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Supreme Court of Kentucky

2015-SC-000657-MR

BAPTIST HEALTH RICHMOND, INC. — APPELLANT

ON REVIEW FROM COURT OF APPEALS
CASE NO. 2015-CA-001175-OA
MADISON CIRCUIT COURT NO. 14-CI-00455

V.

APPELLEE

HON. WILLIAM G. CLOUSE, JR.,
JUDGE MADISON CIRCUIT COURT,
DIVISION I

AND

TIM AGEE, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF EVA LOUISE NALL (AGEE), DECEASED — REAL PARTY IN INTEREST

OPINION OF THE COURT BY JUSTICE KELLER

VACATING AND REMANDING

Baptist Health Richmond, Inc. petitioned the Court of Appeals for a writ prohibiting the Madison Circuit Court from enforcing its order requiring Baptist Health to produce certain documents that had been requested in discovery by the real party in interest. The Court of Appeals denied the petition, and Baptist Health appeals from that denial. The issue on appeal is whether the requested documents are protected from disclosure by the Patient Safety and Quality Improvement Act of 2005 (the Act), 42 U.S.C.A. § 299b-21 *et. seq.* Having reviewed the record and the arguments of the parties, we vacate the trial

court's discovery order and remand for further proceedings consistent with this opinion.

I. BACKGROUND.

Eva Louise Nall (Agee) underwent laproscopic surgery and subsequently died. Her husband, Tim Agee, individually and on behalf of her estate, sued Baptist Health and a number of medical care providers alleging that her death was the result of medical negligence. During discovery, Mr. Agee propounded a request for production of documents to Baptist Health. The request at issue sought: "any and all incident reports, investigation reports, sentinel event reports, root cause analysis reports, Joint Commission reports, Medicare reports, Medicaid reports, peer review reports and reports of any nature relating to Eva Louise Nall (Agee)." Baptist Health designated which documents it believed fell within the request but refused to produce them claiming that they were protected from disclosure by the Act. Mr. Agee filed a motion to compel, which the trial court granted in part, holding that only those documents that had been "collected, maintained, or developed for the sole purpose of disclosure to a Patient Safety Organization pursuant to the [Act]" are protected. As set forth above, Baptist Health then filed an original action in the Court of Appeals seeking a writ of prohibition. The Court of Appeals denied Baptist's request, holding that the "sole purpose" standard applied by the trial court is consistent with this Court's opinion in *Tibbs v. Bunnell,* 448 S.W.3d 796 (Ky. 2014).

II. ANALYSIS.

We begin our analysis with a review of *Tibbs,* a plurality opinion.[1] Although a majority of the Court agreed with the outcome in *Tibbs*, less than a majority agreed on the reasoning; therefore, *Tibbs* has no *stare decisis* effect. *See Ware v. Commonwealth,* Ky., 47 S.W.3d 333, 335 (2001). However, *Tibbs* is certainly persuasive, and we find much with which we can agree in both the plurality and the dissenting opinions.

The trial court in *Tibbs* ordered the hospital to produce an "incident" or "event" report that had been generated by a hospital surgical nurse after the death of a patient. 448 S.W.3d at 798. Several physicians sought to prevent disclosure of that report, arguing that it was protected by the Act. *Id.* The trial court ordered the hospital to produce the report, and the physicians sought protection from the Court of Appeals via a writ of prohibition. *Id.* The Court of Appeals issued the requested writ, but found that the Act's protection only extended to "documents that contain a self-examining analysis." *Id.* at 799. In doing so, the Court of Appeals relied, in large part, on *Francis v. United States*, No. 09 Civ. 4004 (GBD)(KNF), 2011 WL 2224509 (S.D.N.Y. May 31, 2011) which indicated that the scope of the Act's privilege extended only to the analysis and corrective actions related to an adverse event of medical error. *Tibbs,* 448 S.W.3d at 802. Thus, the Court of Appeals remanded the matter to

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[1] Justice Scott wrote the plurality opinion, in which Justices Venters and Cunningham fully concurred. Justice Noble concurred in result only without separate opinion and Justice Hughes wrote a dissenting opinion which Chief Justice Minton joined. Justice Keller did not sit because she had presided over the Court of Appeals panel that granted the requested writ.

the trial court for an *in camera* review to determine if the requested document contained that type of self-examining analysis. *Id.*

In analyzing the Court of Appeals's opinion, the plurality opinion in *Tibbs* pointed out that Congress enacted the Act:

> [I]n order to encourage health care providers to voluntarily associate and communicate privileged patient safety work product . . . among themselves through in-house patient safety evaluation systems . . . and with and through affiliated patient safety organizations . . . in order to hopefully create an enduring national system capable of studying, analyzing, disseminating, and acting on events, solutions, and recommendations for the betterment of national patient safety, healthcare quality, and healthcare outcomes.

Tibbs, 448 S.W.3d at 800. To incentivize participation, the Act provides protection from disclosure to "certain categories of documents and communications termed 'patient safety work product' that are developed in connection with newly created patient safety organizations. This patient safety work product is considered privileged and, therefore, cannot be subject to disclosure." *Id.* at 801 (*quoting* H.R. Rep. No. 109-197, 9 (2005)).

The plurality opinion then noted that the Court of Appeals's reliance on *Francis* was misplaced because the language cited by the Court was *dicta*. *Id.* at 802. Furthermore, the plurality opinion noted that "the Court of Appeals relied on commentary from *Francis* regarding a prior version of the Act that never became law, rather than on the Act itself." *Id.* Therefore, the plurality opinion determined that the Court of Appeals erred by limiting the scope of review by the trial court to "documents employing a self-critical analysis." *Id.* at 802.

The plurality opinion then undertook its own analysis of the Act and set forth what it believed to be the proper scope of the Act's privilege and the resultant scope of the trial court's review. As cited by the plurality opinion, the Act defines patient safety work product as:

> any data, reports, records, memoranda, and 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 healthcare 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.

Tibbs, 448 S.W.3d at 803 (*quoting* 42 U.S.C.A. § 299b–21 (7)(A)). However, as the plurality opinion noted, Section (B) of 42 U.S.C.A. § 299b-21 (7) excepts certain material from being considered patient safety work product. *Id.*

> (i) Information described in subparagraph (A) *does not include* a patient's medical record, billing and discharge information, or any other original patient or provider record.
>
> (ii) Information described in subparagraph (A) 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.
>
> (iii) Nothing 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.

Id. Thus, the plurality opinion determined that the Act does not "protect information 'collected, maintained or developed separately, or existing separately from a patient safety evaluation system' even if collected by a Patient Safety Evaluation System and reported to a Patient Safety Organization." *Tibbs*, 448 S.W.3d at 803-04. As the plurality opinion noted,

> [T]he [Act] did not intend to supplant, or invalidate, traditional state monitoring or regulation of health providers. *See* 42 U.S.C.A. § 299b-21(7)(B)(i)-(iii). . . . [T]he United States Department of Health and Human Services' own final rules negate any such intent: "The Patient Safety Act establishes a protected space or system that is separate, distinct, and resides alongside *but does not replace* other information collection activities mandated by laws, regulations, and accrediting and licensing requirements as well as voluntary reporting activities that occur for the purpose of maintaining accountability in the health care system."

Id. at 807 (*quoting* Patient Safety and Quality Improvement, 73 FR 70732-01 at 70742) (emphasis added in opinion). Thus, the Act recognizes that providers who participate in the Act may be subject to "dual reporting obligations." *Id.*

The plurality opinion noted that Kentucky mandates that:

> Administrative reports shall be *established, maintained and utilized* as necessary to guide the operation . . . of" [health care facilities.]

> 902 KAR 20:016 § 3(3)(a) (emphasis added). Such reports shall include, among others, "incident investigation reports . . . and . . . [o]ther pertinent reports made in the regular course of business." *Id.* And such facilities shall "have written policies and procedures governing all aspects of the operation of the facility and the services provided, including: . . . (g) [a]n effective procedure for recording accidents involving a patient . . . , including incidents of transfusion reactions, drug reactions, medication errors, and similar events . . . ." 902. KAR 20:016 § 3(4).

Id. at 808.

Based on the preceding, the plurality opinion determined that the information in the incident report in question "would be found in an incident report which is required by Kentucky regulations to be 'established, maintained and utilized as necessary to guide the operation . . . of the facility.' 902 KAR 20:016 § 3(3)(a)." *Id.* at 809. The plurality opinion noted that the physicians claimed the privilege applied because the information was not kept separately but "was filed and stored in a database ostensibly dedicated to the Hospital's Patient Safety Evaluation System operated by its Risk Management Department and to which the hospital's [patient safety organization] has access." *Tibbs,* 448 S.W.3d at 809. However, the plurality opinion concluded that, while the information might "be relevant to [the hospital's] endeavors under the Act, it is not, nor can it be, patient safety work product, since its collection, creation, maintenance, and utilization is mandated by the Commonwealth of Kentucky as part of its regulatory oversight of its healthcare facilities." *Id.* Thus, the plurality opinion concluded that the trial court should, on remand, separate the information "normally contained in . . . state-

mandated incident reports" from "material properly privileged under the Act," and permit discovery of the non-privileged information. *Id.*

The dissent agreed with much of what the plurality opinion said about the Act and that "patients or their estates are entitled to" information contained in state mandated reports. *Id.* at 810. As the dissent noted, the Act does not displace state law because:

> *[W]hen laws or regulations require the reporting of the information regarding the type of events also reported to [patient safety organizations], the Patient Safety Act does not shield providers from their obligation to comply with such requirements.* These external obligations must be met with information that is not patient safety work product and oversight entities continue to have access to this original information in the same manner as such entities have had access prior to the passage of the Patient Safety Act.

Id., at 814 (*quoting* Patient Safety and Quality Improvement, 73 FR 70732-01 at 70742)(emphasis added in opinion).

However, the dissent also noted that:

> [The Senate Committee found] that broad protections are essential to encourage reporting. Currently, there are few incentives and many barriers for providers to collect and report information regarding patient safety. The primary barrier relates to concerns that information shared to promote patient safety would expose providers to liability. Unless this information can be freely shared, errors will continue to be hidden and errors will be repeated. A more open, nonpunitive learning environment is needed to encourage health care professionals and organizations to identify, analyze, and report errors without facing the threat of litigation and, at the same time, without compromising plaintiffs' legal rights or affecting existing and future public reporting initiatives with respect to the underlying data.

Tibbs, at 813-14.

According to the dissent, permitting judges "to sift through federally protected patient safety data for otherwise discoverable material under state law . . . [would] frustrate the Act's intent." *Id.* 810. Thus, the dissent concluded that material, once included in the patient safety evaluation system or submitted to a patient safety organization, is protected until removed from that system or organization. Therefore, the only questions for a trial court to answer in a discovery dispute would be: was the requested information ever included in the patient evaluation system and, if it was included, was it removed. If the answer to the first question is, "Yes," and the answer to the second question is, "No," then the information would be protected from discovery.

While this matter has been pending, the Department of Health and Human Services (HHS) issued additional guidance regarding interpretation and implementation of the Act. In pertinent part, HHS stated that "the 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." Patient Safety and Quality Improvement Act of 2005—HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations, 81 FR 32655-01 at 32657. HHS went on to note that providers have been misusing the Act in two ways to shield from discovery otherwise discoverable documents.

> First, some providers with recordkeeping or record maintenance requirements appear to be maintaining the required records only in their [patient safety evaluation system] and then refusing to disclose the records, asserting that the records in their [patient

> safety evaluation system] fulfill the applicable regulatory requirements while at the same time maintaining that the records are privileged and confidential [patient safety work product]. Second, some providers appear to develop records to meet external obligations outside of the [patient safety evaluation system], place a duplicate copy of the required record into the [patient safety evaluation system], then destroy the original outside of the [patient safety evaluation system] and refuse to disclose the remaining copy of the information, asserting that the copy is confidential and privileged [patient safety work product]. The Patient Safety Act was not intended to give providers such methods to evade their regulatory obligations.

Id. at 32657-58. Therefore,

> HHS interprets "original provider records" to include: (1) Original 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; and (2) copies of records residing within the provider's [patient safety evaluation system] that were prepared to satisfy a Federal, state, or local public health or health oversight record maintenance requirement, if while the provider is obligated to maintain such information, the information is only maintained by the provider within the [patient safety evaluation system] (e.g., if the records or documents that were being maintained outside the [patient safety evaluation system] to fulfill the external obligation were lost or destroyed).

Id. at 32658 (footnote omitted). Thus, reports that are required by the Commonwealth do not become privileged because the provider puts them in its patient safety evaluation system.

The dissent noted that there might be times when a hospital would not "generate a state-mandated record or report" thus frustrating a civil plaintiff's legitimate request for information. *Tibbs,* 448 at 815-16. The dissent's solution to this dilemma is for "an interested party to demand that a required record or report be generated." *Id.* at 816. However, as HHS states, the

solution is "for providers . . . to satisfy their external obligations outside of a [patient safety evaluation system]." 81 FR 32655-01 at 32658. Providers who satisfy those obligations should then have no fear that trial courts will be meddling in federally protected documentation.

Having reviewed *Tibbs,* the arguments of the parties, the *amicus curiae* herein, and the new HHS guidance, we believe that the correct result in this case lies in middle ground between the plurality and the dissenting opinions in *Tibbs*. We agree with the dissent that mandating invasion of "the hospital's patient safety evaluation system" by trial courts every time there is a discovery dispute would "discourage participation in the patient safety system by Kentucky's healthcare providers." *Id.* at 816. However, permitting hospitals to place and leave otherwise discoverable information in the patient safety evaluation system in order to shield it from discovery is equally unacceptable and, as noted by HHS, is not in keeping with the Act. Furthermore, the dissent in *Tibbs* did not state how an interested party would make a demand that a provider generate a report; to whom that demand would be made; or what mechanism exists to enforce any order granting such a demand. Thus, we believe that the solution offered by the dissent in *Tibbs* is not viable.

In summary, a provider who participates in the Act may collect information within its patient safety evaluation system that complies with the Act and that also complies with state statutory and regulatory requirements. However, doing so does not relieve the provider from complying with those state requirements and, to the extent information collected in the provider's internal

patient safety evaluation system is needed to comply with those state requirements, it is not privileged.

The existence of the Act does not relieve providers from fulfilling their statutory and regulatory reporting obligations. As long as a provider fulfills those obligations, the trial court has no reason to review the information in the provider's patient safety evaluation system. However, if a provider fails to fulfill those obligations, the court can conduct an *in camera* review of the documents in the provider's patient safety evaluation system. In conducting that review, the court should separate the information that is usually contained in state-mandated reports from information that is not usually contained in those reports. The information that is usually contained in state-mandated reports is not protected by the patient safety work product privilege provided in the Act and will be discoverable. Because the provider is claiming the privilege, it bears the burden of proving that it complied with the statutory and regulatory reporting requirements. If the provider fails to meet that burden, the party seeking the information then bears the burden of establishing what information is generally contained in state-mandated reports.

III. CONCLUSION.

For the foregoing reasons, we vacate the trial court's order requiring Baptist Health Richmond, Inc. to produce documents, and we remand with instructions for the court to undertake the review as set forth herein.

All sitting. Keller, Cunningham, Noble and Venters, JJ., concur. Hughes, J., concurs by separate opinion in which Minton, C.J. and Wright, J., join.

HUGHES, J., CONCURRING: I concur. After this Court's issuance of *Tibbs v. Bunnell*, 448 S.W.3d 796 (Ky. 2014) and the Court of Appeals' denial of a writ in this case, as Justice Keller notes, the Department of Health and Human Services (HHS) issued a much-needed "Guidance Regarding Patient Safety Work Product and Providers' External Obligations" (Guidance). In that May 24, 2016 document, HHS clarified that records, or copies of records, required of a provider "to meet any Federal, state, or local public health or health oversight requirement," regardless of where maintained, are "original provider records" not subject to the privilege arising under the Patient Safety and Quality Improvement Act of 2005 (PSQIA). The Guidance answers the thorny question of what happens if a provider objects to production on the grounds that certain documents reside only in their patient safety evaluation system created pursuant to PSQIA. I write separately simply to clarify my understanding as to how a document request should be handled in cases where the PSQIA is raised as a defense to production.

First, the trial court should determine whether any of the documents and reports requested (and, obviously, relevant to the case before it) qualify as "original provider records" under the above-cited Guidance definition regarding Federal, state, or local public health or health oversight requirements. Notably, HHS actually referenced a Kentucky administrative regulation as an example of

a state mandating that a provider maintain a particular record, *i.e.*, an incident investigation report: "In Kentucky, hospitals are required to 'establish[], maintain[], and utilize[]' administrative reports, including incident investigation reports, 'to guide the operation, measure productivity, and reflect the programs of the facility.' 902 KAR 20:016 Section 3(3)(a)." Guidance at n.3. To the extent any document or record is state-mandated or otherwise fits within the "original provider record" definition from the Guidance, the court should order its production. While there was some ambiguity prior to May 24, 2016, it is now clear that even if that record is maintained solely in a patient safety evaluation system, an order of production is proper and the PSQIA poses no obstacle. Providers such as Baptist Health Richmond, Inc., undoubtedly recognize their so-called "external obligations," as explained in the Guidance, and should have such records available for prompt production. Only if they have failed to fulfill those obligations, as Justice Keller notes, should the trial court proceed to an *in camera* review of the contents of the provider's patient safety evaluation system.

Minton, C.J. and Wright, J., join.

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