**No. 14-**

IN THE

# Supreme Court of the United States

PHILLIP TIBBS, *et al.*,

*Petitioners,*

v.

ESTATE OF LUVETTA GOFF, *et al.*,

*Respondents.*

**On Petition for a Writ of Certiorari to the Kentucky Supreme Court**

## PETITION FOR A WRIT OF CERTIORARI


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## QUESTION PRESENTED

To reduce preventable medical errors, Congress created a nationwide patient-safety system that facilitates the sharing and analysis of safety-event information by healthcare professionals. To induce participation, Congress made this information, known as "patient safety work product," privileged and confidential, regardless of contrary state law. Congress broadly defined patient safety work product to include "any data, reports, records, memoranda, and analyses" a healthcare provider assembles for or reports to a "patient safety organization." 42 U.S.C. § 299b-21(7). Both the statute and its implementing regulations make clear that the federal privilege expressly preempts state reporting or recordkeeping laws to the extent they might render protected information discoverable.

The question presented in this case is:

Whether state law may nullify the federal "patient safety work product" privilege, or whether, instead, the Kentucky Supreme Court erred by interpreting it not to protect information "normally contained in" documents subject to state reporting or recordkeeping requirements.

## PARTIES TO THE PROCEEDINGS

Petitioners, Phillip Tibbs, Joel E. Norman, and Barrett W. Brown, were the defendants-appellants below.

Judge Kimberly N. Bunnell, Fayette Circuit Court, was the nominal appellee below, and Respondents Clyde Goff and the estate of Luvetta Goff were the plaintiffs and real parties in interest.

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## PETITION FOR A WRIT OF CERTIORARI

Petitioners, Phillip Tibbs, Joel E. Norman, and Barrett W. Brown, respectfully petition for a writ of certiorari to review the judgment of the Kentucky Supreme Court in this case.

## OPINIONS BELOW

The opinion of the Kentucky Supreme Court is reported at *Tibbs* v. *Bunnell*, 448 S.W.3d 796 (Ky. 2014), and is reproduced at Petition Appendix (Pet. App.) 1a–41a. The order of the Kentucky Supreme Court denying rehearing is reproduced at Pet. App. 52a. The decisions of the Kentucky Court of Appeals and the Fayette Circuit Court are reproduced at Pet. App. 42a–48a and 49a–51a, respectively.

## JURISDICTION

The Kentucky Supreme Court issued its opinion on August 21, 2014. Pet. App. 1a. Petitioners thereafter filed a timely petition for rehearing on September 11, 2014. The court denied the petition on December 18, 2014, Pet. App. 52a, making the opinion final as of that date. Ky. R. Civ. P. 76.30(2)(c). This Court has jurisdiction pursuant to 28 U.S.C. § 1257.

The Kentucky Supreme Court's decision is final for purposes of this Court's review. Petitioners invoked the Patient Safety Act's privilege by seeking a writ of prohibition in the Kentucky appellate courts. The Kentucky Supreme Court's decision terminated the writ-of-prohibition action, which under Kentucky law "is a separate civil action … not an interlocutory appeal from the underlying action." *Lexington Pub. Library* v. *Clark*, 90 S.W.3d 53, 56 (Ky. 2002). Accordingly, "[t]he State Supreme Court's judgment finally disposing of the writ of prohibition is a final judgment

reviewable here under 28 U.S.C. § 1257." *Madruga* v. *Superior Court*, 346 U.S. 556, 557 n.1 (1954).

## CONSTITUTIONAL AND STATUTORY PROVISIONS

The Supremacy Clause of the United States Constitution provides, in pertinent part, that "the Laws of the United States … shall be the supreme Law of the Land … any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

The relevant provisions of the Patient Safety and Quality Improvement Act of 2005 ("Patient Safety Act" or "Act"), Pub. L. No. 109–41, 119 Stat. 424, codified at 42 U.S.C. §299b-21 *et seq*., are reproduced at Pet. App. 53a–66a.

The regulations promulgated by the U.S. Department of Health and Human Services to implement the Patient Safety Act, 42 C.F.R. § 3.10 *et seq*., are reproduced at Pet. App. 67a–81a.

## INTRODUCTION

This case concerns whether state law may nullify a federal privilege. By preempting state civil discovery rules (indeed, all discovery rules) and protecting a broad class of "patient safety work product," Congress sought in 2005 to reduce medical errors by establishing a national system for the reporting, aggregation, and analysis of information about patient safety events. To ensure that the creation and sharing of such information did not result in discoverable material that could be used against those who report adverse medical outcomes, Congress made the information collected for or contained within the system privileged and confidential, notwithstanding any pro-

vision of state or local law. 42 U.S.C. § 299b-22(a)–(b).

Protection of patient safety work product is essential for at least two reasons: Congress intended to create a "culture of safety" in which providers could share adverse-event information without fear of increasing their exposure to malpractice liability, and Congress attempted to induce widespread, voluntary participation of providers who, without the privilege, would have little incentive to disclose information about their possible medical errors.

But the Kentucky Supreme Court has fatally undermined the privilege. It directed discovery of federally protected work product if a trial judge, after in camera review, determines the records contain information "normally" required by state record-keeping or reporting laws. This freewheeling and utterly subjective inquiry will expose a huge and indeterminate amount of voluntarily disclosed information to tort plaintiffs, contrary to Congress' clear intent and instruction.

Even the threat of such disclosure, moreover, will destroy the federal incentive offered to providers to voluntarily report all possible medical errors. By sapping providers' confidence in the privilege, the court below does serious violence to this important federal program just as it begins to take hold in the U.S. healthcare sector. Few providers are likely to participate, given the risk of court-ordered disclosure. And the organizations charged with housing, studying, and disseminating what little information is shared will be subjected to the prospect of conflicting legal obligations—for if a state court orders disclosure of a record in their possession, they face either contempt of the state court's order or substantial civil penalties under federal laws that bar disclosure.

Such dueling standards are intolerable within a national program that expressly preempts state law.

The confused decisions of the Kentucky Supreme Court and other state and federal courts make plain the need to clarify the scope and application of this federal privilege. This case presents an excellent vehicle through which to do so. Because this issue arises almost exclusively in discovery disputes in state malpractice litigation, few cases presenting this question will be litigated to final judgment in the federal courts of appeals or state courts of last resort. This case, however, arises at the conclusion of a writ-of-prohibition proceeding that squarely and cleanly presents the question, disentangled from the merits and procedure of the underlying malpractice suit.

The Court should therefore grant the petition for review or, at a minimum, seek the views of the Solicitor General regarding the consequences of the Kentucky Supreme Court's decision for the patient safety network Congress established.

## STATEMENT OF THE CASE

### I. STATUTORY BACKGROUND

1. Preventable medical errors kill a large number of Americans every year—as many as 98,000, according to the seminal analysis by the Institute of Medicine. IOM, *To Err Is Human: Building a Safer System* 1 (1999) ("IOM Report"). Such errors injure many more patients each year. And they impose huge costs—up to $29 *billion*—on the nation's healthcare system and the broader economy every year. H.R. Rep. No. 109-197, at 9 (2005) (citing IOM Report).

Despite their frequency and scale, however, historically no comprehensive federal program ever at-

tempted to *prevent* those mistakes. The threat of malpractice liability was long the only significant check on medical errors. But in the wake of the IOM Report, it became clear to Congress that state negligence law, standing alone, was not up to the task. Indeed, the threat of litigation unintentionally exacerbated the problem: fear of civil discovery discouraged hospitals, doctors, and other providers from recording or sharing information about adverse events and near-misses. See 73 Fed. Reg. 8,112, 8,113 (proposed Feb. 12, 2008). Rather than using data to explore the causes of medical errors and identify potential solutions, prevailing state law largely suppressed evidence-based analysis.

Congress took action, in 2005, to fill this gap in the nation's healthcare system. The Patient Safety Act responded directly to the IOM Report's prescription for voluntary error reporting. H.R. Rep. No. 109-197, at 9; S. Rep. No. 108-196, at 3–4 (2003). The system Congress created allows healthcare providers and researchers to share and study medical-error data in a manner that is aggregated, anonymous, and privileged. Helping researchers develop and disseminate evidence-based analyses, Congress envisioned, would help doctors, nurses, and health systems avoid future mistakes. This, in turn, would enhance the quality of care for individual patients and reduce costs throughout the healthcare system. *Id.* The goal was to replace a "culture of blame," 73 Fed. Reg. 70,732, 70,749 (Nov. 21, 2008); IOM Report at ix, with a "culture of safety," 42 U.S.C. § 299b-21(5)(D) ("patient safety activities" under the Act are intended to "encourag[e] a culture of safety and of providing feedback and assistance to effectively minimize patient risk").

A federal program was necessary for at least two reasons.

*First*, a national patient safety system would have the structure and scope to facilitate widespread information sharing. The healthcare delivery system's "decentralized and fragmented" nature impeded information sharing within and across institutions, a problem that was exacerbated by a patchwork of inconsistent state-level programs. IOM Report at 3, 90; *see also* 73 Fed. Reg. at 8,113.

*Second*, a strong and uniform privilege was necessary to expand state peer-review protections. State laws were too narrow and varied to support data-sharing on a scale that would enable robust disclosure, research, and analysis. IOM Report at 120–21. "Traditional state-based legal protections for such health care quality improvement activities, collectively known as peer review protections, are limited in scope" and "do not exist in all states." 73 Fed. Reg. at 8,113. Additionally, state protections generally apply only within a provider organization, preventing the sharing and aggregation of information on a broad scale. *Id.*

2. The Patient Safety Act created a federal system to provide the structure and protection required for robust nationwide sharing and analysis of safety data.

The system is structured around patient safety organizations, or PSOs, which serve as the repository for medical-error reports. PSOs have members—hospitals, doctors, and other providers—which collect safety information and transmit it to the PSO. The PSO then aggregates and removes identifying patient and provider information, so that the information may be studied by researchers seeking to understand

why certain errors occur and how they can be prevented. The reports generated by the PSO are in turn distributed to the members, who incorporate the findings into their operations and patient care; the research may also be published in peer-reviewed journals or other forums.[1] Today over 80 PSOs, often organized on a regional or specialty basis, operate across all 50 states. At the national level, PSOs share data through a central clearinghouse known as the Network of Patient Safety Databases, intended to recognize and disseminate trends and best practices at the national level. 42 U.S.C. § 299b-23.

The Act provides "substantial and broad" protections for the "patient safety work product" data gathered for and submitted to a PSO. 73 Fed. Reg. at 70,741. That information is defined expansively to include "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" created for and supplied to a PSO. 42 U.S.C. § 299b-21(7)(A).[2] To preserve patients' and states' ability to access the "original records underlying patient safety work product," 73 Fed. Reg. at 70,732, the term excludes original patient and provider records, as well as information "collected, main-

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[1] *See, e.g.*, Williams et al., *Guidewires Unintentionally Retained During Central Venous Catheterization*, 19 J. Ass'n Vascular Access 29 (2014) (recommending device design change, later adopted by manufacturer, based on review of incident reports contained in PSO database).

[2] The privilege also applies to information collected within a provider's patient safety evaluation system. *See* 42 U.S.C. § 299b-21(7)(A)(ii); 73 Fed. Reg. at 70,741. "Patient safety evaluation system" refers to "the collection, management, or analysis of information for reporting to or by a patient safety organization." 42 U.S.C. § 229b-21(6). The distinguish between "PSO" and "PSES" information is generally not material to the discussion in this petition.

tained, or developed separately" from the patient safety reporting process, 42 U.S.C. § 299b-21(7)(B)(i)–(ii).

To overcome resistance to information sharing and induce provider participation, patient safety work product is treated as confidential and privileged. § 299b-22(a)–(c). "Notwithstanding any other provision of Federal, State, or local law," patient safety work product is therefore protected from discovery or disclosure in civil, criminal, and administrative proceedings. *Id.* The few statutory exceptions to these protections are narrow and detailed. *See, e.g.*, § 299b-22(c)(1)(A) (patient safety work product may be disclosed "for use in a criminal proceeding, but only after a court makes an in camera determination that" it contains material evidence of a crime and is not reasonably available from another source). Unauthorized disclosure of federally protected information is punishable by civil penalties of up to $11,000 per act. § 299b-22(f); 42 C.F.R. § 3.402–.408; 74 Fed. Reg. 42,777, 42,779 (Aug. 25, 2009).

Assuring providers that their records are protected from disclosure is crucial to their participation in the patient safety regime. *E.g.*, 73 Fed. Reg. at 70,741. Cooperation is essential because most providers' participation is purely voluntary; only hospitals with more than 50 beds and facilities with problematic readmission rates must participate. *See* 42 U.S.C. §§ 280j-3 (readmission rates), 18031(h)(1)(A)(i) (50-bed requirement).

Absent the privilege, there would be scant incentive for healthcare providers to gather and report information that candidly and critically assesses the performance of physicians, hospitals, and others involved in patient safety events. The privilege thus serves to "facilitate an environment in which health care pro-

viders are able to discuss errors openly and learn from them," H.R. Rep. No. 109-197, at 9, by "enabl[ing] all health care providers … to share data within a protected legal environment, both within and across states, without the threat of information being used against [them]," 73 Fed. Reg. at 8,113. The privilege is therefore critical to the Act's goal of fostering "a culture of safety [that] provid[es] feedback and assistance to effectively minimize patient risk." 42 U.S.C. § 299b-21(5)(D).

3. Many states require providers to maintain or report certain records to healthcare regulators. *See, e.g.*, 902 Ky. Admin. Reg. 20:016 § 3(3)(a) ("Administrative reports shall be established, maintained and utilized ….."). Congress expressly addressed the question of how the Act's preemptive force would affect such state reporting and recordkeeping requirements. State-law subpoena and discovery obligations, it is clear, cannot require the disclosure or production of patient safety work product. *See* 42 U.S.C. § 299b-22(a)–(b) ("Notwithstanding any other provision of Federal, State, or local law … patient safety work product shall be privileged and shall not be [*inter alia*] subject to a Federal, State, or local civil, criminal, or administrative subpoena or order ….."). The Act also specifies that the privilege and confidentiality provisions do not "limit" "reporting" or "recordkeeping obligation[s] … under Federal, State, or local law." § 299b-21(7)(B)(ii)–(iii).

Implementing regulations promulgated by the Department of Health and Human Services (HHS) likewise address the relationship between federal protection and state records requirements. The Final Rule clarifies that "providers need not maintain duplicate systems to separate information to be reported to a PSO from information that may be required to fulfill

state reporting obligations." 73 Fed. Reg. at 70,742. Such parallel obligations would, of course, increase the burden on providers without providing the benefit of protection. *See* 42 U.S.C. § 299b-21(7)(B)(ii) (patient safety work product "does not include information that is collected, maintained, or developed separately … from a patient safety evaluation system"). Instead, providers may collect all patient safety work product in one system for submission to a PSO, where it remains protected unless and until the provider removes it from that system for use in satisfying the provider's reporting obligations. 73 Fed. Reg. at 70,742.

## II. PROCEEDINGS BELOW

1. This action arises from a medical malpractice suit filed by the spouse and estate of Luvetta Goff, who died from complications during spinal surgery. After the surgery, a nurse prepared an incident report and submitted it to the hospital's patient-safety system. The hospital then submitted it to its PSO—University HealthSystem Consortium.

The plaintiffs sued the three surgeons who operated on Goff. The plaintiffs sought discovery of any incident reports concerning her care—reports that are not privileged as a matter of Kentucky law. *See Saleba* v. *Schrand*, 300 S.W.3d 177, 183–84 (Ky. 2009); *Sweazy* v. *Kings' Daughters Mem'l Hosp.*, 771 S.W.2d 812, 814 (Ky. 1989). The defendants moved for a protective order, contending the incident report was privileged patient safety work product under the Patient Safety Act. The trial court denied the motion, ruling the report was not privileged and ordering its production. *See* Pet. App. 50a.

The defendants (petitioners here) then filed an original action for a writ of prohibition and challenged

the trial court's order in the Kentucky Court of Appeals, again invoking the Patient Safety Act's privilege. The Court of Appeals granted the writ of prohibition, but held that the report was privileged only to the extent the documents contained a "self-examining analysis." *See* Pet. App. 48a (citing *Francis* v. *United States*, No. 09-cv-4004, 2011 WL 2224509 (S.D.N.Y. May 31, 2011)). The Court of Appeals remanded the matter to the trial court to determine, after in camera review, whether the report contained such an analysis. *Id.*

2. The defendants appealed to the Kentucky Supreme Court. The Court of Appeals erred, they contended, by limiting the federal privilege for patient safety work product to "self-examining analysis," a term drawn not from the Patient Safety Act, but from cases discussing peer-review privilege under federal common law. *See* Pet. App. 9a–11a. The Kentucky Supreme Court unanimously held that the Court of Appeals erred by focusing on whether the report contained "self-examining analysis." *Id.* at 11a.

A closely divided Court went on to hold, however, that the Act's privilege turns on whether *state* law requires providers to report or record similar information. By a vote of 4-2, with one justice concurring in the result only and one not participating,[3] the Court announced that the definition of "patient safety work product" does not include "information normally contained in" documents that states require health-

[3] Justice Noble concurred in the result only, and did not write an opinion explaining her vote. On reconsideration, however, she voted with the dissenting Justices to grant rehearing. *See infra* at 14–15. Justice Keller did not participate in either the merits or reconsideration phases of the proceedings below.

care providers to create or maintain. Pet. App. 24a–25a.

The controlling opinion discerned this exception in the Act's "clarification" that the privilege does not cover information that is collected or maintained "'separately … from a patient safety evaluation system.'" Pet. App. 14a (quoting 42 U.S.C. § 299b-21(7)(B)(ii)). The Court viewed this clarification as indicating that any information that falls under a state reporting or recordkeeping requirement cannot be privileged patient safety work product—even if, as here, the information exists only in a record kept by a PSO. *See id.* at 24a–25a. Because Kentucky law requires hospitals to "maintai[n]" incident reports "as part of [state] regulatory oversight of its healthcare facilities," the report the University submitted to its PSO "is not, nor can it be, patient safety work product." *Id.* at 25a. "Congress never intended the Act to deprive the states of state-mandated information relevant to their regulatory duties." *Id.* That universe of information "relevant to [state] regulatory duties," however, is quite broad. Apparently acknowledging that a great deal of otherwise privileged material could fall within this category, the opinion instructed the trial court to conduct in camera review to parse the "intermingled" privileged and discoverable information. *Id.* at 26a.

3. Two justices dissented. The dissenting opinion perceived the full scope of the materials covered by the federal privilege: "anything—data, reports, analyses, statements, etc.—processed within a patient safety evaluation system for submission to a PSO." Pet. App. 34a (Abramson, J., dissenting). Outside the privilege are "records, reports, and other information existing separately from the Act's patient safety system." *Id.* The privilege inquiry thus turns on a

straightforward factual determination: whether the record was in fact collected for or held by a PSO, or whether the provider instead held the record separately from the PSO system. See *id.* at 34a–37a.

That information within a PSO is also subject to a state-law reporting or record-keeping requirement, the dissent explained, does not forfeit the privilege. Pet. App. 36a–37a. Rather, the Act "'establishes a protected space or system that is separate, distinct, and resides alongside *but does not replace* other information collection activities.'" *Id.* at 35a (quoting 73 Fed. Reg. at 70,742 (emphasis added)). If information submitted to a PSO is necessary to satisfy a state reporting requirement, the provider may remove that information. *See* 73 Fed. Reg. at 70,741–42. But that step is up to the provider, not a judge deciding a discovery dispute: "Until [the record] is removed," information collected in the PSO system "retains its federal protection." Pet. App. 37a.

The protection persists, the dissent explained, even if a provider is in violation of a state law requiring disclosure of information within a PSO. Pet. App. 37a–38a. In that circumstance, the answer "cannot be … that a trial court may then rummage through the provider's [PSO] submissions in search of … information 'normally contained' in separate records and reports." *Id.* at 37a. That remedy, the dissent recognized, "would completely undermine Congress's assurance to providers that they may participate in the patient safety system without fear of liability or harm to reputation. *Id.* at 38a. *See also id.* at 39a (Act "precludes an adverse party's—and a trial court's—invasion of the patient safety evaluation system itself") (citing S. Rep. 108-196, at 8). Although the provider might be subject to state-law penalties for violating a recordkeeping or reporting obligation,

the Act does not contemplate state judges ordering disclosure under state regulations in the face of a federal statute expressly preempting disclosure under state law. *See id.* at 39a–40a (citing 42 U.S.C. § 229b-22(a)–(b)).

The subjective approach of the controlling opinion, the dissent emphasized, produced an unworkable rule squarely at odds with Congress's purpose. Congress's "intent to assure providers that their participation in the patient safety system is not to be used against them in either the tort or the peer-review system could hardly be clearer." Pet. App. 32a. Refusing to strictly construe the privilege "will discourage participation in the patient safety system." *Id.* at 39a–40a. "It is hard to imagine a holding more at odds with Congress's clear intent to foster provider trust in the patient safety system." *Id.* at 38a. Moreover, generalist judges are clearly ill-suited for the task of "sift[ing] through federally protected patient safety data for otherwise discoverable material under state law," *id.* at 27a, in an effort to divine what medical "information is normally contained in an incident report" subject to state regulation, *id.* at 28a n.19.

"By disregarding the purpose of the [Patient Safety Act], and by misconstruing the privilege it creates," the dissent concluded, "the Court undermines Kentucky's healthcare providers' full participation in the patient safety system and to that extent, at least, both frustrates Congress's intent and denies Kentuckians the benefits of [the Act's] approach to healthcare safety." Pet. App. 40a–41a.

4. The defendants, supported by several *amici*, timely submitted a petition for rehearing. An equally divided court denied the defendants' petition. Justice Noble, who had concurred only in the result at the

merits stage, voted with the two dissenters to rehear the appeal. Pet. App. 52a.

## REASONS FOR GRANTING THE PETITION

This case implicates an important federal program whose effectiveness will be severely hampered by the Kentucky Supreme Court's misguided interpretation of federal law. Other courts' applications of the "patient safety work product" privilege likewise reveal significant confusion among state and federal courts about the Act's preemptive scope. Confusion is particularly harmful in this context, because participation in a voluntary federal program will inevitably be deterred by unduly restrictive and unpredictable applications of the privilege Congress created. Because this case presents an excellent vehicle for *certiorari* review, the Court should grant the petition to eliminate this confusion or, at a minimum, call for the views of the Solicitor General.

### I. REVIEW IS WARRANTED TO RESOLVE CONFUSION EVIDENT IN THE DECISION BELOW AND IN OTHER LOWER COURTS REGARDING THE EFFECT OF THE PRIVILEGE ON STATE LAW.

The decision below reflects substantial divergence among the lower courts and uncertainty among affected parties over the scope of the privilege Congress created. The Kentucky Supreme Court and other courts have revealed their confusion over the effect of the federal privilege on state regulatory or common-law obligations that may otherwise allow discovery of peer-review or other patient-safety information.

1. The question addressed by the Kentucky Supreme Court was whether the Patient Safety Act protected information that was subject to state reporting

or recordkeeping requirements. Because "Congress never intended the Act to deprive the states of state-mandated information relevant to their regulatory duties," the Court held that state-mandated "incident information sources [did not] acquire a federal privilege by virtue of the healthcare provider's act of putting them solely into a [PSO] system." Pet. App. 25a.

That understanding of the Patient Safety Act is wrong: the incident report at issue was both privileged under federal law (because it was stored in a PSO) *and* subject to recordkeeping requirements under state law (because Kentucky requires hospitals to establish and maintain such records). Three fundamental mistakes in the decision below explain its incorrect statutory interpretation and reflect broader confusion in the courts about the scope of the federal privilege.

*First*, the Kentucky Supreme Court set up a false choice between federal-law protection and state-law compliance. The Act allows for both.

It is common ground that the Act did not relieve providers of state-law reporting and recordkeeping obligations. The Act clearly states that it does not limit either "the reporting of information … to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes," or "a provider's recordkeeping obligation … under Federal, State, or local law." 42 U.S.C. § 299b-21(7)(B)(iii)(II)–(III). The opinion below recognized Congress' intent to preserve state reporting and recordkeeping requirements. Pet. App. 25a. But it took this to mean that "patient safety work product," *by definition*, does not include material subject to such laws. *Id.* ("[W]hile the incident information may be relevant to … 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.").

It simply does not follow that materials subject to state-law requirements cannot also be patient safety work product.[4] To the contrary, Congress made clear that patient safety work product can include such information. "Notwithstanding *any other provision* of Federal, State, or local law … patient safety work product shall be privileged and shall not be … subject to a Federal, State, or local civil, criminal, or administrative subpoena or order …." 42 U.S.C. § 299b-22(a)(1) (emphasis added). HHS's implementing regulations expressly address the situation where documents required by state law reside within the PSO program. *See* 42 C.F.R. § 3.20(2)(ii) ("patient safety work product") (Pet. App. 69a); 73 Fed. Reg. at 70,742. Such documents still receive the benefit of the federal privilege unless and until the provider removes them from its PSO reporting process in order to comply with state law. 73 Fed. Reg. at 70,742.

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[4] The preamble to the Final Rule makes this clear. The Act "is quite specific that these protections do not relieve a provider from its obligation to comply with other Federal, State, or local laws pertaining to information that is not privileged or confidential under the Patient Safety Act …." Section 299b-22(g)(5) "states that the Patient Safety Act does not affect any State law requiring a provider to report information that is not patient safety work product. The fact that information is collected, developed, or analyzed under the protections of the Patient Safety Act does not shield a provider from needing to undertake similar activities, if applicable, outside the ambit of the statute, so that the provider can meet its obligations with non-patient safety work product." 73 Fed. Reg. at 70,732; *see also* 73 Fed. Reg. at 8,114 (notice of proposed rulemaking).

This either-or fallacy, falsely distinguishing between federal protection and state regulation, underlies much of the court's confusion about the scope of the privilege. Contrary to the controlling opinion, the federal and state regimes are not mutually exclusive. For example, a state recordkeeping rule may require a provider merely to keep a record on file; in that case, the provider may comply with both federal and state law by creating the required document and storing it with a PSO. And if state law requires disclosure to regulators of information that exists only within the patient safety system, the HHS regulations set forth a straightforward process: a provider may remove the records from the PSO program. *Id.* (describing removal process, which may occur at any point before the ultimate depositing of the record with the PSO). Thus providers—not trial judges—make their own determinations regarding whether they can report to a PSO and still comply with state law. This orderly approach is practically the opposite of the ad hoc approach adopted below, which looks to a generalist judge's ex post determination of the "normal" applicability of healthcare records requirements. Pet. App. 24a–25a.

*Second*, the court below misunderstood how the Act defines patient safety work product. It held that such information cannot include material that is normally part of a state-required record or report, because otherwise providers could evade state obligations by opportunistically submitting materials to the federal PSO network instead.

But no such limit on the definition of "patient safety work product" appears in the Act, either explicitly or implicitly. The Act sets forth detailed definitions of the materials covered, and equally detailed exceptions for materials exempted. *Compare* 42 U.S.C.

§ 299b-21(7)(A) (work product includes "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" prepared for or by a PSO), *with* § 299b-21(7)(B)(i) (work product "does not include a patient's medical record, billing and discharge information, or any other original patient or provider record"). The exception divined by the Kentucky Supreme Court appears to have been constructed from whole cloth; certainly it is not among the specific and narrow exceptions set forth in the text of the statute.

Plainly, the Act does not contemplate in camera review *every time* the privilege is invoked. Rather, Congress authorized in camera review of patient safety work product in one specific circumstance: in criminal cases to determine whether it contains evidence of a criminal act, is material to the proceeding, and is not reasonably available from another source. § 299b-22(c)(1)(A). Because Congress has *expressly* authorized limited in camera review and specified the standard by which that review should be conducted, courts should be particularly reluctant to infer additional unwritten exceptions. "'Where Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent.'" *TRW Inc.* v. *Andrews*, 534 U.S. 19, 28 (2001) (quoting *Andrus* v. *Glover Constr. Co.,* 446 U.S. 608, 616–17 (1980)).

In stark contrast to the approach of the court below, the Act sets forth a straightforward and objective way to tell whether a document is privileged: ask whether it exists inside the PSO program. If so, it is protected; if not, it is not. *See* Pet. App. 34a–35a (Abramson,

J., dissenting) (quoting 73 Fed. Reg. at 70,741).[5] In practice, if a state regulator demands access to a document before PSO submission, the provider may remove the document and forego the federal privilege. 73 Fed. Reg. at 70,742. Or it could report the document to the PSO and identify other information, outside the PSO process, to comply with the state requirement. *See* Pet. App. 38a–40a (Abramson, J., dissenting); 73 Fed. Reg. at 8,114. Or the provider could simply accept a state penalty, if any, for failing to comply with state law. Pet. App. 37a. Regardless of how the provider chooses to comply with state law, the document remains privileged until removed from the PSO program. And respecting that privilege would not, contrary to the opinion below, "deprive the states of state-mandated information relevant to their regulatory duties." *Id.* at 25a.

*Third*, the mistaken *Tibbs* approach effectively authorizes state nullification of federal law. *Contra Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 105–06 (1992) (allowing "'state legislatures to nullify … unwanted federal legislation'" would be "'at odds with the approach taken in nearly all our Supremacy Clause cases'"). Whether the federal privilege preempts discovery of incident reports, for example, would turn on whether state law spoke to the same materials. *See, e.g.*, Pet. App. 14a–15a (describing Kentucky regulations governing incident reports). If it did, state rather than federal law would apply, despite the Act's express language of preemption. 42 U.S.C. § 229b-22(a)–(c). This illogical approach turns preemption on its head.

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[5] The PSO program, in this context, includes both patient-safety evaluation by the provider in anticipation of submission to a PSO, as well as the PSO's own housing and use of the information. *See supra* note 2.

It is implausible that states would control the scope of the federal privilege. The Act was a direct response to criticism of the prior system, in which states set their own discovery policies and little information was shared across state lines. IOM Report at 91–93, 120–21, 127–28. Allowing state recordkeeping and reporting laws to mark out the scope of the privilege would mean that state policymakers could trump any contrary federal law simply by enacting a new recordkeeping or reporting requirement. "States would then be free to nullify for their own people the legislative decisions that Congress has made on behalf of all the People." *Howlett ex rel Howlett* v. *Rose*, 496 U.S. 356, 383 (1990) (refusing to allow state common-law immunity rules to narrow a federal cause of action). Notwithstanding that federal law expressly identifies root cause analyses as an example of patient safety work product, 42 U.S.C. § 299b-21(7)(A), under the *Tibbs* theory the state could eviscerate that federal statutory definition simply by expanding recordkeeping or reporting requirements to cover root cause analyses. This is hardly the usual relationship between state and federal laws. *See, e.g.*, *Miss. Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43-44 (1989) (federal statutes are generally intended to have uniform nationwide application, and state laws are usually read not to impair operation of federal programs). Congress, which well understood the barriers to information-sharing erected by state law, did not enact a statute so flimsy that state law could nullify its protections.

2. The disagreement and confusion among the members of the Kentucky Supreme Court in this case is reflected in the state and federal courts that have confronted the Patient Safety Act. In particular, the courts take divergent approaches to the question

whether the contours of the work-product privilege depend on the reach of state law. The resulting unpredictability will have drastic effects on the willingness of healthcare providers to participate in the PSO regime.

In contrast to the controlling decision below, some courts properly have recognized that the Patient Safety Act "creates a tightly crafted federal privilege for 'patient safety work product' actually reported to a 'patient safety organization.'" *Lee Med., Inc.* v. *Beecher*, 312 S.W.3d 515, 535 (Tenn. 2010) (footnotes omitted). These courts have declined to carve out atextual exceptions to the federal privilege, asking only whether the information in question was developed for, and reported to, a PSO.

In *Department of Financial & Professional Regulation* v. *Walgreen Co.*, for example, a state agency issued administrative subpoenas seeking quality-improvement reports related to three of the company's pharmacists. 970 N.E.2d 552, 555 (Ill. App. Ct. 2012). The appellate court rejected the agency's attempt to enforce subpoenas under state law because the reports in question had been submitted to a PSO. *Id.* at 557–58. The court distinguished these reports from other, potentially discoverable materials that the pharmacy maintained *outside* the PSO program for non-PSO purposes. *See id.* at 558. The *Walgreen* court's focus on the key statutory question—whether the reports were created for and provided to a PSO—reflects a proper application of the Act's privilege. *See also KD ex rel. Dieffenbach* v. *United States*, 715 F. Supp. 2d 587, 595–96 (D. Del. 2010) (acknowledging that "the [Patient Safety Act] protects all … data, reports, records, memoranda, analyses, or written or oral statements which … are assembled or developed

by a provider for reporting to a [PSO] and are reported to a [PSO]").

Similarly, a federal district court in Kentucky held that the Act protected numerous documents from disclosure, rejecting a pharmacist's attempt to compel their production in a suit under the Americans with Disabilities Act. *Tinal* v. *Norton Healthcare, Inc.*, No. 11-cv-596, slip op. at 21–22 (W.D. Ky. July 15, 2014) (ECF No. 59). The court recognized that the Patient Safety Act "creates a broad privilege for patient safety work product that a provider reports to [a] PSO," *id.* at 20 n.45, and found that each document qualified as patient safety work product and was reported to a PSO. No more was required for the privilege to apply. *See id.* at 21. Despite arising contemporaneously and in the same state as *Tibbs*, the *Tinal* court did not consider the state-law reporting requirements that the Kentucky Supreme Court found to trump the Patient Safety Act's privilege. Now, at least within Kentucky, the applicability of two conflicting rulings—one in state court and one in federal court—create a risk of outcome-determinative forum shopping that calls for this Court's attention.

A Florida court, however, agreed with the *Tibbs* approach and concluded that the scope of the federal privilege depends on the Act's "interaction" with state reporting laws. *See Charles* v. *S. Baptist Hosp. of Fla., Inc.*, No. 12-CA-002677 (Fla. Cir. Ct. July 30, 2014) (Pet. App. 85a–86a). In this malpractice action, the plaintiffs sought discovery of hospital incident reports under a Florida law that gives patients access to healthcare records "relating to any adverse incident." *Id.* at 86a (quoting Fla. Const. Art. 10, § 25). The court, noting that the Patient Safety Act does not relieve providers of the duty to comply with state reporting obligations, held categorically that adverse

incident reports that were "created, or maintained pursuant to any statutory, regulatory, licensing, or accreditation requirements are not protected from discovery under the [Act]." *Id.* at 89a–93a. By addressing the defendants' obligations under state law rather than whether the materials were prepared for or submitted to a PSO, the Florida court committed the same error seen in *Tibbs*.[6]

Still other courts have ignored the contours of the statutory text in another way—concluding that the Patient Safety Act's policy goal of protecting peer review work product supports the application of a federal common law privilege. These courts "have examined the legislative history of the [Act] and construed it as signaling a 'shift in congressional policy' aimed at providing broad protection for peer review work product," and have thus recognized a privilege that applies to documents that "are *like* the 'patient safety work product' protected under the [Act]." *Tep* v. *Southcoast Hosps. Grp., Inc.*, No. 13-11887, 2014 WL 6873137, at *5 (D. Mass. Dec. 4, 2014) (emphasis added) (citing *Sevilla* v. *United States*, 852 F. Supp. 2d 1057, 1068–69 (N.D. Ill. 2012); *Francis* v. *United States*, No. 09-4004, 2011 WL 2224509, at *7 (S.D.N.Y. May 31, 2011); *Dieffenbach*, 715 F. Supp. 2d at 592).[7] By considering patient safety

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[6] *Cf.* Michael Arnold, *Peer Review Is Threatened, but (P)So What: Patient Safety Organization Utilization in Florida After Amendment 7 As A Troubling Sign for PSQIA*, 46 Colum. J.L. & Soc. Probs. 291, 317 (2013) (recognizing that "the disclosure[s] mandated by [the Florida constitution] and forbidden by [the Act] are clearly in conflict").

[7] *But see Schlegel* v. *Kaiser Found. Health Plan*, No. CIV 07-0520, 2008 WL 4570619, at *4 (E.D. Cal. Oct. 14, 2008) ("Congress had the opportunity to provide a broad peer review privilege when it enacted 42 U.S.C. § 299b, [but] it did not do so; ra-

work product untethered from the statutory text, in the amorphous context of federal common law, these cases further amplify the confusion surrounding its proper preemptive scope.

Considered against this backdrop of disparate lower-court rulings, the thorough, published decision of a state high court is certain to have an outsized effect on the application of the Patient Safety Act. Questions regarding its applicability and preemptive force usually arise in trial-court discovery disputes. Those may feature little or no briefing, and only rarely will the judge have the time or inclination to research and analyze the law and its context. The likelier course will be to defer to the Kentucky Supreme Court's seemingly thorough, but erroneous, decision.

## II. REVIEW IS WARRANTED BECAUSE THE COURT'S DECISION DISRUPTS AN IMPORTANT FEDERAL PROGRAM AND IMPOSES INCONSISTENT LEGAL OBLIGATIONS.

The many repercussions of the decision below run far beyond the parties and their dispute in this case. Each militates in favor of this Court's swift review.

*First*, and most obviously, the ruling stymies the Patient Safety Act's goal of creating a culture of safety through information sharing without fear of discovery. *See* 42 U.S.C. § 299b-21(5)(d); H.R. Rep. No. 109-197, at 9; IOM Report at 15. As the dissent noted, that aim is plainly frustrated by this rule; litigants will almost always have a colorable argument that medical information is the sort "normally contained in" documents subject to a state reporting or recordkeeping obligation. Pet. App. 26a–27a, 32a.

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ther it carved out a limited exception to which the privilege would apply.").

Unsurprisingly, providers must maintain any number of records for state oversight purposes, *see, e.g.*, 902 Ky. Admin. Regs. 20:016 § 3(3), (4), so it will frequently be the case that "information normally contained in" such records arguably overlaps with material reported to a PSO, *see* Pet. App. 24a–26a. *See also id.* at 37a n.21 (Abramson, J., dissenting) ("This case concerns [an] incident report, but … nothing in the Court's reasoning … would prevent the trial court from looking for and disclosing information 'normally contained' in any required record or report whatsoever."). The robust protection Congress codified for patient safety work product—as evidenced by the breadth of the statutory definition, the construction provision, and the strong preemptive language, see 42 U.S.C. §§ 299b-21(7)(A), 299b-22(a), (d)(3)[8]—is to little effect if courts are to ask whether *state law* renders the information discoverable.

*Second*, determining whether peer-review material is discoverable in light of state law poses an extraordinary challenge. The court below assigned trial courts an unworkable rule to apply. On remand, the lower court must review the incident report in camera and compel production of any "information normally contained in an incident report" subject to state reporting or recordkeeping obligations. Pet. App. 25a. The statute, however, neither contemplates in camera review nor supplies any standards to guide that analysis. *Contra supra* 19 (discussing limited exception for in camera review in certain criminal

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[8] *See, e.g.*, 73 Fed. Reg. at 8,121 ("[T]his expansive list [of patient safety work product] will maximize provider flexibility in operating its patient safety evaluation system by enabling the broadest possible incorporation and protection of information by providers and PSOs.").

cases). And a number of vexing practical questions face the trial court:

- How to determine the scope and applicability of state reporting and record-keeping obligations divorced from the underlying malpractice dispute;
- How to determine what information is "normally contained in" those records subject to state regulatory requirements;
- Whether to redact, excerpt, or otherwise distinguish information contained within PSO documents that is subject to discovery from the information that is not; and
- How to compel non-party PSOs, which are clearly barred by federal law from disclosing peer-review documents,[9] to produce documents within their custody.

Despite the creation of a formal national data-sharing framework, and the promulgation of detailed federal implementing regulations, the scope of protection will come down to a state judge's in camera interpretation of state regulations. This imposes a tremendous burden on trial judges, and virtually ensures a high error rate. The "*in camera* review," the dissent noted, "raises serious practical concerns since judges, not typically being medically trained, may have difficulty identifying what information is normally contained in an incident report." Pet. App. 28a n.19.

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[9] *See* 42 U.S.C. § 299b-22(a)(1)–(4) (patient safety work product submitted to a PSO shall not be subject to subpoena, order, discovery, or disclosure, or otherwise admitted as evidence).

*Third*, what *is* clear from the foregoing analysis is that this constriction of the privilege will have an intense impact on the primary conduct of healthcare providers. In enacting the Patient Safety Act, Congress sought to induce the participation of doctors and hospitals that would prefer to engage in peer review, but who did not because of a lack of protection from civil discovery. S. Rep. No. 108-196, at 7 ("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."). Congress broadly articulated the protections of the Patient Safety Act precisely in order to overcome those fears. But the Kentucky Supreme Court read into the Act an unwritten and subjective state-law exception. *See* Pet. App. 25a–26a. Under this rule, providers cannot know ex ante—when the decision whether to collect or report work product to a PSO must be made—whether the federal protection will suffice if the documents are later subpoenaed. *Id.* at 40a–41a (Abramson, J., dissenting).

Unless the Patient Safety Act's protections are restored, it is inevitable that fewer doctors and hospitals will participate in the patient-safety activities envisioned by the Act. *See, e.g.*, Cal. Hosp. PSO, *Why Are Some Organizations Reluctant to Participate in a PSO?* (July 2013) ("Some organizations question the strength of the protections promised by the [Act]" in light of legal challenges in Kentucky and elsewhere), http://www.chpso.org/lessons-learned/are-some-organizations-reluctant-participate-pso. Such a reaction is unfortunate, given Congress' goals, but rational, given the uncertainty and exposure providers face when they surrender peer-review materials regarding

patient safety events. After all, the "confidentiality provisions are included in the Patient Safety Act to encourage provider participation. Without such protections, providers will be reluctant to participate in the expanded reporting and analysis of patient safety events, and low participation will severely inhibit the opportunity to reap the benefits from efforts to improve patient safety." *See* 73 Fed. Reg. at 8,170.

And because a privilege is involved, it is not only the fact but the *perception* of protection that shapes primary conduct. As this Court has made clear, an "uncertain privilege, or one which purports to be certain but results in widely varying applications by the courts, is little better than no privilege at all." *Upjohn Co.* v. *United States*, 449 U.S. 383, 393 (1981) (reversing because the "very terms of the test adopted by the court below suggest the unpredictability of its application").[10] Even where lawyers are the ones called to interpret the scope of a privilege, "courts must be particularly careful not to craft rules that cause application of the privilege to turn on the answers to extremely difficult substantive legal questions." *Wachtel* v. *Health Net, Inc.*, 482 F.3d 225, 237 (3d Cir. 2007). This applies with extra force to doc-

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[10] *See also Jaffee* v. *Redmond*, 518 U.S. 1, 15–17 (1996) ("Making the promise of confidentiality contingent upon a trial judge's later evaluation of the relative importance of the patient's interest in privacy and the evidentiary need for disclosure would eviscerate the effectiveness of the [therapist-patient] privilege."); *United States* v. *Jicarilla Apache Nation*, 131 S. Ct. 2313, 2328 (2011) (rejecting as unworkable a case-by-case approach to attorney-client privilege in context of government's trusteeship of Indian funds); *Swidler & Berlin* v. *United States*, 524 U.S. 399, 409 (1998) (rejecting posthumous limitations on attorney-client privilege, because even limited "[b]alancing *ex post* [of] the importance of the information against client interests … introduces substantial uncertainty into the privilege's application").

tors and other medical professionals untrained in the law. For "if the purpose of the … privilege is to be served, the [provider] must be able to predict with some degree of certainty whether particular [materials] will be protected." *Upjohn*, 449 U.S. at 393.

*Fourth*, the ruling below also will perversely affect the conduct of PSOs, which are subject to potentially conflicting legal obligations. The decision below contemplates that a state court could compel a PSO to violate its federal-law obligation not to release patient safety information. *See* 42 U.S.C. § 229b-22(a)–(b), (d)(4)(A)(i). Violations of this rule are punishable by civil monetary penalties of up to $11,000 per act. *See* § 229b-22(f)(1) ("a person who discloses identifiable patient safety work product in knowing or reckless violation ... of this section shall be subject to a civil monetary penalty of not more than $10,000"); 42 C.F.R. § 3.402–.408; 74 Fed. Reg. at 42,777, 42,779 (increasing maximum penalty to $11,000). While the Secretary may opt not to enforce the Patient Safety Act penalty provisions against a PSO complying with a judicial order on pain of contempt, *see* 73 Fed. Reg. at 8,158, the fact remains that the *Tibbs* rule subjects PSOs to contradictory legal obligations. And the need for federal uniformity is particularly acute for the many PSOs that operate across multiple states; their operations could be subject to not just two, but many more differing legal requirements. *Contra id.* at 8,113 ("For the first time, there will now be a uniform set of Federal protections that will be available in all states and U.S. territories and that extend to all health care practitioners and institutional providers.").

All of which indicates that the ruling below significantly impedes the operation of the national patient-safety system created by Congress. That system de-

pends, first and foremost, on the participation of providers. For most, the decision to participate is entirely voluntary; without the protection of confidentiality, providers have little incentive to report peer-review information that plaintiffs may one day obtain in discovery. 73 Fed. Reg. at 70,741. Other providers will be required by federal law to participate in PSOs. *See* 42 U.S.C. §§ 280j-3 (readmission rates), 18031(h)(1)(A)(i) (50-bed requirement). Thus the misinterpretation of "patient safety work product" could have spillover effects for other federal programs as well. And even the information that *is* reported to PSOs may be distorted by the constriction of the federal privilege: if providers are reporting some information but holding back potentially embarrassing or damaging material, that will skew the data used by PSOs and researchers to develop safety recommendations for the broader healthcare system. *Cf. Baldrige* v. *Shapiro*, 455 U.S. 345, 354 (1982) ("an accurate census depends in large part on public cooperation," which Congress attempted to stimulate by "provid[ing] assurances that information furnished to the Secretary by individuals is to be treated as confidential"). Plainly, the Patient Safety Act is unlikely to achieve its aim of a "culture of safety" and collaboration if providers cannot depend on the federal privilege.

## III. THIS CASE PRESENTS AN EXCELLENT VEHICLE FOR THIS COURT'S REVIEW.

This case presents a clean and attractive vehicle for the Court to review the scope of the patient safety work product privilege. Already, PSOs house an enormous trove of patient and event data from across the nation. If the patient safety system works as Congress intended, vast amounts of additional data will be added each year. Until decisions such as

*Tibbs* are overturned, lawyers will seek to uncover PSO information in litigation. Whether that information is rendered discoverable by state disclosure requirements is a question trial courts will face repeatedly.

But the question will not often emerge in a manner suitable for this Court's review. The issue is litigated most frequently in medical-malpractice suits in state court. Those discovery disputes are where the federal privilege has its real-world impact on the law and on provider behavior. But because of their interlocutory posture, the questions rarely bubble above the surface, only occasionally giving rise to reasoned state appellate decisions on the scope of the privilege. *See*, *e.g.*, Elkins, *New Decision Splits Courts on Privilege*, Va. Lawyers Weekly, Mar. 17, 2015 (Pet. App. 94a–98a) (describing three Virginia trial courts' divergent applications of the patient safety work product privilege). Fewer still are the cases litigated to final judgment independent of the underlying state tort case, which would inevitably obscure the pure question of federal statutory interpretation at issue.

The Kentucky Supreme Court's decision in *Tibbs*, by contrast, arrives at this Court at the conclusion of a writ-of-prohibition proceeding—a distinct civil action that terminated with the Kentucky Supreme Court's ruling. *See Clark*, 90 S.W.3d at 56; *Grange Mut. Ins. Co.* v. *Trude*, 151 S.W.3d 803, 810 & n.19 (Ky. 2004). The decision is therefore final for purposes of this Court's review. *See Fisher* v. *Dist. Court*, 424 U.S. 382, 385 n.7 (1976); *Madruga*, 346 U.S. at 557 n.1. In this respect, this case resembles other important federal privilege issues the Court has reviewed. *See Pierce Cnty.* v. *Guillen*, 537 U.S. 129, 134 (2003) (considering scope and validity of federal privilege for road-safety information compiled by local

governments, 23 U.S.C. § 409, in context of state public-records suit separate from underlying state tort case).

The applicability of the privilege is squarely presented, without any extraneous questions of federal or state law interfering with this Court's review. And the arguments for and against discovery are set forth in thorough written opinions that canvas the relevant statutory text and legal context. The Court is unlikely to soon confront this question in as clean a vehicle as the one before it. Waiting for another case or a more mature split, moreover, may prove illusory. The chill on PSO participation caused by *Tibbs*, *see supra* at 28–30, likely will diminish the number of providers willing to report patient safety work product or to litigate its privileged and confidential status. Thus, the fundamental purpose of Congress will be defeated absent intervention now by this Court.

## CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be granted or, at a minimum, the Court should call for the views of the Solicitor General.

Respectfully submitted,

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March 18, 2015

# APPENDIX

**APPENDIX A**

SUPREME COURT OF KENTUCKY

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No. 2012-SC-000603-MR

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PHILLIP TIBBS, M.D., *et al*.,
*Appellants,*

v.

HON. KIMBERLY N. BUNNELL
(JUDGE, FAYETTE CIRCUIT COURT),
*Appellee,*

and

ESTATE OF LUVETTA GOFF, *et al*.,
*Real Parties in Interest.*

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Aug. 21, 2014. As Corrected Sept. 10, 2014.
Rehearing Denied Dec. 18, 2014.

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OPINION

Opinion of the Court by Justice SCOTT.

Appellants, Phillip Tibbs, M.D., Joel E. Norman, M.D., and Barrett W. Brown, M.D., petitioned the Court of Appeals for a writ of prohibition directing the Fayette County Circuit Court to prohibit the production of an "incident" or "event" report created after the death of patient Luvetta Goff, arguing that it fell within the federal privilege created by the Patient Safety and Quality Improvement Act of 2005 ("PSQIA" or "the Act"), 42 U.S.C.A. § 299b-21 *et seq*. The Court of Appeals granted Appellants the writ, but Appellants appealed to this Court as a matter of right, Ky. Const. § 110(2)(b), arguing that the Court of

Appeals erroneously limited the protective scope of the privilege. No cross-appeals were filed.

Appellants now present a question of first impression to this Court regarding the proper scope of the privilege established by the Act. As such, the issuance of the writ is *not* before us, and therefore stands, as does the order of remand for further review. We only address the scope of the Act's privilege, as this is the sole issue presented on appeal. For the reasons that follow, we reverse and clarify the scope of the Act's privilege to be applied on remand.

## I. BACKGROUND

The underlying case is a medical malpractice action in which Goff died as a result of complications from an elective spine surgery performed by Appellants at the University of Kentucky Hospital. Goff's estate filed a wrongful death and medical malpractice action against Appellants, and this appeal stems from a discovery dispute regarding an alleged post-incident or event report generated by a UK Hospital surgical nurse concerning the surgery through the UK HealthCare Patient Safety Evaluation System on the day of the event.[1]

During discovery, Goff's estate requested the following:

> *INTERROGATORY NO. 26:* Please state whether any investigation, including but not limited to peer review and/or incident reports, has been conducted upon the medical treatment, surgery or care rendered to the Plaintiff, by you, or anyone at

[1] The UK HealthCare Risk Management Department now oversees the daily operation of UK Healthcare's Patient Safety Evaluation System (PSES).

> your direction or control, and if so, by whom, when and the results thereof. If yes, produce such documents.
>
> . . . .
>
> *REQUEST NO. 7:* Please produce any and all documents generated by any investigation, including but not limited to, peer review and/or incident reports of the events of January 3, 2011 through January 26, 2011, as identified in your answer to interrogatory No. 26.

Appellants then moved for a protective order concerning the report, asserting that the only post-incident report that exists is a "report created through UK Healthcare's Patient Safety Evaluation System" and, thus, it is protected from discovery by the new federal privilege for patient safety work product created by the Act.[2]

The trial court denied Appellants' motion and ordered production of the document *if* it was generated by "someone involved in or with actual knowledge of the medical care,"[3] at UK.

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[2] Peer review documents and incident reports are not otherwise privileged in malpractice litigation in Kentucky. *Saleba v. Schrand*, 300 S.W.3d 177 (Ky.2009).

[3] Particularly, the trial court ordered:

> 1. The Court finds that the incident report subject to the defendants' motion is not entitled to the privilege contained in the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §§ 299b-22(a) and 299b-21 (the "Act"). The Court holds that the incident report is not "patient safety work product" because it is exempted from the definition of "patient safety work product" by the "clarification" contained § 299b-21(7)(B) of the Act.

Appellants then sought a writ of prohibition preventing the trial court from ordering production of the report, and the Court of Appeals entered an order granting the writ of prohibition, holding the Act's federal privilege preempted the trial court from ordering the disclosure of information privileged under federal statutory law,[4] but that the Act's privilege is limited to

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2. The Court holds that the incident report is discoverable only if it was prepared by someone involved in or with actual knowledge of the medical care rendered to Mrs. Goff at the University of Kentucky ("UK"). Therefore, the defendants' motion for a protective order is OVERRULED if the incident report was prepared by a person who was involved in and had actual knowledge of Mrs. Goff's medical care at UK. The motion for protective order is SUSTAINED if the incident report was prepared by a person who was not involved in and did not have actual knowledge of Mrs. Goff's medical care at UK. Within 20 days of the entry of this order, the defendants shall either produce the incident report or advise the Court and opposing counsel that it is not being produced because it was prepared by a person who was not involved in and did not have actual knowledge of Mrs. Goffs medical care at UK.

3. If the incident report is produced pursuant to this Order, it shall be maintained in a confidential manner, shall not be used for any purpose outside of this litigation, and shall not be disclosed to any person, party, or attorney who is not involved in this litigation. The Court will also allow appropriate redactions of elements of the form (as opposed to the substantive content inserted therein) if deemed necessary to protect any proprietary information regarding the form itself.

[4] The section in the Code of Federal Regulations dealing with the privilege for patient safety work product states:

(a) Privilege. Notwithstanding any other provision of Federal, State, local, or Tribal law and subject to paragraph (b) of this section and § 3.208 of this subpart, patient safety work product shall be privileged and shall not be:

"documents that contain a self-examining analysis," and, thus, remanded the matter to the trial court with instructions to conduct an *in camera* review of the document at issue to determine if it contained the required "self-examining analysis."[5]

Appellants now appeal from the Court of Appeals' opinion and order alleging that the Court of Appeals erroneously limited the scope of the privilege. Appellants base their appeal on the portion of the Court of Appeals order limiting the privilege to documents containing a "self-examining analysis," arguing that the term "self-examining analysis" is neither found nor implied in the Act or its legislative history.

## II. PSQIA

Before we address the scope of the Act's privilege, we feel that it is important to discuss the history and purpose of the Act as established by the United States Congress. Congress enacted this legislation in order to encourage health care providers to voluntarily associate and communicate privileged patient safety work product (PSWP) among themselves through in-house patient safety evaluation systems (PSES) and with and through affiliated patient safety organizations

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> (1) Subject to a Federal, State, local, or Tribal civil, criminal, or administrative subpoena or order, including in a Federal, State, local, or Tribal civil or administrative disciplinary proceeding against a provider; . . . .

42 C.F.R. § 3.204

[5] The alleged "incident report," or, as Appellants refer to it, the "incident/event report," has yet to be produced. However, given Appellants' petition for a writ, the current appeal, and the fact that the report was generated by a UK surgical nurse on the day of the event, the probability that the report was prepared by someone "not involved in, nor having actual knowledge of the underlying treatment is very low."

(PSO) 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. 42 U.S.C.A. § 299b-21, *et seq.; see also Dep't of Fin. & Prof'l Regulation v. Walgreen Co.*, 361 Ill.Dec. 186, 970 N.E.2d 552, 557 (Ill.App.Ct.2012) ("The Patient Safety Act 'announces a more general approval of the medical peer review process and more sweeping evidentiary protections for materials used therein.'" (citation omitted)).[6]

Congress took such action following the Institute of Medicine's (IOM) publication of a report entitled *To Err Is Human: Building a Safer Health System*, in

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[6] Traditionally, "medical malpractice suits . . . [were] considered to be the cornerstone mechanism of regulating patient safety in the United States." Levy, et. al., *The Patient Safety and Quality Improvement Act of 2005 Preventing Error and Promoting Patient Safety*, 31 J. Legal Med. at 400. "One defect [of this litigation, however,] is that [it] only addresses negligent care that actually [causes] damage." *Id.* "Beyond medical malpractice, medical peer review is the other main institutional process that deals with patient safety. Medical peer review is a mechanism in which a committee, composed of medical professionals, evaluates the appropriateness of care or determines the adequacy of practitioners' credentials. The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations, or JCAHO), the Medicare program, and all states require a peer review process for providers." *Id*. at 400-01 (footnotes omitted). "Through its accreditation activities, The Joint Commission promotes patient safety by requiring member organizations to report serious adverse patient health events and performing root cause analysis on those events." *Id.* at 406. "However, such serious events are a very small proportion of patient care errors. There [were no] mechanisms for evaluating 'near misses' that [did] not result in serious harm." *Id.*

which it was estimated that up to 98,000 Americans die each year as a result of medical errors, most of which "errors were not the result of personal recklessness but rather resulted from faulty systems, processes, and conditions." *Lee Med., Inc. v. Beecher*, 312 S.W.3d 515, 534 (Tenn.2010) (*citing* Institute of Medicine, Committee on Quality of Health Care in America, *To Err Is Human: Building a Safer Health System*, 49-66 (2000)). Prior to the Act, providers had little incentive to communicate amongst themselves and to report and analyze errors nationally due to fear that such communications or analysis might well generate litigation and/or be discoverable therein.

The intended purpose of the Act is set out in the House of Representatives report, as follows:

> The IOM report offered several recommendations to improve patient safety and reduce medical error, including that Congress pass legislation to extend peer review protections to data related to patient safety and quality improvement that are developed and analyzed by health care organizations for internal use or shared with others solely for the purpose of improving safety and quality.
>
> This bill's intended purpose is to encourage the reporting and analysis of medical errors and health care systems by providing peer review protection of information reported to patient safety organizations for the purposes of quality improvement and patient safety. These protections will facilitate an environment in which health care providers are able to discuss errors openly and learn from them. The protections apply to certain categories of documents and communications termed "patient safety work product" that are developed in connec-

> tion with newly created patient safety organizations. This patient safety work product is considered privileged and, therefore, cannot be subject to disclosure . . . .

H.R.Rep. No. 109-197 (2005). Complementing the privilege is a confidentiality provision establishing that "patient safety work product shall be confidential and shall not be disclosed" except as authorized by the Act itself. 42 U.S.C.A. § 299b-22(b); *see also* 42 C.F.R. § 3.206(b).[7]

## III. ANALYSIS

Appellants raise a very narrow issue before this Court: whether the Court of Appeals erred in limiting the privilege to documents employing a "self-examining analysis" rather than the statutory language used in the Act. If Appellants are correct, the secondary question becomes: what is "patient safety work product"?

On direct appeal from the Court of Appeals in a case involving a writ of prohibition, this Court reviews the Court of Appeals legal rulings *de novo*. *Commonwealth v. Shepherd*, 366 S.W.3d 1, 4 (Ky.2012) (*citing Grange Mutual Ins. Co. v. Trude*, 151 S.W.3d 803 (Ky.2004)).

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[7] The Act empowers the Secretary of Health and Human Services to commence enforcement proceedings against anyone (including any healthcare provider) who knowingly or recklessly discloses identifiable patient safety work product in violation of the confidentiality provision. 42 U.S.C.A. § 299b-22(f); 42 C.F.R. §§ 3.402-3.552. Violations of the confidentiality provision are punishable by civil monetary penalties of up to $11,000 per violation. *Id.*

A. Applicability of *Francis*

In granting Appellants' petition for writ of prohibition, the Court of Appeals construed the privilege under the Act to be limited to documents, or portions thereof, containing a "self-examining analysis," thereby instructing the trial court upon remand to review the document at issue *in camera* to determine what portions qualified for the privilege. In support of its opinion, the Court of Appeals cited to *Francis v. United States*, No. 09 Civ. 4004(GBD)(KNF), 2011 WL 2224509 (S.D.N.Y. May 31, 2011).

Appellants argue that the Court of Appeals erred in applying *Francis* to determine the scope of the privilege granted by the Act, since the Act was not applicable therein[8] and *Francis* applied a different federal common law privilege involving a "self-examining analysis."[9]

On review, we agree that the Court of Appeals misapplied *Francis* to the present case given that it relied on *dictum* from *Francis* to support its finding that the Act's privilege is limited solely to documents, or portions thereof, that employ a "self-examining analysis," to wit:

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[8] *Francis*, 2011 WL 2224509, at *6 ("The quality assurance review documents at issue in this action are not protected under the PSQIA, since they were not provided to a PSO.").

[9] Appellees agree with this point, but nevertheless assert that incident reports are not privileged under the Act. Their position is consistent with paragraph one of the trial court's order, which states "[t]he Court holds that the incident report is not 'patient safety work product' because it is exempted from the definition of 'patient safety work product' by the 'clarification' contained in § 299-21(7)(B) of the Act."

> Inasmuch as the self-critical analysis privilege "is based upon the concern that disclosure of documents reflecting candid self-examination will deter or suppress socially useful investigations and evaluations[,]" it stands to reason that only quality assurance review documents containing self-examining statements are privileged. This conclusion is in line with Congress' intent regarding the scope of the [Act's] privilege, which extends only to "the analysis of, and subsequent corrective actions related to [an] adverse event or medical errors. [sic]

*Id*. at *7 (citations omitted).

The final portion of this quote was extracted from a Senate report that accompanied a 2003 proposed version of the Patient Safety Act that was not enacted. Therefore, 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. Furthermore, the Court of Appeals failed to take into consideration the entire context of that Senate report. The full text demonstrates that it was not the intent of the Senate under the prior draft to limit the scope of the privilege to only documents employing a self-critical analysis.

> The legislation grants an evidentiary privilege for information collected and developed by providers and PSO's through this voluntary reporting system. The privilege encompasses not only the report to the patient safety organization but also all aspects of the analysis of, and subsequent corrective actions related to, adverse events, medical errors, and "near misses" reported as patient safety data. It covers all deliberations, including oral and written communications, and work

> products that meet the requirements for patient safety data.

Sen. Rep. No. 108-196, at 5 (2003).

Given that *Francis* involved the application of a common law privilege under a different federal statute, referred to a Senate report that accompanied a prior version of the Act that predated the actual passage of the Act, and failed to consider the full context of that Senate report, we believe that the Court of Appeals was misguided in its ultimate limitations on the scope of the privilege. In fact, as the statutory language indicates, the privilege also extends to certain types of information and data underlying, supporting, or triggering such an analysis. 42 U.S.C.A. § 299b-21(7). We therefore reverse the opinion of the Court of Appeals to the extent it limited the scope of the Act's privilege to documents containing a "self-examining analysis." We will now analyze and clarify the scope of the Act's privilege.

B. Proper Scope of Analysis

In order to determine whether or not something falls under the protection of the privilege established by the Act, one must first look to the plain language of the Act itself. "The cardinal rule of statutory construction is that the intention of the legislature should be ascertained and given effect." *Jefferson Cnty. Bd. of Educ. v. Fell*, 391 S.W.3d 713, 718 (Ky.2012) (*citing MPM Fin. Grp., Inc. v. Morton*, 289 S.W.3d 193, 197 (Ky.2009)). "Thus, we first look at the language employed by [Congress], relying generally on the common meaning of the particular words chosen." *Id*. at 719 (*citing Caesars Riverboat Casino, LLC v. Beach*, 336 S.W.3d 51, 58 (Ky.2011)).

Therefore the first analysis to undertake when a party asserts the Act's privilege is to determine whether the information satisfies the statutory definition for patient safety work product as established by the Act, to wit:

> (A) In general
>
> Except as provided in subparagraph (B), the term "patient safety work product" means 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.

42 U.S.C.A. § 299b-21(7). To the extent this may be done, we need go no further.

Here, the language of the Act's definition of "patient safety work product" establishes that the categories of items defined in subsection A shall be deemed to be patient safety work product, *unless* it falls within one

of the exceptions established in subparagraph B. One must then look to subsection B to determine if an item falls within the exception stated:

> (B) Clarification:
>
> (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.

42 U.S.C.A. § 299b-21(7)(B) (emphasis added).

C. Goff's "Incident Report" is Not Protected by the PSQIA

We now turn in the present case to the determination of whether "incident reports" are protected under the Act's privilege.

By its plain and express terms, the Act does not protect a "patient's medical record, billing and discharge information, or any other original patient or provider record." 42 U.S.C.A. § 299b-21(7)(B)(i). Nor does it 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. 42 U.S.C.A. § 299b-21(7)(B)(ii).

Kentucky Administrative Regulations relating to Kentucky hospitals provide that: "administrative reports shall be *established, maintained and utilized* as necessary to guide the operation, measure of productivity and reflect the programs of the facility." 902 KAR 20:016 § 3(3)(a) (emphasis added). These reports "shall include: . . . (5) [i]ncident investigation reports; [10, 11]and (6) [o]ther pertinent reports made in

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[10] Occurrence or incident reports are "to be used by employees in the ordinary course of business when significant events occur to document their experience and observations for subsequent review by the hospital's risk management staff in assessing legal liability issues." *Univ. Med. Ctr., Inc. v. Beglin*, 375 S.W.3d 783, 787 (Ky.2011). As such, it is not a patient record, but, rather, a hospital record. 902 KAR 20:016 § 3(3)(a).

[11] Reports of adverse patient health events are also required to maintain a hospital's accreditation with the Joint Commission. Levy, et al., *The Patient Safety and Quality Improvement Act of 2005 Preventing Error and Promoting Patient Safety*, 31 J. Legal Med. at 406. We note, however, that 42 U.S.C.A. 299b-22(c)(2)(E) waives confidentiality regarding disclosure to an "accrediting

the regular course of business." *Id.* Such required documents also include peer review and credentialing records. *See* 902 KAR 20:016 § 8(b)(1)-(2). Under Kentucky law, these types of reports are required in the regular course of the hospital's business, are hospital records, and, thus, are generally discoverable. *See Saleba*, 300 S.W.3d at 184 ("[W]e reiterate that KRS 311.377(2) does not extend the privilege for peer review documents to medical malpractice suits.").

This position conforms with the United States Department for Health and Human Services' own interpretation of the Act in its enactment of its final rules and regulations covering its implementation, to wit:

> 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. Information 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 (FDA); certification or licensing records for compliance with health oversight agency requirements; reporting to the National Practitioner Data Bank of physician disciplinary actions; complying with required disclosures by particular providers or suppliers

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body that accredits that provider." We find no countervailing waiver to a state regulatory body.

> pursuant to Medicare's conditions of participation or conditions of coverage; or provision of access to records by Protection and Advocacy organizations as required by law.

Patient Safety and Quality Improvement, 73 FR 70732-01 at 70742-43.

As a rule, courts give deference to agency interpretations of the statutes which they administer. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, *Inc.*, 467 U.S. 837, 844, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984) ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations." (footnote omitted)). Moreover, an agency's interpretation of its own regulations is controlling unless it is "plainly erroneous or inconsistent with the regulation." *Auer v. Robbins*, 519 U.S. 452, 461, 117 S.Ct. 905, 137 L.Ed.2d 79 (1997) (citations omitted).

Here, UK Healthcare's Risk Management Director's affidavit establishes, in relevant part, that:

> 1. "The UK HealthCare Risk Management Department oversees the daily operation of [UK Healthcare's] Patient Safety Evaluation System ("PSES")."[12]

[12] The UK HealthCare Incident Reporting Committee is designated as a component of the UK HealthCare PSES, as is most of UK HealthCare's staff, departments, and committees, including the Senior Administration Group and Senior Operations Group. UK HealthCare Policy and Procedure, Policy # A06-035, Patient Safety Evaluation System, p. 3.

2. "[T]he University subsequently entered into a contract with [University HealthSystem Consortium (UHC)] for UHC to serve as the University's [Patient Safety Organization (PSO)]."

3. "One of UHC's services as the University's PSO is to provide UK HealthCare with the use of UHC's Patient Safety Net® system."

4. "The Patient Safety Net® is a real-time, Web-based event reporting system, which serves as the data collection tool and the *repository for information* submitted to the UHC PSO through a provider's PSES." (Emphasis added.)

5. "The Patient Safety Net® collects and compiles UK Healthcare's reported events data (incident reports) and generates analyses and reports for Patient Safety Net® participants with the ability to generate reports and to compare statistics between participants."[13]

6. "A wide range of events are reported to the Patient Safety Net® including Patient Events, Staff Events, Visitor Events and Unsafe Conditions. There are many types of reportable events in the Patient Events category, which include complications of surgery or anesthesia, including, but not limited to, death or hemorrhage requiring an unexpected transfusion or return to the OR. The intraoperative complication that occurred during Luvetta Goff's surgery was appropriately reported to the Patient Safety Net® . . . ."

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[13] UHC is an alliance of 116 academic medical centers and 260 of their affiliated hospitals, representing almost 90% of the nation's non-profit academic medical centers, including the University of Louisville Hospital.

> 7. "Since the creation of UK Healthcare's PSES, all incident reports at UK HealthCare facilities, including the incident report concerning Luvetta Goff, have been generated exclusively through UHC's Patient Safety Net® system. Thus, to create an incident report, a UK HealthCare employee must input data through UHC's web-based system."
>
> 8. "The Patient Safety Net® requires incident reports to include certain common data elements, including the date of the submission, any person harmed or affected by the incident, the location where the event occurred, and a description of the event."
>
> 9. "All incident reports completed by a UK HealthCare employee using the Patient Safety Net® are automatically transmitted to UHC every 45 days."

In support of their argument that the Act mandates a privilege for the incident or event report in this instance, Appellants cite to *Dep't of Fin. & Prof'l Regulation v. Walgreen Co.*, 361 Ill.Dec. 186, 970 N.E.2d 552 (Ill.App.Ct.2012) and *K.D. ex rel. Dieffenbach v. United States*, 715 F.Supp.2d 587 (D.Del.2010). *K.D.* was an action under the Federal Tort Claims Act (FTCA), 28 U.S.C.A. § 2671, *et seq*., wherein production was sought of documents concerning monitoring of a National Institutes of Health (NIH) research protocol in which K.D. had participated.[14]

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[14] Given the documents at issue and the circumstances involved, the PSQIA was not applicable. *K.D.*, 715 F.Supp.2d at 596 ("Whether or not the NIH review bodies at issue here meet the technical requirements for listing as PSOs, they clearly

*K.D.*, like *Francis*, relied on the 2003 Senate Report on the Act (which refers to an earlier draft that was never enacted) in its general analysis of the Act. *Id*. at 595. Moreover, in analogizing the common law privilege involved to information privileged under the Act, it did not address 42 U.S.C.A. § 299b-21(7)(B) dealing with the exceptions to "patient safety work product."

*Walgreen*, however, upheld a trial court's order prohibiting production and discovery under the PSQIA of Walgreen incident reports of medication error by three of its pharmacists, sought by the Illinois Department of Financial and Professional Regulation (the Department). *Walgreen*, 361 Ill.Dec. 186, 970 N.E.2d at 558. The Department had claimed the pharmacy incident reports were exempted from the Act's privilege as they "could have been created, maintained, or used for a purpose other than reporting to a PSO." *Id*., 361 Ill.Dec. 186, 970 N.E.2d at 557. Thus, it argued they would not be privileged pursuant to 42 U.S.C.A. § 299b-21(7)(B)(ii).

Walgreen, on the other hand, established by affidavit, that it "does not create, maintain, or otherwise have in its possession incident reports pertaining to medication error other than the STARS reports referenced in [its] original affidavit. There are no other incident reports pertaining to medication error that are collected or maintained separately from the STARS reporting system." *Walgreen*, 361 Ill.Dec. 186, 970 N.E.2d at 558. Walgreen's affidavit further evidenced that the STARS reports were transmitted to a PSO.

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perform the same functions Congress intended the PSQIA to encourage.").

Pursuant to the foregoing, the court in *Walgreen* held the "STARS reports were privileged pursuant to section 299b-21(7) of the . . . Act." *Id*. However, the opinion did not disclose any obligations Walgreen had to create, maintain, or file medication error incident reports with the Illinois Department, other than noting that the Illinois Medical Studies Act was not applicable to pharmacies and the Department sought an order compelling their production.[15]

Plainly, however, the PSQIA 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). As previously noted, the 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." Patient Safety and Quality Improvement, 73 FR 70732-01 at 70742

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[15] Pharmacies are not required to file incident reports with the Illinois Department, as sections 8-2101 to 8-2105 of the Illinois Code of Civil Procedure (Code) pertaining to medical studies (the Medical Studies Act) (735 ILCS 5/8-2101 to 8-2105 (West 2010)) do not apply to pharmacies. *See Walgreen*, 361 Ill.Dec. 186, 970 N.E.2d at 559 ("Because pharmacies are not listed in the pertinent section of the Medical Studies Act . . ., the circuit court improperly determined that the statute applied to [Walgreen].") In Kentucky, there is no administrative regulation that requires the direct reporting of incidents to the Kentucky Board of Pharmacists, however, pharmacies are to keep patient and quality assurance records available shall the Board request such records. *See* 201 KAR 2:170; 201 KAR 2:205.

(emphasis added). Thus, as noted in the House Report regarding the Act:

> Paragraphs 7(B)(i) and (ii) explains documents or communications that are not included under clause (7)(A). The Committee understands that it is likely and appropriate for a provider to keep a copy of documents and possible logs of communications that are reported to the patient safety organization. Generally, such copies are also patient safety work product because they are part of the patient safety evaluation system. Such items would not be considered original provider records as set out under 7(B)(i).
>
> On the other hand, there may be documents or communications that are part of traditional health care operations or record keeping (including but not limited to 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)*. Such information may be in communications or copies of documents sent to a patient safety organization. Originals or copies of such documents are both original provider records and separate information that is developed, collected, maintained or exist separately from any patient safety evaluation system. *Both these original documents and ordinary information about health care operations may be relevant to a patient safety evaluation system but are not themselves patient safety work product.*

H.R. Rep. 109-197, 14 (emphasis added). To date, no opinion has directly addressed the effect of the Act's recognition of these dual reporting obligations.

One Florida federal discrimination action, *Awwad v. Largo Med. Ctr., Inc.*, 8:11-CV-1638-T-24TBM, 2012 WL 1231982 (M.D.Fla. Apr. 12, 2012), touched on the applicability of the Act to the discovery of credentialing and peer review files, but held, without explanation, "any privilege created by the PSQIA appears inapplicable to the circumstances of this case." *Id*. at *2. It is noted, however, that Florida has a constitutional provision and statutes mandating patient rights of access to "any records made or received in the course of business by a health care facility or health care provider relating to any adverse medical incident."[16] Fla. Const. art. X, § 25(a); *see also* Fla. Stat. Ann. § 381.028 (the pre-2013 version of which was held unconstitutional in part by *W. Florida Reg'l Med. Ctr., Inc. v. See*, 79 So.3d 1 (Fla.2012)). Thus, according to one Florida writer, "neither annual reports nor Code 15 reports are protected as PSWP" in Florida under the Act. Kelly G. Dunberg, *Just What the Doctor Ordered? How the Patient Safety and Quality Improvement Act May Cure Florida's Patients' Right to Know*

[16] Florida's Constitution defines "adverse medical incident," to wit:

> The phrase "adverse medical incident" means medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient, including, but not limited to, those incidents that are required by state or federal law to be reported to any governmental agency or body, and incidents that are reported to or reviewed by any health care facility peer review, risk management, quality assurance, credentials, or similar committee, or any representative of any such committees.

Fla. Const. art. X, § 25(c)(3).

*About Adverse Medical Incidents (Amendment 7)*, 64 Fla. L.Rev. 513, 542 (2012).[17]

Although this issue might have also been addressed in *Lee Mem'l Health Sys. v. Guillermo*, 2:10-CV-00700-FTM-36, 2011 WL 5826672, ("Counts One through Four of the Amended Complaint seek declaratory relief to the effect that Amendment 7 [ (Fla. Const. art. X, § 25) ] is preempted by the . . . PSQIA."), the federal district court abstained from exercising jurisdiction and dismissed the case, stating that "Florida Circuit Courts, District Courts of Appeal, and the Supreme Court of Florida have shown themselves to be very capable of adjudicating these federal issues." *Id.* The following year (in 2012), in *W. Florida Reg'l Med. Ctr.*, 79 So.3d 1, an issue was raised by the hospital as to whether an incident report was protected by various Florida statutes, as well as the Health Care Quality Improvement Act of 1986 (HCQIA), 42 U.S.C.A. § 11101, *et. seq*. However, it is notable that no issue was raised in that case as to the applicability of PSQIA. *Id.*

One other opinion handled the issue of event reports peripherally, *Venosh v. Henzes*, No. 11CV3058, 2013 WL 9593953 (Pa.Com.Pl. July 17, 2013). However,

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[17] "A Code 15 report is a report that a health care facility must file with Florida's Agency for Health Care Administration within fifteen calendar days after the occurrence of an "adverse incident" as defined in [Fla. Stat. Ann.] section 395.0197(7)." *W. Florida Reg'l Med. Ctr.*, 79 So.3d at 7. More importantly, however, *W. Florida Reg'l Med. Ctr. did not limit discovery to only incidents documented in "code 15" and annual reports. Id*. at 15 ("More specifically, [Fla. Const. art. X, § 25] provides that patients shall have access to records of adverse incidents, including those records 'reported to or reviewed by any health care facility . . . "*risk management*" committee.") (emphasis added).

*Venosh* was decided on the basis that there was no evidence that the two event reports were provided to a duly certified PSO. *Id*. at *1. This was the same rationale noted in *Francis, supra*.

In Kentucky, KRS 216B.042 grants the Cabinet for Health and Family Services the responsibility for licensing and regulating healthcare facilities including the right to "[e]stablish licensure standards and procedures to ensure safe, adequate, and efficient . . . health facilities and health services," KRS 216B.042(c), as well as the right to "enter upon the premises of any health care facility for the purpose of inspection," KRS 216B-042(2). And, as previously stated, pursuant to its regulations, "[a]dministrative reports shall be *established, maintained and utilized* as necessary to guide the operation . . . of the facility." 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).

Here, we have incident information reported by a hospital surgical nurse that normally 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). Yet, it appears the information has not been completed or maintained separately as a hospital record (in a normal incident

report), 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 PSO has access. For this reason, it is claimed to be privileged under the Act.

Yet, while the incident information may be relevant to its 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. As evidenced by its recognition of dual reporting requirements, Congress never intended the Act to deprive the states of state-mandated information relevant to their regulatory duties. 42 U.S.C.A. § 299b-21(7)(B); H.R. Rep. 109-197, 14 ("Both these original documents and ordinary information about health care operations may be relevant to a patient safety evaluation system but are not themselves patient safety work product.").[18] Thus, Congress did not intend for separately-mandated incident information sources to be able to acquire a federal privilege by virtue of the healthcare provider's act of putting them solely into a PSES repository system (here, "Patient Safety Net®") for the use of the healthcare provider's PSES and its PSO. Thus, information normally contained in an incident report is not privileged under the Act and may be discovered, following an *in camera* review, and its information compelled.

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[18] The dissent acknowledges this point, but would nevertheless grant protection for the incident report information until such time as the healthcare organization is forced to disgorge the material in other litigation in some other form.

To the extent the information normally contained in such state-mandated incident reports is intermingled with other material properly privileged under the Act, they may be separated from each other by the trial court *in camera*. We do not otherwise disturb or review the trial court's order of confidentiality.

## IV. CONCLUSION

We reiterate, the Court of Appeals' issuance of the writ is not properly before us and stands, as does the order of remand. For the aforementioned reasons, we reverse the opinion of the Court of Appeals regarding the scope of the privilege under the Act, and remand this matter to the trial court for *in camera* review, consistent with this opinion.

CUNNINGHAM and VENTERS, JJ., concur. NOBLE, J., concurs in result only. ABRAMSON, J., dissents by separate opinion in which MINTON, C.J., joins. KELLER, J., not sitting.

ABRAMSON, J., dissenting:

Respectfully I dissent. Although I agree with much of what Justice Scott has to say about the Patient Safety and Quality Improvement Act's (PSQIA, the Patient Safety Act, or the Act) history, I believe the Court has given too little regard to the Act's purpose, has misconstrued the privilege the Act creates, and thereby has undercut the Act's effectiveness in advancing patient safety in Kentucky. The Act envisions a national medical error reporting system apart from and insulated from the fault-based tort (professional liability) and peer-review (professional discipline) systems, a system that will enhance patient care by identifying systemic failures in health care delivery through the vast collection and analysis of pertinent data. Participation in what has come to be referred to

as the "patient safety" approach to medical errors will be discouraged if the attendant privilege is not strictly construed as Congress intended. The majority's decision allows Kentucky judges to sift through federally protected patient safety data for otherwise discoverable material under state law, and thus, frustrates the Act's intent. That said, I agree that the Patient Safety Act was never intended to displace state law and that Kentucky clearly requires hospitals to maintain incident investigation reports and other records which are discoverable by a patient or her estate. A hospital's participation in the national reporting system created by the Patient Safety Act does not excuse compliance with those state record-keeping requirements. In my view, patients continue to have access to those records available to them under Kentucky law prior to the Patient Safety Act but now, as then, the source of the records must be the hospital's state-mandated internal record system and not the in-house patient safety system or data clearinghouse used by the hospital to participate voluntarily in the PSQIA.

## RELEVANT FACTS

Underlying the discovery dispute at issue here is a medical malpractice action brought by the estate of Luvetta Goff against three surgeons who performed back surgery on Ms. Goff at the University of Kentucky Hospital in January 2011. Ms. Goff died during the procedure, and the estate alleges that her death was caused by the surgeons' negligence. Following Ms. Goffs death, a hospital nurse entered a post-event report into the hospital's Patient Safety Evaluation System, an information collection and management system implemented at the hospital pursuant to the Patient Safety Act. When the estate

made a discovery demand that the report be disclosed, the defendants moved for a protective order on the ground that under the Act the report is privileged.

The trial court denied the defendants' motion, whereupon the defendants sought mandamus relief in the Court of Appeals. That Court agreed with the defendants to the extent of recognizing a federal privilege under the Act independent of any state-law privileges, but ruled that the federal privilege applies only to "documents that contain a self-examining analysis." Accordingly the Court remanded the matter to the trial court with instructions to review the nurse's report *in camera* and to grant or to deny discovery based on its view of whether the report contained such an analysis.

Arguing that the Court of Appeals read a limitation into the Patient Safety Act's privilege that Congress did not put there, the defendants have asked this Court to correct its ruling and to order the trial court simply to deny discovery of the nurse's report. The majority agrees that the Court of Appeals improperly rewrote the federal statute, but then undertakes its own revision and holds that the federal privilege does not apply to information "normally contained" in a state-mandated incident report. The majority authorizes the trial judge to conduct an *in camera* review to extract that "information normally contained in an incident report."[19] While I agree that patients or their

[19] In addition to disregarding the clear import of the Act, this *in camera* review raises serious practical concerns since judges, not typically being medically trained, may have difficulty identifying what information is normally contained in an incident report. Judicially created "incident reports" are no substitute for the real thing prepared by trained medical professionals.

estates are entitled to that information, I strongly disagree with this manner of obtaining it.

ANALYSIS

As the Court recounts, Congress passed the PSQIA, 42 U.S.C. §§ 299b-21—299b-26, in 2005 in response to wide-spread concerns that an alarming number of preventable medical errors result not from or not primarily from a particular practitioner's carelessness, the sort of error the tort and peer-review systems respond to and seek to deter, but rather from systemic failures. Randall R. Bovbjerg and Robert H. Miller, *Paths to Reducing Medical Injury: Professional Liability and Discipline vs. Patient Safety—and the Need for a Third Way*, 29 J.L. Med. & Ethics 369 (2001) (discussing the 1999 Institute of Medicine's report, *To Err is Human: Building a Safer Health System*, and its spawning of the "patient safety" movement); Frederick Levy, M.D., J.D., *et al., The Patient Safety and Quality Improvement Act of 2005: Preventing Error and Promoting Patient Safety*, 31 J. Legal Med. 397 (2010) (discussing the PSQIA as a congressional response to patient-safety-movement concerns). Hoping to borrow from the non-fault-based systems approach to safety improvement successfully employed by other industries, in particular the aviation industry, Congress created a system whereby health care providers can (the system is entirely voluntary) establish an in-house "patient safety evaluation system" for the "collection, management, or analysis" of patient safety-related information. 42 U.S.C. § 299b-21(6). The providers may then submit the collected information to data clearing houses referred to in the Act as Patient Safety Organizations (PSOs). 42 U.S.C. § 299b-24. The PSOs in turn, having rendered the data submitted to them nonidentifiable,

provide it to "a network of patient safety databases," which "shall have the capacity to accept, aggregate across the network, and analyze nonidentifiable patient safety work product." 42 U.S.C. § 299b-23. This network-wide aggregation and analysis is intended to enable researchers to identify flaws in health care delivery practices and to recommend improvements to the health care providers. The purpose of the Act, as explained in the Senate Report accompanying the Act's very similar 2003 version, is thus

> to encourage a "culture of safety" and quality in the U.S. health care system by providing for broad confidentiality and legal protections of information collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety. These protections will facilitate an environment in which health care professionals and organizations report and evaluate health care errors and share their experiences with others in order to prevent similar occurrences.

Senate Report No. 108-196, at 3 (Nov.2003).[20]

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[20] As the majority correctly notes, the 2003 Senate version of the legislation (S.720) is not the version ultimately enacted in 2005. It was, however, a very close precursor of that version, both in its general purposes and structure and in its specific terms. *See* Robert A. Kerr, *The Patient Safety and Quality Improvement Act of 2005: Who Should Pay For Improved Outcomes*, 17 Health Matrix 319, 328 (2007) (noting that the 2005 version of the Act was to a large extent simply a reintroduction of the Senate's 2003 version). In particular, S. 720 provided a privilege for "patient safety data" identical to the Act's privilege for "patient safety work product," defined "patient safety data" in terms nearly identical to those in the Act defining "patient safety work product," and similarly limited that definition so as not to include

Plainly, the success of the system is contingent upon the willingness of providers to supply safety-related information, including information about errors and near errors, to the PSOs. Accordingly the Act seeks to encourage provider participation by protecting their information. Specifically the Act provides in pertinent part as follows:

Notwithstanding any other provision of Federal, State, or local law, . . . 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;
>
> (3) subject to disclosure pursuant to section 552 of Title 5 (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;
>
> (4) admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal

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"information (including a patient's medical record) that is collected or developed separately from and that exists separately from patient safety data. Such separate information or a copy thereof submitted to a patient safety organization shall not itself be considered as patient safety data." Senate Report No. 108-196, at 24. The Report accompanying S. 720, in other words, provides, in my view, meaningful insight into the congressional intent animating the PSQIA.

> proceeding, administrative rule making proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider, or
>
> (5) admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

42 U.S.C. § 299b-22(a). The intent to assure providers that their participation in the patient safety system is not to be used against them in either the tort or the peer-review system could hardly be clearer. Indeed, the Senate Report accompanying the 2003 version of the Act explained that the legislation

> establishes confidentiality protections for this written and oral patient safety data to promote the reporting of medical errors. As a result, health care providers will be able to report and analyze medical errors, without fear that these reports will become public or be used in litigation. This nonpunitive environment will foster the sharing of medical error information that is a significant step in a process to improve the safety, quality, and outcomes of medical care.

Senate Report 108-196 at 5.

On the other hand, the patient safety system fashioned by the PSQIA is not intended to supplant or to disable in any way the existing state-law tort and peer-review systems. This intent emerges from Congress's careful distinction between "patient safety work product," to which the privilege applies, and records or information existing apart from the patient safety system, to which state law discovery rules continue to be applicable:

Patient safety work product

(A) In general

Except as provided in subparagraph (B), the term "patient safety work product" means 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.

(B) Clarification

(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.

42 U.S.C. § 299b-21(7). The Act's privilege thus applies to anything—data, reports, analyses, statements, etc.—processed within a patient safety evaluation system for submission to a PSO. It does not apply, however, to records, reports, and other information existing separately from the Act's patient safety system.

Discussing this distinction, the Secretary of the Department of Health and Human Services, the agency responsible for implementing the PSQIA, has explained that

> The Department recognizes that the Patient Safety Act's protections are the foundation to furthering the overall goal of the statute to develop a national system for analyzing and learning from patient safety events. To encourage voluntary reporting of patient safety events by providers, the protections must be substantial and broad enough so that providers can participate in the system without fear of liability or harm to reputation. Further, we believe the protections should attach in a manner that is as administratively flexible as permitted to accommodate the many varied business processes and systems of providers and to not run afoul of the statute's

> express intent to not interfere with other Federal, State, or local reporting obligations on providers.

73 FR 70741 (emphasis supplied). Or, as the Senate Committee explained

> The committee finds 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.

Senate Report 108-196 at 7.

To those ends,

> 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.

73 FR 70742. To give effect to this separate, protected system,

> Generally, information may become patient safety work product when reported to a PSO. Information may also become patient safety work product upon collection within a patient safety evaluation system. Such information may be voluntarily removed from a patient safety evaluation system if it has not been reported and would no longer be patient safety work product. As a result, providers need not maintain duplicate systems to separate information to be reported to a PSO from information that may be required to fulfill state reporting obligations. All of this information, collected in one patient safety evaluation system, is protected as patient safety work product unless the provider determines that certain information must be removed from the patient safety evaluation system for reporting to the state. *Once removed* from the patient safety evaluation system, this information is no longer patient safety work product.

73 FR 70742 (emphasis added). The Act is not intended to and does not displace state law, for

> *when laws or regulations require the reporting of the information regarding the type of events also reported to PSOs, 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. Providers should carefully consider

> the need for this information to meet their external reporting or health oversight obligations, such as for meeting public health reporting obligations. Providers have the flexibility to protect this information as patient safety work product within their patient safety evaluation system while they consider whether the information is needed to meet external reporting obligations. Information can be removed from the patient safety evaluation system before it is reported to a PSO to fulfill external reporting obligations. *Once the information is removed*, it is no longer patient safety work product and is no longer subject to the confidentiality provisions.

73 FR 70742 (emphasis added). Until it is removed, however, such as by inclusion in a medical or hospital record or in a separately required report, information collected and being assessed in the patient safety evaluation system or information submitted to a PSO retains its federal protection.

What then about a provider who fails to generate a state-mandated record or report, a record or report a civil plaintiff would like to see, as in this case? The remedy cannot be, as either the Court of Appeals or the majority would have it, that a trial court may then rummage through the provider's patient safety evaluation system and PSO submissions in search of documents that do not "contain a self-examining analysis" or information "normally contained" in separate records and reports.[21] Such a remedy would

[21] This case concerns what the Court refers to as a mandated incident report, but as Goffs brief demonstrates, there is nothing in the Court's reasoning that would prevent the trial court from looking for and disclosing information "normally contained" in any required record or report whatsoever.

completely undermine Congress's assurance to providers that they may participate in the patient safety system without fear of liability or harm to reputation. It is hard to imagine a holding more at odds with Congress's clear intent to foster provider trust in the patient safety system. *See Dep't of Fin. & Prof'l Regulation v. Walgreen Co.*, 361 Ill.Dec. 186, 970 N.E.2d 552 (Ill.App.2012) (holding that incident reports submitted by a pharmacy to its PSO were privileged under the Act).

The remedy for a recalcitrant provider is not to seek judicial assistance in disregarding the terms and the clear intent of the Patient Safety Act. Instead, a provider's failure under state law to report or to record may be remedied as the Secretary noted, in "the same manner as . . . [it could have been remedied] prior to the passage of" the Act. The estate, of course, has not alleged that the hospital has breached a state-law duty to report,[22] but because various regulations require that providers generate incident reports, it maintains, and the majority has acceded to this, that it should be allowed access to anything incident-report-like within the hospital's patient safety evaluation system.

As explained above, however, that is not how the Act's privilege is meant to operate. Under the Act, state law governs a patient or her representative's access to records and reports existing outside the

[22] The estate acknowledges, in fact, that it has been provided with Ms. Goffs medical records. It alleges that the records are incomplete, but rather than asserting that the trial court should be free to sift through the hospital's patient safety evaluation system for information "normally contained" in medical records, it recognizes that any dispute over the medical records is "a fight for another day." So should be any dispute over allegedly missing incident reports.

patient safety evaluation system, and state law may well entitle an interested party to demand that a required record or report be generated. That pertinent information has been placed in the patient safety evaluation system would be no answer to such a demand. The federal privilege, however, precludes an adverse party's—and a trial court's—invasion of the patient safety evaluation system itself, since under the Patient Safety Act providers must be assured that their participation in the patient safety system will not subject them to adverse consequences. As the Senate Report explained,

> 'protecting data in a reporting system . . . does not mean that the plaintiff in a lawsuit could not try to obtain such information through other avenues if it is important in securing redress for harm, it just means that the plaintiff would not be assisted by the presence of a reporting system designed specifically for other purposes beneficial to society.' Importantly, the bill does not alter existing rights or remedies available to injured patients. Laws that provide greater confidentiality or privilege protections are also not affected by this legislation.

Senate Report 108-196 at 8 (quoting from the Institute of Medicine's 1999 report, *To Err is Human*).

The Act, in other words, should have no bearing, one way or the other, on the state's medical malpractice liability system. A provider's submission of materials to a patient safety evaluation system or to a PSO does not shield it from state law record-keeping and reporting obligations, but neither should it expose it to state law liabilities. The majority's failure to recognize the latter as well as the former of these facts will destroy the balance Congress has sought to create and

will discourage participation in the patient safety system by Kentucky's healthcare providers. While the hospital could be compelled to prepare the incident report required by state law and such a report would be discoverable, the Court's willingness to short-circuit those determinations and to permit the invasion of the hospital's patient safely evaluation system violates the PSQIA. As the matter currently stands, I would grant the writ the defendants seek.

## CONCLUSION

In sum, with the PSQIA, Congress has sought to provide for the healthcare industry an error-analyzing capacity that draws on safety data collected from healthcare providers throughout the country. This non-fault-based approach to identifying and mitigating safety hazards, an approach that has come to be referred to as "patient safety," is modeled on similar data collecting and analyzing systems successfully employed in other industries. The system depends on provider candor, and since that candor will be inhibited to the extent that it is apt to be used against the provider in a malpractice setting, the PSQIA creates a broad privilege for information within the patient safety system. Significantly, the privilege does not excuse providers from state record-keeping and report-filing requirements, nor does it impact state-law discovery rules respecting those records and reports. It does, however, protect provider safety data until it is published somehow outside the patient safety system. By disregarding the purpose of the PSQIA, and by misconstruing the privilege it creates, the Court undermines Kentucky's healthcare providers' full participation in the patient safety system and to that extent, at least, both frustrates Congress's intent

and denies Kentuckians the benefits of PSQIA's approach to healthcare safety. I respectfully dissent.

MINTON, C.J., joins.

**APPENDIX B**

COMMONWEALTH OF KENTUCKY
COURT OF APPEALS

[Filed: Aug. 20, 2012]

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No. 2012-CA-000916-OA

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PHILLIP TIBBS, M.D.,
JOEL E. NORMAN, M.D.,
and BARRETT W. BROWN, M.D.,
*Petitioners,*

v.

HONORABLE KIMBERLY N. BUNNELL,
JUDGE, FAYETTE CIRCUIT COURT,
*Respondent,*

ESTATE OF LUVETTA GOFF,
and CLYDE GOFF
*Real Parties in Interest.*

———

An Original Action
Arising From Fayette Circuit Court
Action No. 12-CI-392

———

ORDER
GRANTING PETITION FOR WRIT OF
PROHIBITION

** ** ** **

BEFORE: COMBS, KELLER, AND TAYLOR, JUDGES.

Petitioners, Phillip Tibbs, M.D., Joel E. Norman, M.D., and Barrett W. Brown, M.D., have filed a petition for a writ to prohibit the trial court from enforcing an order compelling the production of an incident report in a medical malpractice case. Having considered the petition and being otherwise sufficiently advised, the Court ORDERS that the petition be, and it is hereby, GRANTED.

As a preliminary matter, Petitioners request this Court to hear oral argument. Having considered the motion and being otherwise sufficiently advised, the Court ORDERS that the motion for oral argument be, and it is hereby, DENIED.

Luvetta Goff died from complications arising during surgery performed at the University of Kentucky Hospital on January 26, 2011. On the same day, a surgical nurse used UK's Patient Safety Net computer system to generate a report concerning Ms. Goff's complications and death. The incident report was the only report compiled regarding the event. The report was submitted to an independent entity, University HealthSystem Consortium, which operates as a designated Patient Safety Organization for the purpose of compiling and analyzing data to improve health care quality.

On January 23, 2012, the Estate filed a medical malpractice action against the Petitioners in Fayette Circuit Court. During discovery, the Estate requested copies of any incident reports concerning the care of Ms. Goff. Petitioners sought a protective order claiming that the incident report was privileged under the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. § 299b-21, *et seq*. (The Act). Following a

hearing, the trial court entered an order ruling that the incident report was not entitled to the privilege contained in 42 U.S.C. § 299b-22. The trial court further ordered that the report be maintained in a confidential manner and that it should not be disclosed outside the present litigation. The court also stated that it would allow appropriate redactions if necessary. This petition for writ of prohibition followed.

Petitioners argue that the trial court erred by ruling that the federal privilege did not apply to the incident report.

The standard of review for writs of prohibition is well established:

> A writ of prohibition is an extraordinary remedy, and we have always been cautious in granting such relief. In order for a writ of prohibition to be appropriate in cases where jurisdiction is not challenged, a petitioner must show that: (1) he would have no adequate remedy on appeal; and (2) he would suffer great and irreparable injury if the trial court is acting in error and the writ is denied.

*Wal-Mart Stores, Inc. v. Dickinson*, 29 S.W.3d 796, 800 (Ky. 2000)(Internal citations omitted). "Whenever a discovery violation occurs that allegedly allows discovery in error, a party will not have an adequate remedy by appeal because 'once the information is furnished it cannot be recalled.'" *Id.* The issuance of a writ is always discretionary. *Hoskins v. Maricle*, 150 S.W.3d 1, 9 (Ky. 2004).

The Supreme Court of Kentucky last ruled on the issue of what privilege applies to peer review documents in a medical malpractice case in *Saleba v. Schrand*, 300 S.W.3d 177 (Ky. 2009). In *Saleba*, the

Supreme Court determined that such documents are subject to discovery. *Id*. at 183. When the Supreme Court has spoken on an issue, we are bound to follow the Court's lead. SCR 1.030(8)(a). However, in *Saleba*, the Supreme Court did not speak with regard to the Act.

The Supreme Court rendered its Opinion in *Saleba* in 2009, approximately four years after the Act became law. While the Act became law in 2005, the regulations implementing the Act were not promulgated until November 2008. The underlying litigation regarding the release of the peer documents in *Saleba* all took place well before November 2008. Furthermore, the actions that comprised the alleged medical malpractice took place in 2000, before the Act became law. The hospital in *Saleba* could not have had in place the mechanisms to implement the Act and to take advantage of the privilege provided by the Act.

Also, in *Saleba*, the Supreme Court was asked to determine whether to apply Ohio law, which provides a blanket privilege for peer review documents, or Kentucky law, which does not provide such a broad privilege. The Court was not asked to address the Act or how it interacts with Kentucky law. In fact, the Court does not mention the Act in its opinion nor does it appear that the parties raised the Act as an issue.

Because the Supreme Court has not made a specific ruling on this issue, we are not prevented from doing so. As noted above, the Supreme Court has not addressed whether the Act applies because it likely was not asked to do so. Therefore, this Court should not read anything into the Court's failure to address the application of the Act to Kentucky law.

In *Wright v. General Elec. Co.*, 242 S.W.3d 674, 678 (Ky.App. 2007), this Court set forth the elements of preemption as follows:

> Determination of whether a federal statute preempts a state cause of action depends on the purpose of Congress in enacting the federal statute. *Malone v. White Motor Corp.*, 435 U.S. 497, 98 S.Ct. 1185, 55 L.Ed.2d 443 (1978); *Niehoff v. Surgidev Corp.*, 950 S.W.2d 816, 820 (Ky. 1997). "Congressional intent is the touchstone of all preemption analysis." *Keck v. Corn. ex rel. Golden*, 998 S.W.2d 13, 15 fn. 4 (Ky.App. 1999).
>
> The congressional purpose to preempt a state remedy may be determined in either of two ways. The first is whether the preemption is found in the express language of the statute. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). The second is to find preemption implied from the structure and purpose of the statute. Implied preemption occurs when the state law actually conflicts with federal law or where the federal law so thoroughly occupies the legislative field that it may be reasonably inferred that Congress left no room for the state to supplement it. *Niehoff* at 820.

42 U.S.C.A. § 299b-22 states in pertinent part:

> (a) Privilege
>
> 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;
>
> (3) subject to disclosure pursuant to section 552 of Title 5 (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;
>
> (4) admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or
>
> (5) admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

We hold that Congress explicitly intended the Act to preempt state law. However, the privilege is not as far-reaching as Petitioners seem to believe. As noted by the United States District Court for the Southern District of New York:

> [T]he self-critical analysis privilege "is based upon the concern that disclosure of documents reflecting candid self-examination will deter or suppress socially useful investigations and evaluations[,]" it stands to reason that only quality assurance review documents containing self-examining statements are privileged. This conclusion is in line with Congress' intent regarding the scope of the [Act's] privilege, which extends only to "the

> analysis of, and subsequent corrective actions related to [an] adverse event or medical errors[.]"

*Francis v. United States*, 09 CIV. 4004 GBD KNF, 2011 WL 2224509 (S.D.N.Y. May 31, 2011) (internal citations and footnotes omitted). We find this analysis to be persuasive and remand this matter to the trial court with instructions that it conduct an *in camera* review of the documents at issue. Those documents that the court determines contain self-examining analysis are to be afforded the privilege provided for in the Act. However, those documents that do not contain such analysis are not to be afforded the privilege and must be disclosed.

Therefore, the Court ORDERS that the petition for writ of prohibition be hereby GRANTED.

COMBS AND KELLER, JUDGES, CONCUR.

TAYLOR, JUDGE, DISSENTS, AND WRITES SEPARATELY.

ENTERED: AUG. 16, 2012

/s/ [Illegible]
JUDGE, COURT OF APPEALS

TAYLOR, JUDGE, DISSENTING. Respectfully I dissent for two reasons. First, I have serious doubt that the Patients Safety and Quality Improvement Act has preempted state law or other applicable rules regarding discovery of peer review records in Kentucky. Second, I cannot agree that our review of this issue should be guided by an unpersuasive, unpublished memorandum and order issued by a federal district court judge in New York. I would deny the petition.

**APPENDIX C**

COMMONWEALTH OF KENTUCKY
FAYETTE CIRCUIT COURT
DIVISION 9

[Filed: May 01, 2012]

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No. 12-CI-392

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ESTATE OF LUVETTA GOFF,
*Plaintiff,*

v.

PHILLIP TIBBS, M.D., *et al.,*
*Defendants.*

---

ORDER

* * * * * *

This matter came before the Court on April 6, 2012, for a hearing on the defendants' motion for a protective order regarding the plaintiff's request for production of any incident report(s) concerning the care of the decedent, Luvetta Goff, at the University of Kentucky Hospital. The defendants assert that an incident report concerning Mrs. Goff exists, but it is confidential and protected from discovery in this action by a privilege created by the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §§ 299b-22(a), 299b-21. The Court has considered the defendants' memorandum in support of their motion, as well as the plaintiff's response memorandum and the argument of the parties' counsel. The Court being sufficiently advised;

IT IS HEREBY FOUND, ADJUDGED, AND ORDERED as follows:

1. The Court finds that the incident report subject to the defendants' motion is not entitled to the privilege contained in the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §§ 299b-22(a) and 299b-21 (the "Act"). The Court holds that the incident report is not "patient safety work product" because it is exempted from the definition of "patient safety work product" by the "clarification" contained § 299b-21(7)(B) of the Act.

2. The Court holds that the incident report is discoverable only if it was prepared by someone involved in or with actual knowledge of the medical care rendered to Mrs. Goff at the University of Kentucky ("UK"). Therefore, the defendants' motion for a protective order is OVERRULED if the incident report was prepared by a person who was involved in and had actual knowledge of Mrs. Goff's medical care at UK. The motion for protective order is SUSTAINED if the incident report was prepared by a person who was not involved in and did not have actual knowledge of Mrs. Gaff's medical care at UK. Within 20 days of the entry of this order, the defendants shall either produce the incident report or advise the Court and opposing counsel that it is not being produced because it was prepared by a person who was not involved in and did not have actual knowledge of Mrs. Gaff's medical care at UK.

3. If the incident report is produced pursuant to this Order, it shall be maintained in a confidential manner, shall not be used for any purpose outside of this litigation, and shall not be disclosed to

any person, party, or attorney who is not involved in this litigation. The Court will also allow appropriate redactions of elements of the form (as opposed to the substantive content inserted therein) if deemed necessary to protect any proprietary information regarding the form itself.

Dated this 1st day of May, 2012.

/s/ [Illegible]
JUDGE, FAYETTE CIRCUIT COURT,
NINTH DIVISION

**APPENDIX D**

SUPREME COURT OF KENTUCKY

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2012-SC-000603-MR

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PHILLIP TIBBS, M.D.; JOEL E. NORMAN, M.D.;
and BARRETT W.BROWN, M.D.,
*Appellants,*

v.

HONORABLE KIMBERLY N. BUNNELL,
JUDGE, FAYETTE CIRCUIT COURT,
*Appellee,*

AND

ESTATE OF LUVETTA GOFF;
and CLYDE GOFF
*Real Parties in Interest*.

———

On Appeal from Court of Appeals
Case No. No. 2012-CA-000916-OA
Fayette Circuit Court No. 12-CI-00392

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ORDER DENYING PETITION FOR REHEARING

The vote of the six members of this Court participating in the determination of this appeal being equally divided, pursuant to SCR 1.020, the petition for rehearing filed by Appellant is hereby DENIED.

Cunningham, Scott and Venters, JJ., would not grant rehearing. Minton, C.J.; Abramson and Noble, JJ., would grant rehearing. Keller, J., not sitting.

ENTERED: December 18, 2014.

/s/ [Illegible]
CHIEF JUSTICE

# APPENDIX E

## FEDERAL STATUTES

### 42 U.S.C. § 299b-21. Definitions

In this part:

* * * *

(4) Patient safety organization

The term "patient safety organization" means a private or public entity or component thereof that is listed by the Secretary pursuant to section 299b-24(d) of this title.

(5) Patient safety activities

The term "patient safety activities" means the following activities:

(A) Efforts to improve patient safety and the quality of health care delivery.

(B) The collection and analysis of patient safety work product.

(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

(D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

(E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.

(F) The provision of appropriate security measures with respect to patient safety work product.

(G) The utilization of qualified staff.

(H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

(6) Patient safety evaluation system

The term "patient safety evaluation system" means the collection, management, or analysis of information for reporting to or by a patient safety organization.

(7) Patient safety work product

(A) In general

Except as provided in subparagraph (B), the term "patient safety work product" means 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.

(B) Clarification

(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.

(8) Provider

The term "provider" means—

(A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including—

(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

(B) any other individual or entity specified in regulations promulgated by the Secretary.

**42 U.S.C. § 299b-22. Privilege and confidentiality protections**

(a) Privilege

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;

(3) subject to disclosure pursuant to section 552 of Title 5 (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;

(4) admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding,

or administrative adjudicatory proceeding, including any such proceeding against a provider; or

(5) admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

(b) Confidentiality of patient safety work product

Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be confidential and shall not be disclosed.

(c) Exceptions

Except as provided in subsection (g)(3) of this section—

(1) Exceptions from privilege and confidentiality

Subsections (a) and (b) of this section shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an in camera determination that such patient safety work product contains evidence of a criminal act and that such patient safety work product is material to the proceeding and not reasonably available from any other source.

(B) Disclosure of patient safety work product to the extent required to carry out subsection (f)(4)(A) of this section.

(C) Disclosure of identifiable patient safety work product if authorized by each provider identified in such work product.

(2) Exceptions from confidentiality

Subsection (b) of this section shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of patient safety work product to carry out patient safety activities.

(B) Disclosure of nonidentifiable patient safety work product.

(C) Disclosure of patient safety work product to grantees, contractors, or other entities carrying out research, evaluation, or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research to the extent that disclosure of protected health information would be allowed for such purpose under the HIPAA confidentiality regulations.

(D) Disclosure by a provider to the Food and Drug Administration with respect to a product or activity regulated by the Food and Drug Administration.

(E) Voluntary disclosure of patient safety work product by a provider to an accrediting body that accredits that provider.

(F) Disclosures that the Secretary may determine, by rule or other means, are necessary for business operations and are consistent with the goals of this part.

(G) Disclosure of patient safety work product to law enforcement authorities relating to the commission of a crime (or to an event reasonably believed to be a crime) if the person making the

disclosure believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

(H) With respect to a person other than a patient safety organization, the disclosure of patient safety work product that does not include materials that—

(i) assess the quality of care of an identifiable provider; or

(ii) describe or pertain to one or more actions or failures to act by an identifiable provider.

(3) Exception from privilege

Subsection (a) of this section shall not apply to (and shall not be construed to prohibit) voluntary disclosure of nonidentifiable patient safety work product.

(d) Continued protection of information after disclosure

(1) In general

Patient safety work product that is disclosed under subsection (c) of this section shall continue to be privileged and confidential as provided for in subsections (a) and (b) of this section, and such disclosure shall not be treated as a waiver of privilege or confidentiality, and the privileged and confidential nature of such work product shall also apply to such work product in the possession or control of a person to whom such work product was disclosed.

(2) Exception

Notwithstanding paragraph (1), and subject to paragraph (3)—

(A) if patient safety work product is disclosed in a criminal proceeding, the confidentiality protections provided for in subsection (b) of this section shall no longer apply to the work product so disclosed; and

(B) if patient safety work product is disclosed as provided for in subsection (c)(2)(B) of this section (relating to disclosure of nonidentifiable patient safety work product), the privilege and confidentiality protections provided for in subsections (a) and (b) of this section shall no longer apply to such work product.

(3) Construction

Paragraph (2) shall not be construed as terminating or limiting the privilege or confidentiality protections provided for in subsection (a) or (b) of this section with respect to patient safety work product other than the specific patient safety work product disclosed as provided for in subsection (c) of this section.

(4) Limitations on actions

(A) Patient safety organizations

(i) In general

A patient safety organization shall not be compelled to disclose information collected or developed under this part whether or not such information is patient safety work product unless such information is identified, is not patient safety work product, and is not reasonably available from another source.

(ii) Nonapplication

The limitation contained in clause (i) shall not apply in an action against a patient safety organization or with respect to disclosures pursuant to subsection (c)(1) of this section.

(B) Providers

An accrediting body shall not take an accrediting action against a provider based on the good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety work product in accordance with this part. An accrediting body may not require a provider to reveal its communications with any patient safety organization established in accordance with this part.

(e) Reporter protection

(1) In general

A provider may not take an adverse employment action, as described in paragraph (2), against an individual based upon the fact that the individual in good faith reported information—

(A) to the provider with the intention of having the information reported to a patient safety organization; or

(B) directly to a patient safety organization.

(2) Adverse employment action

For purposes of this subsection, an "adverse employment action" includes—

(A) loss of employment, the failure to promote an individual, or the failure to provide any other employment-related benefit for which the individual would otherwise be eligible; or

(B) an adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual.

(f) Enforcement

(1) Civil monetary penalty

Subject to paragraphs (2) and (3), a person who discloses identifiable patient safety work product in knowing or reckless violation of subsection (b) of this section shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.

(2) Procedure

The provisions of section 1320a-7a of this title, other than subsections (a) and (b) and the first sentence of subsection (c)(1), shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a of this title.

(3) Relation to HIPAA

Penalties shall not be imposed both under this subsection and under the regulations issued pursuant to section 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note) for a single act or omission.

(4) Equitable relief

(A) In general

Without limiting remedies available to other parties, a civil action may be brought by any aggrieved individual to enjoin any act or practice that violates subsection (e) of this section and to obtain other appropriate equitable relief (includ-

ing reinstatement, back pay, and restoration of benefits) to redress such violation.

(B) Against State employees

An entity that is a State or an agency of a State government may not assert the privilege described in subsection (a) of this section unless before the time of the assertion, the entity or, in the case of and with respect to an agency, the State has consented to be subject to an action described in subparagraph (A), and that consent has remained in effect.

(g) Rule of construction

Nothing in this section shall be construed—

(1) to limit the application of other Federal, State, or local laws that provide greater privilege or confidentiality protections than the privilege and confidentiality protections provided for in this section;

(2) to limit, alter, or affect the requirements of Federal, State, or local law pertaining to information that is not privileged or confidential under this section;

(3) except as provided in subsection (i) of this section, to alter or affect the implementation of any provision of the HIPAA confidentiality regulations or section 1320d-5 of this title (or regulations promulgated under such section);

(4) to limit the authority of any provider, patient safety organization, or other entity to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this section;

(5) as preempting or otherwise affecting any State law requiring a provider to report information that is not patient safety work product; or

(6) to limit, alter, or affect any requirement for reporting to the Food and Drug Administration information regarding the safety of a product or activity regulated by the Food and Drug Administration.

(h) Clarification

Nothing in this part prohibits any person from conducting additional analysis for any purpose regardless of whether such additional analysis involves issues identical to or similar to those for which information was reported to or assessed by a patient safety organization or a patient safety evaluation system.

(i) Clarification of application of HIPAA confidentiality regulations to patient safety organizations

For purposes of applying the HIPAA confidentiality regulations—

(1) patient safety organizations shall be treated as business associates; and

(2) patient safety activities of such organizations in relation to a provider are deemed to be health care operations (as defined in such regulations) of the provider.

(j) Reports on strategies to improve patient safety

(1) Draft report

Not later than the date that is 18 months after any network of patient safety databases is operational, the Secretary, in consultation with the Director, shall prepare a draft report on effective strategies

for reducing medical errors and increasing patient safety. The draft report shall include any measure determined appropriate by the Secretary to encourage the appropriate use of such strategies, including use in any federally funded programs. The Secretary shall make the draft report available for public comment and submit the draft report to the Institute of Medicine for review.

(2) Final report

Not later than 1 year after the date described in paragraph (1), the Secretary shall submit a final report to the Congress.

**42 U.S.C. § 299b-23. Network of patient safety databases**

(a) In general

The Secretary shall facilitate the creation of, and maintain, a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other entities. The network of databases shall have the capacity to accept, aggregate across the network, and analyze nonidentifiable patient safety work product voluntarily reported by patient safety organizations, providers, or other entities. The Secretary shall assess the feasibility of providing for a single point of access to the network for qualified researchers for information aggregated across the network and, if feasible, provide for implementation.

(b) Data standards

The Secretary may determine common formats for the reporting to and among the network of patient safety databases maintained under subsection (a) of this section of nonidentifiable patient safety work product,

including necessary work product elements, common and consistent definitions, and a standardized computer interface for the processing of such work product. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act [42 U.S.C. § 1320d et seq.].

(c) Use of information

Information reported to and among the network of patient safety databases under subsection (a) of this section shall be used to analyze national and regional statistics, including trends and patterns of health care errors. The information resulting from such analyses shall be made available to the public and included in the annual quality reports prepared under section 299b-2(b)(2) of this title.

# APPENDIX F

## FEDERAL REGULATIONS

### 42 C.F.R. § 3.10. Purpose.

The purpose of this part is to implement the Patient Safety and Quality Improvement Act of 2005 (Pub.L. 109–41), which amended Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) by adding sections 921 through 926, 42 U.S.C. 299b–21 through 299b–26.

### 42 C.F.R. § 3.20. Definitions.

* * * *

Patient Safety Act means the Patient Safety and Quality Improvement Act of 2005 (Pub.L. 109–41), which amended Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) by inserting a new Part C, sections 921 through 926, which are codified at 42 U.S.C. 299b–21 through 299b–26.

Patient safety activities means the following activities carried out by or on behalf of a PSO or a provider:

(1) Efforts to improve patient safety and the quality of health care delivery;

(2) The collection and analysis of patient safety work product;

(3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;

(4) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;

(5) The maintenance of procedures to preserve confidentiality with respect to patient safety work product;

(6) The provision of appropriate security measures with respect to patient safety work product;

(7) The utilization of qualified staff; and

(8) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

Patient safety evaluation system means the collection, management, or analysis of information for reporting to or by a PSO.

Patient safety organization (PSO) means a private or public entity or component thereof that is listed as a PSO by the Secretary in accordance with subpart B. A health insurance issuer or a component organization of a health insurance issuer may not be a PSO. See also the exclusions in § 3.102 of this part.

Patient safety work product:

(1) Except as provided in paragraph (2) of this definition, patient safety work product means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material)

(i) Which could improve patient safety, health care quality, or health care outcomes; and

(A) Which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a patient safety evaluation system for reporting to a PSO, and such

documentation includes the date the information entered the patient safety evaluation system; or

(B) Are developed by a PSO for the conduct of patient safety activities; or

(ii) Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

(2)(i) Patient safety work product does not include a patient's medical record, billing and discharge information, or any other original patient or provider information; nor does it 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 PSO shall not by reason of its reporting be considered patient safety work product.

(ii) Patient safety work product assembled or developed by a provider for reporting to a PSO may be removed from a patient safety evaluation system and no longer considered patient safety work product if:

(A) The information has not yet been reported to a PSO; and

(B) The provider documents the act and date of removal of such information from the patient safety evaluation system.

(iii) Nothing in this part shall be construed to limit information that is not patient safety work product from being:

(A) Discovered or admitted in a criminal, civil or administrative proceeding;

(B) Reported to a Federal, State, local or Tribal governmental agency for public health or health oversight purposes; or

(C) Maintained as part of a provider's recordkeeping obligation under Federal, State, local or Tribal law.

Person means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Provider means:

(1) An individual or entity licensed or otherwise authorized under State law to provide health care services, including—

(i) A hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office (includes a group practice), long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

(ii) A physician, physician assistant, registered nurse, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner;

(2) Agencies, organizations, and individuals within Federal, State, local, or Tribal governments that deliver health care, organizations engaged as contractors by the Federal, State, local, or Tribal governments to deliver health care, and individual health care

practitioners employed or engaged as contractors by the Federal State, local, or Tribal governments to deliver health care; or

(3) A parent organization of one or more entities described in paragraph (1)(i) of this definition or a Federal, State, local, or Tribal government unit that manages or controls one or more entities described in paragraphs (1)(i) or (2) of this definition.

Research has the same meaning as the term is defined in the HIPAA Privacy Rule at 45 CFR 164.501.

Respondent means a provider, PSO, or responsible person who is the subject of a complaint or a compliance review.

Responsible person means a person, other than a provider or a PSO, who has possession or custody of identifiable patient safety work product and is subject to the confidentiality provisions.

Workforce means employees, volunteers, trainees, contractors, or other persons whose conduct, in the performance of work for a provider, PSO or responsible person, is under the direct control of such provider, PSO or responsible person, whether or not they are paid by the provider, PSO or responsible person.

**42 C.F.R. § 3.204. Privilege of patient safety work product.**

(a) Privilege. Notwithstanding any other provision of Federal, State, local, or Tribal law and subject to paragraph (b) of this section and § 3.208 of this subpart, patient safety work product shall be privileged and shall not be:

(1) Subject to a Federal, State, local, or Tribal civil, criminal, or administrative subpoena or order, including in a Federal, State, local, or Tribal civil or

administrative disciplinary proceeding against a provider;

(2) Subject to discovery in connection with a Federal, State, local, or Tribal civil, criminal, or administrative proceeding, including in a Federal, State, local, or Tribal civil or administrative disciplinary proceeding against a provider;

(3) Subject to disclosure pursuant to section 552 of Title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal, State, local, or Tribal law;

(4) Admitted as evidence in any Federal, State, local, or Tribal governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or

(5) Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

(b) Exceptions to privilege. Privilege shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(1) Disclosure of relevant patient safety work product for use in a criminal proceeding, subject to the conditions at § 3.206(b)(1) of this subpart.

(2) Disclosure to the extent required to permit equitable relief subject to the conditions at § 3.206(b)(2) of this subpart.

(3) Disclosure pursuant to provider authorizations subject to the conditions at § 3.206(b)(3) of this subpart.

(4) Disclosure of non-identifiable patient safety work product subject to the conditions at § 3.206(b)(5) of this subpart.

(c) Implementation and enforcement by the Secretary. Privilege shall not apply to (and shall not be construed to prohibit) disclosures of relevant patient safety work product to or by the Secretary if such patient safety work product is needed to investigate or determine compliance, or to seek or impose civil money penalties, with respect to this part or the HIPAA Privacy Rule, or to make or support decisions with respect to listing of a PSO.

**42 C.F.R. § 3.206. Confidentiality of patient safety work product.**

(a) Confidentiality. Subject to paragraphs (b) through (e) of this section, and §§ 3.208 and 3.210 of this subpart, patient safety work product shall be confidential and shall not be disclosed.

(b) Exceptions to confidentiality. The confidentiality provisions shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(1) Disclosure in criminal proceedings. Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an in-camera determination that:

(i) Such patient safety work product contains evidence of a criminal act;

(ii) Such patient safety work product is material to the proceeding; and

(iii) Such patient safety work product is not reasonably available from any other source.

(2) Disclosure to permit equitable relief for reporters. Disclosure of patient safety work product to the extent required to permit equitable relief under section 922 (f)(4)(A) of the Public Health Service Act, provided the court or administrative tribunal has issued a protective order to protect the confidentiality of the patient safety work product in the course of the proceeding.

(3) Disclosure authorized by identified providers.

(i) Disclosure of identifiable patient safety work product consistent with a valid authorization if such authorization is obtained from each provider identified in such work product prior to disclosure. A valid authorization must:

(A) Be in writing and signed by the provider from whom authorization is sought; and

(B) Contain sufficient detail to fairly inform the provider of the nature and scope of the disclosures being authorized;

(ii) A valid authorization must be retained by the disclosing entity for six years from the date of the last disclosure made in reliance on the authorization and made available to the Secretary upon request.

(4) Disclosure for patient safety activities—

(i) Disclosure between a provider and a PSO. Disclosure of patient safety work product for patient safety activities by a provider to a PSO or by a PSO to that disclosing provider.

(ii) Disclosure to a contractor of a provider or a PSO. A provider or a PSO may disclose patient safety work product for patient safety activities to

an entity with which it has contracted to undertake patient safety activities on its behalf. A contractor receiving patient safety work product for patient safety activities may not further disclose patient safety work product, except to the provider or PSO with which it is contracted.

(iii) Disclosure among affiliated providers. Disclosure of patient safety work product for patient safety activities by a provider to an affiliated provider.

(iv) Disclosure to another PSO or provider. Disclosure of patient safety work product for patient safety activities by a PSO to another PSO or to another provider that has reported to the PSO, or, except as otherwise permitted in paragraph (b)(4)(iii) of this section, by a provider to another provider, provided:

(A) The following direct identifiers of any providers and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce, or household members of such providers are removed:

(1) Names;

(2) Postal address information, other than town or city, State and zip code;

(3) Telephone numbers;

(4) Fax numbers;

(5) Electronic mail addresses;

(6) Social security numbers or taxpayer identification numbers;

(7) Provider or practitioner credentialing or DEA numbers;

(8) National provider identification number;

(9) Certificate/license numbers;

(10) Web Universal Resource Locators (URLs);

(11) Internet Protocol (IP) address numbers;

(12) Biometric identifiers, including finger and voice prints; and

(13) Full face photographic images and any comparable images; and

(B) With respect to any individually identifiable health information in such patient safety work product, the direct identifiers listed at 45 CFR 164.514(e)(2) have been removed.

(5) Disclosure of nonidentifiable patient safety work product. Disclosure of nonidentifiable patient safety work product when patient safety work product meets the standard for nonidentification in accordance with § 3.212 of this subpart.

(6) Disclosure for research.

(i) Disclosure of patient safety work product to persons carrying out research, evaluation or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research.

(ii) If the patient safety work product disclosed pursuant to paragraph (b)(6)(i) of this section is by a HIPAA covered entity as defined at 45 CFR 160.103 and contains protected health information as defined by the HIPAA Privacy Rule at 45 CFR 160.103, such patient safety work product may only be disclosed under this exception in the

same manner as would be permitted under the HIPAA Privacy Rule.

(7) Disclosure to the Food and Drug Administration (FDA) and entities required to report to FDA.

(i) Disclosure by a provider of patient safety work product concerning an FDA–regulated product or activity to the FDA, an entity required to report to the FDA concerning the quality, safety, or effectiveness of an FDA–regulated product or activity, or a contractor acting on behalf of FDA or such entity for these purposes.

(ii) Any person permitted to receive patient safety work product pursuant to paragraph (b)(7)(i) of this section may only further disclose such patient safety work product for the purpose of evaluating the quality, safety, or effectiveness of that product or activity to another such person or the disclosing provider.

(8) Voluntary disclosure to an accrediting body.

(i) Voluntary disclosure by a provider of patient safety work product to an accrediting body that accredits that provider, provided, with respect to any identified provider other than the provider making the disclosure:

(A) The provider agrees to the disclosure; or

(B) The identifiers at § 3.206(b)(4)(iv)(A) are removed.

(ii) An accrediting body may not further disclose patient safety work product it receives pursuant to paragraph (b)(8)(i) of this section.

(iii) An accrediting body may not take an accrediting action against a provider based on a

good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety work product in accordance with this Part. An accrediting body may not require a provider to reveal its communications with any PSO.

(9) Disclosure for business operations.

(i) Disclosure of patient safety work product by a provider or a PSO for business operations to attorneys, accountants, and other professionals. Such contractors may not further disclose patient safety work product, except to the entity from which they received the information.

(ii) Disclosure of patient safety work product for such other business operations that the Secretary may prescribe by regulation as consistent with the goals of this part.

(10) Disclosure to law enforcement.

(i) Disclosure of patient safety work product to an appropriate law enforcement authority relating to an event that either constitutes the commission of a crime, or for which the disclosing person reasonably believes constitutes the commission of a crime, provided that the disclosing person believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

(ii) Law enforcement personnel receiving patient safety work product pursuant to paragraph (b)(10)(i) of this section only may disclose that patient safety work product to other law enforcement authorities as needed for law enforcement

activities related to the event that gave rise to the disclosure under paragraph (b)(10)(i) of this section.

(c) Safe harbor. A provider or responsible person, but not a PSO, is not considered to have violated the requirements of this subpart if a member of its workforce discloses patient safety work product, provided that the disclosure does not include materials, including oral statements, that:

(1) Assess the quality of care of an identifiable provider; or

(2) Describe or pertain to one or more actions or failures to act by an identifiable provider.

(d) Implementation and enforcement by the Secretary. The confidentiality provisions shall not apply to (and shall not be construed to prohibit) disclosures of relevant patient safety work product to or by the Secretary if such patient safety work product is needed to investigate or determine compliance or to seek or impose civil money penalties, with respect to this part or the HIPAA Privacy Rule, or to make or support decisions with respect to listing of a PSO.

(e) No limitation on authority to limit or delegate disclosure or use. Nothing in subpart C of this part shall be construed to limit the authority of any person to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this subpart.

**42 C.F.R. § 3.402. Basis for a civil money penalty.**

(a) General rule. A person who discloses identifiable patient safety work product in knowing or reckless

violation of the confidentiality provisions shall be subject to a civil money penalty for each act constituting such violation.

(b) Violation attributed to a principal. A principal is independently liable, in accordance with the federal common law of agency, for a civil money penalty based on the act of the principal's agent, including a workforce member, acting within the scope of the agency if such act could give rise to a civil money penalty in accordance with § 3.402(a) of this subpart.

**42 C.F.R. § 3.404. Amount of a civil money penalty.**

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section and § 3.408 of this subpart.

(b) The Secretary may impose a civil money penalty in the amount of not more than $11,000.

**42 C.F.R. § 3.408. Factors considered in determining the amount of a civil money penalty.**

In determining the amount of any civil money penalty, the Secretary may consider as aggravating or mitigating factors, as appropriate, any of the following:

(a) The nature of the violation.

(b) The circumstances, including the consequences, of the violation, including:

(1) The time period during which the violation(s) occurred; and

(2) Whether the violation caused physical or financial harm or reputational damage;

(c) The degree of culpability of the respondent, including:

(1) Whether the violation was intentional; and

(2) Whether the violation was beyond the direct control of the respondent.

(d) Any history of prior compliance with the Patient Safety Act, including violations, by the respondent, including:

(1) Whether the current violation is the same or similar to prior violation(s);

(2) Whether and to what extent the respondent has attempted to correct previous violations;

(3) How the respondent has responded to technical assistance from the Secretary provided in the context of a compliance effort; and

(4) How the respondent has responded to prior complaints.

(e) The financial condition of the respondent, including:

(1) Whether the respondent had financial difficulties that affected its ability to comply;

(2) Whether the imposition of a civil money penalty would jeopardize the ability of the respondent to continue to provide health care or patient safety activities; and

(3) The size of the respondent.

(f) Such other matters as justice may require.

**APPENDIX G**

IN THE CIRCUIT COURT,
FOURTH JUDICIAL CIRCUIT,
IN AND FOR DUVAL COUNTY, FLORIDA

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No.: 16-2012-CA-002677
Division: CV-H

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JEAN CHARLES, JR., as next friend and duly appointed Guardian of his sister MARIE CHARLES, and her minor children, ERVIN ALSTON, ANGEL ALSTON and JAZMIN HOUSTON, minors,
*Plaintiffs,*

vs.

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC. d/b/a BAPTIST MEDICAL CENTER-SOUTH, KRISTIN FERNANDEZ, D.O., Gynecologist, YUVAL Z. NAOT, M.D., Hematologist/Oncologist, SAFEER A.ASHRAF, M.D., Hematologist/Oncologist, INTEGRATED COMMUNITY ONCOLOGY NETWORK, LLC., a Florida limited liability corporation, ANDREW NAMEN, M.D., Pulmonologist, GREGORY J. SENGSTOCK, M.D., Neurologist, JOHN D. PENNINGTON, M.D. Internist, EUGENE R. BEBEAU, M.D., Anesthesiologist, and ROBERT E. ROSEMUND, M.D., Family Practitioner,
*Defendants.*

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ORDER ON PLANTIFFS' MOTION TO COMPEL THE PRODUCTION OF AMENDMENT 7 DOCUMENTS

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I. Background and Procedural Posture

This is a medical malpractice case. The Plaintiffs have alleged that Marie Charles suffered neurological injuries as the result of the negligence of the Defendants while she was a patient at Baptist Medical Center-South and Baptist Medical Center-Downtown. Specifically, the Plaintiffs allege that Marie Charles was subject to an unnecessary, and contra-indicated, surgery while under the care of the Defendants at Baptist Medical Center-South. They further allege that, due to complicating medical factors known to the Defendants, Marie Charles suffered a stroke while undergoing this surgery. Finally, the Plaintiffs allege that the treatment given to Marie Charles at Baptist Medical Center-South and Baptist Medical Center-Downtown after suffering her stroke was untimely and negligent.

On July 24, 2013, the Plaintiff served a third set of requests for production on Defendant Baptist. In brief, these requests asked, pursuant to Art. 10 Sec. 25 of the Florida Constitution (Amendment 7), for adverse incident reports (as defined by Amendment 7) relating to the following:

1. Marie Charles;
2. The defendant doctors;
3. Any physicians working at Baptist Medical Center-South between 2007 and the present;
4. Any physicians working at any Baptist Medical Center facility between 2007 and the present;
5. Emergency care at any Baptist Medical Center facility between 2007 and the present;

6. Any care and/or treatment at any Baptist Medical Center facility between 2007 and the present;

7. Any care and/or treatment at Baptist Medical Center-South between 2007 and the present;

In addition, each request contained the following explanatory language:

> This request is limited to adverse incident documents (as described above) that are ***created*** by you, or ***maintained*** by you, or provided by you to any state or federal agency, pursuant to any obligation or requirement in any state or federal law, rule, or regulation. As limited, this request includes, but is not limited to, documents ***created*** by you, or ***maintained*** by you pursuant to Fla. Stat. § 395.0197, 766.010, and 395.0193. This request, as limited, specifically includes, but is not limited to, your annual adverse incident summary report and any and all Code 15 Reports.

(Emphasis added).

On August, 23 2013, Baptist responded to Plaintiffs' Third Request For Production. Baptist stated it had no documents responsive to Requests 1 and 2, and agreed to produce documents responsive to Requests 3 through 7. Baptist then produced Code 15 Reports and Annual Reports. Baptist and the Plaintiffs then exchanged a number of letters regarding Baptist's response to the Plaintiffs' Third Request for Production. At the end of this exchange, Baptist acknowledged that it had other potentially responsive documents, but claimed that these documents were protected from discovery under the Federal Patient Safety and Quality Improvement Act ("PSQIA")—42 U.S.C. § 299b-21 et. seq.

The Plaintiffs then filed a motion to compel the production of all remaining Amendment 7 documents responsive to their Third Request For Production. Following the filing of this motion, the Court heard argument regarding the production of Amendment 7 documents on several occasions, and both the Plaintiff and Baptist submitted case law and other authority for the Court's consideration. In addition, the parties engaged in negotiations, attempting to work out a compromise on this issue. During these negotiations, Baptist produced two incident reports relating directly to the care of Marie Charles that gives rise to this case.

The parties have now reached an impasse. Baptist has produced Annual Reports, Code 15 Reports, and two incident reports relating to Marie Charles. It maintains its objection under the PSQIA to the production of any other documents. On June 24, 2014 the Plaintiffs brought this issue back before the Court. The Plaintiffs seek an order granting their motion to compel the production of all Amendment 7 Documents that were created or maintained by Baptist as required by state or federal law or regulation or credentialing entity requirements, or which were provided by Baptist to any state or federal agency or other credentialing entity pursuant to any obligation or requirement in any state or federal law, rule, regulation, or licensing or accreditation obligation. Baptist asks that the Court deny the Plaintiffs' motion to the extent it seeks documents not already produced.

II. Analysis

The Plaintiffs' Motion to Compel Production of Amendment 7 Documents deals with the interaction of Amendment 7 and the PSQIA. Amendment 7 gave Floridians broad access to adverse incident records from medical providers. The PSQIA creates a privilege

protecting documents that qualify as so called "Patient Safety Work Product."

Passed in 2004, Amendment 7 provides that patients have a right to any records made or received in the course of business by a health care facility or provider relating to any adverse incident. *Fla. Const. Art. 10 § 25*. "Adverse incidents" are broadly defined to include: medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or the death of a patient. *Id.* These categories include, but are not limited to, those incidents that are required by state or federal law to be reported to any governmental agency or body, and incidents that are reported to or reviewed by any health care facility peer review, risk management, quality assurance, credentials, or similar committee, or any representative of any such committees. *Id.*

Since 2004, Amendment 7 has been the subject of extensive litigation. Florida appellate courts have ruled on issues relating to Amendment 7, turning back several common law and statutory challenges to the law. *See*: *Cedars Healthcare Group v. Martinez*, 39 Fla. L. Weekly, S60 (Fla. Jan. 30, 2014); *Florida Hospital Waterman v. Buster*, 984 So.2d 478 (Fla. 2008); *West Florida Regional Medical Center v. Lynda See, et al.*, 70 So.3d 1 (Fla. 2012); *Morton Plant Hospital Association, Inc. v. Shabhas*, 960 So.2d 820 (Fla. 2nd DCA 2007); *Columbia Hospital Corporation of South Broward v. Fain*, 16 So.3d 236 (Fla. 4th DCA 2009); *Baldwin v. Shands Teaching Hospital and Clinics, Inc.*, 45 So.3d 119 (Fla. 1st DCA 2010); *Dania Acevedo v. Doctors Hospital, Inc.*, 68 So.3d 949 (Fla. 3rd DCA 2011); *Lakeland Regional Medical Center v. Neely*, 8

So.3d 1268 (Fla. 2nd 2009); *Florida Eye Clinic v. Mary T. Gmash*, 14 So.3d [sic] (Fla 5th DCA 2009).

In this case, Baptist has argued that the documents sought by the Plaintiffs are protected from discovery by the PSQIA. The PSQIA authorizes the creation of patient safety organizations (PSO's). A healthcare provider may collect information through a patient safety evaluation system (PSES) and then share that information with a PSO. The information thus collected and shared may be classified as Patient Safety Work Product (PSWP), but only if the information fits within the Act's definition of PSWP, which is as follows:

> (A) IN GENERAL—
>
> Except as provided in subparagraph (B), the term "patient safety work product" means any data, reports, records, memoranda, analysis (such as root cause analyses), or written or oral statement—
>
> (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.

42 U.S.C. §299b-21(7)(A) (2006). The PSQIA grants privilege from discovery and confidentiality protection to PSWP. *See*: 42 U.S.C. §299b-22(A) and (B) (2006).

However, the Act contains significant restrictions on the definition of PSWP and the applicability of the privilege and confidentiality protections. These restrictions are found under the heading "CLARIFICATION" in § 299b-21(7)(B) and provide in pertinent part as follows:

> (B) CLARIFICATION
>
> (i) . . .
>
> (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 government agency for public health surveillance, investigation, or other public health purposes*; or
> >
> > (III) *a provider's record keeping obligation with respect to information described in this*

> *subparagraph under Federal, State, or local law.*

42 U.S.C. §299b-21(7)(B) (emphasis added).

Under the plain language of the PSQIA, information collected, maintained, or developed for purposes other than submission to a PSO does not constitute PSWP and is not privileged or confidential under the Act. Specifically, information collected, maintained, or developed to fulfill obligations under federal, state, or local law does not constitute PSWP.

The U.S. Department of Health and Human Services, during the rule making process surrounding the implementation of the PSQIA, gave significant guidance to what is and is not PSWP. Both Baptist and the Plaintiff cited extensively to the rule summary found in Fed. Reg. Vol 73, No. 226, 70732 et. seq. (Nov. 21, 2008). In that Summary, HHS explains that reporting obligations under state and federal laws must be met with non-privileged materials:

> Even when laws or regulations require the reporting of the information regarding the type of events also reported to PSOs, 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 70742 (emphasis added). HHS goes on to explain that information collected for state or federal record keeping or reporting requirements is not PSWP:

> The Patient Safety Act establishes a protected space or system that is separate, distinct, and resides alongside but does not replace other information collecting activities mandated by laws, regulations, and accrediting and licensing requirements as well as voluntary reporting activities that occur for the purposes of maintaining accountability in the health care system. *Information is not patient safety work product if it is* ***collected*** *to comply with external obligations, such as: state incident reporting requirements; [or] . . . certification or licensing records for compliance with health oversight agency requirements*. . . .

*Id.* (emphasis added). HHS Further explained that PSWP is limited only to information obtained by a healthcare provider's PSES for the sole purpose of reporting to its PSO, and information collected for other purposes does not become PSWP by virtue of the fact that it was submitted to a PSO:

> Providers should be cautioned to consider whether there are other purposes for which an analysis may be used to determine whether protection as patient safety work product is necessary or warranted. *Further, the definition of patient safety work product is clear that information collected for a purpose other than reporting to a PSO may not become patient safety work product only based upon the reporting of that information to a PSO.*

*Id.* at 70744 (Emphasis added).

The final rules promulgated by HHS reaffirm the limitations referred to above. "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 PSO shall not by reason of its reporting be considered patient safety work product." 42 C.F.R. §3.20, *Patient safety work product* (2)(i) (emphasis added). Sec. 3.20 goes on to state that: "Nothing in this part shall be construed to limit information that is not patient safety work product from being . . . reported to a Federal, State, local or Tribal government agency for public health oversight purposes; or ***maintained*** as part of a providers' record keeping obligation under Federal, State, local or Tribal law. 42 C.F.R. §3.20, *Patient safety work product* (2)(iii) (emphasis added).

Documents are not PSWP if those documents were collected or maintained for a purpose other than submission to a PSO or for a dual purposes. Any documents that are collected pursuant to a healthcare provider's obligation to comply with federal, state, or local laws, or accrediting or licensing requirements are not privileged under the PSQIA, and such documents do not gain privilege by being submitted to the PSO.

Florida's statutes and administrative rules contain numerous requirements for record keeping and reporting of adverse incidents by healthcare providers. For instance, Section 395.0197, Florida Statutes and Fla. Admin. Code 59A-10.0055 establish a system whereby reports of adverse incident are to be created, maintained and reported to ACHA. Section 395.0197(4) mandates that health care providers establish a risk management program that includes written incident reports. Rule 59A-10.0055 describes what information these incident reports must contain. Both Section 395.0197(13) and Rule 59A-10.0055(3)(b) mandate that ACHA shall have access to these reports and can review them upon request. Other statutes

that trigger record keeping and/or reporting requirement include Sections 766.101 and 395.0193. Documents created or maintained pursuant to statutory or regulatory schemes such as these are not PSWP.

The language of the Plaintiffs' Third Request for Production is tailored to ask for only those documents created or maintained pursuant to statutory, regulatory, licensing, or accreditation requirements. Since these documents are not PSWP, they are not privileged or protect [sic] from discovery under the PSQIA.

Baptist argues that, regardless of the purpose behind the collection of information in its possession, only information actually provided to the government entities is not privileged under the PSQIA. However, in referring to non-privileged information, the terms used repeatedly by the statutes and other authorities is "collected" and "maintained." It is the collection and maintenance of information and records for a regulatory purpose, not the actual provision of that information to the government, that takes information out of the ambit of the PSQIA. In the words of the HHS information "***collected*** to comply with external obligations, such as: state incident reporting requirements; [or] . . . certification or licensing records for compliance with health oversight agency requirements . . ." is not privileged. Federal Register, Part III, Vol. 73, No. 226, at 70742 (Nov. 21, 2008) (emphasis added).

Finally, there is a dispute between Baptist and the Plaintiffs on who should bear the cost of the production of the documents at issue. The Plaintiffs argue that no costs are appropriate under the language of Amendment 7, and that the costs asked for by Baptist for similar documents in similar cases is excessive. They have expressed a desire to do discovery on the

issue of such costs. Baptist, for its part, claims entitlement to costs under the provisions of Florida Statutes. The Court is not ruling, at this point, on either entitlement to costs of production or the amount of these costs should they be ordered.

Accordingly, it is

ORDERED:

1. Plaintiffs' Motion to Compel the Production of Amendment 7 Documents is

GRANTED.

2. All adverse incident reports, as defined by Amendment 7, which are created, or maintained pursuant to any statutory, regulatory, licensing, or accreditation requirements are not protected from discovery under the Federal Patient Safety and Quality Improvement Act ("PSQIA").

3. By subsequent Order, the Court will address the breath and scope of the Amendment 7 documents to be produced, the timing of the production and Baptist's demand for reimbursement of the cost of identifying and producing the Amendment 7 documents.

DONE AND ORDERED in chambers at Jacksonville, Duval County, Florida, this __ day of July, 2014.

[ORDER ENTERED: JUL 30, 2014]

Waddell A. Wallace, III
Circuit Judge

Copies furnished to all counsel of record.

## APPENDIX H

VIRGINIA LAWYERS WEEKLY
New decision splits courts on privilege

By: Deborah Elkins

March 17, 2015

A new front has opened up in the discovery fights in Virginia medical malpractice cases.

Lawyers still skirmish over production of hospital policies and procedures and risk management reports. But now they are also battling over the scope of a privilege for internal investigations initiated under a federal statute intended to improve patient safety.

Passed in 2005, the federal Patient Safety and Quality Improvement Act protects certain safety and quality data from discovery during a lawsuit. Plaintiff's lawyers say that provider's lawyers have begun turning to the federal Act because the 2006 Virginia Supreme Court decision in *Johnson v. Riverside Hospital* eroded protections for hospitals' internal incident reports.

"If you don't have Door A, you have to cut a new hole in the house," said Virginia Beach plaintiffs' lawyer Judith M. Cofield.

The federal PSQIA privilege covers "patient safety work product" reported to and analyzed by external Patient Safety Organizations in an ongoing effort to improve health care delivery. In Virginia, a number of providers use the Virginia PSO, administered by the Virginia Hospital & Healthcare Association.

In circuit court cases from Washington County and Newport News, plaintiffs have won documents for which health care providers claimed a PSQIA privilege.

The defense notched a significant win earlier this month when a Norfolk Circuit Court said the federal privilege covered emails between a surgeon and a hospital's designated patient safety officer, even though the hospital did not ultimately report the information to a PSO.

Scope of privilege

Cofield represents the plaintiff in the new case from Norfolk, *Lewis v. Upadhyay* (VLW 015-8-022), which is set for trial in June.

After kidney surgery on a weeks-old infant, the defendant surgeon contacted Dr. Arnold Zaritsky, senior vice president for clinical services at Children's Hospital of the King's Daughters. CHKD is not a party to the *Lewis* case, but Zaritsky is a designated PSQIA patient safety officer for the hospital.

Zaritsky undertook an investigation, which included meeting with health care professionals involved in patient Darnell Lewis' care. Professional staff who were consulted were advised that their communications and information associated with the investigation would be confidential and privileged from disclosure, the hospital asserted.

Zaritsky and the defendant surgeon communicated through a series of emails, and the plaintiff asked for those emails and other electronic communications, arguing that the emails were never actually sent to a PSO.

Under the Act, forwarding the information to a PSO "is a predicate for the privilege, and they didn't forward it," Cofield said.

In earlier litigation, before a nonsuit of the *Lewis* case, Norfolk Circuit Judge Charles Poston had ordered production of the emails, according to lawyers in the case. Norfolk Circuit Judge Junius P. Fulton III alluded to the ruling but took a different tack.

Examining the Act and its regulations, Fulton said the communications were protected. In fact, he said that under the PSQIA regulations' definition of "patient safety work product, information is protected at collection."

Fulton acknowledged that "allowing protection at the time of collection raised concerns. Some commentators feared that since information may be protected back to the time of collection, providers would no longer be required to promptly report information to a PSO to ensure protection."

Fulton rejected decisions from courts in Tennessee, New York and Pennsylvania, and even "a judge of this court" that supported the plaintiff's view that the PSQIA protection was triggered by reporting to a PSO.

Under final agency rules, providers are required to document when information is gathered within a patient safety evaluation system in order to preserve the privilege. And because there is "no expiration date for an event that would prohibit future protection of a report of it as patient safety work product," the protection extended in Lewis' case from the hospital's investigation in 2012 through litigation in 2015.

Although Zaritsky and the defendant failed to document the emails at issue as collected within a patient safety evaluation system, the court said it would presume they were collected within that context, absent evidence to the contrary. A supporting affidavit from Zaritsky affirmed the communications

occurred "as part of and for the purpose of reporting to a PSO."

Cofield challenged the court's reliance on the affidavit as inadmissible hearsay, and said the plaintiff had a right to cross-examine Zaritsky, whose affidavit contradicted earlier deposition testimony. Cofield said she plans to seek reconsideration of Fulton's ruling.

The PSQIA privilege may be waived for information removed from a PSO evaluation in order to be reported through other channels, for instance in a medical or hospital record, or in a separately required report. But in *Lewis*, the hospital reported it was "not aware of an incident report having been created."

Patient safety evaluation systems using PSOs are just one of the ways providers work to systematically improve patient care, according to Norfolk lawyer Jason Davis, who represents the surgeon in the *Lewis* case. Richmond lawyer Ruth Griggs, who represented the hospital in *Lewis*; could not be reached for comment.

Providers "need full, frank and confidential proceedings," Davis said, so the PSO can do what it is tasked to do, and courts will enforce the federal Act's broad protections for providers.

The federal Act is "opening up a new realm of argument," Davis said.

Circuit split

The *Lewis* decision stands in contrast to two earlier plaintiff's wins.

In *Counts, Adm'r v. Johnston Memorial Hospital Inc*. (VLW 014-8-122), Judge Sage Johnson conducted an in camera review, and on Jan. 13, 2014, he ordered

the defendant to produce all seven requested documents, with certain provisions redacted.

On March 20, 2014, Newport News Circuit Judge David F. Pugh ordered production of certain internal documents after Mary Immaculate Hospital Inc. withdrew its PSQIA privilege because the hospital "had not fully implemented and operationalized its" PSO participation when it created the PSO materials.

In *Whitby v. Peninsula Neurosurgical Assocs. Inc*. (VLW 014-8-079), Pugh ordered the hospital to provide plaintiff with all internal "factual investigation, witness interview notes and correspondence" authored by the hospital and not counsel responsive to the plaintiff's subpoena.

In a follow-up order April 1 after an evidentiary hearing, Pugh said hospital documents created for the PSO Quantros and for a hospital internal committee were privileged. But he ordered the hospital to share a portion of a Quantros "Follow-up Preview for Event" that included "factual information of patient care" that was not privileged.

Privilege claims should be closely scrutinized to determine whether providers are in fact qualified to claim PSQIA protection, according to Newport News lawyer Avery T. "Sandy" Waterman Jr., who represented the plaintiff in *Whitby*.

The *Lewis* decision "is at variance with multiple other opinions" that have restricted the PSQIA privilege, Waterman said.