan branch of the organization)
 - **A search warrant is a Court ORDER**
 - Just another FAILED attempt to get around the PSWP privilege



PSWP Cases
and the
State's 7th
Amendment
Issue





Charles v. Southern Baptist Hosp. of Florida (*Charles II*), January 31, 2017 FLORIDA (state case)

(US Supreme Court - Certiorari denied)

- Court held that Congress did not intend to preempt state laws or Amendment 7 through the passage of the PSQIA when creating a voluntary reporting system. The clear intent of the PSQIA was for the voluntary reporting system to function harmoniously within existing state reporting and discovery laws
- PSQIA was not intended to act as a shield for providers, thereby dismantling an important right afforded to Florida citizens through Amendment 7
 - Health care providers should not be able to unilaterally decide which documents will be discoverable, and which will not in medical malpractice cases
 - **The adverse medical incident reports** requested by a patient's representative **were not patient safety work product**



Edwards v. Thomas

October 26, 2017 FLORIDA (state case)



- Amendment 7 removes any barrier to a patient's **discovery of adverse medical incident information, including the peer review protections** provided by the statute
- A request for Amendment 7 materials is **not an ordinary discovery request which can be subjected to overbreadth, irrelevance, or burdensomeness objections by attorneys**
- A patient has the absolute right to **discover records relating to any adverse medical incident** and is not conditioned on the discovery being relevant to a pending claim
- **External peer review reports are discoverable** under Amendment 7





Shands Teaching Hosp. & Clinics, Inc. v. Azar

November 6, 2017 FLORIDA (federal case)

- Patient seeks any and all records related to hospital's membership in and relationship to PSO
- **PSO contract contains provision maintaining the confidentiality of the agreement is a condition of membership in the PSO**
- **Producing the requested PSO-related documents could risk hospital's membership in the PSO**
- **Losing membership in the PSO could prevent hospital from conducting activities to improve patient safety and the quality of healthcare**
 - **PROTECTING THE INFORMATION BY CONTRACT IN FEDERAL COURT**
 - **WOULD IT WORK WITH OTHER PROTECTED INFORMATION SUBMITTED TO A PSO?**



Shands Jacksonville Med. Ctr., Inc. v. Azar June 10, 2020 FLORIDA (federal case)

- Hospital suing DHHS because of conflict between complying with state Supreme Court ruling (Charles II case) based on supremacy of Article 7 of Florida Const over the PSQIA, and breaching PSQIA which will subject it to mandatory federal civil monetary penalties imposed by DHHS
- **Federal Court wimped out** – stated it did not have jurisdiction to handle case because it was a DHHS matter – not true, **it is a federal statutory interpretation matter**
- Then said it was a state Court matter concerning litigation discovery



Hacking v. United States, April 28, 2021 FLORIDA (federal case)

- Fed government seeks to compel two patient safety analyses and one serious event analysis from a non-party hospital - Court conducted an *in-camera* review of all documents
- Patient safety analyses were developed as part of the PSES solely for reporting to PSO, and were reported
- Serious event analysis was not submitted to a PSO, but found that it was privileged PSWP because it was an RCA and reflected deliberations and analysis within the PSES
 - Affidavit of Dir. Patient Safety and document itself clearly showed it was an RCA - included detailed review of causal factors and prevent recurrence - developed in PSES and reflects deliberations and analysis
- **The labels/terminology are not important - it is the essence and nature of the documents that matters**



Tallahassee Mem'l Healthcare, Inc. v. Wiles, November 14, 2022 FLORIDA (state case)

Deals with Federal Pre-Emption Doctrine and Explicit Pre-Emption Clause in PSQIA

- The trial court's order requiring disclosure of the hospital's safety event report was quashed because the report was privileged and confidential PSWP under the PSQIA, which preempted Art. X, § 25, Fla. Const., (commonly known as Amendment 7). The hospital's "Safety Event Report No. 67593" qualified as PSWP under 42 U.S.C.S. § 299b-22(a) and was entitled to confidentiality under the PSQIA because the report was submitted to the hospital's patient safety organization and the document was not an "adverse incident" report, which state law defined and was required to be submitted to the Agency for Health Care Administration. Thus, it was prepared solely for submission to the PSO and did not have a dual purpose

Tallahassee Mem'l Healthcare, Inc. v. Wiles, Cont'd



- **Charles II was distinguished in this opinion.**
- “Charles II addressed preemption in the context of documents that were not patient safety work product (and thus not subject to the privilege protections under federal law). Given our conclusion that Tallahassee Memorial's report is patient safety work product, *Charles II* is not dispositive
- Preemption is grounded in the Supremacy Clause of the United States Constitution which provides that a federal law is "supreme" over any conflicting state law. Art. VI, cl. 2, U.S. Const. (stating that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding")
- ("[U]nder the Supremacy Clause, from our pre-emption doctrine is derived, any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield"



Shands Teaching Hosp. & Clinics v. Beylotte, March 8, 2023 FLORIDA (state case)

Deals with Patient Safety Documents Relating to Injuries of Visitor as Patient Safety Improvement Documents Under PSQIA

- Beylotte was visiting a patient at Shands when she slipped and fell on a clear liquid while walking through a hallway near a nursing station. She sued Shands for injuries she sustained in the fall. Beylotte sought to discover any "investigative report" prepared in response to her fall. Shands objected.
- Shands sought to protect a patient safety report related to Beylotte's fall that was prepared solely for submission to a PSO. The report was placed in a PSES and submitted to the PSO. An uncontradicted Affidavit declaring same was submitted to the Court

Shands Teaching Hosp. & Clinics v. Beylotte, Cont'd



- **The trial Court** reasoned that the PSQIA only applied to records involving *patients* and did not apply to incidents involving staff or visitors
- The Act requires that the report "could result in improved patient safety, health care quality, or health care outcomes." Shands maintains that improving potential slip-and-fall conditions in patient-traversed corridors is necessarily related to improved patient safety. **The Appellate Court agreed**
- The incident occurred on a patient unit of the hospital where patients and visitors walk. It does not matter that Beylotte was not a patient at the time of her fall. Any person—staff, patients, and visitors alike—face similar slip-and-fall risks in a hospital's common areas.

Shands Teaching Hosp. & Clinics v. Beylotte, Cont'd



- Because the report here was assembled by a provider for reporting to a patient safety organization, was in fact reported to a patient safety organization, and could result in improved patient safety **the Court concluded that it qualified as PSWP**
- **The Court cited to Tallahassee Mem'l Healthcare, Inc. v. Wiles, ABOVE**



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Questions

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Answers

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