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The Patient Safety Act 14 Years Later: Lessons Learned and Mistakes to Avoid

Michael R. Callahan, Senior Counsel
Katten Muchin Rosenman LLP
312.902.5634
michael.callahan@katten.com

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Agenda

Maximizing PSQIA and State Peer Review Protections

1. Review of key PSQIA court decisions and takeaways
2. Identify impact of court decisions on PSES policy development
3. Litigation lessons learned in defending against discovery demands for PSWP

Daley v. Ingalls Memorial Hospital

Factual 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 the course of discovery the hospital objected to interrogatories which sought a number of 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").

Factual Background

- 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.
- 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.

Factual Background

- 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 to Motion to Compel

- 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 the means by which the hospital reported this information to Clarity and were prepared "solely" for submission to Clarity.

Hospital's Response to Motion to Compel

- 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.
- 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 Decision

- 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".

Appellate Court's Decision

- 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".
- 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.

Appellate Court's Decision

- 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 work 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.
  - The information contained in the documents had the ability to improve patient safety and the quality of healthcare.

Appellate Court's Decision

- 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 privileged

- 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.

Appellate Court's Decision

- 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"
- 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"

Appellate Court's Decision

- 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."
- 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.

Appellate Court's Decision

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.

Appellate Court's Decision

- Because this representation was unrebutted by the Plaintiff the court was obligated to accept the hospital's representation.
- Note: There is nothing under the PSA which makes reference 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.

Appellate Court's Decision

- 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.

Appellate Court's Decision

- 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.
- In response, the Court pointed out that the Florida Constitutional Amendment 7 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.

Appellate Court's Decision

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 federal case, Tampa General Hospital v. Azar, that the PSA preempts all laws including 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"

Ungurian v. Beyzman

Factual Background

- Plaintiff is a mother who sued the hospital and multiple physicians and other corporate entities alleging negligence during a cystoscopy procedure to remove kidney stones which led to the total and permanent incapacity of her son
- During discovery, the Plaintiff served requests for documents and interrogatories on all the Defendants
- Hospital asserted that five of the documents requested were privileged from discovery under the Patient Safety Act and/or the Pennsylvania Peer Review Protection Act (“PRPA”)

Factual Background

- The disputed documents were:
  - an event report relating to “surgery, treatment, test, invasive procedure” prepared by a clinical leader (the “Burry Report”)
  - a Serious Safety Event Rating Meeting Summary
  - meeting minutes from the Patient Safety Committee
  - a Root Cause Analysis Report
  - the Hospital’s Quality Improvement Staff Peer Review Report, prepared by an outside physician
- In response to the Plaintiff’s Motion to Strike Objections and Compel Responses, the hospital’s Response included a single affidavit prepared by the Director of Patient Safety Services

Factual Background

- The affidavit stated that the Burry Report was “completed in compliance with Hospital’s Event Reporting Policy” and the RCA was maintained “within its [Event Reporting Policy] for reporting to CHS PSO, LLC and that it electronically submitted the Root Cause Analysis Report to CHS PSO, LLC”
- The hospital did not assert the Patient Safety Act privilege protections regarding the other three documents
- There were multiple hearings and trial court orders regarding the ongoing discovery dispute, but ultimately the trial court ruled that neither the Patient Safety Act nor the PRPA protected any of the documents and, therefore, ordered the hospital to produce them

Factual Background

- The hospital filed an appeal from the various orders, including that they produce the credentialing files of all practitioners who provided care to the Plaintiff's son as well as any National Practitioner Data Bank query responses
- The Appellate Court granted the appeal because it has jurisdiction when such disputes involve assertion of a privilege

Trial and Appellate Court's Decision

- **The Burry Report**
  - The hospital submitted a single affidavit, which was fairly comprehensive in terms of its relationship with the PSO and its development of a PSES policy which was facilitated by its use of the Event Reporting System ("ERS") for the purpose of improving patient safety
  - It was this procedure that resulted in preparation of documents such as the Burry Report
  - The trial court, however, determined that it did not qualify as PSWP because the affidavit did not state that the Report was prepared for the purpose of reporting to the PSO
  - The court cited language in the affidavit that the ERS system "is used to manage information that MAY be reported to the PSO"

Trial and Appellate Court's Decision

- Therefore, the trial court stated that "it could have been developed for a purpose other than reporting to a PSO and still be managed within the ERS"
- The Appellate Court agreed with the trial court's analysis because the hospital had failed to assert in the affidavit that it prepared the Burry Report for the purpose of reporting to a PSO and in fact reported it to the PSO
- It is very important to note that in the hospital's appellate brief, it stated the Burry Report was indeed submitted to the PSO but because no assertion was included in the affidavit and because the record on appeal did not include any evidence that the hospital had indeed made a report, the Appellate Court declined to accept this belated claim

Trial and Appellate Court's Decision

- **RCA**
  - In ruling that the RCA did not qualify as PSWP, the trial court found that the affidavit did not state that it was "also developed for the purpose of reporting to the PSO"
  - In addition, it noted the hospital had admitted that the "information contained in the RCA 'is not solely in the PSES'"
  - Therefore, because the RCA existed outside of the PSES, it was not privileged under the Patient Safety Act
  - The Appellate Court agreed with this analysis

Legal Analysis

- **"Information contained in the RCA is not solely in the PSES"**
  - This statement by the Appellate Court, taken to its extreme, would mean that no information which is collected and maintained within a provider's PSES would ever qualify as PSWP if the information appears elsewhere or is used outside the PSES
  - Under the Patient Safety Act, providers are specifically expected to use PSWP for all internal purposes which are not limited to patient safety activities identified in the PSES
  - Using an RCA as an example, these reports include facts from the medical record and other sources which are not necessarily privileged

Legal Analysis

- Any discussion and analyses that take place in the PSES will include facts and the work product from these PSES identified patient safety activities are shared with committees, work force members and others in their collective effort to improve patient safety and reduce risk
- In a number of reported cases, Plaintiff's have argued that because a claimed PSWP document, such as an incident report, contained facts which are not privileged, the report itself cannot be privileged
- Courts have rejected this argument consistently recognizing that any privileged analysis will always include a discussion of the underlying facts on which the incident report, RCA, etc., is based. (See Daley v. Ingalls Memorial Hospital)

Legal Analysis

- **"Burry Report collected in the ERS did not qualify as PSWP because the affidavit said that such reports 'may be reported to the PSO' and there was nothing in the record establishing that it was reported"**
  - What is not clear in the decision is whether the hospital submits only some ERS reports to the PSO and those which it does not are considered privileged discussions or analyses ("D or A")
  - There is no discussion about the D or A pathway for creating PSWP
  - The court does not cite to the *Rumsey v. The Guthrie Clinic* decision or the *Daley* decision as part of its analysis even though both cases involved a medical malpractice action in which the hospitals were asserting privilege protections under the Patient Safety Act

Lessons Learned and Recommendations

- The heavy burden of establishing that documents and other information are privileged under state laws or the Patient Safety Act is on the provider
- Courts do not like privilege statutes and will look for various ways to rule against the assertion of a privilege
- Most courts have no knowledge or experience in working with or interpreting the Patient Safety Act which makes it imperative that providers seek to effectively educate the court about the Act with citations to favorable cases, including but not limited to Daley v. Ingalls Memorial Hospital and Rumsey v. The Guthrie Clinic
- The use of detailed affidavits also is essential to establish compliance with all of the required elements of the Act including the so-called missing assertions as determined by the trial and Appellate Court in this case

Lessons Learned and Recommendations

- You make your record at the trial level and cannot supplement on appeal
- In addition to a fully detailed affidavit you should consider including the PSES policy which hopefully includes provisions which support the privilege claim as well as the documents or information in dispute
- Consider adding screenshots of either blank forms, reports, etc., of what you treat as PSWP and/or provide the documents in dispute, but with the privileged information redacted.
- Consider submitting the documents for an in camera inspection to the court if this might work in your favor. This obviously is a judgment call that you make with legal counsel. If you choose this route, make sure you obtain a protective order and that you use the written authorization permissible disclosure exception under Final Rule Section 3.206(b)(3)

Lessons Learned and Recommendations

- Use defense attorneys who are well acquainted with your PSES and related policies, the Patient Safety Act and how to assert the privilege and/or with outside legal experts who can assist and collaborate with the provider's defense attorney
- Your PSES policy should be reviewed and updated to capture all of the patient safety activities, reports, analyses, etc., for which you want to assert the privilege protections under the Patient Safety Act
- The PSES policy should specifically delineate what information is being reported to the PSO and what information is being treated as deliberations or analysis
- If the provider is collecting all of certain reports within its PSES but only reporting some of them, the unreported ones should be identified as D or A if you intend to keep them privileged as well.

Lessons Learned and Recommendations

- Although there is no time limit as to when a document must be reported, if that is your intent, not reporting them within a reasonable time period will be used against you
- If holding on to a report for a particular purpose for a longer period of time than usual, you should document the reasons for doing so.
- Keep in mind that once collected and maintained in the PSES and not dropped out, the information remains privileged PSWP

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 in order 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.

Impact and Lessons Learned

Privilege Logs

- Privilege logs are used to identify which information is being withheld from discovery in response to a subpoena or motion to compel based on a state peer review statute, the Patient Safety Act, attorney-client work product, HIPAA or other claimed privilege
- The details of what needs to be included in a privilege log varies from state to state, court to court and in federal courts
- The mere assertion of the claimed privilege along with applicable statutory citation usually is insufficient
- More detail is better, combined with affidavits and legal memos in support of the privilege claim

Impact and Lessons Learned

- Detail to consider adding if asserting the PSA protections
  - Description of Document
    - Date the document was collected/generated in the PSES
    - Date it was reported to the PSO or date it became D or A
    - What person/committee created the PSWP
    - How the PSWP was shared and utilized within PSES
    - That the information was used to improve patient safety and reduce risk

Impact and Lessons Learned

Types of Legal Challenges

- Timing of when provider contracted with a PSO and created its PSES versus dates of the claimed privileged documents.
- Was the information sought identified by the provider/PSO as being collected within a PSES?
- Was it actually 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?

Impact and Lessons Learned

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

Impacts and Lessons Learned

- 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 into 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?

Impact and Lessons Learned

- 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 Raised

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

Questions & Answers

Firm Bio

Michael R. Callahan

Senior Counsel
Health Care

Chicago Office

+1.312.902.5634

michael.callahan@katten.com

https://katten.com/Michael-Callahan

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

The knowledge to identify efficient and practical solutions

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

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

Katten Locations

CHARLOTTE
550 South Tryon Street
Suite 2900
Charlotte, NC 28202-4213
+1.704.444.2000 tel
+1.704.444.2050 fax

CHICAGO
525 West Monroe Street
Chicago, IL 60661-3693
+1.312.902.5200 tel
+1.312.902.1061 fax

DALLAS
2121 North Pearl Street
Suite 1100
Dallas, TX 75201-2591
+1.214.765.3600 tel
+1.214.765.3602 fax

LONDON
Paternoster House
65 St Paul's Churchyard
London EC4M 8AB
United Kingdom
+44 (0) 20 7776 7620 tel
+44 (0) 20 7776 7621 fax

LOS ANGELES – CENTURY CITY
2029 Century Park East
Suite 2600
Los Angeles, CA 90067-3012
+1.310.788.4400 tel
+1.310.788.4471 fax

LOS ANGELES – DOWNTOWN
515 South Flower Street
Suite 4150
Los Angeles, CA 90071-2212
+1.213.443.9000 tel
+1.213.443.9001 fax

NEW YORK
50 Rockefeller Plaza
New York, NY 10020-1605
+1.212.940.8800 tel
+1.212.940.8776 fax

ORANGE COUNTY
100 Spectrum Center Drive
Suite 1050
Irvine, CA 92618-4960
+1.714.966.6819 tel
+1.714.966.6821 fax

SHANGHAI
Suite 4906 Wheelock Square
1717 Nanjing Road West
Shanghai 200040
P.R. China
+86.21.6039.3222 tel
+86.21.6039.3223 fax

WASHINGTON, DC
2900 K Street NW
North Tower - Suite 200
Washington, DC 20007-5118
+1.202.625.3500 tel
+1.202.298.7570 fax