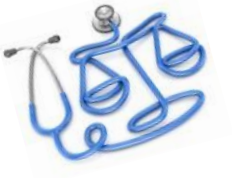
DON'T GET IT TWISTED!!

The Contortion and Corrosion of the PSWP Privilege



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RESOURCE BOOKLET

BIKHAM IT'S THE PURSUIT...

BIKHAM HEALTHCARE CONSULTING

"Knowing is not enough; we must apply.
Willing is not enough; we must do."

— Goethe

33 Resources:

TOOLS & TOOLKITS

- Patient Safety Toolkits
- PSO Toolkits
- CANDOR Program Toolkit

CONTACT INFORMATION

If you would like:

- further information or have questions
- assistance with creating or revising your Patient Safety and Quality Improvement PSWP Program Policies or Procedures
- assistance training your staff with regard to implementing, operating, or maintaining compliance with legal requirements to preserve PSWP privilege, or
- legal assistance communicating with legal counsel on existing matters with regard to their part in asserting, proving, and preserving the PSWP privilege

Contact us at

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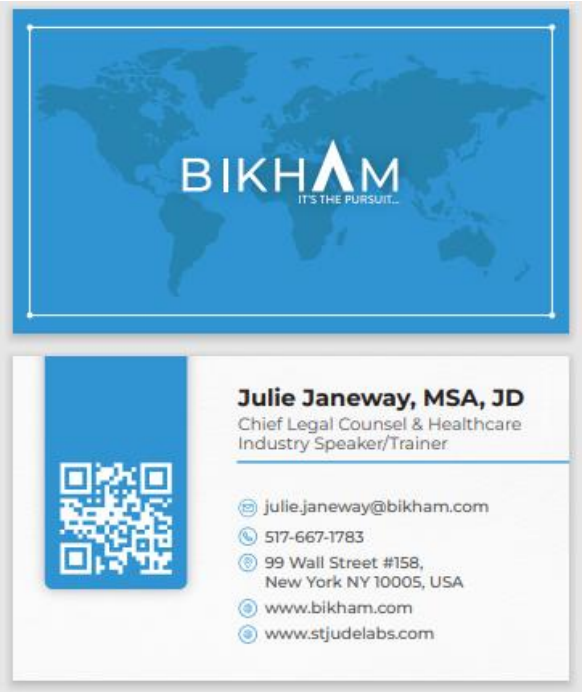

Patient Safety and Quality Improvement Act (PSQIA)

RELEVANT TERMS AND DEFINITIONS

42 USC 299b-21

(1) HIPAA Confidentiality Regulations

The term "HIPAA confidentiality regulations" means regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033).

(2) Identifiable Patient Safety Work Product

The term "identifiable patient safety work product" means patient safety work product that—

(A) is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product;

(B) constitutes individually identifiable health information as that term is defined in the HIPAA confidentiality regulations; or

(C) is presented in a form and manner that allows the identification of an individual who reported information in the manner specified in section 299b–22(e) of this title.

(3) Nonidentifiable Patient Safety Work Product

The term "nonidentifiable patient safety work product" means patient safety work product that is not identifiable patient safety work product (as defined in paragraph (2)).

(4) Patient Safety Organization (PSO)

The term "patient safety organization" **means a private or public entity or component thereof that is listed by the Secretary** pursuant to section 299b–24(d) of this title. **(listed at AHRQ.gov)**

(5) Patient Safety Activities

The term "patient safety activities" means the following activities:

(A) Efforts to improve patient safety and the quality of health care delivery.

(B) The collection and analysis of patient safety work product.

(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

(D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

(E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.

(F) The provision of appropriate security measures with respect to patient safety work product.

(G) The utilization of qualified staff.

(H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

(6) Patient Safety Evaluation System (PSES)

The term "patient safety evaluation system" **means the collection, management, or analysis of information for reporting to or by a patient safety organization**.

(7) Patient Safety Work Product (PSWP)

(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.

(B) Clarification

(i) Information described in subparagraph (A) **does not include a patient's medical record, billing and discharge information, or any other original patient or provider record**.

(ii) Information described in subparagraph (A) **does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.** Such separate information or a copy thereof

reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

(iii) Nothing in this part shall be construed to limit—

(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

(8) Provider

The term "provider" means—

(A) **an individual or entity licensed or otherwise authorized under State law to provide health care services, including**—

(i) **a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center**; or

(ii) **a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner**; or

(B) **any other individual or entity specified in regulations promulgated by the Secretary**.

Patient Safety and Quality Improvement Act of 2005

The Patient Safety and Quality Improvement Act of 2005 (PSQIA) establishes a voluntary reporting system designed to enhance the data available to assess and resolve patient safety and healthcare quality issues. To encourage the reporting and analysis of medical errors, PSQIA encourages reporting of patient safety and healthcare quality information to patient safety organizations (PSO) through a patient safety evaluation system (PSES) by providing Federal confidentiality and privilege over that information, known as patient safety work product (PSWP). The PSQIA also authorizes the Agency for Healthcare Research and Quality (AHRQ) to authorize and list PSOs. PSOs are the external experts that collect and review patient safety information.

Any records assembled or developed by a provider for reporting to a PSO and that 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 PSQIA authorizes HHS to impose civil money penalties for violations of patient safety confidentiality.

- RESOURCE -
PSQIA / PATIENT SAFETY WORK PRODUCT PRIVILEGE

RECENT CASES: October 2017- March 2023

In chronological order:

- **Charles v. Southern Baptist Hosp. of Fla., Inc., (*Charles II),*** 209 So. 3d 1199, **2017 -** Supreme Court of **Florida**
- **Univ. of Ky. v. Bunnell,** 532 S.W.3d 658, **2017** Ky. App. LEXIS 697 - Court of Appeals of **Kentucky**
- **Edwards v. Thomas,** 229 So. 3d 277, **2017 -** Supreme Court of **Florida**
- **Daley v Teruel,** 2018 IL App (1st) 170891 *; 107 N.E.3d 1028 **, **2018 -** Appellate Court of **Illinois**, First District, Fourth Division
- **Crawford v Corizon,** 2018 U.S. Dist. LEXIS 113828, **2018 -** United States District Court for the Western District of **Pennsylvania**
- **Grider v. Shawnee Mission Med. Ctr.,** 2018 U.S. Dist. LEXIS 138236 *; 2018 WL 3862703, **2018 -** United States District Court for the District of **Kansas**
- **Shands Teaching Hosp. & Clinics, Inc. v. Azar,** 2018 U.S. Dist. LEXIS 223787 *, **2018** - United States District Court for the Northern District of **Florida**, Gainesville Division
- **Hyams v. CVS Health Corp.,** 2019 U.S. Dist. LEXIS 213796, **2019** - United States District Court for the Northern District of **California**, San Francisco Division
- **Hite v. Mary Immaculate Hosp., Inc.,** 105 Va. Cir. 121, **2020** - Circuit Court of the City of Newport News, **Virginia**
- **Ungurian v. Beyzman, et al.,** 2020 PA Super 105, **2020** - **Pennsylvania** Superior Court
- **Shands Jacksonville Med. Ctr., Inc. v. Azar,** 2020 U.S. Dist. LEXIS 101957 *, **2020** - United States District Court for the Middle District of **Florida**, Jacksonville Division

- **Thompson v. United States,** 2020 U.S. Dist. LEXIS 122039 *, **2020 -** United States District Court for the Southern District of **Illinois**

- **Penman v. Correct Care Solutions,** 2020 U.S. Dist. LEXIS 131326, **2020** - United States District Court for the Western District of **Kentucky**, Paducah Division

- **Herriges v. Cty. Of Macomb,** 2020 U.S. Dist. LEXIS 146663, **2020 -** United States District Court for the Eastern District of **Michigan**, Southern Division

- **Rice v. St. Louis Univ,** 2020 U.S. Dist. LEXIS 194928 *; 2020 WL 6158029, **2020** - United States District Court for the Eastern District of **Missouri**, Eastern Division

- **McCue v. Integra,** 2021 U.S. Dist. LEXIS 92573, **2021** - United States District Court for the District of **Montana**, Missoula Division

- **La Shanta Hacking v. United States,** Case 2:19-cv-14449-AMC, **2021** - United States District Court for the Southern District of **Florida**

- **Louzi v. Fort Bend County,** 2021 U.S. Dist. LEXIS 85003, **2021 -** United States District Court for the Southern District of **Texas**, Houston Division

- **Givens v St. Louis County,** 2021 U.S. Dist. LEXIS 244869, **2021** - United States District Court for the Eastern District of **Missouri**, Eastern Division

- **Mayotte v. Brattleboro Mem'l Hosp.,** 2022 Vt. Super. LEXIS 77, **2022** - Superior Court of **Vermont**, Windham Unit, Civil Division

- **John Walker v. Ltach @ Riverside, LLC,** 2022 Va. Cir. LEXIS 64, **2022** - Circuit Court of the City of Newport News, **Virginia**

- **Estate of Hultman v Ventura County,** 2022 U.S. Dist. LEXIS 107258, **2022** - United States District Court for the Central District of **California**

- **In re Admin. Subpoenas Duces Tecum,** 2022 U.S. Dist. LEXIS 98583, **2022** - United States District Court for the Eastern District of **Missouri**, Eastern Division

- **McNamara v. City of Philadelphia,** 2022 U.S. Dist. LEXIS 115630, **2022 -** United States District Court for the Eastern District of **Pennsylvania**

- **Dence v. Wellpath, LLC,** 2022 U.S. Dist. LEXIS 193981, **October 25, 2022 -** United States District Court for the District of **Oregon**, Medford Division

- **Tallahassee Mem'l Healthcare, Inc. v. Wiles,** 351 So. 3d 141, **2022 -** Court of Appeal of **Florida**, First District

- **Dence v. Wellpath, LLC,** 2022 U.S. Dist. LEXIS 215149, **November 29, 2022 -** United States District Court for the District of **Oregon**, Medford Division

- **Garcia v. Bd. of Cnty. Comm'rs for the Cnty. of Doña Ana,** 2023 U.S. Dist. LEXIS 146, **2023 -** United States District Court for the District of **New Mexico**

- **Shands Teaching Hosp. & Clinics v. Beylotte,** 2023 Fla. App. LEXIS 1497, **2023 -** Court of Appeal of **Florida**, First District

- **Franco v. Yale New Haven Hosp., Inc.,** 2023 Conn. Super. LEXIS 413, **2023 -** Superior Court of **Connecticut,** Judicial District of New Haven At New Haven

- **Nelms v. Wellpath, LLC, (Nelms 1)** 2023 U.S. Dist. LEXIS 57292, **2023 -** United States District Court for the Eastern District of **Michigan**, Southern Division

- **Nelms v. Wellpath, LLC, (Nelms 2)** 2023 U.S. Dist. LEXIS 57298, **2023 -** United States District Court for the Eastern District of **Michigan**, Southern Division

NOTE: All legal research should be read thoroughly and updated (shepardized or key cited) before use. Consultation with a licensed attorney experienced in this area of health law is recommended.

- RESOURCE -

PSWP PRIVILEGE PROTECTION CHECKLISTS

CHECK YOUR PROGRAM

	Are there detailed, written policies and procedures for your Patient Safety/Quality Improvement PSES/PSO Program? *If no, establish immediately*
	Is there a defined team of people who work on PSES/PSO matters? *If no, establish immediately*
	Are the team members qualified to perform their roles, and could your organization defend that in court? *If no, change out unqualified team members*
	If team members are healthcare providers, are their licenses and certifications up-to-date and in good standing (at all times)? *If no, correct the situation and do not let them participate in PSES/PSO efforts until such correction is made*
	Have all PSES/PSO team members been properly and completely trained on their duties, requirements, prohibitions, and confidentiality requirements? *If no, correct immediately*
	Does your organization have a valid contract with an AHRQ-approved PSO? *If no, get one immediately*
	Has your organization's name, address, or other identifying information changed since the PSO contract was signed? *If yes, see below*
	Have you contacted the PSO in writing to inform it of the name or other information change? *If no, do so immediately*
	Has the PSO acknowledged the changed information in writing? *If no, obtain such a document*

	Has there been an addendum made to the PSO contract noting that the relationship has continued from the old information through to the new information? *If no, obtain and execute such an addendum*
	Has the organization received a formal, written acknowledgement from the PSO that the relationship is continuing from old name to new name especially for any cases that cross-over the name change time period? *If no, obtain acknowledgement*
	Is there a policy or requirement that discussion of, or reference to anything remotely related to the work or documents of the PSES/PSO program are not to be mentioned in emails? *If no, create and discourage such in emails as they are very difficult to establish as PSWP*
	Is all PSWP securely stored and protected at all times, for both physical materials and digital materials? *If no, correct immediately*
	Have the organization and all PSES/PSO team members been strictly and vigilantly compliant with all laws, regulations, internal policies/procedures, and PSO policies, procedures, and requirements? *If no, document period(s) of complete or partial noncompliance, and immediately correct compliance issues*
	Are all Privilege Logs and all PSO Encounter Entry Reports consistent with each other?
	Are all documents, information, materials that are entered into the PSES properly marked (on all pages of each): **Patient Safety Work Product — PSWP created and intended solely for reporting to PSO / This document is protected from disclosure pursuant to 42 U.S.C. § 299b-22** ?

	Is your organization and the PSES/SO team prepared to handle requests or subpoenas for documents with regard to PSWP in Section 1983 federal civil rights cases, employment discrimination cases, wrongful (employment) discharge cases?
	Documents, information, or materials that concern a patient event or other legal matter that occurred *before* the organization was in full and complete compliance with the PSQIA may not qualify for such materials to be PSWP protected – *note any such matters that existed before 100% strict compliance with PSQIA took place and have legal counsel calculate statute of limitations periods on each*
	Is there a protocol for engaging with the defense attorney handling the matter to coordinate content and accuracy of all pleadings, motions, affidavits, planned testimony, etc, regarding PSWP? *If no, create one and designate PSES/PSO program leader to be the liaison*
	Are requirements for compliance with any state court PSWP and/or peer review protections built into the policies, procedures, processes, protocols to serve as a back-up in the event PSWP status under PSQIA is not achieved? *If no, then correct the situation to include*
	Is your Program keeping up with best administration, confidentiality, privilege, and security practices, and the latest relevant Court decisions to ensure continued compliance and the best chance at having PSWP recognized in Court? *If no, then correct the situation by contacting legal counsel or a PSWP consultant*
	Does your Privilege Log contain all the suggested fields provided herein to maximize compliance with FRCP Rule 26? *If no, then correct the situation*

CHECK YOUR DOCUMENTS/INFORMATION

	IS IT PSWP:
	What is the document or other material?
	Why was it created? (peer review, RCA, FMEA, etc.)?
	Was it created for use in reporting for other external requirements? *If yes, then not PSWP*
	Will it possibly improve patient safety, quality improvement, and/or improve healthcare outcomes? *If no, then not PSWP*
	Was it/will it be soon collected and protected in the PSES? *If no, then not PSWP*
	Does it exist, or has it, or any protected part of it, been permitted outside the closed loop system of the PSES and PSO? *If yes, then not PSWP*
	Was it generated solely for the purpose of being submitted to a PSO? *If no, then not PSWP*
	Does the document or information regarding the event or location of the event have any relation to a contract, administrative, or accreditation requirement that may be satisfied, or interpreted by a Court to be satisfying such requirement(s), and thus serving a dual or multi-purpose? *If yes, then likely not PSWP*
	Is the document or information about whether something in particular exists (*e.g.,* proof of a meeting, another document, analysis, interview reports)? *If yes, it may be PSWP depending on how a judge would rule. Enter it into the PSES and the Privilege Log anyway, and submit to the PSO for maximum evidence potential*
	Is the document or information about whether a meeting, event, interview, etc., was held? *If yes, it may be PSWP depending on how a judge would rule*
	Enter it into the PSES and the Privilege Log anyway, and submit to the PSO for maximum evidence potential

	Is it surveillance video, surveillance stills, or still photographs? *If yes, then not PSWP (unless it is photographs taken solely for reporting purposes to the PSO)*
	Does the document, information, or material concern a patient event or other legal matter that occurred before the organization was in full and complete compliance with the PSQIA? *If so, PSWP may not attach depending on how judge rules*
	Quantros/Other Healthcare Performance or Patient Safety Analytical Reports: Is the document a Quantros or other similar healthcare performance, or patient safety analytical report? *If yes, then treat as PSWP – enter into PSES, Privilege Log, and send to PSO*
	Is there any redacted information in reports that are being turned over to plaintiff's counsel? *If yes, see next question*
	Is the redacted information solely relating to deliberations or analyses of or about reporting to PSES or PSO*? If yes, then such explanation must be made for EACH redaction*
	Is the redacted information identifying actual reporting to PSES or PSO? *If yes, then such explanation must be made for EACH redaction*
	Risk Management Worksheets (or similar documents): Were they *solely* created for submission to the PSO, and do they meet the statutory requirements of PSWP? *If yes, then treat as PSWP – enter into PSES, Privilege Log, and send to PSO*
	Have documents, information, material been submitted to PSO *before* requests have been made for them, and *before* any affidavits have to be signed referencing them? (Do not delay in sending to PSO)

	Is there a procedure in place to ensure that all submissions to the PSO are checked for full compliance with all organizational policies, procedures, protocols, as well as those of PSO, including submission of documents in particular file formats or via a particular submission method, software, etc?

CHECK YOUR DUAL / MULTI ORGANIZATION REPORTING SITUATION

	Where do you have to report this information, or part of this information?
	If you must report this information, document, or material to any person or organization outside the PSES/PSO closed-loop system (EXTERNAL reporting), then:
	Determine what information could be used to complete the EXTERNAL reporting.
	Separately, determine what information could be used to complete the PSES/PSO reporting.
	Ensure that the EXTERNAL reporting does not use anything that will be generated by the PSES/PSO team.
	Ensure that the EXTERNAL reporting is completed by individuals who are not working on the PSES/PSO team
	Complete the EXTERNAL reporting FIRST if possible (before anything could even have existed that could be PSWP so that no claim can be made that it was used in the EXTERNAL reporting)
	AFTER the EXTERNAL reporting has been completed, have the PSES/PSO team complete the work necessary for PSES/PSO reporting *and intended solely for same*. Information used in

	EXTERNAL reporting may be used in the PSES/PSO reporting, *but not vice versa*
	Store all records for EXTERNAL and PSES/PSO reporting separately
	Do not let teams for either type of reporting comingle or discuss their work in any way
	Immediately enter all PSES/PSO intended work into the PSES and the Privilege Log
	As soon as is possible, send all PSES information to the PSO
	Put the PSO receipts or reports into the Privilege Log

CHECK YOUR DELIBERATIONS/ANALYSIS

	Did the deliberations or analysis use PSWP? *If yes, then PSWP – enter into PSES, Privilege Log, and send to PSO*
	Did the deliberations or analysis use non-PSWP as underlying information? *If yes, then still PSWP – enter into PSES, Privilege Log, and send to PSO*
	Was the underlying non-PSWP information specifically excluded information (e.g., patient medical records, billing discharge and operations records)? *If yes, then not PSWP*
	Was underlying information used for any external reporting? *If no, then enter into PSES, Privilege Log, and send to PSO for maximum chance at being covered as PSWP in relation to deliberations and analysis*
	Was there a document or information created regarding deliberations or analysis as to sole purpose vs dual purpose of a document or other material? *If yes, then see next question*
	Is the document or information created regarding deliberations or analysis as to sole purpose vs dual

	purpose of a document or other material entered into the PSES? *If yes, then it is PSWP – enter into Privilege Log, and send to PSO*

CHECK THAT YOU DIDN'T

	Did you use PSWP in the creation of an external report or work product? *If yes, then PSWP no longer applies*
	Did you make vague statements in an affidavit or reports with regard to intention to create PSWP solely for reporting to a PSO? *Correct immediately*
	Did you state in an affidavit or report that any documents or information *may* be submitted to a PSO? *Correct immediately*
	Did you over-state or understate on an affidavit? *Correct immediately*
	Was the affidavit noticeably silent on the document's relationship to an existence of an external contract, administrative or accreditation reporting requirement and whether the review and other activities were not also being conducted for the dual purpose of satisfying contract or administrative or accreditation reporting requirement? *Correct immediately*
	In the affidavit did you fail to acknowledge and dispute the plausibility of dual-purpose intent behind creating the document? *Correct immediately*
	If there is an external reporting requirement, and the document was not used for that purpose in any way, did you address whether or not the requirements demand that a document be created and/or shared, and whether that occurred? *Correct immediately*
	Have additional events, documents or issues arisen *after* issuing an affidavit attesting to a defined set of statements, events, documents, or issues, and then fail to

	amend the affidavit to include the later statements, events, documents, or issues to which affiant can attest from first-hand, actual, and complete knowledge? *Correct immediately*
	Submit anything to the PSO that is not 100% in compliance with organization's own policies/procedures, and the policies, procedures, and other requirements of PSO (*e.g.,* submitting in particular file formats [.doc, .pdf, .xls, rtf] or using required forms, formats, abbreviations, etc.?
	Submit anything to PSO containing typos, misspelled names, date or fact inconsistencies, or discrepancies of any kind?
	Does the affidavit fail to state at the bottom, above the affiant's signature and the notary attestation "under penalty of perjury and having been duly sworn, Affiant hereby swears and affirms the foregoing as affirmation of personal knowledge of the facts therein"??? *Correct immediately*
	Did the PSES/PSO team fail to fix any item on these checklists that is out of compliance? *Correct immediately*

CHECK WITH LEGAL COUNSEL

	Has the PSWP privilege been asserted in the legal matter with extreme specificity and in complete compliance with the requirements of the PSQIA, the organizations' policies and procedures, and the requirements of the PSO?
	Have materials at issue been submitted to the judge for *in camera* review?
	Do they meet the definitions of PSWP per the checklist above?

	If so, were they properly marked as being created for the sole and singular purpose of being reported to the PSO (preferably every page)?
	Were they entered into the PSES?
	Have they *and their complete contents* remained 100% within the PSES/PSO closed-loop system?
	Were they timely submitted to the PSO?
	Were they entered into the Privilege Log?
	Does the attorney have a copy of the Privilege Log?
	Were receipts or reports obtained from the PSO showing proof of the documents' submission to the PSO?
	Were the PSO receipts or reports also entered into the Privilege Log?
	Does the attorney have copies of the PSO receipts or reports for the documents/information submitted?
	Is all information contained in affidavits, attestations, and planned testimony 100% accurate and match anything pled or written in legal documents by attorneys, especially dates and document types/names? *If no, then have attorney correct to create consistency and cohesion*
	Have you evaluated the level of familiarity the attorney has with the PSQIA, PSWP privilege, and the previous five years of case law development? *If not, correct immediately and provide the 2017-2022 case law list enclosed in the webinar resource booklet to the attorney*
	Have you received a federal 3486 administrative subpoena?

CHECK YOUR AFFIDAVIT AND TESTIMONY

	Has the PSWP privilege been asserted in the legal matter with extreme specificity and in complete compliance with

	the requirements of the PSQIA, the organizations' policies and procedures, and the requirements of the PSO?
	Is an affidavit going to be submitted in the case with regard to asserting the PSWP privilege over particular documents, information, and materials?
	Is the head of the PSES/PSO program going to be the affiant? *(It must be to meet various court tests)*
	Does affidavit state, and can affiant honestly attest that affiant has first-hand experience and knowledge about everything to which affiant will be attesting (and later testifying)?
	Does affidavit state, and can affiant honestly attest that affiant was the individual who sent the PSWP to the PSO?
	Does affidavit state, and can affiant honestly attest that the organization has been in full compliance with all requirements of PSQIA and Court decisions re: PSWP privilege throughout the entire incident, investigation, and reporting process?
	Does affidavit state, and can affiant honestly attest that affiant and organization were in full compliance with all statutory requirements at all times?
	Does affidavit state, and can affiant honestly attest that affiant and organization were in full compliance with all requirements of organization's own internal policies regarding intending, designating, and protecting PSWP at all times?
	Does affidavit state, and can affiant honestly attest that the organization prepared the documents or other

	information or materials for reporting to a PSO and then actually reported them to a PSO?
	Does affidavit state, and can affiant honestly attest that *each, specific, individual* document or other information or material at issue was prepared for *the sole and singular purpose of reporting to a PSO?*
	Does affidavit state, and can affiant honestly attest that PSWP was not released or existed outside of PSES?
	Does affidavit state, and can affiant honestly attest that PSES/PSO team members are qualified to perform the functions they perform?
	Does affidavit state, and can affiant honestly attest that PSES/PSO team members were properly licensed and in good standing if required?
	Does affidavit state, and can affiant honestly attest that documents/information were sent to the PSO, the identity of the PSO, the title of the documents, and a description of the documents/information was provided?
	Is affiant completely familiar with all related records, documents, information, materials, events, statements, and other particulars as concerns statements in affidavit?
	Does affiant completely understand all particulars, specifics, procedures, protocols, process, and requirements of the entire PSES/PSO program and could testify effectively and competently to same?
	Has affiant reviewed the contents of the sample affidavit provided in the webinar resource booklet before signing an affidavit?
	SEE ALSO, the **Check That You DIDN"T Section and the contents of the SAMPLE AFFIDAVIT** for other Affidavit concerns

- RESOURCES -

PSWP, PSQIA, PSO INTERACTION
and PATIENT SAFETY WEBSITES

Each of the sites below contains a wide variety of resources, tools, kits, forms, case studies, training, and other helpful materials

- **Agency for Healthcare Research and Quality (AHRQ)**
  AHRQ.gov
  The Agency for Healthcare Research and Quality (AHRQ) is the lead Federal agency charged with improving the safety and quality of America's health care system. AHRQ develops the knowledge, tools, and data needed to improve the health care system and help Americans, health care professionals, and policymakers make informed health decisions. AHRQ authorizes and lists PSOs.

- **Patient Safety and Quality Healthcare (PSQH)**
  PSQH.com
  Patient Safety & Quality Healthcare (PSQH) provides insights and analysis on issues related to healthcare improvement, quality, and safety, across all settings. Under the guidance of our experienced editorial team, PSQH provides detailed updates along with first-hand accounts from healthcare executives who have effectively improved the quality of care at their institutions, while keeping facilities and patients safe. Published daily online, PSQH serves the needs of those dedicated to ensuring the highest levels of quality and safety, including the c-suite, quality and safety management, and their teams.

- **PSNet**
  PSNet.ahrq.gov
  AHRQ Patient Safety Network (PSNet) is a national web-based resource featuring the latest news and essential resources on patient safety. The site offers weekly updates of patient safety literature, news, tools, and meetings ("Current Issue"), and a vast set of carefully annotated links to important research and other information on patient safety ("The Collection").

- **Institute for Healthcare Improvement (IHI)**
  IHI.org
  For 30 years, the Institute for Healthcare Improvement (IHI) has used improvement science to advance and sustain better outcomes in health and health care across the world. We bring awareness of safety and quality to millions, accelerate learning and the systematic improvement of care, develop solutions to previously intractable challenges, and mobilize health systems, communities, regions, and nations to

reduce harm and deaths. We work in collaboration with the growing IHI community to spark bold, inventive ways to improve the health of individuals and populations. We generate optimism, harvest fresh ideas, and support anyone, anywhere who wants to profoundly change health and health care for the better.

- **National Quality Forum (NQF)**
  qualityforum.org
  The National Quality Forum (NQF) is a not-for-profit, nonpartisan, membership-based organization that works to catalyze improvements in healthcare. NQF measures and standards serve as a critically important foundation for initiatives to enhance healthcare value, make patient care safer, and achieve better outcomes.

- **National Committee for Quality Assurance (NCQA)**
  NCQA.org
  Points the way to health care that science says works. Studies how well health plans and doctors provide scientifically recommended care. Identifies organizations that are run in ways that make care better.

- **National Patient Safety Foundation (NPSF)**
  NPSF.digitellinc.com/npsf/
  NPSF partners with patients and families, the health care community, and key stakeholders to advance patient safety and health care workforce safety and disseminate strategies to prevent harm.

- **The Joint Commission (TJC)**
  Jointcommission.org
  Through leading practices, unmatched knowledge and expertise, we help organizations across the continuum of care lead the way to zero harm. The mission of The Joint Commission is to continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value. Its vision is that all people always experience the safest, highest quality, best-value health care across all settings.

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RESOURCE

SAMPLE HEALTHCARE PSES / PRIVILEGE LOG

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)

SAMPLE PSES AND PRIVILEGE LOG

Document #	# Pages	Doc Title/ Email Subject	File Extension Type	Properly Marked as PSWP	Created by	Recipients	Privilege Claimed (type)	Locus – physical or digital	Custodian	Privilege Reviewer	PSWP Privilege Verified	PSES Entry by	PSES Entered on	Family #	Sent to PSO on	Sent to PSO by	PSO Receipt Confirmed on	Comments
1	4	MM Report	doc	Y	jsmith42	Dbrown1 G Hill	PSWP	Digital QI Dept	LFrank2	SJones	11/5/21	BToms	11/1/21	6	11/11/21	LFrank2	11/7/21	Marked as PSWP
2	1	PSO Submit receipt	pdf	No – corrected on 11/6/21	PSO	Our PSES	PSWP	Digital QI Dept	LFrank2	SJones	11/6/21	BToms	11/3/21	2	Rec'd from PSO on 11/3/21	Rec'd from PSO	N/A	
3																		
4																		
5																		
6																		
7																		

- RESOURCES -

SAMPLE ORGANIZATION REPRESENTATIVE AFFIDAVIT

DISCLAIMER: This is a SAMPLE Affidavit 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 general or specific legal advice to any participant, participant's organization, or any other user. This SAMPLE should not be used by any individual or organization without review by legal counsel familiar with the related legal issues for which the SAMPLE may be used. Use of this SAMPLE is at the user's election and in doing so, user agrees to hold drafter harmless for any and all circumstances or issues that may arise because of its use.

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 or adverse event response activities, _____ 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 or contractual requirement.

14. I am hereby stating and confirming that in the course of providing healthcare or adverse event response activities, _____ collected or generated 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 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 regarding an incident or event that occurred on or about _____, and collected and developed such document and information *for the sole and singular purpose of reporting* to its PSO, and not for any other, dual, or mulit-purpose.

15. [I am hereby stating and confirming that at the time of the incident / event at issue _____ was aware of the existence of an external contract, administrative or accreditation reporting requirement and took specific care to ensure the review and other activities were not also being conducted for the dual purpose of satisfying contract or administrative or accreditation reporting requirement.]

16. [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.]

17. 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 PSO, that such discussions, debates, or deliberations are also intended to be privileged as Patient Safety Work Product ("PSWP"), without regard to the status of the underlying information being considered privileged PSWP, and have been kept secure and confidential as if PSWP privilege protected.

18. I am hereby stating and confirming that the aforementioned data, documents, information, statements, analyses, notes, reports, records, memoranda, worksheets, deliberations, findings, assessments, and studies are collectively known as, intended to be, and considered to be confidential and privileged PSWP pursuant to the provisions of the PSQIA.

19. I am hereby stating and confirming that PSWP is also collected as information and documents in these same forms and formats developed by its PSO for the sole and singular purpose of conducting patient safety activities that could improve patient safety, quality of care, and patient outcomes in compliance with 42 CFR 3.20.

20. I am hereby stating and confirming that such PSWP may only be collected, generated, accessed, or received by properly designated qualified, healthcare professional/provider staff members of _____.

21. I am hereby stating and confirming that only properly designated qualified, healthcare professional/provider staff members of _____ may have access to PSWP documents or information, only for reasons directly related to PSQIA/PSWP covered activities, and only for the sole and singular purpose of reporting to its PSO.

22. I am hereby stating and confirming that information and documentation entered into the PSES is solely and singularly intended for PSQIA covered purposes and

reporting to its PSO, and timely PSO reporting actually takes place in all instances for which information and documentation are entered into the PSES without being previously removed from the PSES or otherwise disclosed apart from the PSES.

23. I am hereby stating and confirming that information and documentation collected in the PSES for the sole and singular purpose of submission to the PSO are timely submitted to the PSO in compliance with the required formats, processes, and procedures of the PSO and of _____'s PSES.

24. I am hereby stating and confirming that in my current employment position and capacity I have significant personal knowledge of every submission of PSWP created for the sole and singular purpose of submission to the PSO and having actually been timely submitted to the PSO in accordance with established PSO procedures and requirements and those of _____.

25. [I am hereby stating and confirming that any PSES/PSO team members who are to maintain their professional or occupational licenses in good standing were at all times properly licensed and in good standing.]

26. [I am hereby stating and confirming that all PSES/PSO team members are qualified to perform the functions they perform.

27. I am hereby stating and confirming that _____ establishes and maintains all required confidentiality, accessibility, and privilege protections through well-entrenched and legally compliant policies, procedures, protocols, systems, and staff training that specifically addresses 1) the maintenance of procedures to preserve confidentiality with respect to PSWP, 2) the provision of appropriate security measures with respect to PSWP, and 3) utilization of qualified, healthcare professional/provider staff with regard to the collection, development, analysis, interpretation, discussion, or deliberation of PSWP.

28. I am hereby stating and confirming that with regard to the incident / event _____ at hand _____ is and has been in complete compliance with the requirements of the PSQIA and its own internal policies, protocols, procedures, and processes with regard to intending, designating, and protecting PSWP.

29. I am hereby stating and confirming that in compliance with 42 USC 299b-21(5)(a-h), _____'s PSWP policies, procedures, protocols, systems, and staff training also exist in support of 1) its efforts to collect permissible and covered PSWP for the purpose(s) of its efforts to improve patient safety and the quality of health care delivery, 2) the collection and analysis of PSWP, 3) the development and dissemination of information regarding patient safety such as recommendations, protocols, or information regarding best practices, 4) the utilization of PSWP for the purposes of encouraging a culture of safety as well as

providing feedback and assistance to effectively minimize patient risk, and 5) activities related to the operation of a PSES and to the provision of feedback to participants in a PSES.

30. I am hereby stating and confirming that with regard to the incident / event, information and documentation collected in the PSES was for the sole and singular purpose of submission to the PSO, was collected in a PSQIA proper and compliant manner, for covered purposes, was never shared or revealed outside of the PSES in any fashion and was at all times intended to be PSWP under the PSQIA.

31. I am hereby stating and confirming that I have significant and personal knowledge that the PSWP that was entered into _____'s PSES concerning the _____ matter, was prepared and collected for the purposes of submitting to its PSO, and I *personally* submitted it to its PSO on the following date(s):_____.

32. I am hereby stating and confirming that _____ has complied fully and absolutely with any requirements its PSO has for collecting, storing, and submitting documents to it, including but not limited to, requirements concerning file formats, file sizes, naming conventions, and others.

33. I am hereby stating and confirming that each PSO Encounter Entry Report was generated specifically for _____'s reporting of information to its PSO, and not for any other purpose, and the PSO Encounter Entry Reports are also intended to be, and protected as PSWP, by _____.

34. I am hereby stating and confirming that pursuant to HIPAA, 42 CFR 3.204(a)(4), and the text of 42 CFR 3.206(a), the PSWP privilege and confidentiality protections cannot be waived, and _____ has not waived them at any time with regard to the matter for which this affidavit has been signed, or any other matter.

    Under penalty of perjury and having been duly sworn, Affiant hereby swears and affirms the foregoing as affirmation of personal knowledge of the facts therein.

    Further Affiant sayeth not.

_____
_____, [DNP, RN, MHA]
TITLE

Subscribed and sworn to before me
this _____ day of _____, 20_____.

_____
_____ , Notary Public, State of _____
My Commission Expires: _____

- RESOURCES -

TOOLS & TOOLKITS

Patient Safety Toolkits

- https://www.ihi.org/resources/Pages/Tools/Patient-Safety-Essentials-Toolkit.aspx
- https://apps.who.int/iris/handle/10665/195709
- https://psnet.ahrq.gov/toolkits
- https://www.ncha.org/wp-content/uploads/2018/06/PSO-Toolkit_2018_FINAL.pdf **(designing a PSES)**
- https://www.healthpartners.com/ucm/groups/public/@hp/@public/documents/documents/vgn_pdf_56420.pdf
- https://pubmed.ncbi.nlm.nih.gov/29461334/
- https://www.health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Quality-And-Safety-of-Healthcare/Patient-Safety/Patient-Safety-Products-And-Services/Toolkits
- https://www.aaahc.org/quality-institute/toolkits/
- https://www.healthcareexcellence.ca/en/resources/patient-safety-and-incident-management-toolkit/

- https://nexusipe.org/informing/resource-center/patient-safety-essentials-toolkit

- https://pso.ahrq.gov/resources/educational-tools

PSO Toolkits

- https://www.bidmc.org/-/media/files/beth-israel-org/research/research-centers/center-for-healthcare-delivery-science/patient-safety-organization-peer-protected.pdf

- https://www.aqips.org/resources

- https://pso.ahrq.gov/

- https://www.ahrq.gov/cpi/about/otherwebsites/pso.ahrq.gov/index.html

- https://pso.ahrq.gov/resources/educational-tools

- https://web.mhanet.com/media-library/high-reliability-organization-toolkit/

CANDOR Program Toolkit

- https://www.ahrq.gov/patient-safety/settings/hospital/candor/modules.html