Best Practices and Litigation Lessons Learned in Defending Against PSWP Discovery Demands

Presented by

Texas Hospital Association Patient Safety Organization

Welcome!

Recording

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Michael R. Callahan

Senior Consultant, Medical Staff Governance, Patient Safety, Quality & Risk, Hardenbergh Group

Michael R. Callahan brings an unparalleled level of healthcare consulting experience. Formerly a healthcare attorney for over 40 years, he provides consultative services, educational programs and thought leadership in his role as Senior Consultant. His areas of focus include hospital/physician relations, medical staff bylaws and policies, peer review policies and investigations, privileging and credentialing issues, National Practitioner Data Bank guidelines and reporting standards, EMTALA standards, accreditation compliance, medical staff integration and hospital/medical staff disputes.

In addition, he is recognized as a national expert involving all aspects of the federal Patient Safety and Quality Improvement Act of 2005.

Cesar J. Lopez

Cesar is a healthcare attorney located in Austin, Texas. Cesar's experience includes helping healthcare professionals and facilities navigate a breadth of state and federal legal, policy, and regulatory issues, and he served as the Vice President, Legal Affairs, for the Texas Hospital Association before starting his own firm in 2024.

With current academic appointments at New York University, the University of Washington, and Texas A&M University-Central Texas, Cesar enjoys using his knowledge to help clients reach solutions that fit their specific needs and resolve their concerns. A native Texan, he received his J.D. at Albany Law School and his Master of Law in Health Law from the University of Washington School of Law.

Learning Objectives

1. Identify key, fundamental terms and definitions within the Patient Safety Act.
2. Examine the importance of robust PSES policies that maximize privilege protections.
3. Discuss recent cases regarding the PSA.
4. Outline best practices to defend against discovery and other demands for disclosing PSWP.

Patient Safety and Quality Improvement Act of 2005

Privileged Patient Safety Work Product

- Any data, reports, records, memoranda, analyses (such as Root Cause Analyses (RCA)), or written or oral statements (or copies of any of this material) which could improve patient safety, health care quality, or health care outcomes;

And that:

- Are assembled or developed by a provider for reporting to a Patient Safety Organization (PSO) and are reported to a PSO, which includes information that is documented as within a patient safety evaluation system (PSES) for reporting to a PSO, and such documentation includes the date the information entered the PSES; or
- Are developed by a PSO for the conduct of patient safety activities; or
- Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES.

Patient Safety Act

What entities are covered under the Act?

- All entities or individuals licensed under state law to provide health care services or which the state otherwise permits to provide such services, i.e., hospitals, SNFs, physicians, physician groups, labs, pharmacies, home health agencies, etc.

- A non-licensed corporate entity that owns, controls, manages or has veto authority over a licensed provider is considered a provider.

Patient Safety Activities

Patient safety activities mean the following activities carried out by or on behalf of a PSO or a provider:

- Efforts to improve patient safety and the quality of health care delivery.
- The collection and analysis of patient safety work product.
- The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.
- 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.
- The maintenance of procedures to preserve confidentiality with respect to patient safety work product.
- The provision of appropriate security measures with respect to patient safety work product.
- The utilization of quality staff.
- 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.

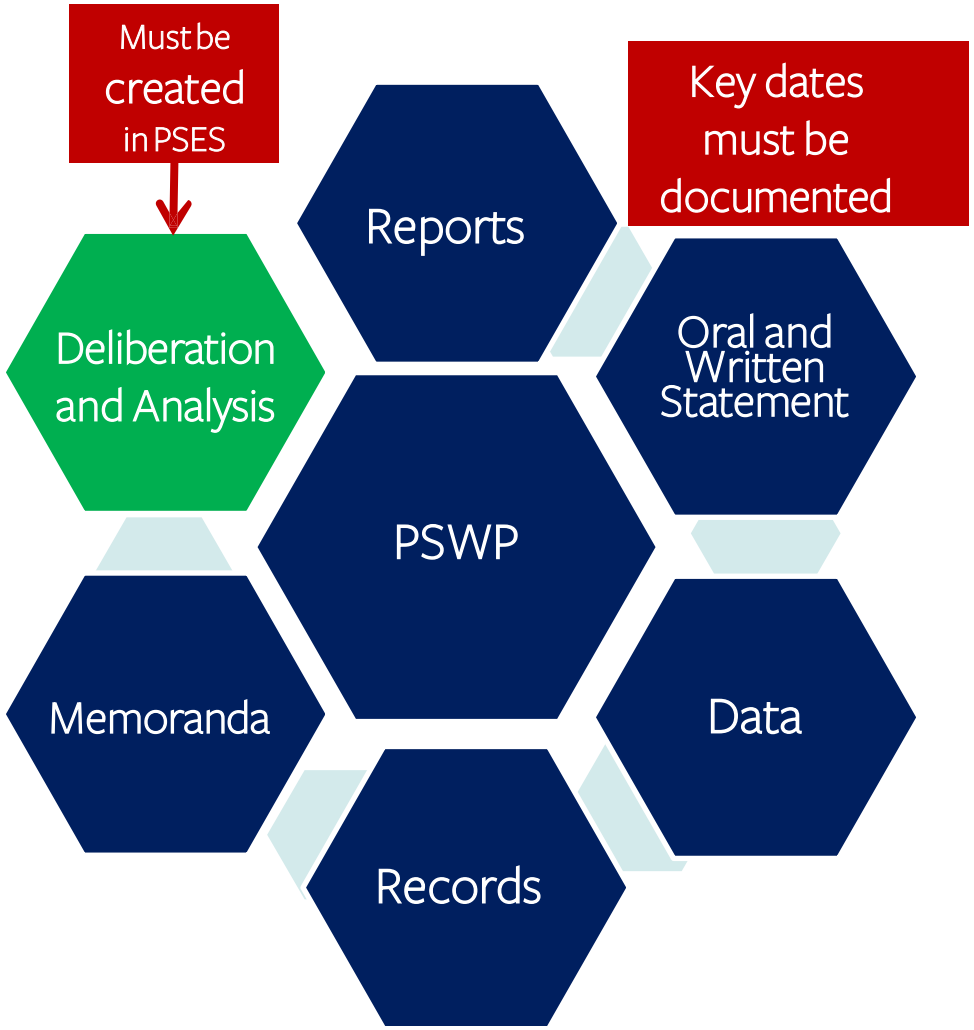
Patient Safety Act

What information can be considered for inclusion in the PSES for collection and reporting to the PSO if used to promote patient safety and quality?

- Medical error or proactive risk assessments, root cause analysis
- Risk Management — Not all activities will qualify such as claims management, but incident reports, investigation notes, interview notes, RCA notes, etc., tied to activities within the PSES can be protected
- Outcome/Quality—may be practitioner specific
- Peer review
- Relevant portions of Committee minutes for activities included in the PSES relating to improving patient quality and reducing risks
- Deliberations or analysis
- Reports that are the subject of mandatory state or federal reporting or which may be collected and maintained pursuant to state or federal laws be treated as PSWP

  Ex: California has mandatory adverse patient event reporting requirements (California Department of Public Health, Health and Safety Code Section 1.279.1(d)(1)-(7)).

What is Patient Safety Work Product (PSWP)?



Requirements

Data which could improve patient safety, health care quality, or health care outcomes

- Data assembled or developed by a provider for reporting to a PSO and are reported to a PSO

Analysis and deliberations conducted within a PSES

- Data developed by a PSO to conduct of patient safety activities

Patient Safety Act

What is not PSWP?

- Patient's medical record, billing and discharge information, or any other original patient or provider information
- Information that is collected, maintained, or developed separately, or exists separately, from a PSES. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered PSWP
- PSWP assembled or developed by a provider for reporting to a PSO but removed from a PSES is no longer considered PSWP if:

  Information has not yet been reported to a PSO; and

  Provider documents the act and date of removal of such information from the PSES

What is Not PSWP?

Requirements

Information collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.

- Data removed from a patient safety evaluation system

Data collected for another reason

PSWP is Privileged

Not Subject to:

- Subpoenas or court order
- Discovery
- FOIA or other similar law
- Requests from accrediting bodies or CMS

Not Admissible in:

- Any state, federal or other legal proceeding
- State licensure proceedings
- Hospital peer review disciplinary proceedings

Patient Safety Act Privilege and Confidentiality Prevail Over State Law Protections

The privileged and confidentiality protections and restriction of disciplinary activity supports development of a Just Learning Culture

State Peer Review

- Limited in scope of covered activities and in scope of covered entities
- State law protections do not apply in federal claims
- State laws usually do not protect information when shared outside the institution – considered waived

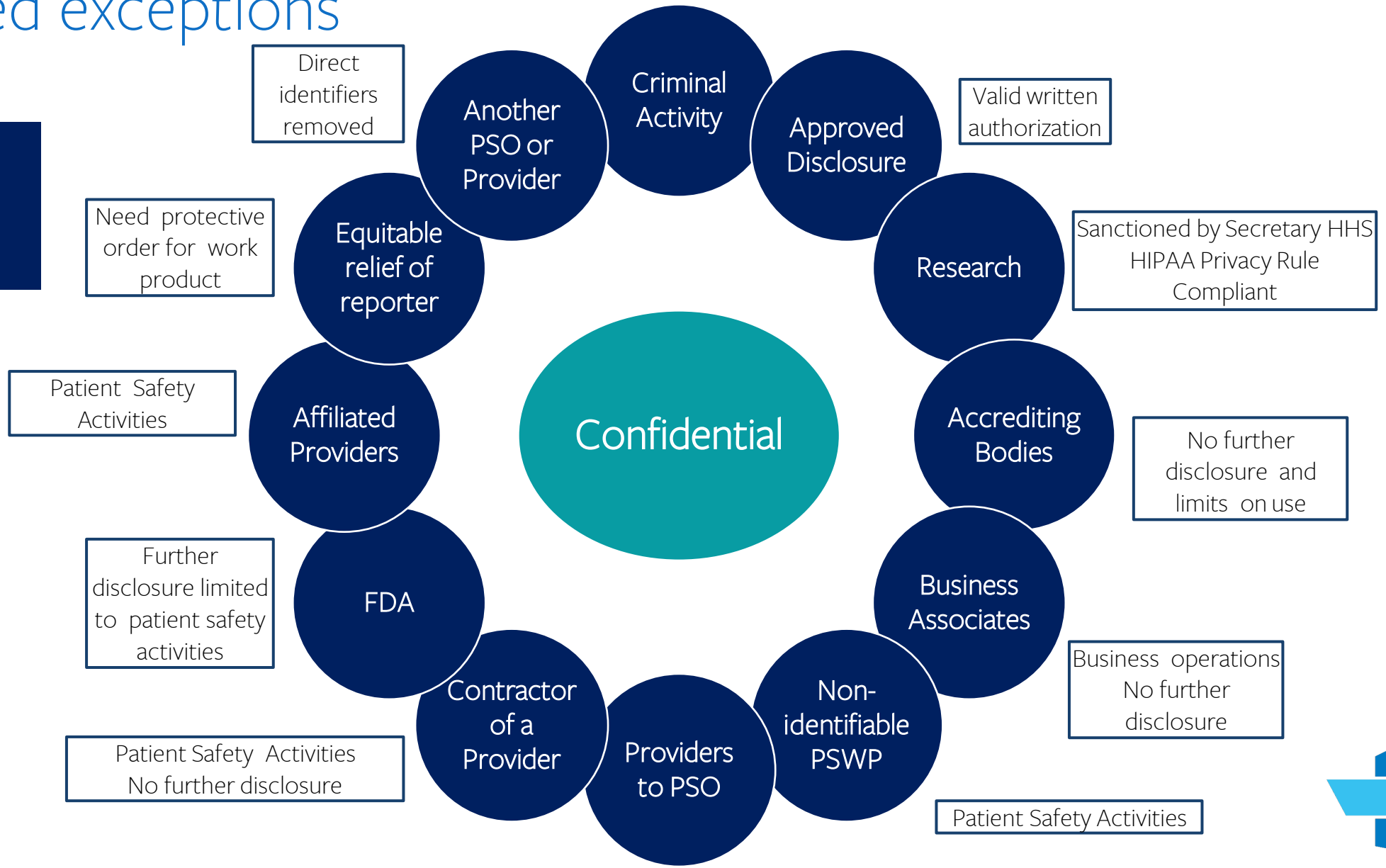
Patient Safety Act

- Consistent national standard
- Applies in all state and federal proceedings
- Scope of covered activities and providers is broader
- Protections can never be waived
- PSWP can be more freely shared throughout a health care system
- PSES can include non-provider corporate parent

Working with a PSO must be implemented in a way that facilitates a Just Learning Environment while taking advantage of privilege and confidentiality protections.

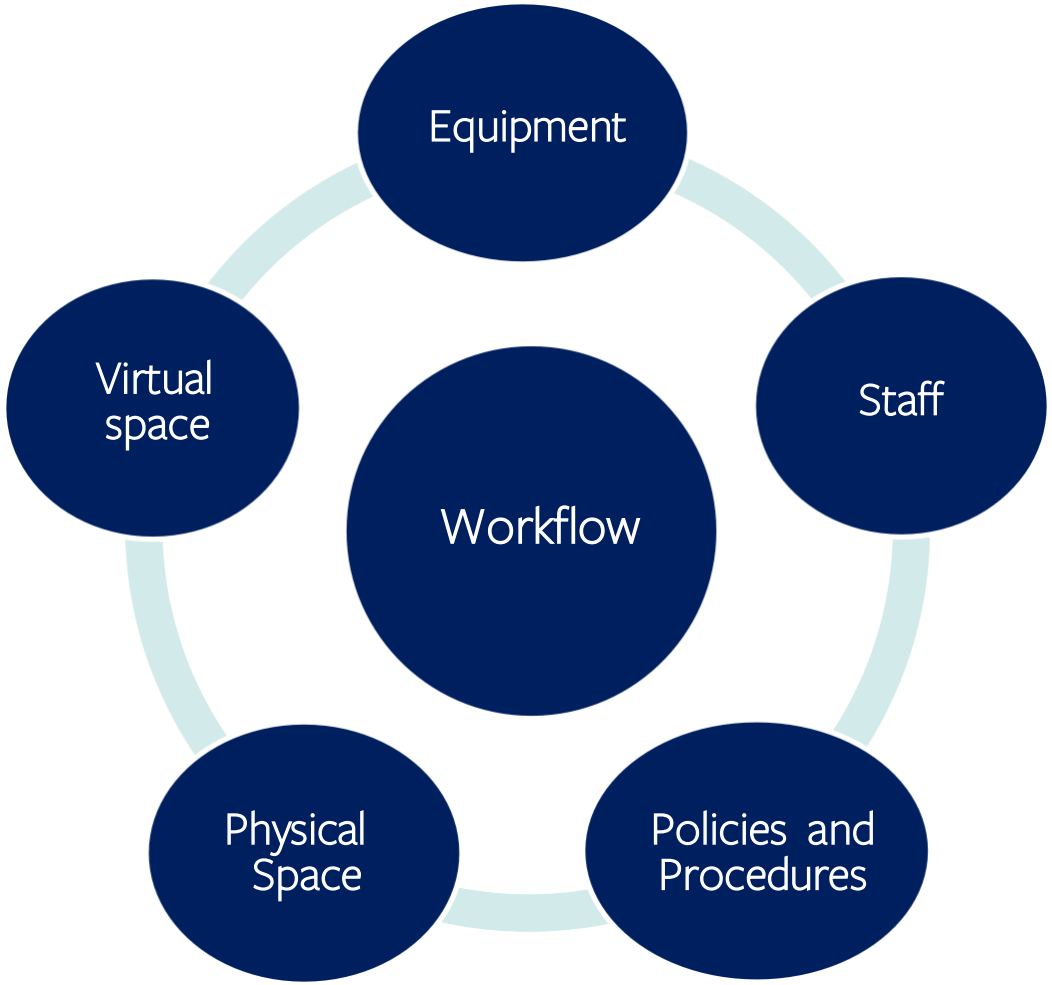
PSWP is confidential and not subject to disclosure, with limited exceptions

See Patient Safety Final Rule



Patient Safety Evaluation System (PSES)

- The collection, management, or analysis of information for reporting to or by a PSO.
- A provider's PSES is an important determinant of what can, and cannot, become patient safety work product.



PSES

Establish and Implement a PSES to:

- Collect data to improve patient safety, healthcare quality and healthcare outcomes
- Review data and act when needed to mitigate harm or improve care
- Analyze data and makes recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes
- Conduct Proactive Risk Assessments, in-depth reviews, and aggregate medication errors
- Determine which data will/will not be reported to the PSO
- Report to PSO
- Conduct auditing procedures

PSES

What Comprises the System's Patient Safety Evaluation System (PSES)?

The PSES includes the collection, management and/or analysis of Patient Safety Concern information recorded in the System's Event Reporting System (ERS) for reporting to a PSO. **It includes information documented in the ERS, and deliberation and analysis of a Patient Safety Concern.**

A Patient Safety Concern includes:

- A patient safety event that reached the patient, whether there was harm;
- A near miss or close call - a patient safety event that did not reach the patient; or
- An unsafe condition - circumstances that increase the probability of a patient safety event.

PSES

It may also include all activities, communications and information reported or developed by individuals or committees, such as data analyses, Root Cause Analyses, outcome reports and minutes, for the purpose of improving patient safety and/or healthcare quality

Creation of PSWP

PSWP is created automatically upon filing an event report in the ERS that involves a Patient Safety Concern. All Patient Safety Concern information is collected and/or developed with the intent to report to the PSO.

If designated by Authorized Staff, PSWP may encompass the data collection efforts leading up to making the Event report. The date of entry into the PSWP is the date these activities occur.

PSES

PSWP is created when deliberations and analysis (D & A) related to a Patient Safety Concern is conducted. The date of entry into the PSES is the date these activities occur.

PSWP protections will apply immediately. D & A cannot be de-designated as PSWP. Documents included in this category include but are not limited to:

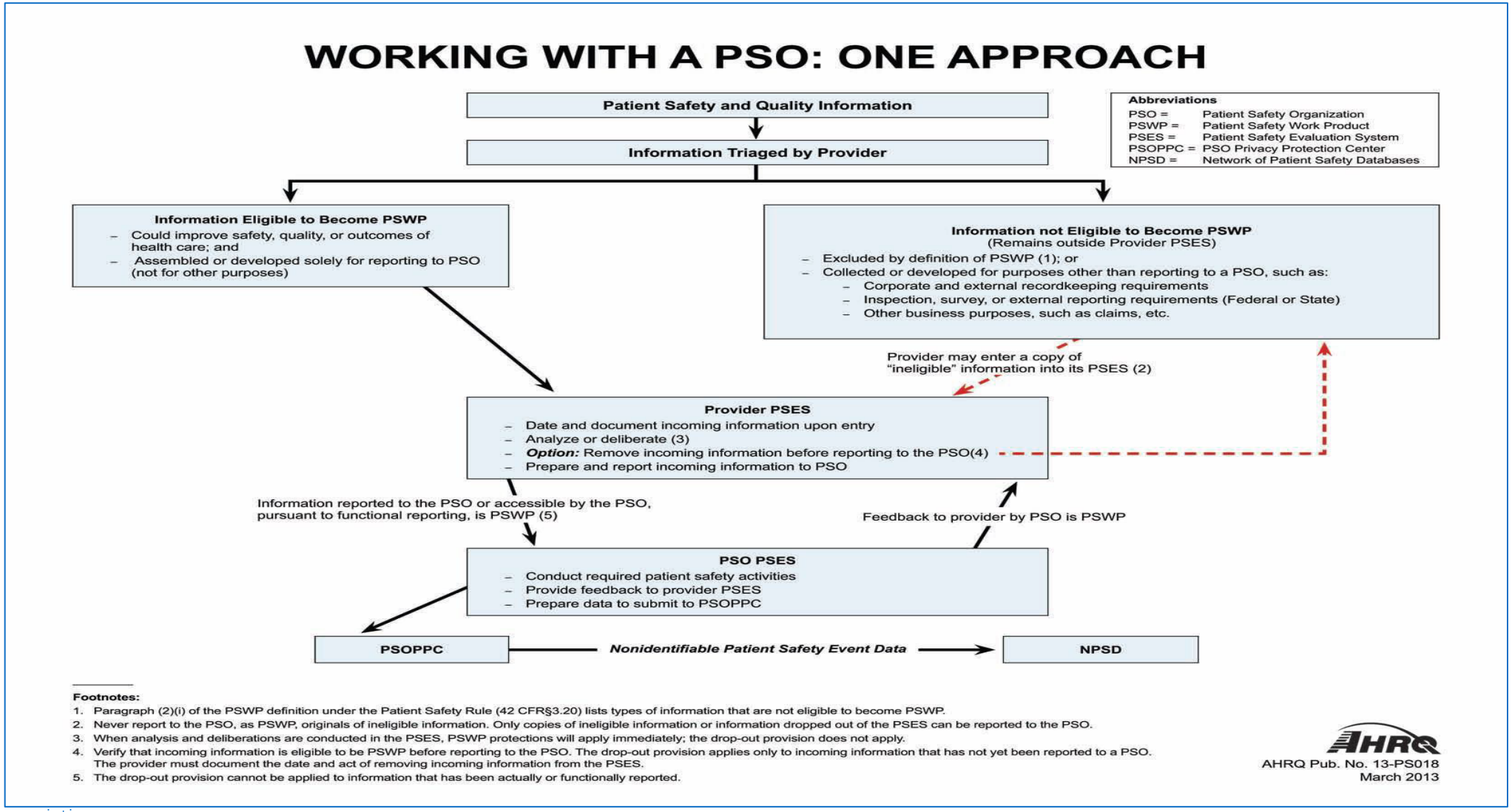
- Failure Mode Effects Analysis (FMEA)
- Root Cause Analysis (RCA) not otherwise reported in the ERS
- Data analysis reports & comparative outcomes
- Patient Safety Committee minutes
- Quality Improvement Committee minutes

PSES

Patient Safety Activities: may be conducted by any individual, committee or body that has assigned responsibility for any such activities. The workforce includes faculty, staff, trainees, volunteers, and contractors who perform work under the direct control of the System. Committees include but are not limited to:

- Patient Safety Committees
- Clinical Performance Improvement Committees
- Risk Management Committees
- System Chief Medical Officers/Chief Nursing Officers
- System Risk Services and/or Committees
- Audits and Compliances Committee
- Peer Review Committees
- Quality Improvement Committees
- Medication Safety Committees
- The System's Health Services Committee
- Center for Healthcare Quality Innovation
- System Data Management System
- Other System committees with jurisdiction

PSO Participation Schematic



Example PSES - Patient Safety Activities

What types of information can be considered for inclusion in the PSES for collection and reporting to the PSO if used to promote patient safety and quality and treated as PSWP?

- Medical error or proactive risk assessments, root cause analysis
- Risk Management — Not all activities will qualify such as claims and litigation management, but incident reports, investigation notes, interview notes, RCA notes, etc., tied to activities within the PSES can be protected
- Outcome/Quality—may be practitioner specific
- Peer review
- Relevant portions of Committee minutes for activities included in the PSES relating to improving patient quality and reducing risks
- Deliberations or analysis
- Incident/adverse event reports

PSES Policy

Develop Both a Specific and Broadly Worded PSES policy:

- One of the fundamental documents for internal educational purposes as well as to be introduced to a court in demonstrating that the materials in dispute are indeed PSWP is a provider's PSES policy.
- The courts are not going to simply accept the word of the hospital or other provider that information qualifies as PSWP.
- The provider should conduct an inventory of all of its performance improvement, quality assurance, peer review and other related patient activities as well as the various committees, reports and other analyses being conducted within the organization.
- This is the starting point when determining the scope of activities, you wish to include within the PSES and therefore claim as privileged PSWP. The details of these activities and the information to be protected should be reflected within the PSES.

PSES Policy

- When seeking to claim privilege protections over an incident report, committee minutes or other internal analysis, a provider can then cite to the specific reference within the PSES as evidence of the hospital's intent to treat this information as PSWP.
- The provider should also include the phrase "including but not limited to" a "catch all" to account for other privileged patient safety activities in the PSES policy.
- PSES Policy needs to be updated annually.
- May want to cross-reference to related policies.

Carefully Describe Your PSWP Pathway

- As reflected in the Appellate Court's decision in Daley, a provider can create PSWP via actual reporting, function reporting or through deliberations or analysis.
- It is critical that your PSES policy distinguish which forms of information, incident reports, etc., are being reported to the PSO or scanned and downloaded and reported and what forms of information are being treated as deliberations or analysis.

PSES Policy

- As a practical matter, most patient safety activities can be characterized as deliberations or analysis.
- Information that is deliberations or analysis automatically becomes PSWP when collected within the PSES and does not need to be reported to the PSO although reporting is certainly an option.
- Most of the PSO appellate court decisions, including the Daley decision, involved actual reporting and not deliberations or analysis.
- Rumsey v. Guthrie Clinic is the first "deliberations or analysis" decision.
- Keep in mind too, that information which is being treated as deliberations or analysis cannot be "dropped out" and used for other purposes but can be shared if you meet one or more of the disclosure exceptions. These include disclosing to consultants, your attorney, and independent contractors that are assisting the hospital in patient safety activities and other disclosures permitted under the PSA.
- It is unlikely the hospital reports every single incident report to the PSO. Your PSES policy, therefore, should treat these unreported incident reports as deliberations or analysis.

“Peer Review”

- The process of improving quality and safety in healthcare organizations
- Privileging and credentialing
- Performance of a medical or quality assurance review function
- Utilization review
- Concurrent and retrospective review of medical cases and adverse events
- Root cause analysis
- FPPE and OPPE
- Collegial intervention
- Monitoring, proctoring, consultation requirements and similar remedial measures
- Medical research

“Peer Review”

- Efforts to improve patient care and reduce morbidity or mortality
- Tracking, investigating and managing unacceptable behavior identified in Code of Conduct - Disruptive Behavior Policies
- Physician wellness evaluations and activities
- Evaluating healthcare providers regarding performance, skill, technique, competence, utilization and compliance with hospital and medical staff bylaws, rules, regulations and policies
- Review and establishment of standards of care
- Analyses undertaken for the purpose of reducing the risk of harm
- Peer review investigations and hearings
- All the discussions, analyses and work product produced by these activates

Use of PSWP in Peer Review Disciplinary Matters

Under a "just culture" approach, the goal is to move away from the "blame game" and instead use other remedial measures to help the physician, advanced practice nurse and other healthcare providers to "get back on track" to improve the future delivery of patient care services. Examples include:

- Use of an FPPE plan,
- Concurrent/retrospective review of cases
- Collegial intervention, monitoring
- Proctoring and reeducation

At some point, if all these efforts fail, the hospital and medical staff may have no other alternative but to consider the use of disciplinary action which, if approved by the Board of Directors, may result or require a report to the National Practitioner Data Bank or to the state.

But can peer review PSWP be used for disciplinary actions?

Use of PSWP in Peer Review Disciplinary Matters

The short answer is YES. The Preamble to the Patient Safety Act specifically points out that PSWP can be used for this purpose.

But!

- Is this "use" consistent with Just Culture?
- If anticipating that the healthcare provider will sue if the recommended disciplinary action is upheld, you must keep in mind that PSWP cannot be introduced into any state or federal proceedings to defend the hospital's actions.
- The inability to introduce PSWP can both benefit the hospital, in the sense that the provider cannot discover or introduce PSWP into evidence to prove up a breach of contract, malicious interference, defamation or a discrimination action, but neither can the hospital introduce this privileged information—double-edged sword.

Use of PSWP in Peer Review Disciplinary Matters

But if not using PSWP in a disciplinary hearing, how does the hospital make a sufficient "evidentiary" record to support the disciplinary action? What are the options?:

- Repeat the internal, external reviews and other PSWP on which the disciplinary action was based outside of the PSES.
- Rely on the "facts" and medical record and non-privileged information to support the adverse decision.
- If the information supporting the disciplinary action utilized the reporting method of creating PSWP, hold onto the information and drop it out for use in disciplinary hearings and possible litigation.
- Keep in mind that a state peer review privilege may apply which has the same consequences concerning non-discovery or non-admissibility into evidence.

Use of PSWP for HR and Risk Management

Remember the distinction between a "use" and a "disclosure":

- PSWP can be used/shared for all internal purposes consistent with PSES and confidentiality requirements
- An example of a permitted use is sharing PSWP with attorneys and accountants
- PSWP, however, also can be used "outside of the PSES" but you should be able to document why such use is necessary to fulfill a business or related purpose
- A "disclosure" is sharing PSWP to an unrelated third party which meets one of the permissible disclosure exceptions, i.e.:

  Independent contractors

  Accrediting bodies

  Affiliated entities

  From one PSO to another PSO

Use of PSWP for HR and Risk Management

- PSWP which is disclosed under one or more of the permissible disclosure exceptions remains PSWP—the privilege is not waived
- Sharing PSWP with HR and risk management is considered a use and not a disclosure

Important considerations:

- Must be able to establish that any PSWP which is shared with HR and/or risk management was developed for the purpose of improving patient care and not for employment or claims and litigation management purposes
- Does HR and risk management really need access to PSWP whether identifiable or non-identifiable?

Use of PSWP for HR and Risk Management

PSWP should not be placed in the employees HR File because:

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

PSWP FAQ

What should be included or referenced in minutes/documentation in order to access the privilege?

- Make sure the committees or activities producing the minutes are reflected in the PSES
- Determine whether the minutes/reports are going to be actually reported to the PSO and are reported with the date on which they are reported or are being treated as deliberations or analysis – clarify which method is being utilized for the information in the PSES
- The language "Privileged and Confidential under the Patient Safety and Quality Improvement Act of 2005 [and the _____ Act]" for those portions of the minutes you are treating as privileged
- Some hospitals have an email system which includes this or similar language of privileged emails
- Remember, it is not fatal if this language is not inserted. It is more important that the minutes be identified in the PSES

PSWP FAQ

Who can review PWSP minutes/documentation?

- Workforce members who have been identified by the provider – these are the individuals who prepare or need to access PSWP as part of their job responsibilities

What PSWP can be shared from the Peer Review process and who can see it?

- Workforce members
- Hospital identifiable PSWP can be shared with affiliated entities, including the parent corporation and their workforce members, who are members of the PSO and are in a single system PSES
- PSWP can be shared/disclosed if utilizing a permissible disclosure exception, i.e. attorneys, accountants, business associates, accreditation bodies, etc. (See Section 3.206 of the Final Rule)

PSWP FAQ

Is any report, analysis, study, etc., prepared by a PSO considered PSWP?

- Yes

If CMS or other government agency demands PSWP, must it be turned over to them?

- No – HHS in its May 2016 Guidance for Patient Safety Rule stated that government agencies cannot require providers to turn over PSWP, but must otherwise demonstrate compliance
- Sharing physician identifiable PSWP generated within a hospital is considered a use and not a disclosure and therefore can be shared with the hospital's workforce members
- To share physician identifiable PSWP generated in the hospital with outside entities, including affiliated providers, the physician must sign a written authorization permitting the disclosure of this information. Authorization can be included in a separate form or in the appointment/reappointment application, or an employment agreement.

Scope of Protected Activities

In Texas "Medical Peer Review" is defined as:

- The evaluation of medical and healthcare services
- Evaluation of the qualifications and professional conduct of professional healthcare practitioners of patient care provided by those practitioners
- The merits of a complaint relating to a healthcare practitioner and a determination or recommendation regarding the complaint
- Accuracy of the diagnosis
- Quality of the care provided by a healthcare practitioner
- Report made to a medical peer review committee concerning activities under the committee's review authority
- Report made by a medical peer review committee to another committee or to the board as permitted or required by law
- Implementation of the duties of a medical peer review committee by a member, agent, or employee of the committee

Scope of Protected Activities (cont'd)

Patient Safety Act defines "Patient Safety Activities" as:

- Efforts to improve patient safety and the quality of healthcare delivery
- The collection and analysis of patient safety work product
- The development and dissemination of information with respect to improving patient safety such as recommendations, protocols or information regarding thus practices
- The utilization of patient safety work product for the purpose of encouraging a culture of safety and the providing of feedback and assistance to effectively minimize patient risk
- The maintenance of procedures to preserve confidentiality with respect to patient safety work product
- The provision of appropriate security measures with respect to patient safety work product
- The utilization of qualified staff
- Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in the patient safety evaluation system

Scope of Covered Entities

In Texas:

"Medical Peer Review Committee" is defined as:

- A committee of a healthcare entity
- A governing board of a healthcare entity
- The medical staff of a healthcare entity that operates under written bylaws approved by the policy making body or governing board of the healthcare entity and is authorized to evaluate the quality of medical and healthcare services or the competence of physicians including evaluation of the performance of those functions set forth above

"Healthcare Entity" is defined as:

- A hospital
- An entity including an HMO, group medical practice, nursing home, health science center, university medical school, hospital district, hospital authority or other healthcare facility that:
  - -- Provides or pays for healthcare or healthcare services
  - -- Follows a formal peer review process to further quality medical care of healthcare

Scope of Covered Entities (cont'd)

In the Patient Safety Act, "Provider" means:

- An individual or entity licensed or otherwise authorized under state law to provide healthcare services
- Agencies, organizations and individuals within the federal, state, local or tribal governments that deliver healthcare
- A parent organization of one or more licensed provider

Scope of Privileged Protections

Texas

- The records and proceedings of a medical committee are confidential and are not subject to court subpoena
- A record or determination of or a communication to a medical peer review committee is not subject to subpoena or discovery and is not admissible as evidence in any civil, judicial, or administrative proceeding without waiver of the privilege executed in writing by the committee

The Patient Safety Act:

"Privileged Patient Safety Work Product" means:

- Any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements or copies of any of this material which could improve patient safety, healthcare quality or healthcare outcomes and which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO that is document as within a patient safety evaluation system for reporting to a PSO which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant a PSES

Original records cannot be considered PSWP

Application of Privileged Protections in State, Federal or other Proceedings

Texas

- Texas privileged statutes only apply in state, judicial or administrative proceedings. The protections will not be used in federal court to preempt a federal cause of action.

Patient Safety Act

- Privileged PSWP is not admissible nor discover in all proceedings, including state and federal

Waiver

Texas

- The privilege protections cannot be waived unless a medical peer review committee expressly authorizes waiver of the protections in writing
- There is case law which states that a voluntary disclosure by a committee or impermissible disclosure arguably could constitute a waiver

Patient Safety Act

- The privilege protections under the Patient Safety Act are not waived under any circumstances

Disclosure of Privileged Information within a Healthcare System

Texas

- The scope of protected activities in Texas is more limited than the Patient Safety Ac
- It is not clear whether privileged peer review information can be freely shared across a healthcare system as opposed to one medical peer review committee to another committee

Patient Safety Act

- PSWP can be shared among affiliated providers
- Affiliated providers can include a non-licensed corporate parent or parent organization that owns, controls, manages or has veto authority over a licensed healthcare facility or provider

Daley v. Ingalls Memorial Hospital

Background

- Case involves a lawsuit brought by the estate of a patient alleging that Ingalls Memorial Hospital and its employees committed malpractice when it failed to adequately monitor the patient's blood glucose levels.

  The lawsuit further alleged that the patient's subsequent injuries caused by this negligence contributed to her death.
- During discovery, the hospital objected to interrogatories which sought several incident reports and complaints arguing that the information was privileged from discovery under both the Illinois Medical Studies Act and the Patient Safety and Quality Improvement Act of 2005 ("PSA").
- The plaintiff also requested that the hospital produce documents which described any statements made by the decedent, a family member or anyone with knowledge regarding issues addressed in the lawsuit.

  Upon refusal to produce the documents, the plaintiff filed a motion to compel.

Daley v. Ingalls Memorial

- Ultimately, only three documents remained in dispute which included two incident reports involving the patient's care and the complaint made by the patient's daughter to a hospital employee regarding the patient's treatment.
- All three documents, which were electronically reported to the hospital's PSO, contained the heading "Healthcare Safety Zone Portal" in addition to the name "Clarity Group Inc. Copyright" at the bottom of each page.
- Each document also included the date on which the documents were created and reported to the PSO.

Hospital's Response

In support of its response to the motion to compel, the hospital submitted two affidavits from its associate general counsel which contained the following representations:

- The hospital contracted with Clarity PSO in 2009 to improve the hospital's patient safety and quality of care.
- The documents in dispute were created, prepared and generated for submission to the PSO.
- The Healthcare Safety Zone Portal provided how the hospital reported this information to Clarity and were prepared "solely" for submission to Clarity.
- The documents were not part of the patient's original medical records which had already been produced to the plaintiff.
- The documents had never been removed from the hospital's PSES for any purpose other than for internal quality purposes.

Hospital's Response

- The documents have not been reported to or investigated by any agency or organization other than Clarity.
- There were no other reports pertaining to the incidents alleged in the plaintiff's complaint that were collected or maintained separately from the hospital's PSES.
- Interestingly and importantly, the plaintiff never filed a response nor did the attorney object or attempt to rebut information contained in the affidavits.

Trial Court's Decisions

- The trial court ordered, and the hospital agreed to submit the disputed documents for an in-camera inspection.

- Upon review of the documents, the court determined that some of the information in the incident reports sent to the PSO should have been included in the patient's medical records and therefore ordered the hospital to turn over to the plaintiff those portions of the incident reports.

- The hospital refused and was therefore held in "friendly contempt" which allowed for an automatic appeal to the Appellate Court.

Appellate Court's Decision

- The Appellate Court began its analysis of the PSA by citing to the 1999 report from the Institute of Medicine entitled "to Err is Human: Building a Safer Health System" which served as the primary basis for the passage of the Act.

- The PSA identified that the privilege protections that are incorporated into the law are "the foundation to furthering the overall goal of the statute to develop a national system for analyzing and learning from patient safety events".

- In determining whether the documents in dispute were privileged Patient Safety Work Product ("PSWP") the Court recognized that there are three distinct ways of creating privileged documents, the "reporting pathway", which includes actual "functional reporting", as well as treating information as "deliberations or analysis".

Appellate Court's Decision

Because the hospital argued that the documents were PSWP through the reporting pathway the court examined whether the hospital met all of their requirements under the PSA and further whether any exceptions applied that would prohibit the information from being privileged.

In determining that the documents did qualify as PSWP, the court made the following findings:

- The court documents demonstrate "that they are an amalgamation of data, reports, discussions, and reflections, the very type of information that is by definition patient safety or product".
- The affidavits established that the documents were assembled and prepared by Ingalls "solely" for submission to Clarity PSO and were reported to the PSO.

Appellate Court's Decision

- The information contained in the documents had the ability to improve patient safety and the quality of healthcare.
- The documents themselves bear the dates information was entered into the patient safety evaluation system as represented in the unrebutted affidavits.
- The Court then responded to the plaintiff's arguments that the documents were not PSWP because one or more exceptions under the Act applied.

Appellate Court's Decision

The information was required to be in the patient's medical record and therefore was not privilege:

- Under the PSA, "original records" such as a patient's medical record, billing and other related information are not privileged.
- The trial court ruled that factual information which was included in the reported incident reports contained information which should have been included in the patient's medical record.
- The plaintiff also argued that there was a significant lack of information in the medical record which had been produced to the plaintiff as well as significant gaps of time during which other information should have been included in the medical record. The hospital, therefore, was trying to hide information under the "guise of patient safety work product".

Appellate Court's Decision

- The Court recognized the Illinois Hospital Licensing Act requires that a medical record meet certain documentation requirements and that the PSA "does not permit providers to use privilege and confidentiality protections... to shield records required by external record keeping or reporting, and if the hospital in fact failed to meet these requirements there are "associated consequences for such failure".

- This failure, even if it occurred, does not mean that the information loses its privileged status simply because a report may include facts or other information that might also be found in the medical records.

- The Court further noted that the documents in question were created weeks after the patient was treated at the hospital and therefore "nothing in the records lead us to believe that the documents were [patient's] original medical records or contained information that should have been included in the original medical records."

Appellate Court's Decision

The Court also pointed out that discovery had not yet been completed and that the Plaintiff was entitled to depose individuals regarding any facts surrounding the patient's treatment.

The documents were not collected solely for the purpose of reporting to a PSO.

- Under the PSA, documents, reports, analyses, and other information that is collected for a purpose other than reporting to a PSO or which is collected outside of a provider's PSES is not privileged.

- The affidavit submitted by the hospital indicated that the documents in question were in fact prepared "solely" for submission to the PSO.

- Because this representation was unrebutted by the Plaintiff the court was obligated to accept the hospital's representation.

Appellate Court's Decision

- Note: There is nothing under the PSA which refers to the word "solely". This so-called standard, which is reflected in the HHS PSO Guidance, and on which plaintiffs and courts have sometimes relied, does not mean that the information collected within the PSES and reported to the PSO or treated as deliberations or analysis cannot be used for other internal purposes. In fact, it is expected that PSWP is used by the hospital to improve patient safety and reduce risk.

- If, however, the information in question was required to satisfy an external obligation or was used for a purpose which is separate from improving patient care or reducing risk and is not identified within the PSES, a provider cannot make an after the fact argument that the information is now privileged and not subject to discovery.

Appellate Court's Decision

Information was collected to satisfy a reporting requirement and therefore did not qualify as PSWP.

- The PSA clearly states that if a report that the hospital claimed as privileged was required to be made to a state or federal government or agency, the hospital cannot try to hide that information within its PSES and claim it was privileged.
- In this case, the plaintiff cited to the Illinois Adverse Healthcare Events Reporting Law of 2005 which requires the reporting of certain identified adverse events to the Illinois Department of Public Health.
- The Plaintiff also cited to the Florida Supreme Court's in Charles v. Southern Baptist Hospital as well as other state court decisions to further support its argument that the disputed documents were not privileged.

Appellate Court's Decision

- In response, the Court pointed out that the Act in question had never been implemented in Illinois and therefore was not applicable.
- The plaintiff did not cite to any other statute requiring that the disputed documents had to be reported or had to be collected and maintained and made available to a state or federal agency. Therefore, this argument by the plaintiff was rejected.

Allowing the documents to remain privileged will permit healthcare providers to hide valuable information and thus impede the truth-seeking process.

- This is an argument that was made by both the plaintiff and an amicus brief submitted by the Illinois Trial Lawyers Association. In response to this argument the Court provided the following analysis:

  "However, nothing about these documents being privileged renders the facts that underline the [PSWP] as also privileged."

Appellate Court's Decision

- *"Plaintiffs can still obtain medical records, as plaintiff did in this case, have their experts analyze and make opinions about those records, and depose doctors and nurses regarding an incident."*

- *"When there is no indication that a healthcare provider has failed to comply with its external record-keeping and reporting requirements and it creates supplementary information for purposes of working with a Patient Safety Organization to improve patient safety and the quality of healthcare, that provider is furthering the Patient Safety Act's objectives while not preventing the discovery of information normally available to a medical malpractice plaintiff. Under these circumstances, that additional information must be protected from disclosure."*

Appellate Court's Decision

Preemption Analysis:

- Under the PSA, the federal privilege protections preempt any state or other law which would otherwise require that the information be subject to discovery and admissible into evidence.

- This preemption standard was ignored by the Florida Supreme Court in the *Charles* decision in which it determined a state constitutional amendment, which gives patients broad access to any and all information relating to a hospital or physicians qualifications or past adverse events, preempted the PSA rather than the other way around.

Appellate Court's Decision

- This decision has been roundly criticized and in fact, HHS has stated in a pending federal case that the PSA preempts all laws including Amendment 7, the Florida constitutional amendment cited by the Florida Supreme Court.

- **The Appellate Court agreed with the preemption standard in the PSA and stated as follows:**

  "In other words, when information is patient safety work product, the Patient Safety Act should be construed as preempting any state action requiring a provider to disclose such work product... [c]onsequently, the Patient Safety Act preempts the circuit court's production order"

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019)

Background

- This is a medical malpractice case arising from a claim that the defendants failed to test or treat him for a MRSA infection which because worse subsequent to an elective procedure.

  The case was in federal court based on diversity jurisdiction.

- Plaintiff sought to discover information regarding Guthrie's infection-prevention procedures.

  Defendant Clinic asserted privilege protections under the:

  PSQIA

  Pennsylvania Medical Care Availability and Reduction of Error Act ("MCARE")

  Pennsylvania Peer Review Protection Act

Rumsey v. Guthrie Medical Group

Disputed Documents and Decision

- "A copy of all infection prevention and infection control materials which Defendants' received prior to May 1, 2017, from Vizient PSO and/or any other company"
- MCARE does not apply to Vizient materials because it only protects documents "solely prepared or created for the purpose of complying with [state law] or of reporting..."
- MCARE only applies to providers. Vizient is and therefore MCARE did not provide any protection to prevent discovery.
- The court, however, found that the PSQIA applies to documents produced by a PSO for the purpose of conducting patient safety activities and therefore the Vizient materials were privileged under the Act.

Rumsey v. Guthrie Medical Group

"A copy of any and all correspondence and communications between defendant and any federal, state, county or local governmental agency within the past 5 years on the subject of infection prevention, infection reporting, infection management and infection rates"

- *Government correspondence is not part of Guthrie's PSES was bit dusckised to Vizient PSO. Consequently, these communications are not privileged under PSQIA or any other statute.*

A copy of Defendant's agenda, notes and any and all written records of Defendant's monthly (or other than monthly) quality committee meetings…insofar as they discuss infection prevention or infection control"

- *"The is the quintessential example of patient safety work product"*
- *"Quality committee meetings are a core aspect of Guthrie's [PSES]"*

Rumsey v. Guthrie Medical Group

"Agendas, notes and other written records from these meetings are squarely work product and are 'deliberations or analyses' of a [PSES]"

- *All these materials are privileged under the PSQIA, MCARE and the Pennsylvania Peer Review Protection Act*

Deposition of Clinic witness about quality committee meetings, knowledge gained through the PSES, how the committee meetings determine infection preparedness, the data used to reach preparedness conclusions and why they collected certain data and not others.

- *This information was privileged because the questions sought information generated within the PSES*
- *Policies are not privileged*

Rumsey v. Guthrie Medical Group

Impact and Takeaways:

- Stresses the importance of a provider's PSES policy and detailed identification of patient safety activities and what is considered and treated as PSWP
- Multiple privilege statutes can apply – they are not mutually exclusive
- First reported case to rely on "deliberations and analyses" standard for creating PSWP
- Policies are not protected
- Communications with government officials are not protected
- Does not rely on the "sole purpose" standard which is a requirement under MCARE although the court did reference that documents were prepared "for reporting to a PSO"

In Re: BayCare Medical Group, 2024 WL 2150114 (11th Cir. Court of Appeals (May 14, 2024)

Background:

- A physician brought an employment discrimination case after her termination by BayCare Medical Group and St. Joseph's Hospital in Tampa, Florida.
- The termination was based on her alleged commission of several surgical errors.
- During discovery she sought to require that BayCare be required to disclose "internal documents about the performance of other doctors who were not fired despite also committing errors".
- She also demanded production of "referral logs" which identified complaints brought against other physicians.
- BayCare argued that these documents (collectively the "quality files') were privileged under the Patient Safety Act and therefore not subject to discover.

BayCare Medical Group

District Court Decision:

- The District Court ruled that the Patient Safety Act does not privilege documents if they had a "dual purpose" as opposed to the "sole purpose" of reporting to a PSO.

- Because the documents were also used for internal patient safety analysis and peer review, the Court ruled that they therefore were not used for the sole purpose of reporting toa a PSO and therefore were not privileged.

- BayCare subsequently filed a writ of mandamus requesting that the 11th Circuit Court of Appeals direct the District Court to vacate its order compelling disclosure of the documents arguing that the Patient Safety Act does not have a "sole purpose" requirement.

BayCare Medical Group

Circuit Court of Appeals Decision:

- The Circuit Court rejected the District Court's "sole purpose" interpretation of the Patient Safety Act. In doing so it stated:

- "We agree with BayCare. Under the plain text of this statute, it does not matter whether BayCare created, used, or maintained the disputed documents for multiple purposes. Contrary to the district court's order, nowhere does the statute require that privileged information be "kept solely for provision to a Patient Safety Organization. Instead, the Act privileges work product so long as it "identif[ies] or constitute[s] the deliberations or analysis of, or identifies the fact of reporting pursuant to a "patient safety evaluation system" (citation) regardless of whether it is reported to a patient safety organization. The relevant administrative rule confirms as much. BayCare "may use patient safety work product for any purpose within [its] legal entity". Patient Safety and Quality Improvement, 72 Fed. Reg. 70732-01 at 70779 (Nov. 21, 2008). Nothing prohibits the disclosure of patient safety work product among physicians and other health care professionals, particular for educational purposes or for preventing or ameliorating harm." Id at 70778.

- The Circuit ruled that the District Court abused its discretion and directed that the Court vacate its order and reconsider BayCare's privilege arguments.

Burke v. The Ingalls Memorial Hospital, NO. 2023-L-006063 Cir. Ct. Cook County (September 2024)

Background

- Plaintiff in this malpractice action was a 76- year- old patient who was admitted to the inpatient rehab unit at Ingalls Memorial Hospital after a three-week hospital stay for cancer treatment.
- He was identified as a fall risk and therefore relevant precautions were taken consistent with relevant Hospital policies.
- Plaintiff later had an unwitnessed fall in his room and was taken to the ICU after sustaining a head injury.
- That same day, a nurse created an occurrence report in the Ingalls Healthcare Safety Zone portal which is the event reporting system used by Ingalls to report PSWP to its PSO, Clarity PSO.
- The report triggered a patient safety investigation which resulted in a nursing peer review process.
- All the materials generated by these reviews also were reported to the PSO.
- Ingalls argued that all these materials were PSWP under the Patient Safety Act

Burke v. The Ingalls Memorial Hospital

Hospital's Response to Plaintiff's Motion to Strike Ingalls Privilege Assertion

- During the discovery process Ingalls provided a privilege log which identified the 13 pages which were at issue as PSWP under the Patient Safety Act along with citation to an Illinois Appellate Court decision in Daley v. Teruel/Ingalls Memorial Hospital, 2018 IL App (1st) 17091, which upheld the Patient Safety Act privilege protections in a nearly identical privilege dispute involving Ingalls.

- The Hospital also introduced its PSES policy, its Occurrence Reporting Policy and its Quality plan in addition to an affidavit from its Vice President of Clinical Performance Excellence as well as the Executive Director of Clarity PSO. These affidavits reflected the process by which Ingalls collected these materials in its PSES and reported them to Clarity PSO. Receipt of this PSWP was confirmed by Clarity in addition to how the PSO uses such reports in efforts to support its members, including Ingalls, to support their efforts to improve patient health care and reduce risk.

Burke v. The Ingalls Memorial Hospital

Trial Court's Decision to Reject the "sole purpose" and "ordinary course of business" arguments

- The trial court initially attempted to issue language in the Daley decision to maintain that the "sole purpose" standard was not met in the Ingalls arguments.
- During oral argument, counsel pointed out that the Daley Appellate Court was imply referencing Ingalls affidavit which referenced the term "sole purpose" but not that it was a recognized requirement.
- Counsel also submitted to the court the recent decision in BayCare which rejected the "sole purpose" argument
- Plaintiff also raised an argument which one or more Cook County judges relied upon that claim that documents which were created for the purpose of improving patent care and reducing risk were created in the hospital's "ordinary course of business" and therefore were not privileged under the Patient Safety Act.
- Ingalls pointed out that a hospital's primary goal through all of its policies, procedures, and standards along with accreditation and other regulatory requirements, is to improve quality and reduce risk to patients as part of its "ordinary course of business"
- In its legal brief and arguments to the court, if these standard quality improvement and patient safety activities were no longer privileged, such a ruling would completely nullify the privilege protections under existing Illinois law and the Patient Safety Act.

Burke v. The Ingalls Memorial Hospital

Trial Court's Decision:

- Somewhat reluctantly, the trial court ruled that the hospital, through submission of its policies, affidavits, and reliance on the decisions in Daley and BayCare, had met its burden of establishing that the documents in dispute were PSWP.

Crawford v. Corizon Health, Inc. (U.S. Dist. Ct. W. Dist. Penn. (July 10, 2018)

Background

- Plaintiff brought suit on behalf of her son who committed suicide while detained in jail.
- The allegation was that he was denied necessary medications and their deliberate indifference to his needs was in violation of the 8th Amendment.
- A lawsuit was brought against Corizon which was contracted to provide medical and health care services to the county jail.
- Plaintiff sought "any and all reports evidencing any investigation into the death of any inmate at the...jail"
- Court initially held that eight of the nine disputed documents, including deaths of four other inmates, were not privileged.

Crawford v. Corizon Health, Inc.

In response to a rule to show cause as to why the four documents should not be produced the defendant, for the first time, asserted that they were privileged under the PSQIA.

Court's Decision

- Corizon argued that the reports were submitted to its PSO.
- Affidavit states that documents were placed in Corizon's PSES, were "created for submission into Corizon's PSES" and that it "makes information available and reports information contained in its PSES at the request of its" PSO.
- Court states that under the HHS PSO Guidance, with a citation to the Daley v. Teruel decision, the documents must be created "for the purpose of reporting" to a PSO which, in this case, Corizon did not assert.

Crawford v. Corizon Health, Inc.

- "Significantly, the Declaration omits seemingly critical details about the timing of the submission to the PSO, giving rise to a reasonable inference that these documents were reported to the PSO only after plaintiff's requested them in this proceeding. Whether or not this is true, what is certain is that Corizon has failed to demonstrate the necessary element of the claimed PSQIA privilege."

- It did not help that some of the documents were "made for the purpose of security legal advice."

- Court also says that "most of the documents that issued were created in the ordinary course of Corizon's business — providing and improving care."

Crawford v. Corizon Health, Inc.

Court also found that the attorney's client work product privileged did not apply because the documents were created for the purpose of improving patient care and not in anticipation of litigation.

Impact and Takeaway

- This is an example of needing to meet all substantive and technical PSQIA requirements.
- In this case, the affidavit was defective because it did not reference that the documents were created for the purpose of reporting to PSO and there was no evidence as to when the reports actually were reported.
- There is no reference in the opinion as to whether the information was being treated as deliberations or analysis.
- Be prepared for the "ordinary course of business" argument which, taken to its extreme, would totally undermine the PSQIA protections.
- Emphasizes the need to educate the court regarding the PSQIA.

Impact and Lessons Learned

Use Detailed Affidavits to Support Argument:

- The role of the provider and its legal counsel is to effectively educate the courts about the PSA so the judges have a better understanding as to the context as to why the disputed materials are PSWP.
- As is true in most cases, courts rely heavily on the affidavits that were submitted to demonstrate compliance with the PSA requirements to determine whether the information qualified as PSWP.
- All representations in an affidavit are accepted as true unless they are otherwise rebutted.
- Sometimes multiple affidavits maybe required.

Impact and Lessons Learned

The type of representations and documents to include within an affidavit include the following:

- The PSO AHRQ certification and recertification letters
- The provider's PSO membership agreement.
- The PSES policy.
- Citations to the policy where disputed documents are referenced and whether the information was reported to a PSO or treated as deliberations or analysis.
- Screenshots of the redacted forms, reports, etc., for which the privilege is being asserted.
- Documentation as to when the information was reported, either electronically or functionally, or when the information qualified as "deliberations or analysis" under this separate pathway.

Impact and Lessons Learned

- A description of how information is collected within the PSES, how it qualifies as PSWP, if not otherwise set forth in the PSES.
- Representation as to how the PSWP was or is used for internal patient safety activities and used by the PSO.
- Representation that the information has not been collected for unrelated purposes, such as satisfying a state or federal mandated reporting requirement but is being collected for reporting to a PSO.
- If possible, a representation that the provider is not required by state or federal law to make the information available to a government agency or other third party.

Impact and Lessons Learned

- An affidavit from the PSO acknowledging the provider's membership and that the information, if reported, was received and is being used to further the provider's and the PSO's privileged patient safety activities
- Make sure that use of outside experts used to conduct patient safety activities to benefit the hospital or PSO are correctly documented and use references in PSES. Considering including the engagement letter with PSES.
- Remember, risk management information and activities relating to claims and litigation support will not be considered PSWP.
- Assert other privilege protections if applicable.
- Policies are not privileged.

Additional Litigation, Lessons Learned, and Questions

Types of Legal Challenges:

- Timing of when provider contracted with a PSO and adopted its PSES policy versus dates of the claimed privileged documents.
- Was the information sought identified by the provider/PSO as being collected within a PSES?
- Was it collected and either actually or functionally reported to the PSO?
- What evidence/documentation?
- If not yet reported, what is the justification for not doing so? How long has information been held? Does your PSES policy reflect a practice or standard for retention?
- Is the information being treated as deliberations or analysis?

Additional Litigation, Lessons Learned, and Questions

- Has information been dropped out? Did you document this action?
- Is it eligible for protection?

  May be protected under state law.

- Is provider/PSO asserting multiple protections?

  If collected for another purpose, even if for attorney-client, or in anticipation of litigation or protected under state statute, plaintiff can argue information was collected for another purpose and therefore the PSQIA protections do not apply – cannot be PSWP and privileged under attorney-client

Additional Litigation, Lessons Learned, and Questions

- Is provider/PSO attempting to use information that was reported or which cannot be dropped out, i.e., an analysis, for another purpose, such as to defend itself in a lawsuit or government investigation?

  Once it becomes PSWP, a provider may not disclose to a third party or introduce as evidence to establish a defense.

- Is the provider required to collect and maintain the disputed documents pursuant to a state or federal statute, regulation or other law or pursuant to an accreditation standard?

- Was the information being used for HR, claims management or litigation management purposes?

Additional Litigation Lessons Learned and Questions

- Document, document, document
- PSO member agreement
- PSES policies
- Forms
- Documentation of how and when PSWP is collected, reported or dropped out
- Detailed affidavits
- Separate Attorney-client privilege protections
- Independent contractor agreements
- Utilization of disclosure exceptions

Additional Litigation, Lessons Learned, and Questions

- Advise PSO when served with discovery request.
- Get a handle on how adverse discovery rulings can be challenged on appeal.

Regulators Demand for PSWP: How To Respond

Information Categories: Information subject to mandatory reports to a state or federal governmental entity (Not eligible for PSWP protection)

Texas requires mandated reports for 48 Preventable Adverse Events ("PAE") and healthcare associated infections ("HAIs") effective 1/1/20 by licensed – not comprehensive medical rehab hospitals or special hospitals that do not provide surgery or OB services

PAE Questions include:

- Record Type
- Preventable Adverse Event
- Date Event Occurred or Discovered
- Medical Record Number or Patient ID
- Level of Harm
- Do You Want DSHS to Delete This Record

Regulators Demand for PSWP: How To Respond

What about additional root cause questions?

- Optional or encouraged but not required

If participating and reporting to a PSO are the reports still required?

- Yes

Information not subject to mandatory reporting nor is there a requirement to be make information available for inspection by a governmental entity.

- Information is eligible for PSWP protection if collected in the PSES and reported to the PSO or treated as D or A

Regulators Demand for PSWP: How To Respond

Information which must be collected and maintained and/or must be made available for inspection by a governmental entity:

- Grey area
- HHS PSO Guidance states that such information is not eligible for PSWP protection under the Patient Safety Act
- One important question is whether the collection and maintenance of information/reports is voluntary or mandatory
- Guidance is not binding
- Recommendation is to err on the side of asserting the privilege under state and/or federal law

  But also need to consider the political impact of denying the request

Regulators Demand for PSWP: How To Respond

Step by Step Guidance

- Do not prevent surveyors from entering the facility
- Are they there on behalf of CMS and/or the state?
- Do not panic
- Make sure that appropriate personnel including legal counsel is contacted and decide who will accompany the surveyors
- Review documents requested by surveyor if in writing or if verbally requested
- Determine whether any of the information requested is PSWP or privileged under Texas law
- If PSWP is requested, provide them the "Information for State and Federal Regulators form (See Attached A)

Regulators Demand for PSWP: How To Respond

If acting on behalf of CMS, provide them the statement from the following statement is set forth in the HHS Guidance Regarding Patient Safety Work Product and Provider's External Obligations:

"As described above, the protected system established under the Patient Safety Act works in concert with the external obligations of providers to ensure accountability and transparency while encouraging the improvement of patient safety and reduction of medical errors through a culture of safety. It is the provider's ultimate responsibility to understand what information is required to meet all of its external obligations. If a provider is uncertain what information is required of it to fulfil an external obligation, the provider should reach out to the external entity to clarify the requirement. HHS has heard anecdotal reports of providers, PSOs, and regulators working together to ensure that the regulators can obtain the information they need without requesting that providers impermissibly disclose PSWP. HHS encourages such communication. Regulatory agencies and other entities requesting information of providers or PSOs are reminded that, subject to the limited exceptions set forth in the Patient Safety Act and Patient Safety Rule, PSWP is privileged and confidential, and it may not be used to satisfy external obligations. Therefore, such entities should not demand PSWP from providers or PSOs." (Emphasis added) (41 Fed. Reg. at 32659 (May 26, 2016))

Regulators Demand for PSWP: How To Respond

Be prepared to provide a copy of the following:

- PSO certification letter from AHRQ
- Copy of PSO member agreement
- Copy of PSES policy along with pointing out that the information they are seeking is PSWP under the policy
- Screen shots or blank/redacted forms which are used to report PSWP to the PSO or are treated as D or A
- Provide copies of non-privileged information:
    - Medical/patient care records
    - Relevant policies and procedures
    - Action plan relating to the incident if not PSWP
    - Permit interviews of involved personnel but cannot discuss or disclose PSWP

Regulators Demand for PSWP: How To Respond

What Should You Do If Providing this Information Does not Satisfy the Regulators?

- If acting on behalf of CMS, contact the applicable CMS Regional Office 6 to confirm that facility is not required to turn over PSWP
- If acting on behalf of the state, consider using Provider Authorization to Disclose PSWP form (See Attachment B)
- Contact legal counsel

Information for state and federal regulators (or other seeking compulsory access to PSWP

The information you have requested is protected by federal law (the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 et. seq., and 42 C.F.R. Part 3, §§ 3.10 et. seq.) as Patient Safety Work Product. Identifiable Patient Safety Work Product may not be disclosed outside of this facility.

The following is a statement set forth in the HHS Guidance Regarding Patient Safety Work Product and Provider's External Obligations:

"As described above, the protected system established under the Patient Safety Act works in concert with the external obligations of providers to ensure accountability and transparency while encouraging the improvement of patient safety and reduction of medical errors through a culture of safety. It is the provider's ultimate responsibility to understand what information is required to meet all of its external obligations. If a provider is uncertain what information is required of it to fulfil an external obligation, the provider should reach out to the external entity to clarify the requirement. HHS has heard anecdotal reports of providers, PSOs, and regulators working together to ensure that the regulators can obtain the information they need without requesting that providers impermissibly disclose PSWP. HHS encourages such communication. Regulatory agencies and other entities requesting information of providers or PSOs are reminded that, subject to the limited exceptions set forth in the Patient Safety Act and Patient Safety Rule, PSWP is privileged and confidential, and it may not be used to satisfy externa obligations. Therefore, such entities should not demand PSWP from providers or PSOs." (41 Fed. Reg. at 32659 (May 26, 2016)) (Emphasis added).

Any questions about access to this information should be directed to (Hospital) General Counsel, attention:

(Hospital)

Attn: General Counsel

(address)

Provider Authorization to disclose PSWP

Name of Provider _____

The above-named provider hereby authorizes disclosure to:

_____

_____

[Insert name of individual or entity to which PSWP may be disclosed]

Of the following Patient Safety Work Product information:

_____

_____

[Insert description of the information to be disclosed]

_____

_____

Signature: _____

Date: _____

For (Hospital) Use:
Information was disclosed pursuant to this authorization on: [*list below all dates upon which disclosure was disclosure was made]*

Date	Signature of Risk Manager/designee releasing information
_____	_____

This authorization is to be delivered to the (Hospital) Risk Manager and retained for 6 years from the date of the last disclosure made pursuant to this authorization.

Information for law enforcement officials about permitted uses and disclosure of PSWP

To: [*insert name of law enforcement official and agency to whom PSWP is given]*
The information you have requested is protected by federal law (the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 et. seq., and 42 C.F.R. Part 3, §§ 3.10 et. seq.) as Patient Safety Work Product. These provisions permit your access to this information only in the following circumstances and subject to the following conditions:
42 CFR 3.206:

(b)(10) Disclosure to law enforcement.

(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.

(ii) Law enforcement personnel receiving patient safety work product pursuant to paragraph (b)(10)(i) of this section only may disclose that patient safety work product to other law enforcement authorities as needed for law enforcement activities related to the event that gave rise to the disclosure under paragraph (b)(10)(i) of this section.

By your signature below, you confirm that your request for access to this information is consistent with the above-cited federal law, and that you will maintain confidentiality of the information as required by federal law.

Date: _____ Signature:_____

Retain signed original for (Hospital) files; a copy of this document should be provided to the law enforcement official who obtains a copy of the PSWP.

Questions?

Thank you!

Email with slide deck and instructions for obtaining CE will be sent out by end of next week.