Illinois Official Reports

Appellate Court

***Daley v. Teruel*, 2018 IL App (1st) 170891**

Appellate Court Caption	TERRI DALEY, Independent Administrator of the Estate of Rosalie Galmore Jones, Deceased, Plaintiff-Appellee, v. KEVIN TERUEL, RN; VICTORIA HALL, RN; and INGALLS MEMORIAL HOSPITAL, Defendants (Ingalls Memorial Hospital, Defendant-Contemnor-Appellant).
District & No.	First District, Fourth Division Docket No. 1-17-0891
Filed	June 28, 2018
Decision Under Review	Appeal from the Circuit Court of Cook County, No. 15-L-11684; the Hon. Moira S. Johnson, Judge, presiding.
Judgment	Reversed and remanded.
Counsel on Appeal	Karen Kies DeGrand, Sherri M. Arrigo, and Laura Coffey Ieremia, of Donohue Brown Mathewson & Smyth LLC, of Chicago, for appellant. Matthew D. Ports, of Pfaff, Gill & Ports, Ltd., of Chicago, for appellee. Sarah F. King, of Clifford Law Offices, P.C., of Chicago, for *amicus curiae* Illinois Trial Lawyers Association.

Michael R. Callahan, of Katten Muchin Rosenman LLP, and Leonard A. Nelson, both of Chicago, Mark D. Deaton and Marilyn E. Hanzal, of Naperville, Richard R. King II and Sherri DeVito, of Springfield, and Peggy Binzer, of Alexandra, Virginia, for *amici curiae* Illinois Health and Hospital Association *et al.*

Panel

PRESIDING JUSTICE BURKE delivered the judgment of the court, with opinion.
Justices McBride and Ellis concurred in the judgment and opinion.

OPINION

¶ 1 Plaintiff Terri Daley, as independent administrator of the estate of Rosalie Galmore Jones, deceased, sued defendants Kevin Teruel, RN; Victoria Hall, RN; and Ingalls Memorial Hospital (Ingalls) (collectively, defendants) for medical malpractice. During discovery, in response to one of plaintiff's written interrogatories and a request to produce, Ingalls claimed a privilege on certain documents based on the federal Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) (42 U.S.C. § 299b-21 *et seq.* (2012)). Plaintiff subsequently filed a motion to compel the production of the documents, which the Cook County circuit court granted. Ingalls refused, based on the Patient Safety Act and sought a contempt finding in order to facilitate appellate review. The court found Ingalls in contempt, and Ingalls appealed.

¶ 2 In this appeal, Ingalls contends that the documents constitute patient safety work product under the Patient Safety Act and the federal law preempts the circuit court's production order. We agree with both contentions, and accordingly, we reverse and remand the matter for further proceedings.

¶ 3 I. BACKGROUND

¶ 4 A. The Patient Safety Act

¶ 5 The Patient Safety Act (Pub. L. No. 109-41, 119 Stat. 424 (codified at 42 U.S.C. § 299b-21 *et seq.*)) established a voluntary reporting system of patient safety information by health care providers designed to analyze and improve patient safety and the quality of health care. Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,732 (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3). In order to encourage the voluntary reporting, the law provides privilege and confidentiality protections for patient safety information (*id.*), known as "patient safety work product," a broad set of information, such as data, reports, records, and written statements, that could help improve patient safety and the quality of health care. 42 U.S.C. § 299b-21(7)(A) (2012)). Health care providers share this information with patient safety organizations, which are federally certified groups who collect and analyze patient safety work product and, in turn, recommend strategies to improve patient safety and the quality of health care. *Id.* §§ 299b-21(4), 299b-24; S. Rep. No. 108-196, at 5 (2003). Because the privilege and confidentiality protections are essential to the functioning of the system created by the Patient

Safety Act, health care providers who disclose patient safety work product can face monetary fines of up to $10,000 per disclosure. 42 U.S.C. § 299b-22(f)(1) (2012).

¶ 6 B. The Litigation

¶ 7 Plaintiff's February 2016 amended complaint frames this appeal. Her lawsuit alleged that defendants committed medical malpractice when they failed to adequately monitor and treat the blood glucose levels of Rosalie Galmore Jones over the course of November 17 and 18, 2013. As a result of defendants' alleged negligence, plaintiff asserted that Jones suffered injuries that caused or contributed to her eventual death in October 2014.

¶ 8 Ingalls and Teruel filed an answer, denying any negligence. Hall filed a motion to dismiss based on her noninvolvement in Jones's care, though the record is unclear whether that motion was resolved prior to this appeal. All the meanwhile, the parties were conducting discovery.

¶ 9 In one of plaintiff's written interrogatories, she asked Ingalls to state whether the incident identified in the complaint was reported to, or investigated by, any hospital or governmental committee, agency, or body. Ingalls objected, as the interrogatory sought privileged information and directed plaintiff to an attached privilege log, in which it claimed privilege on six documents: incident review No. 25472, incident review No. 25753, complaint No. 5101, complaint No. 5478, the security department incident report, and the privilege file of Dr. Rita Oganwu. Concerning the first five documents, Ingalls claimed that they were privileged under the Illinois Medical Studies Act (735 ILCS 5/8-2101 *et seq.* (West 2016)) and the federal Patient Safety Act (42 U.S.C. § 299b-21 *et seq.* (2012)). Concerning the file of Dr. Oganwu, Ingalls claimed it was privileged under Illinois's Health Care Professional Credentials Data Collection Act (410 ILCS 517/1 *et seq.* (West 2016)).

¶ 10 Additionally, in one of plaintiff's requests to produce, she asked Ingalls to produce any documents that describe statements made by Jones, her family, anyone with knowledge of the events at issue in the complaint, or anyone investigating the events at issue in the complaint. In response, Ingalls stated that it had turned over several responsive documents already and directed plaintiff to an attached privilege log, in which it claimed privilege on the same six documents on the same bases as it did in its response to plaintiff's interrogatory.

¶ 11 Plaintiff subsequently filed a motion to compel the production of the allegedly privileged documents, arguing that, "[i]n light of Illinois broad discovery rules, if there is any doubt" about whether the documents should be produced, they should be produced. The circuit court ordered Ingalls to articulate the reasons for its claims of privilege and provide the documents for an *in camera* review.[1] Shortly thereafter, Ingalls produced the security department incident report and the privilege file of Dr. Rita Oganwu for plaintiff, and it accordingly updated its privilege log to include only the four remaining documents. Ingalls provided the remaining documents for the court's review.

¶ 12 All four documents contain the heading "Healthcare Safety Zone Portal" on the top of the page, and all four bear the name "Clarity Group, Inc. Copyright" at the bottom of the page. Generally, incident review No. 25472 detailed an incident that occurred on November 18, 2013, and its aftermath involving Jones's blood glucose levels while she was hospitalized at Ingalls. The document appears to have been created on December 5, 2013. Incident review No.

[1]These documents have been included in the record on appeal under seal.

25753 detailed an incident involving Jones that occurred while she was hospitalized at Ingalls, but does not relate to her blood glucose treatment around November 17 and 18, 2013. The document appears to have been created on January 8, 2014. Complaint No. 5101 detailed an in-person complaint made by Gladys Galmore, the daughter of Jones, to an employee at Ingalls regarding the treatment administered to Jones on November 18, 2013. Galmore's complaint itself was received by Ingalls on December 4, 2013, and it appears the report was created on December 11, 2013. Lastly, complaint No. 5478 detailed an incident not relevant to this appeal.

¶ 13 Ingalls also responded to the circuit court's order and plaintiff's motion, arguing that, under the Medical Studies Act and the Patient Safety Act, the documents were privileged. Under the Patient Safety Act, Ingalls posited that the documents constituted patient safety work product, as they were assembled for submission to a patient safety organization for the purpose of improving patient safety and the quality of health care.

¶ 14 Ingalls attached an affidavit from Linda Conway, its associate general counsel, who averred that, in 2009, Ingalls contracted with Clarity Patient Safety Organization (Clarity), a federally certified patient safety organization, to conduct activities to improve the hospital's patient safety and quality of health care pursuant to the Patient Safety Act. Conway asserted that the documents at issue were created, prepared, and generated for submission to Clarity for those purposes. According to Conway, the documents were patient safety work product, and the health care safety zone portal provided the means for Ingalls to report such work product to Clarity.

¶ 15 Plaintiff did not reply to Ingalls's filing.

¶ 16 On November 28, 2016, following a hearing on plaintiff's motion to compel, the circuit court granted the motion in part and denied the motion in part, requiring Ingalls to disclose only the portions of the documents that it had circled, which were parts of incident review No. 25472, incident review No. 25753, and complaint No. 5101. The court determined that the information it circled was "obtained prior to the peer review" and thus discoverable. Ingalls's attorney posited that, while that may be the standard under the Illinois Medical Studies Act, it was not under the federal Patient Safety Act, which required only that the work product be assembled for purposes of reporting to a patient safety organization and actually be reported. The circuit court responded that, unless the information in the documents had been tendered to plaintiff in some other form, such as medical records, Ingalls could not broadly assert a privilege on the information circled in the documents. The court observed that the documents contained "some of plaintiff's medical history" and conversations with her family and that Ingalls could not simply use the documents in peer review for purposes of shielding them from disclosure. The court, however, ordered complaint No. 5478 not to be disclosed in its entirety.

¶ 17 Ingalls filed a motion to reconsider, focusing its argument entirely on the documents being privileged under the Patient Safety Act. Ingalls attached a supplemental affidavit from Conway, who averred that Ingalls maintained a patient safety evaluation system for purposes of collecting information in order to report it to Clarity. She additionally stated that the information contained in incident review No. 25472, incident review No. 25753, and complaint No. 5101 was assembled, developed, and prepared "solely" for submission to Clarity and that Ingalls reported the documents to Clarity through its health care safety zone portal. Conway added that the documents were not Jones's original medical records and Ingalls had produced all original medical records to plaintiff. Conway asserted that the

documents had never been removed from the patient safety evaluation system for any purpose other than for internal quality purposes and they had not been reported to, or investigated by, any other agency or organization other than Clarity. Lastly, she stated that there were no other reports pertaining to the incidents alleged in plaintiff's complaint that were collected or maintained separately from Ingalls's patient safety evaluation system.

¶ 18 Plaintiff did not file a response, but during the hearing on the motion to reconsider, her attorney asserted that this was because he was "not privy" to the documents and thus could not adequately address the Patient Safety Act's application to them. The circuit court denied Ingalls's motion. Thereafter, Ingalls refused to comply with the court's production order and requested that the court find it in "friendly contempt" in order to facilitate appellate review of the privilege issue. The court subsequently found Ingalls in contempt and imposed a sanction of $1.

¶ 19 Ingalls timely appealed the circuit court's order finding it in contempt pursuant to Illinois Supreme Court Rule 304(b)(5) (eff. Mar. 8, 2016), which provides for the appeal of contempt orders imposing monetary sanctions. When a party appeals a contempt order based on a discovery violation, the underlying discovery order also becomes subject to appellate review. *Harris v. One Hope United, Inc.*, 2015 IL 117200, ¶ 6.

¶ 20 During the pendency of this appeal, we allowed the Illinois Health and Hospital Association, the American Medical Association, the Alliance for Quality Improvement and Patient Safety, the Illinois State Medical Society, and Clarity to file a joint *amicus curiae* brief in support of Ingalls. We also allowed the Illinois Trial Lawyers Association to file an *amicus curiae* brief in support of plaintiff.

¶ 21 II. ANALYSIS

¶ 22 On appeal, Ingalls contends that the circuit court erred in ordering the disclosure of the documents because they constitute patient safety work product and are privileged under the plain language of the Patient Safety Act. Ingalls further contends that the Patient Safety Act's privilege protection on such work product preempts the court's production order.

¶ 23 A. Whether the Documents Constitute Patient Safety Work Product

¶ 24 1. Discovery Generally

¶ 25 We begin by addressing the propriety of the circuit court's discovery order, which compelled the production of incident review No. 25472, incident review No. 25753, and complaint No. 5101. In plaintiff's brief, she does not identify on what basis she had a right to the documents, but in her motion to compel filed in the circuit court, she argued that they should be discoverable because of "Illinois broad discovery rules." Presumably plaintiff was referring to our supreme court rules on discovery, particularly Rule 201(b), which defines the scope of discovery in civil cases. See Ill. S. Ct. R. 201(b) (eff. July 1, 2014). Under the rule, "full disclosure" is the default discovery rule with only a few delineated exceptions, and a party may obtain discovery "regarding any matter relevant to the subject matter involved in the pending action, whether it relates to the claim or defense of the party seeking disclosure or of any other party, including the existence, description, nature, custody, condition, and location of any documents or tangible things, and the identity and location of persons having knowledge of relevant facts." Ill. S. Ct. R. 201(b)(1) (eff. July 1, 2014).

¶ 26 One such exception to the full disclosure requirement is privileged documents. Ill. S. Ct. R. 201(b)(2) (eff. July 1, 2014). Privileges are created "to protect interests outside the truth-seeking process," and therefore, they must "be strictly construed as exceptions to the general duty to disclose." *Klaine v. Southern Illinois Hospital Services*, 2016 IL 118217, ¶ 15. The burden of establishing the applicability of a privilege is on the party seeking to invoke it, here Ingalls. *Eid v. Loyola University Medical Center*, 2017 IL App (1st) 143967, ¶ 40. A party may meet this burden by submitting the allegedly privileged materials for an *in camera* review or by submitting affidavits setting forth facts sufficient to establish the applicability of the privilege to the particular documents being withheld. *Nielson v. SwedishAmerican Hospital*, 2017 IL App (2d) 160743, ¶ 39. Ingalls did both in this case.

¶ 27 2. Standard of Review

¶ 28 Generally, we review an order of the circuit court compelling discovery for an abuse of discretion. *Klaine*, 2016 IL 118217, ¶ 13. However, where a party challenges a discovery order on the basis that documents are subject to a statutory privilege, the issue becomes one of statutory construction, which is a question of law, and we therefore review the issue *de novo*. *Id.* As this case causes us to interpret the Patient Safety Act, we are guided by well-settled principles of statutory construction. The primary objective in construing a statute is to determine and give effect to the intent of the legislature. *Id.* ¶ 14. "The most reliable indicator of legislative intent is the language of the statute, given its plain, ordinary, and popularly understood meaning." *Id.* If the statute's language is unambiguous, the statute must be interpreted as written without resorting to any external aids of statutory construction. *Id.* Yet, we also must presume that the legislature did not intend for the effect of a statute to cause absurd or unjust results. *Id.*

¶ 29 3. The Patient Safety Act

¶ 30 In 1999, the Institute of Medicine released a report titled "To Err Is Human: Building a Safer Health System," in which it estimated that as many as 98,000 Americans die every year as a result of preventable medical errors. S. Rep. No. 108-196, at 2 (2003). The Institute of Medicine concluded that most errors were triggered by failures of the health care system and advocated for the creation of a reporting system "through which medical error information can be identified, analyzed and utilized to prevent further medical errors." *Id.* The Institute of Medicine, however, observed the difficulty of obtaining participation in such a system because "the threat of malpractice litigation discourages health care professionals and organizations from disclosing, sharing, and discussing information about medical errors." *Id.* Given this reluctance, the Institute of Medicine recommended that Congress pass legislation that encouraged the sharing of information but gave health care providers legal protection in return. *Id.*

¶ 31 In 2005, partially in response to the Institute of Medicine's report, Congress enacted the Patient Safety Act. Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (codified at 42 U.S.C. § 299b-21 *et seq.*). The federal law created a system of voluntary, confidential, and nonpunitive sharing of health care errors to facilitate and promote strategies to improve patient safety and the quality of health care. Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,732 (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3). To facilitate the sharing of medical errors, Congress provided for the creation of patient safety

organizations, private or public entities certified by the United States Department of Health and Human Services (HHS), to receive information about medical errors, analyze the errors, and recommend strategies to health care providers to prevent such errors in the future. 42 U.S.C. §§ 299b-21(4), 299b-24 (2012); S. Rep. No. 108-196, at 5 (2003); H.R. Rep. No. 109-197, at 9 (2005).

¶ 32 Aware that health care providers would be reluctant to share such sensitive patient safety information, Congress included "privilege and confidentiality protections" to encourage the sharing of "data within a protected legal environment, both within and across states, without the threat that the information will be used against the subject providers." Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,732 (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3). These 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." *Id.* at 70,741.

¶ 33 To this end, in relevant part, the Patient Safety Act provides:

> "Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be privileged and shall not be—
>
> (1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;
>
> (2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider[.]" 42 U.S.C. § 299b-22(a)(1), (2) (2012).

"Patient safety work product" is

> "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—
>
> (i) which—
>
> (I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or
>
> (II) are developed by a patient safety organization for the conduct of patient safety activities;
>
> and which could result in improved patient safety, health care quality, or health care outcomes; or
>
> (ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system." *Id.* § 299b-21(7)(A).

Thus, this definition provides three distinct ways that information can become patient safety work product. See Patient Safety and Quality Improvement Act of 2005—HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations, 81 Fed. Reg. 32,655, 32,656 (May 24, 2016) (to be codified at 42 C.F.R. pt. 3) (hereinafter Patient Safety Act Guidance).

¶ 34 A "provider" includes large health care entities such as hospitals or nursing facilities as well as individual providers such as physicians, nurse practitioners, or physical therapists. 42

U.S.C. § 299b-21(8) (2012). A provider's overall process of collecting patient safety work product in order to report the information to a patient safety organization is considered a "patient safety evaluation system." *Id.* § 299b-21(6). The Secretary of HHS compiles and maintains a list of the federally certified patient safety organizations, and providers face fines of up to $10,000 each time they knowingly or recklessly disclose certain patient safety work product. *Id.* §§ 299b-22(f)(1); 299b-24(d).

¶ 35 Here, there is no dispute that Ingalls, as a hospital, is a statutorily defined provider, nor is there any dispute that Clarity is a federally certified patient safety organization. Consequently, this appeal turns on whether the information contained in incident review No. 25472, incident review No. 25753, and complaint No. 5101 constitutes patient safety work product.

¶ 36 4. Patient Safety Work Product

¶ 37 As discussed, there are three distinct ways that information can become patient safety work product. See *id.* § 299b-21(7)(A). Ingalls argues that its documents constitute patient safety work product under the first method, which is considered the "reporting pathway." Patient Safety Act Guidance, 81 Fed. Reg. 32,655, 32,656 (May 24, 2016) (to be codified at 42 C.F.R. pt. 3).[2] Under the reporting pathway, patient safety work product is "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" that "are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization" and "which could result in improved patient safety, health care quality, or health care outcomes." 42 U.S.C. § 299b-21(7)(A)(i)(I) (2012). The regulations substantially echo this formulation but add that the documentation must include the date the information is entered into the patient safety evaluation system. 42 C.F.R. § 3.20 (2016). Under the reporting pathway, the critical inquiry is the purpose of creating the information, and the information will only be considering patient safety work product if it is created "*for the purpose of* reporting" to a patient safety organization. (Emphasis in original.) Patient Safety Act Guidance, 81 Fed. Reg. 32,655, 32,656 (May 24, 2016) (to be codified at 42 C.F.R. pt. 3).

¶ 38 Based on the plain language of the statute and regulations, there are four requirements necessary for the broad class of information to be considered patient safety work product under the reporting pathway: (1) the information must be developed by a provider for the purpose of reporting to a patient safety organization; (2) that information must have the ability to improve patient safety and the quality of health care; (3) that information must be reported to the patient safety organization, though there is some leeway for "functional reporting" of the information (see Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,741 (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3)), which is not relevant to this appeal; and (4) the information contains the date it was entered into the patient safety evaluation system.

¶ 39 Although the Patient Safety Act provides protection for information constituting patient safety work product, Congress did not intend the law to provide absolute protection for all documents related to patient safety. See H.R. Rep. No. 109-197, at 9 (2005) (explaining that the disclosure protections only apply to "certain categories of documents and

[2]While the interpretation of a statute by the agency charged with its administration is not binding on courts, the interpretation is entitled to deference. *Chevron, U.S.A., Inc. v. National Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984).

communications"). In turn, the Patient Safety Act contains a "Clarification" to the definition of patient safety work product and lists two exceptions. 42 U.S.C. § 299b-21(7)(B) (2012).

¶ 40 Under the first exception, "[i]nformation described in [the general definition of patient safety work product] does not include a patient's medical record, billing and discharge information, or any other original patient or provider record." *Id.* § 299b-21(7)(B)(i). The regulations do not expound on this exception. See 42 C.F.R. § 3.20 (2016). But the legislative history of the Patient Safety Act explains that "there may be documents or communications that are part of traditional health care operations or record keeping" such as "medical records, billing records, guidance on procedures, physician notes, hospital policies, logs of operations, records of drug deliveries, and primary information at the time of events." H.R. Rep. No. 109-197, at 14 (2005). While "these original documents and ordinary information about health care operations may be relevant to a patient safety evaluation system," they "are not themselves patient safety work product." *Id.*; see also Patient Safety Act Guidance, 81 Fed. Reg. 32,655, 32,658 (May 24, 2016) (to be codified at 42 C.F.R. pt. 3) (stating that "original provider records" include "[o]riginal records (*e.g.*, reports or documents) that are required of a provider to meet any Federal, state, or local public health or health oversight requirement regardless of whether such records are maintained inside or outside of the provider's [patient safety evaluation system]").

¶ 41 Under the second exception, "[i]nformation described in [the general definition of patient safety work product] does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product." 42 U.S.C. § 299b-21(7)(B)(ii) (2012). In other words, if information was created for "purposes other than reporting" to a patient safety organization, it is not considered patient safety work product. Patient Safety Act Guidance, 81 Fed. Reg. 32,655, 32,656 (May 24, 2016) (to be codified at 42 C.F.R. pt. 3). The Patient Safety Act created a protected system that does not replace, but rather resides alongside, external collection activities mandated by state and federal laws and regulations. *Id.* at 32,657. For example, "[i]nformation is not patient safety work product if it is collected to comply with external obligations" such as "state incident reporting requirements," "adverse drug event information reporting to the Food and Drug Administration," or "certification or licensing records for compliance with health oversight agency requirements," among other obligations. Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,742-43 (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3).

¶ 42 Although there could be instances where documents fit both exceptions, the crux of the exceptions are that, where health care providers create records for more than one purpose, the records themselves do not qualify as patient safety work product because the intent of the Patient Safety Act "is to protect the additional information created through voluntary patient safety activities, not to protect records created through providers' mandatory information collection activities." Patient Safety Act Guidance, 81 Fed. Reg. 32,655, 32,655 (May 24, 2016) (to be codified at 42 C.F.R. pt. 3). Where other laws require the reporting of health care information, the burden is on providers to assemble separate and original information for purposes of meeting those reporting requirements and then create additional information as part of their voluntary participation under the Patient Safety Act. See Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,743 (Nov. 21, 2008) (to be codified at 42

C.F.R. pt. 3) ("The final rule is clear that providers must comply with applicable regulatory requirements and that the protection of information as patient safety work product does not relieve a provider of any obligation to maintain information separately."); see also *University of Kentucky v. Bunnell*, 532 S.W.3d 658, 668 (Ky. Ct. App. 2017) ("When a provider participates in this voluntary program, the data it generates for that program must be superfluous to the documentation necessary for patient care or regulatory compliance."). Health care providers should not commingle information necessary to satisfy mandatory record keeping or reporting obligations with information used in their voluntary participation under the Patient Safety Act. See Patient Safety Act Guidance, 81 Fed. Reg. 32,655, 32,659 (May 24, 2016) (to be codified at 42 C.F.R. pt. 3) (recommending that a provider maintain at least two separate systems, one where it maintains records necessary to satisfy external obligations and the other, its patient safety evaluation system, where it maintains patient safety work product).

¶ 43 Lastly, the statutory "Clarification" provides that

> "[n]othing in this part shall be construed to limit—
>
> (I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;
>
> (II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or
>
> (III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law." 42 U.S.C. § 299b-21(7)(B)(iii) (2012).

The regulations explain that this language simply means that "[n]othing in this part shall be construed to limit information that is not patient safety work product from being" discovered in civil proceedings, reported to other government agencies for public health purposes, or maintained as part of a provider's record-keeping obligations under any other law. 42 C.F.R. § 3.20 (2016).

¶ 44 5. Illinois Precedent on the Patient Safety Act

¶ 45 The only case in Illinois that has examined the Patient Safety Act is *Department of Financial & Professional Regulation v. Walgreen Co.*, 2012 IL App (2d) 110452, which was filed four years before HHS issued additional guidance on the law. See Patient Safety Act Guidance, 81 Fed. Reg. 32,655 (May 24, 2016) (to be codified at 42 C.F.R. pt. 3). In the case, the Department of Financial and Professional Regulation (Department) issued three subpoenas to Walgreen Company, requesting reports of medication error involving three pharmacists it employed. *Walgreen*, 2012 IL App (2d) 110452, ¶ 3. Months later, after Walgreen failed to turn over the reports, the Department filed a petition to enforce the subpoenas. *Id.* Walgreen responded by filing a motion to dismiss, arguing that the requested reports were privileged under the Patient Safety Act as patient safety work product. *Id.* ¶¶ 4-5. Walgreen attached an uncontested affidavit to its motion from its vice president of pharmacy services, who averred that Walgreen maintained reports containing information about improperly processed or filled prescriptions. *Id.* ¶ 6. Walgreen created a report each time one of its pharmacists made a prescription error and eventually submitted the reports to Walgreen's patient safety

organization. *Id.* In Walgreen's reply to its motion to dismiss, it attached another uncontested affidavit where its vice president of pharmacy services averred that the reports were the only ones created pertaining to medication error. *Id.* ¶ 8. The circuit court ultimately found that the reports were privileged patient safety work product and granted Walgreen's motion to dismiss. *Id.* ¶¶ 10-11.

¶ 46 On appeal, the Appellate Court, Second District, observed that the Patient Safety Act contained broad evidentiary protections to further the law's intent to improve patient safety through voluntary reporting of patient safety data. *Id.* ¶ 16. The court determined that the reports were created by Walgreen for purposes of reporting the information contained in them to its patient safety organization and that the reports were transmitted to the patient safety organization. *Id.* ¶ 18. The court accordingly found the reports privileged under the Patient Safety Act. *Id.* It did not, however, explicitly address the issue of preemption.

¶ 47 6. The Instant Case

¶ 48 In light of the Patient Safety Act, its regulations, the HHS guidance, and the decision in *Walgreen*, incident review No. 25472, incident review No. 25753, and complaint No. 5101 constitute patient safety work product. Our review of these documents 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. See 42 U.S.C. § 299b-21(7)(A) (2012). The affidavits from Linda Conway, Ingalls's associate general counsel, establish that the documents were assembled and prepared by Ingalls "solely" for submission to Clarity and they were reported to Clarity. See *id.* § 299b-21(7)(A)(i)(I); *Bunnell*, 532 S.W.3d at 690 (finding that, where a report "was created for the sole purpose of submission" to a patient safety organization "in accordance with" the Patient Safety Act "and for no other use whatsoever," the report was patient safety work product). Furthermore, based on Conway's affidavits, the information contained in the documents had the ability to improve patient safety and the quality of health care, and the documents themselves bear the dates information was entered into the patient safety evaluation system. See 42 U.S.C. § 299b-21(7)(A)(i)(I) (2012); 42 C.F.R. § 3.20 (2016). Therefore, the documents satisfied the requirements of patient safety work product.

¶ 49 Plaintiff, however, argues that these documents met three of the statutory exceptions to patient safety work product. See 42 U.S.C. § 299b-21(7)(B) (2012). First, plaintiff posits that information required to be in a patient's medical record is excluded from the definition of patient safety work product and thus not privileged. Under the Hospital Licensing Act, hospitals licensed in Illinois must create a medical record for each patient. 210 ILCS 85/6.17(a) (West 2016). The medical record must be "adequate, accurate, timely, and complete." 77 Ill. Adm. Code 250.1510(b)(2) (2017). The medical record must contain at a minimum several items, including, "[d]iagnostic and therapeutic reports on laboratory test results, x-ray findings, any surgical procedure performed, any pathological examination, any consultation, and any other diagnostic or therapeutic procedure performed," "[o]rders and progress notes made by the attending physician and, when applicable, by other members of the medical staff and allied health personnel," "[o]bservations notes and vital sign charting made by nursing personnel," and "[c]onclusions as to the primary and any associated diagnoses." *Id.*

¶ 50 As we interpret the Patient Safety Act, the "medical records" exception to patient safety work product means that, if a document is created for purposes of reporting to a patient safety

organization and that document references medical records, the original medical records themselves do not become part of the patient safety work product merely by being referenced. Instead, those records remain discoverable. According to HHS's final rule, while "information underlying an analysis may be protected," "underlying information that is original medical records may not be protected if it is excluded by the definition of patient safety work product." Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,743 (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3). In other words, if the information related to a patient's care or treatment is created as part of the patient's original medical record, that information is not patient safety work product. See Patient Safety Act Guidance, 81 Fed. Reg. 32,655, 32,657 (May 24, 2016) (to be codified at 42 C.F.R. pt. 3). But, if that same information is included within documents that are intended to be submitted to a patient safety organization, the documents containing the information are privileged. See *id.* Thus, contrary to plaintiff's argument, merely because information required to be in Jones'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.

¶ 51 Plaintiff further asserts that, based on the circuit court's comments following its review of the documents, it appears that information that should have been included in Jones's medical record, but was not, was instead only contained within the allegedly privileged documents. Highlighting what she considers "a large gap of time" and "ambiguity" in the care Jones received from Ingalls, plaintiff posits that the medical records currently disclosed during discovery "are almost entirely silent on the most important issues for approximately [seven] hours." In light of this, plaintiff insinuates that Ingalls had a nefarious intent when creating Jones's medical records and sought to abuse the Patient Safety Act by improperly concealing valuable health care information under the guise of patient safety work product to the detriment of the original medical records.

¶ 52 However, we cannot assume Ingalls violated its record-keeping requirements based on supposition. Ingalls's participation in the Patient Safety Act does not obviate its requirements to create an adequate, accurate, timely, and complete medical record for each patient. See *id.* ("[T]he Patient Safety Act does not permit providers to use the privilege and confidentiality protections for [patient safety work product] to shield records required by external recordkeeping or reporting requirements."). If Ingalls fails to properly record certain information mandated by law, there are associated consequences. See, *e.g.*, 210 ILCS 85/7(a) (West 2016) (providing that a hospital who fails to comply with the requirements of the Hospital Licensing Act, such as properly creating a patient's medical record, risks losing its operating license).

¶ 53 Furthermore, as Ingalls notes, the documents were not created contemporaneously with any treatment of Jones and were actually created more than two weeks after November 17 and 18, 2013, the critical time period according to the complaint. Ingalls further highlights that the author of the documents referenced reviewing Jones's actual medical records followed by a description of the data obtained from the records. We additionally reiterate that all three documents bear the notations of Ingalls's health care safety zone portal and "Clarity Group, Inc. Copyright." Based on Conway's affidavits, which establish that the documents were created solely for the purpose of submission to Clarity, the Healthcare Safety Zone Portal was the means of transmission to Clarity and the documents were actually submitted to Clarity, it is clear these documents were created for the specific purpose of submission to a patient safety

organization. See *Bunnell*, 532 S.W.3d at 672 (finding in part that, where a record was "created post-care for the specific purpose of submission to a [patient safety organization,]" the "subject matter" of the report was the event summarized in the report, "not the patient identified in the report" and, accordingly, the report did not constitute an original patient record). Consequently, nothing in the record leads us to believe that the documents were Jones's original medical records or contained information that should have been included in her original medical records.

¶ 54 Plaintiff next argues that the documents fall under a second exception to the definition of patient safety work product, positing that, based on the circuit court's comments following its review of them, it appears that the information contained in the documents was not collected solely for the purpose of reporting to a patient safety organization. Plaintiff highlights the court's statement that, while the documents were created for peer review, the content of the documents was "obtained prior to the peer review." As such, plaintiff asserts that these comments show the information in documents was created for a purpose other than for reporting directly to Clarity, including possibly for peer review under the Illinois Medical Studies Act, which Ingalls initially stated as a reason the documents were privileged.

¶ 55 As previously discussed, another exception to the definition of patient safety work product is information collected, maintained, or developed for a purpose other than reporting to a patient safety organization. 42 U.S.C. § 299b-21(7)(B)(ii) (2012). However, plaintiff ignores the unrebutted supplemental affidavit submitted by Ingalls, wherein Conway averred that the information in the documents was assembled, developed, and prepared "solely" for submission to Clarity, averments that we must accept as true. See *Nielson*, 2017 IL App (2d) 160743, ¶ 39; see also *Walgreen*, 2012 IL App (2d) 110452, ¶ 18 (rejecting a similar argument based on an unrebutted affidavit). Consequently, nothing in the record leads us to believe that the information in the documents was assembled, developed, or prepared for a purpose other than reporting to Ingalls's patient safety organization.

¶ 56 Lastly, plaintiff argues that the documents fall under a third exception to the definition of patient safety work product. Citing to section 299b-21(7)(B)(iii)(II) of the Patient Safety Act (42 U.S.C. § 299b-21(7)(B)(iii)(II) (2012)), plaintiff posits that any information collected to satisfy a reporting requirement to a state agency is not patient safety work product. In turn, plaintiff highlights the Illinois Adverse Health Care Events Reporting Law of 2005 (Adverse Events Law), which requires Illinois hospitals to report an adverse health care event to the Illinois Department of Public Health within 30 days of the event. 410 ILCS 522/10-10, 10-15 (West 2016).

¶ 57 Initially, we note that plaintiff misconstrues section 299b-21(7)(B)(iii)(II) of the Patient Safety Act (42 U.S.C. § 299b-21(7)(B)(iii)(II) (2012)). As discussed earlier, this subsection is not an exception to the definition of patient safety work product but, rather, a clarification on what the legislation does not prohibit. The regulations explain that this subsection simply means that "[n]othing in this part shall be construed to limit information that is not patient safety work product from being" discovered in civil proceedings, reported to other government agencies for public health purposes, or maintained as part of a provider's record-keeping obligations under any other law. 42 C.F.R. § 3.20 (2016). Rather, plaintiff's argument here falls under the second exception of the definition of patient safety work product (see 42 U.S.C. § 299b-21(7)(B)(ii) (2012)), where "[i]nformation is not patient safety work product if it is collected to comply with external obligations" such as "state incident reporting requirements."

Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,742 (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3). Regardless of this misconstruction, plaintiff posits that, because Ingalls had a reporting obligation under the Adverse Events Law, the information reported to Clarity under the Patient Safety Act can no longer be considered patient safety work product.

¶ 58 In *Charles v. Southern Baptist Hospital of Florida, Inc.*, 209 So. 3d 1199, 1205-06 (Fla. 2017), a hospital sought to shield certain adverse medical incident records from disclosure to a plaintiff. But the Supreme Court of Florida held that, because Florida's statutes and administrative rules required health care providers to create and maintain adverse medical incident reports, the hospital's reports "were not created solely" for the purpose of providing them to a patient safety organization and thus not patient safety work product. *Id.* at 1216. Similarly, in *Tibbs v. Bunnell*, 448 S.W.3d 796, 798 (Ky. 2014), a group of physicians sought to shield from disclosure to a plaintiff an incident report created by a surgical nurse shortly after a patient died during surgery. But the Supreme Court of Kentucky held that, because Kentucky's administrative regulations required incident investigation reports and the postincident report contained information that normally would be found in a report required by the regulations, the postincident report was not privileged despite the report being created in the physicians' patient safety evaluation system. *Id.* at 809.

¶ 59 Plaintiff would like for us to find just as the courts in *Charles* and *Tibbs* did, but as observed by Ingalls, Illinois's Adverse Events Law is not even operational at this point. According to the law, the Illinois Department of Public Health was required to establish an adverse health events reporting system by January 1, 2008 (410 ILCS 522/10-30(a) (West 2016)), but as of today, the law has not been implemented. See *Adverse Health Care Events*, Ill. Dep't of Pub. Health, http://dph.illinois.gov/topics-services/prevention-wellness/patient-safety-quality/adverse-health-care-events#laws-rules (last visited June 25, 2018) (stating that the Illinois Department of Public Health "is in the process of implementing this Act"). Thus, on the dates relevant to the complaint, Ingalls had no obligation to report any adverse health care events under the Adverse Events Law, rendering plaintiff's argument meritless.

¶ 60 In sum, plaintiff has failed to demonstrate that these documents fall under an exception to the definition of patient safety work product. But still, she and the Illinois Trial Lawyers Association, as *amicus curiae* in support of plaintiff, believe that allowing these documents to remain privileged would allow health care providers to hide valuable information and thus impede the truth-seeking process. However, nothing 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 health care 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 health care, 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.

¶ 61 B. Preemption

¶ 62 Having concluded that incident review No. 25472, incident review No. 25753, and complaint No. 5101 are patient safety work product, we next must determine whether the Patient Safety Act preempts the circuit court's production order of the documents. See *Diaz v. Provena Hospitals*, 352 Ill. App. 3d 1165, 1171 (2004) (after concluding that the federal Health Care Quality Improvement Act of 1986 required a hospital to file a report on a doctor, determining whether the federal law preempted the circuit court's orders to the contrary). As mentioned, the court's production order was presumably based on the full disclosure discovery rule found in our supreme court rules. See Ill. S. Ct. R. 201(b) (eff. July 1, 2014).

¶ 63 The supremacy clause of the United States Constitution provides that the laws of the United States "shall be the supreme Law of the Land" and "any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI. Under the supremacy clause, state action is " 'without effect' " where it conflicts with federal law. *Busch v. Graphic Color Corp.*, 169 Ill. 2d 325, 334 (1996) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). A federal statute will preempt state action in any of three circumstances: "(1) express preemption—where Congress has expressly preempted state action; (2) implied field preemption—where Congress has implemented a comprehensive regulatory scheme in an area, thus removing the entire field from the state realm; or (3) implied conflict preemption—where state action actually conflicts with federal law." *Carter v. SSC Odin Operating Co.*, 237 Ill. 2d 30, 39-40 (2010). Whether a federal law preempts state action is a question of law, and we therefore review the question *de novo*. *Kinkel v. Cingular Wireless, LLC*, 223 Ill. 2d 1, 15 (2006).

¶ 64 Preemption is not favored (*Bishop v. Burgard*, 198 Ill. 2d 495, 501 (2002)), and because of this, we generally begin with the presumption that Congress did not intent to preempt contrary state action. *Performance Marketing Ass'n v. Hamer*, 2013 IL 114496, ¶ 50 (citing *Maryland*, 451 U.S. at 746). However, if a federal statute contains an express preemption clause, we do not apply such a presumption. *Puerto Rico v. Franklin California Tax-Free Trust*, 579 U.S. ___, ___, 136 S. Ct. 1938, 1946 (2016). Thus, we begin by determining whether or not the Patient Safety Act contains an express preemption clause.

¶ 65 The Patient Safety Act states:

> "*Notwithstanding any other provision of Federal, State, or local law*, and subject to subsection (c) of this section, patient safety work product shall be privileged and shall not be—
>
> (1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;
>
> (2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider[.]" (Emphasis added.) 42 U.S.C. § 299b-22(a)(1), (2) (2012).

This language is clearly an express preemption clause. See *Bunnell*, 532 S.W.3d at 665 (stating that the Patient Safety Act uses "the language of federal preemption"). Additionally, in *State Bank of Cherry v. CGB Enterprises, Inc.*, 2012 IL App (3d) 100495, *aff'd*, 2013 IL 113836, we found an express preemption clause with similar wording. There, this court determined that the federal Food Security Act of 1985 (7 U.S.C. § 1631(d) (2006)) contained "a clear expression of an intent to preempt state law" when the federal law used the language: " 'Except as provided in subsection (e) of this section *and notwithstanding any other provision of Federal, State, or local law* ***.' " (Emphasis in original.) *Cherry*, 2012 IL App (3d) 100495, ¶¶ 14-16 (quoting 7 U.S.C. § 1631(d) (2006)). The language used in the Food Security Act is identical to that of the Patient Safety Act.

¶ 66 Despite our finding that the Patient Safety Act contains an express preemption clause, our inquiry does not end, as such language informs "us that Congress intended to supersede or modify state law to some extent, but courts must still deal with the task of determining the substance and scope of Congress' displacement of state law." *Performance Marketing*, 2013 IL 114496, ¶ 51. "If the text of a preemption provision is open to more than one plausible reading, courts ordinarily accept the reading that disfavors preemption." *Id.*

¶ 67 Here, the express preemption clause in the Patient Safety Act demonstrates Congress's intent to supersede any court order requiring the production of documents that meet the definition of patient safety work product. See *Quimbey v. Community Health Systems Professional Services Corp.*, 222 F. Supp. 3d 1038, 1043 (D.N.M. 2016) (finding that "the express language of the [the Patient Safety Act] demonstrates Congressional intent to preempt" any state laws providing for less protection of documents that constitute patient safety work product); Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,774 (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3) (stating that the Patient Safety Act "generally preempt[s] State or other laws that would permit or require disclosure of information contained within patient safety work product").

¶ 68 Furthermore, section 299b-22(g)(5) of the Patient Safety Act (42 U.S.C. § 299b-22(g)(5) (2012)) provides that nothing in the law should be construed as "preempting or otherwise affecting any State law requiring a provider to report information that is not patient safety work product." 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. Lastly, plaintiff's argument on the preemption issue buttresses our conclusion, as she only argues that, because the documents are not patient safety work product, the law cannot preempt the court's production order. With this argument, plaintiff, in essence, tacitly concedes the preemptive effect of the Patient Safety Act on the discovery order. Consequently, the Patient Safety Act preempts the circuit court's production order.

¶ 69 We briefly note the Supreme Court of Florida's decision in *Charles*, where, during discovery, the plaintiff filed requests for production pursuant to Florida's "Amendment 7," a provision in the Florida Constitution that provided patients a right to access any adverse medical incident records created by a health care provider in the course of business. *Charles*, 209 So. 3d at 1203-05 (citing Fla. Const., art. X, § 25(a)). Although potentially responsive to the request, the hospital refused to produce adverse medical incident records based on them being privileged under the Patient Safety Act. *Id.* at 1206. The plaintiff moved to compel the production of the documents, which the circuit court granted, finding that the documents were not patient safety work product. *Id.*

¶ 70 On appeal to the Supreme Court of Florida, after finding that the documents were not patient safety work product and not privileged, the court analyzed the preemption issue and ultimately found neither express nor implied preemption of "Amendment 7." *Id.* at 1213-16. Concerning express preemption, the court simply held: "[T]he documents to which citizens have a right to access pursuant to Amendment 7 are not patient safety work product under the Federal Act's definition. Accordingly, the Federal Act does not contain any express statement of preemption relating to Amendment 7." *Id.* at 1213. The court did not discuss express preemption any further beyond this holding.

¶ 71 Although we do not quite follow the legal reasoning employed in *Charles* to find that the Patient Safety Act did not contain an express preemption provision, we nevertheless find *Charles* plainly distinguishable from the instant case. First, the documents at issue in this case *are* patient safety work product. And second, plaintiff has failed to identify any similar Illinois constitutional provision mandating a patient's right to access his or her medical records like Florida's. But to the extent that the Supreme Court of Florida would find that the Patient Safety Act does not contain an express preemption provision with respect to documents that *are* patient safety work product, we disagree. As previously discussed, the Patient Safety Act contains an unambiguous express preemption clause (see 42 U.S.C. § 299b-22(a) (2012)), which clearly demonstrates Congress's intent to supersede any circuit court order requiring the production of documents that meet the definition of patient safety work product. See *Quimbey*, 222 F. Supp. 3d at 1043; *Bunnell*, 532 S.W.3d at 665; Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,774 (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3).

¶ 72 C. Contempt Finding

¶ 73 Lastly, Ingalls appealed this case pursuant to Illinois Supreme Court Rule 304(b)(5) (eff. Mar. 8, 2016), which allows the appeal of contempt findings. As discussed, when a party appeals a contempt order based on a discovery violation, the underlying discovery order also becomes subject to appellate review. *Harris*, 2015 IL 117200, ¶ 6. "If the discovery order is invalid, then the contempt order, for failure to comply with that discovery order, must be reversed." *In re D.H.*, 319 Ill. App. 3d 771, 773 (2001). As the discovery order in this case was invalid, we must reverse the circuit court's order finding Ingalls in contempt based on its failure to comply with the discovery order.

¶ 74 III. CONCLUSION

¶ 75 For the foregoing reasons, the orders of the circuit court of Cook County are reversed and the matter is remanded for further proceedings.

¶ 76 Reversed and remanded.