COMMONWEALTH OF KENTUCKY
SUPREME COURT
NO. 2012-SC-000603

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

v. — **Appeal from the Kentucky Court of Appeals Original Action No. 2012-CA-916-OA**

HON. KIMBERLY N. BUNNELL, JUDGE, FAYETTE CIRCUIT COURT, — **APPELLEE**

And

ESTATE OF LUVETTA GOFF, and CLYDE GOFF — **REAL PARTIES IN INTEREST**

BRIEF OF *AMICUS CURIAE* IN SUPPORT OF APPELLANTS' PETITION FOR REHEARING BY THE AMERICAN HOSPITAL ASSOCIATION, KENTUCKY HOSPITAL ASSOCIATION, KENTUCKY MEDICAL ASSOCIATION, KENTUCKY CHAMBER OF COMMERCE AND THE INDIVIDUAL KENTUCKY HOSPITALS NAMED ON BACK OF COVER

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that copies of this brief have been served via U.S. mail on this 10th day of September, 2014 to: Hon. Kimberly N. Bunnell, Fayette Circuit Court, 120 N. Limestone, Lexington, Kentucky 40507; Michael Lucas, Esq., Carter & Lucas, 151 Main Street, P.O. Box 852, Pikeville, Kentucky 41502; Bradley A. Case, Esq., Dinsmore & Shohl LLP, 101 S. Fifth Street, Suite 2500, Louisville, Kentucky 40202; William E. Thro, Esq., University of Kentucky, 301 Main Building, Lexington, Kentucky 40506-0032; and Samuel P. Givens, Jr., Clerk, Court of Appeals, 360 Democrat Drive, Frankfort, KY 40601. The undersigned also certifies that the record on appeal was not withdrawn by *amicus curiae*.

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STATEMENT OF POINTS AND AUTHORITIES

Purpose and Issues

The Kentucky Supreme Court's interpretation of the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. § 299b-21 *et seq.*, (the "Act"), in this matter is contrary to the Act's plain language, inconsistent with regulatory guidance by the Agency for Healthcare Research and Quality, ("AHRQ"), and authorizes trial judges to void the Act by subjective application. The Court's analysis and remand instructions invite trial courts to inconsistently and subjectively apply the definition of Patient Safety Work Product, ("PSWP"), or worse to disregard it altogether so as to snub the Act's preemptive effect in Kentucky. The detrimental effects of the Court's opinion are myriad and demoralizing to Kentucky's hospitals, which rely upon the Act to encourage health care professionals to openly and without guard discuss patient safety and quality. The American Hospital Association ("AHA"), the Kentucky Hospital Association ("KHA"), the Kentucky Medical Association ("KMA"), the Kentucky Chamber of Commerce ("Commerce"), and the individually-named hospitals and health systems are united in their request that the Court grant the petition for rehearing sought by Drs. Tibbs, Norman and Brown, ("Appellants").

Argument

A. The Tibbs Opinion Contradicts the Plain Language of the Act and Turns the System on its Head

The Court interprets PSWP in a manner that is in conflict with the Act and upends the greater system created by Congress so as to void it.[1] The Court concludes that information that may be responsive to a "state-mandate" is ineligible to be PSWP.[2] Yet, no language in the definition of PSWP supports this interpretation and such a construction is

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[1] "One of the fundamental maxims of statutory construction is that an act "is to be read as a whole[,]" *i.e.*, "any language in the [act] is to be read in light of the whole [act], not just a portion of it. The point of this maxim is that the whole [act] provides the context into which to place any language found in the [act]." Popplewell's Alligator Dock No. 1 v. Revenue Cab., 133 S.W.3d 456, 465 (Ky. 2004).

[2] Tibbs, at p. 22.

contrary to the Act's operation. Only "medical records, billing and discharge information, or any other original patient or provider record" are categorically ineligible from being PSWP.[3] Neither this Court nor the trial court make a factual finding that the Appellant's incident report constitutes one of these types of records.

The Act also states that information a provider separates from its process of reporting to a PSO is precluded from being PSWP, but this preclusion is the result of the provider's decision and action.[4] Neither this Court nor the trial court make a factual finding that the Appellants kept the incident report separate from the Patient Safety Evaluation System, ("PSES"). In fact, the Tibbs opinion admits the incident report was maintained in the provider's PSES, (at p. 22), but dismisses this fact, (at p. 13), by adding language to 42 U.S.C. §299b-21(7)(B)(ii) that does not exist in the statute:

> 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...." (Emphasis added.)

This language does not exist in the definition of PSWP and creates circular logic. The added language negates the purpose and meaning of PSWP by taking a question of fact ("Did a provider collect information separate from its PSES?") and making it a conclusion of law.

Congress clarifies that the definition of PSWP shall not be construed to limit the discovery, admissibility, public reporting and record-keeping of information that is not PSWP.[5] This limiting language applies only to information that is not PSWP and shows,

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[3] 42 U.S.C. §299b-21(7)(B)(i).

[4] 42 U.S.C. §299b-21(7)(B)(ii). As AHRQ notes, "The fact that information is collected, developed, or analyzed under the protections of the [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[-PSWP]." 73 Fed. Reg. 70732 (November 21, 2008).

[5] The operational context of 42 U.S.C. §299b-21(7)(B)(iii) is made clear in 42 U.S.C. §299b-22(g)(2) and (5), which state that providers must still comply with other public health laws so long as a provider does not report or disclose PSWP. This construction is validated by AHRQ numerous times, "...the [Act] does not affect any

therefore, that Congress does intend to limit the discoverability, admissibility, public reporting and record-keeping of information that is PSWP. AHRQ acknowledges this operation of the Act by affirming a provider's ability to protect public reporting and record-keeping information in its PSES, while also permitting the provider to remove the information from the PSES prior to publicly reporting or disclosing the information:

> 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 PSWP within their PSES while they consider whether the information is needed to meet external reporting obligations. Information can be removed from the PSES before it is reported to a PSO to fulfill external reporting obligations. Once the information is removed, it is no longer PSWP and is no longer subject to the confidentiality provisions.[6]

PSWP may not be disclosed to comply with state reporting and recording keeping obligations, but the language of the definition does not preclude such information from being eligible as PSWP. To read it otherwise would render AHRQ's guidance nonsense.

B. The Tibbs Opinion Clearly Conflicts with the Federal Opinion in Tinal v. Norton Healthcare, Inc. in Its Analysis and Application of PSWP

The Tibbs opinion reviews several cases regarding PSWP, but fails to reference any consideration of the comprehensive and complete analysis of PSWP in the case of Tinal v. Norton Healthcare, Inc.[7] issued by the Western District of Kentucky. The Federal court in Tinal affirmed the broad application of the privilege protections and articulates a point-by-point outline of the PSWP definition to analyze the applicability of the privilege.

State law requiring a provider to report information that is not [PSWP.]", (73 Fed. Reg. at 70732); and "These external obligations must be met with information that is not [PSWP]....", (73 Fed. Reg. at 70742).

[6] 73 Fed. Reg. at 70742.

[7] Tinal v. Norton Healthcare, Inc., Case No. 3:11-CV-596-S, (W.D.Ky. July 15, 2014)(To be published by Order entered July 14, 2014.)

Specifically, the Court determined in Tinal that medication event reports (i.e., incident reports) are eligible as PSWP.[8]

The Tinal opinion also considered whether information was "separate" from the hospital's PSES, but properly addressed the issue as a question of fact.[9] The Federal court analyzed whether the privileged information was publicly disclosed or reported, whether the provider separated the information from its PSES, and whether the information was removed from the PSES by the provider.[10] The Federal court approached each of these points as a question of fact based upon the language of the Act and its overall operational construct. Rehearing is warranted for the Court to consider the obvious conflict the Tibbs opinion creates with the Federal court in Tinal.

C. The Tibbs Opinion Impedes for Kentucky the Act's Benefits and Purpose

Congress could not intend an interpretation of PSWP that runs counter to the Act's purpose and operation. Though the Act's privilege and confidentiality protections are unequivocally broad and strong, the Court's opinion makes those protections illusory because it narrows the door through which information may qualify for protection. Congress clearly intended the Act's protections to foster robust reporting of safety and quality information by providers; yet the Court's opinion accomplishes just the opposite. Since the Act's passage in 2005 the KHA can attest that Kentucky's hospitals have noted a substantial and meaningful change in the culture of patient safety and quality improvements as a direct result of hospitals reporting information to a PSO and the protections promised by the Act. The lessons from such aggregated results mean that Kentucky hospitals are learning from each other in a protected environment, exactly as Congress intended. The

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[8] Id. at 22.

[9] Id. at 21-22.

[10] Id.

Court's opinion, however, now minimizes the incentive of participation in the PSO construct because the Tibbs opinion makes the Act's protections subjective and uncertain. The result of the opinion is that the future of health care safety and quality in Kentucky will revert to the very environment excoriated by the Institute of Medicine in its 1999 seminal report. Kentucky's hospitals have seen the benefits of improvement under the Act and they have no desire of turning back the clock of progress.

The Court's opinion also upsets the health care reporting system created by Congress and implemented by AHRQ. Kentucky hospitals have collectively spent millions of dollars to establish PSO relationships, to create internal mechanisms in compliance with the Act, and to expand personnel dedicated to safety and quality improvement. Hospitals made these investments in reliance upon an objective application of the definition of PSWP. The Tibbs opinion creates a privilege analysis that invites subjectivity and, therefore, uncertainty.

The Tibbs opinion obligates trial courts to evaluate the application of PSWP by policing state licensure standards. This necessarily means that a hospital will not – and cannot – know whether any particular safety and quality information will qualify as PSWP unless later resolved by a court in litigation. The uncertainty in the protections will naturally suppress provider participation in patient safety activities. Moreover, the Court's analysis is just as likely to expose Kentucky's hospitals to federal civil monetary penalties of $11,000 because the Court's statement of what is eligible as PSWP is distinctly different from guidance by AHRQ. The Court's opinion has destabilized an entire health care plan envisioned by Congress and implemented by AHRQ by means of an uncertain and subjective analysis of PSWP.

Finally, the Tibbs opinion leaves many practical questions for trial judges and litigants. How will trial courts apply the Act's protections to exclude information "normally

contained" in an incident report? Is the qualifier "normally" evaluated from the perspective of the provider, geographically, or from the health care industry in general? Kentucky laws and regulations do not define the elements of an incident report and Kentucky does not require incident reports to be externally reported. Does the Tibbs opinion invalidate the Act's protections for any record which may comply with a regulatory requirement? The conclusion of the Tibbs opinion does not support such an argument, but certainly some will argue that the Court declares every document ineligible as PSWP since all patient safety activities may be argued to have a regulatory origin or basis. Such a construction allows trial judges to selectively avoid the preemptive effect of the Act and erodes the progress of safety and quality in the delivery of health care.

Conclusion

For the foregoing reasons, *amicus curiae,* the AHA, KHA, KMA and Chamber and the individually named hospitals and health systems respectfully request the Court grant Appellants' petition for rehearing.

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