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Illinois Appellate Court Upholds Privilege Protections Under the Patient Safety and Quality Improvement Act of 2005

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Executive Summary

In a case of first impression involving a medical malpractice lawsuit, the Illinois Appellate Court reversed the ruling by the trial court in Daley vs. Ingalls Memorial Hospital, which ordered a hospital to produce three documents it had collected within its patient safety evaluation system (PSES), and reported to Clarity PSO, a federally certified patient safety organization. The court, in a detailed analysis, ruled that the hospital had demonstrated through its policies, documents and unrebutted affidavits that the materials in dispute qualified as privileged patient safety work product (PSWP) under the Patient Safety and Quality Improvement Act of 2005 (PSQIA) and, therefore, were not discoverable.

The court also found, contrary to the plaintiff's arguments, that the documents did not constitute medical records, which are not privileged under the PSQIA; that the hospital was not obligated to report the documents to the Illinois Department of Public Health under Illinois law; and finally, that the materials which were used for internal quality purposes were not collected for a purpose other than reporting to Clarity PSO. In addition, the Court held that the PSQIA contains an express preemption clause, contrary to the decision of the Florida Supreme Court in the case of *Charles vs. Southern Baptist Hospital of Florida, Inc.* Therefore, because the information qualified as PSWP, the PSQIA preempted the trial court's order requiring the hospital to turn over the documents to the plaintiff.

I. Factual Background

This case involves a lawsuit brought by the estate of a patient alleging that Ingalls Hospital and its employees committed malpractice on November 17 and 18, 2013, when it failed to adequately monitor and treat her blood glucose levels. The lawsuit further alleges that the patient's subsequent injuries caused by this negligence contributed to her death in October of 2014.

During the course of discovery, the hospital objected to interrogatories which sought a number of incident reports and complaints, arguing they were privileged from discovery under both the Illinois Medical Studies Act and the PSQIA. Plaintiff also requested that the hospital produce documents which described any statements made by the decedent, family member

or anyone with knowledge regarding issues addressed in the complaint.

Upon refusal to produce the documents, the plaintiff filed a motion to compel. Ultimately, only three documents remained in dispute, two incident reports involving the patient's care and a complaint that was made by the patient's daughter to a hospital employee regarding the patient's treatment. All three documents, which were electronically reported to Clarity PSO, contained the heading "Healthcare Safety Zone Portal" in addition to the name "Clarity Group, Inc. Copyright" at the bottom of each page, as well as the dates on which the documents were created. The three documents were provided to the trial court for in-camera review. The hospital later limited its arguments to a claim that the materials constituted privilege patient safety work product (PSWP) under the PSQIA.

In support of its response to the motion to compel, the hospital submitted an affidavit from its associate general counsel, as well as a supplemental affidavit which contained the follow representations:

- The hospital contracted with Clarity Patient Safety Organization in 2009 to improve the hospital's patient safety and quality of health care.
- The documents in dispute were created, prepared and generated for submission to Clarity.
- 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.
- The documents were not part of the patient's original medical records, which already had 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 had 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 she object or attempt to rebut information contained in the affidavits.

Upon reviewing the documents, the trial court circled certain information in each and required that these portions be produced to the plaintiff. The hospital refused to comply and was held in "friendly contempt," which allows for an automatic appeal to the appellate court.

A joint *amicus curie* brief in support of the hospital was filed by the Illinois Health & Hospital Association, The American Medical Association, The Alliance for Quality Improvement and Patient Safety, The Illinois State Medical Society and Clarity PSO. The Illinois Trial Lawyers Association filed an amicus brief in support of the plaintiff.

II. Analysis

The Appellate Court begin its analysis of the PSQIA by citing 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 PSQIA which identified that the privilege protections were "the foundation to furthering the overall goal of the statute to develop a national system for analyzing and learning from patient safety events."

In its discussion regarding PSWP, the court recognized that there are three distinct ways of creating privileged documents via the "reporting pathway," which includes actual and "functional reporting," as well as treating this information as "deliberations or analysis." Because Ingalls argued that the documents were PSWP through the reporting pathway, the court examined whether the hospital met all of the requirements under the PSQIA and further, whether any of the exceptions applied as per the PSQIA and the HHS PSO Guidance. In determining that the documents were indeed 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 and were reported to Clarity.
- "The information contained in the documents had the ability to improve patient safety and the quality of healthcare, and the documents themselves bear the dates information was entered into the patient safety evaluation system" as represented in the unrebutted affidavits.

The court next addressed the plaintiff's arguments, discussed below, that the documents met three of the exceptions as to whether they qualified as PSWP.

A. **The Information was Required To Be in the Patient's Medical Record and, Therefore, was Not Privileged**

Although the plaintiff did not see any of the disputed documents, she argued that information in the reports should have been in the medical records. The court acknowledged that the PSQIA does not allow original medical records to be patient's safety work product:

"But, if that same information is included within documents that are intended to be submitted to a patient's safety organization, the documents containing the information are privileged (citation). Thus, contrary to plaintiff's argument, merely because information required to be [the descendant's] medical record might also be contained in the documents at issue, this fact does not mean the documents themselves are no longer patient safety work product."

Plaintiff also argued that there was "a large gap of time" and "ambiguity" in the record because there was little, if any, documentation over a critical seven hour period of time while the patient was in the hospital. The hospital, she claims, was hiding important information under the "guise of patient safety work product."

The court recognized that under the Illinois Hospital Licensing Act, a medical record must meet certain documentation requirements and that the PSQIA "does not permit providers to use the privilege and confidentiality protection . . . to shield records required by external recordkeeping or reporting." The court importantly noted, however, that if the hospital failed to create an adequate medical record, there are "associated consequences" for such failure, including losing its operating license. In other words, the result should not be that information, prepared for the purpose of reporting to a PSO and which is reported to a PSO, loses its privileged status because it may include facts and other information in the medical records. The court further

stated that the documents in question were created weeks after the patient was treated at the hospital. Thus, the court determined that "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."

B. **The Documents Were Not Collected Solely for the Purpose of Reporting to a Patient Safety Organization**

The court previously identified that one of the exceptions to whether a document qualifies as PSWP is if it was collected, maintained or developed for a purpose other than for reporting to a PSO. But in this case, the plaintiff failed to rebut the hospital's affidavit that the documents in question were prepared "solely" for submission to Clarity. Therefore, as a matter of law, the court was required to accept this representation. Also, there was nothing else in the record which suggested that the documents were prepared for a different or separate reason other than for internal quality purposes.

C. **Information Collected To Satisfy a Reporting Requirement Does Not Qualify as PSWP**

To support this argument, the plaintiff cited the Illinois Adverse Health Care 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 the Florida Supreme Court decision in *Charles vs. Southern Baptist Hospital Florida* and the Kentucky Supreme Court decision in *Tibbs vs. Bunnell* as further support. Both of these decisions determined that the states in question, Florida and Kentucky, imposed a record reporting or recordkeeping obligation on the documents in dispute, and therefore, they did not qualify as PSWP under the PSQIA.

The Appellate Court did not comment on whether these decisions were or were not correct because, as pointed out by the hospital, the statute in question has not yet been implemented in Illinois, and therefore, the hospital had no mandated reporting obligation.

D. **Allowing the Documents To Remain Privileged Will Permit Health Care Providers To Hide Valuable Information and, Thus, Impede the Truth Seeking Process**

This is an argument which was made by both the plaintiff and in the *amicus brief* submitted by the Illinois Trial Lawyers Association. In response to this contention, the Appellate Court makes an important statement, which is true in all medical malpractice actions.

"However, nothing about these documents being privileged renders the facts that underlie the [PSWP] as also privileged. 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. See *Jenkins vs. Wu*, 102 Il.2d 468, 479 (1984) (finding that, while privileged protections under the Illinois Medical Studies Act may deny plaintiffs access to documents in a medical malpractice case, the denial 'should have little impact' on plaintiffs' abilities to maintain such

causes of action because they can obtain their medical records, depose all persons involved in their treatment and engage experts to give opinions as to the quality of care received'). 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's 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."

E. **Preemption Analysis**

The Appellate Court also engaged in analysis as to whether the PSQIA "preempts the Circuit Court's production order of the documents." In reviewing the language of the statute, the court determined that while the PSQIA clearly has an express preemption clause, a judge must still determine the substantive scope of Congress' intent to displace state law. Citing other cases which have addressed this question, as well as the PSQIA itself, the court held that the preemption clause "demonstrates Congress' intent to supersede any court order requiring production of documents that meet the definition of patient safety or product . . . [I]n other words, when information is patient safety work product, the Patient Safety Act should be construed as preempting any state action or requiring a provider to disclose such work product . . . [c]onsequently, the Patient Safety Act preempts the circuit court's production order."

III. Impact and Lessons Learned

Although state court decisions have no precedential value or binding effect in other jurisdictions, they can influence other courts, especially when there are so few published appellate decisions which have addressed the scope of the privilege protections under the PSQIA and no reported decisions at all in the particular state. The state Supreme Court decisions in *Tibbs, Clouse* and *Charles*, which provided a narrow, if not an erroneous, interpretation of these protections, have been relied on by those courts which seem to be predisposed to ignoring the broad privilege afforded under the PSQIA. And plaintiff's attorneys seeking access to internal peer review, quality and related information to support their malpractice and other claims against health care providers have tried to use these cases to support their demands, as was true in this case.

The *Daley* decision, coupled with the fairly recent decision by the Kentucky Appellate Court in *University of Kentucky vs. Bunnell* (532 S.W.3d 658 Ky Ct. App. 2017), provides a more accurate and objective interpretation of the PSQIA consistent with the intent of Congress to encourage all licensed providers to actively engage in patient safety activities designed to improve health care services and reduce patient risk. Unfortunately, many providers, even those who have contracted with a PSO, have been somewhat sitting on the sidelines and not taking full advantage of the PSQIA because there are no reported decisions within their state. Hopefully, the decisions in *Daley* and *Bunnell* will serve as additional motivation to take advantage of these privilege protections, which typically are broader than those offered under a state's peer review statute.

All of the reported PSQIA decisions, whether favorable or not, provide insight and various "lessons learned" in order to assist providers in making the strongest case against attempts

by plaintiffs and other parties to gain access to privileged PSWP. These lessons include the following.

A. **Develop a Specific and Broadly Worded PSES Policy**

One of the fundamental documents to be introduced to a court in demonstrating that the materials in dispute are indeed PSWP is a provider's PSES policy. Courts are not going to simply accept the word of a hospital or other provider that information qualifies as PSWP. The provider should conduct an inventory of all its performance improvement, quality assurance, peer review and other related patient safety 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 is privileged PSWP. The details of these activities and the information to be protected should be reflected within the PSES. When seeking to claim privilege protections over an incident report, committee minutes or other internal analysis, a provider can then cite the specific reference within the PSES as evidence of the hospital's intent to treat this information as privileged. The provider also should include a "catch all" paragraph to account for other privileged patient safety activities that are not included in the PSES policy.

B. **Use Supporting Detailed Affidavits**

Judges generally are very bright and well-educated individuals, but have little practical or substantive knowledge about the inner workings of a hospital or the scope of the ongoing patient safety activities which take place.

The role of the provider and its legal counsel is to effectively educate the court so that judges have a better understanding as to the context of why the disputed materials are indeed PSWP. As was true in the *Walgreens* and *Daley* decisions, the Appellate Court in each case relied heavily on the affidavits that were submitted to demonstrate compliance with the PSQIA requirements in order to determine whether the information qualified as PSWP. In the *Daley* decision, the Appellate Court accepted all of the representations as true, as it is required to do, especially when these representations were not rebutted by the plaintiff.

The types of representations and documents to include with the affidavit include the following:

1. The PSO AHRQ certification and recertification letters.
2. The provider's PSO membership agreement.
3. The PSES policy.
4. Screen shots of the redacted forms, reports, etc., for which the privilege is being asserted.
5. 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.
6. A description of how information is collected within the PSES, and how it qualifies as PSWP, if not otherwise set forth in the PSES.
7. A representation as to how the PSWP is used for internal patient safety activities.
8. A representation that the information has not been collected for unrelated purposes, such as satisfying a state or federal mandated reporting requirement.
9. If possible, a representation that the provider is not required by state or federal law to

make the information available to a governmental agency or other third party.

10. 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.

C. **Carefully Describe Your PSWP Pathway**

As noted by the Appellate Court in *Daley*, a provider can create PSWP via actual reporting, functional reporting or through deliberations or analysis.

The PSES policy should specifically identify which materials or information falls into which pathway. Keep in mind that privileged information via the deliberations or analysis pathway automatically becomes PSWP and cannot be dropped out for another purpose.

Many hospitals which are members in a PSO, such as Ingalls Hospital, electronically report their incident reports. Incident reports obviously take many different forms. But the reality is a hospital generates hundreds, if not thousands, of incident reports and more likely than not, does not send every single one of them to the PSO. If your PSES policy states all such incident reports are to be reported, but are not in fact sent to the PSO, a plaintiff attorney could argue that report should not be considered PSWP. If the hospital does want to treat them as PSWP, then these unreported incident and other reports should either be functionally reported or treated as deliberations or analysis.

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