Legislative Background: Patient Safety and Quality Improvement Act of 2005

Faced with evidence that preventable medical errors resulting from systemic failures claimed the lives of as many as 98,000 Americans each year, Congress sought to implement a comprehensive framework that would create a "culture of safety" to improve patient safety and quality of care. S. Rep. No. 108-196, at 2-3 (2003); HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations, 81 Fed. Reg. 32655, 32655 (May 24, 2016) (to be codified at 42 C.F.R. pt. 3). The Act thus facilitates a method for filling a need in the American healthcare system by creating a nationwide system targeted at identifying, analyzing and correcting errors that cause harm to patients. 151 Cong. Rec. H6676 (daily ed. July 27, 2005) (statement of Rep. Nathan Deal).

Congress recognized, however, that achieving the Act's goal of improving patient safety and quality of care depended upon the cooperation of healthcare providers. Through the Act, Congress created a system in which healthcare providers may voluntarily contract with patient safety organizations ("PSO") approved by the United States Secretary of the Department of Health and Human Services for the purposes of communicating information toward the goal of improving patient safety, healthcare quality, and patient outcomes. Patient Safety and Quality Improvement, 73 Fed. Reg. 70732, 70732 (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3).

A PSO must meet criteria assuring its independence and integrity as well as confidentiality of the information supplied to it. 42 U.S.C. § 299b-24(b). PSOs, serving as contractors for participating hospitals, collect and analyze the data received from healthcare providers through their patient safety evaluation systems and offer providers feedback on how to improve patient safety and quality of care. 73 Fed. Reg. at 70732; see also S. Rep. No. 108-196, at 5 (2003). Through the collection of reports provided by multiple participating providers, a PSO may, through

this network of information, identify recurring medical errors, isolate causes of adverse events and recognize national trends. 151 Cong. Rec. S8741 (daily ed. July 22, 2005) (statement of Sen. Michael Enzi). A PSO ultimately reports to the Secretary for Health and Human Services, who has implemented and maintained "a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations and other entities." 42 U.S.C. § 299b-23(a). The network facilitates the implementation of systems to prevent future errors and recommends improvements in practices to the benefit of the entire American healthcare system. 151 Cong. Rec. S8741 (daily ed. July 22, 2005) (statement of Sen. Michael Enzi); see also S. Rep. No. 108-196, at 5 (2003).

To incentivize healthcare providers to evaluate patient care and assure that their self-evaluations offered for purposes of improving the healthcare system would not expose them to liability, the Act grants privilege and confidentiality protections for information meeting the definition of patient safety work product. See 42 U.S.C. § 299b-22(a); 42 U.S.C. § 299b-22(b). Under the Act, patient safety work product "shall be privileged and shall not be subject to discovery in connection with a Federal, State, or local civil, criminal or administrative proceeding *** against a provider." 42 U.S.C. § 299b-22(a)(2).

Through the Act, Congress sought to achieve a balance between motivating healthcare providers to report medical errors without fear of liability and respecting the systems in place for holding healthcare providers accountable for negligent harm to patients. See 151 Cong. Rec. S8713 (daily ed. July 21, 2005) (statement of Sen. Edward Kennedy); see also 151 Cong. Rec. H6673-77 (daily ed. July 27, 2005) (statement of Rep. Sherrod Brown). Congress did not intend that the protections granted to healthcare providers for reporting under the Act would shield them from liability or prevent plaintiffs from accessing the evidence needed to seek judicial redress. *Id.*; see

also 151 Cong. Rec. H6673-76 (daily ed. July 27, 2005) (statement of Rep. Gus Bilirakis). Rather, the privilege and confidentiality provisions of the Act are meant to encourage healthcare providers to engage in self-critical analysis—to the benefit of all patients—by guaranteeing that the information generated for reporting to a PSO does not expose providers to liability. 151 Cong. Rec. S8741 (daily ed. July 22, 2005) (statement of Sen. Michael Enzi). To achieve the appropriate balance between these goals, the Act protects specific information—that is, the information that healthcare providers compiled pursuant to the Act. See 81 Fed Reg. at 32657 (the Act "was intended to spur the development of *additional* information created through voluntary patient safety activities and provide privilege and confidentiality protections for such *new* information").

***Daley v. Ingalls Memorial Hospital*, 2018 IL App (1st) 170891: Illinois Appellate Court Upholds Privilege Under the Patient Safety and Quality Improvement Act of 2005**

In a case of first impression in Illinois involving a medical malpractice lawsuit, the Illinois Appellate Court reversed the ruling by the trial court in *Daley v. Ingalls Memorial Hospital*, 2018 IL App (1st) 170891. The trial court ordered a hospital to produce three documents it had collected within its patient safety evaluation system, and reported to Clarity PSO, a federally certified patient safety organization. The appellate 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 under the Patient Safety and Quality Improvement Act of 2005 (the "Act" or "Patient Safety Act") 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 Act; 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 appellate court held that the Act contains an express preemption clause, contrary to the decision of the Florida Supreme Court in the case of *Charles v. Southern Baptist Hospital of Florida, Inc.* Therefore, because the information qualified as patient safety work product, the Act preempted the trial court's order requiring the hospital to turn over the documents to the plaintiff.

I. Factual Background

In *Daley*, a medical malpractice lawsuit, the estate of a patient alleged that Ingalls Hospital and its employees failed to adequately monitor and treat the patient's blood glucose levels. Plaintiff claimed that subsequent injuries allegedly contributed to the patient's death in October 2014. During 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 Patient Safety Act. 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 the hospital's refusal to answer certain interrogatories and produce the documents, the plaintiff moved to compel. Ultimately, 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 under the Act.

In support of its response to the motion to compel, the hospital submitted affidavits from its associate general counsel 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 patient safety evaluation system 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 patient safety evaluation system.

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.

The Illinois Trial Lawyers Association filed an amicus brief in support of the plaintiff. 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 filed a joint *amicus curiae* brief in support of the hospital's position.

II. Analysis

The appellate court began its analysis of the Patient Safety Act by citing a 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 report identified the privilege protections as "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 patient safety work product, the appellate court recognized 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 patient safety work product through the reporting pathway, the court examined whether the hospital met all of the requirements under the Act and, further, whether any of the exceptions applied as per the Act and the HHS PSO Guidance. In determining that the documents were patient safety work product, the appellate court made the following findings:

- The record demonstrates "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 a PSO, 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.

A. Plaintiff's arguments that the documents did not qualify as patient safety work product.

The plaintiff argued that information in the hospital's reports should have been in the medical records. The appellate court acknowledged that the Patient Safety Act does not allow *original* medical records to be patient's safety work product, but did not agree with plaintiff's characterization of the material:

> "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 medical record concerning a seven-hour period of time while the patient was in the hospital. Plaintiff argued the hospital was hiding important information under the "guise of patient safety work product."

The appellate court recognized that the Illinois Hospital Licensing Act requires a medical record to meet certain documentation requirements, and that the Patient Safety Act "does not permit providers to use the privilege and confidentiality protection … to shield records required by external recordkeeping or reporting." The appellate court noted, however, that if a hospital fails 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 appellate 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."

Plaintiff also argued that the documents were not collected solely for the purpose of reporting to a patient safety organization. The appellate court previously identified as one of the exceptions to whether a document qualifies as patient safety work product 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, nothing else in the record suggested that the documents were prepared for a different or separate reason other than for internal quality purposes.

Further, plaintiff argued that information collected to satisfy a reporting requirement does not qualify as patient safety work product. 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 v. Southern Baptist Hospital Florida* and the Kentucky Supreme Court decision in *Tibbs v. 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 patient safety work product under the Act.

The appellate court did not comment on whether the Florida and Kentucky decisions were or were not correct because, as the hospital pointed out, the statute in question has not yet been implemented in Illinois. Therefore, the hospital had no mandated reporting obligation.

Both the plaintiff and the Illinois Trial Lawyers Association in its amicus brief argued that allowing the documents to remain privileged will permit health care providers to hide valuable information and, thus, impede the truth-seeking process. In response to this contention, the appellate court recognized that:

> "[N]othing about these documents being privileged renders the facts that underlie the [patient safety work product] 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 v. Wu*, 102 Ill. 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."

B. Preemption Analysis

The appellate court also analyzed whether the Act "preempts the circuit court's production order of the documents." In reviewing the language of the statute, the court determined that while the Patient Safety Act 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 Patient Safety Act itself, the appellate 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."

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