"In addition to the attached brief filed in *Norton Hospitals v. Cunningham*, an identical brief was filed in the *Tibbs v. Bunnell* case, which raised the same issue, on October 26, 2012 in the Kentucky Supreme Court."

COMMONWEALTH OF KENTUCKY
SUPREME COURT
NO. 2012-SC-000604

NORTON HOSPITALS, INC. d/b/a NORTON HOSPITAL — APPELLANT/CROSS-APPELLEE

Appeal from the Kentucky Court of Appeals
v. Original Action No. 2012-CA-000746-OA

HON. CHARLES L. CUNNINGHAM, JR., JUDGE JEFFERSON CIRCUIT COURT, DIVISION FOUR — APPELLEE/CROSS-APPELLANT

And

ESTATE OF JACOB HILL, By and Through The Personal Representative KAYLA HILL, and KAYLA HILL, Individually — REAL PARTIES IN INTEREST

BRIEF OF *AMICUS CURIAE* KENTUCKY HOSPITAL ASSOCIATION and AMERICAN HOSPITAL ASSOCIATION

Respectfully submitted,

Dean T. Wellman
WELLMAN, NICHOLS & SMITH, PLLC
444 Lewis Hargett Circle, Suite 170
Lexington, KY 40502
Tel. 859-368-8116
COUNSEL FOR *AMICUS CURIAE*

CERTIFICATE OF SERVICE

The undersigned hereby certifies that copies of this brief have been served via First Class U.S. mail on this 26th day of October, 2012 to the following: Hon. Charles L. Cunningham, Jr., Jefferson Circuit Court, Division Four, Jefferson County Judicial Center, 700 West Jefferson Street, Louisville, Kentucky 40202; James M. Bolus, Jr., Esq., Bolus Law Offices, 600 West Main Street, Suite 500, Louisville, Kentucky 40202; A. Nicholas Naiser, Esq., Naiser Law Office, 600 West Main Street, Suite 500, Louisville, Kentucky 40202; Ed Monarch, Esq., Blackburn, Domene & Burchett, PLLC, 614 West Main Street, Suite 3000, Louisville, Kentucky 40202; Wesley R. Butler, Esq., Barnett, Benvenuti & Butler, 489 East Main Street, Suite 300, Lexington, Kentucky 40507; and Samuel P. Givens, Jr., Clerk, Court of Appeals, 360 Democrat Drive, Frankfort, KY 40601. The undersigned certifies that the record on appeal was not withdrawn by *amicus curiae*.

COUNSEL FOR *AMICUS CURIAE*

STATEMENT OF POINTS AND AUTHORITIES

Purpose and Issues

The federal government created a new dynamic in the practice of health care by enacting the Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 42 U.S.C. § 299b-21 *et seq.* ("Patient Safety Act" or the "Act"). Although health care safety and quality has long been predominantly the purview of state laws and regulations, Congress found that the state-by-state approaches to patient safety were wholly lacking. In response, Congress established a new health care framework allowing providers to share patient safety information within an environment covered by privilege and confidentiality protections. The Kentucky Court of Appeals' Order concerning the Patient Safety Act fails to interpret apply the Act in the manner as expressed and as intended by Congress.

The Kentucky Hospital Association ("KHA") is a non-profit state association of hospitals, related health care organizations, and integrated health care systems. The KHA represents virtually every hospital and health system in Kentucky. The KHA's mission is to develop and implement health policies that enhance its members' ability to deliver health care services to their communities by engaging in advocacy and representation efforts promoting quality health care efficiently. The KHA works diligently with its members and other stakeholders in health care to identify and recommend health care initiatives meant to improve the provision of health care services for persons seeking health care in the Commonwealth.

The KHA is one of many hospital associations nationwide that followed the Patient Safety Act's lead by establishing a component patient safety organization, called the Kentucky Institute for Patient Safety and Quality, or KIPSQ. The KHA's mission is to improve the quality and safety of health care services delivered to all Kentuckians

throughout the state. KIPSQ has been certified and listed by the federal government as an authorized patient safety organization since November 26, 2008.

The American Hospital Association ("AHA") represents more than 5,000 hospitals, health care systems, and other health care organizations, and nearly 200,000 employed physicians in those organizations. The AHA and its members are committed to improving the health of communities they serve and to helping ensure that care is available to, and affordable for, all Americans. The AHA educates its members on health care issues and advocates to ensure that their perspectives are considered in formulating health care policy.

Integral to AHA's mission of advancing the health of individuals and communities is enabling hospitals to improve the safety and quality of the care Americans receive. That is why the AHA supported passage of the Patient Safety and Quality Improvement Act of 2005. It provides a key step in improving patient safety – ensuring that anyone involved in the care of a patient is able to share information when mistakes happen so that all patients get the benefit of lessons learned across the country about how to prevent such errors. That is also why the Institute of Medicine, in its report "To Err is Human," urged that Congress pass legislation to provide legal protections for data related to patient safety and quality, bring to health care a strategy reflecting lessons learned in the aviation industry over more than 25 years. Every day, the doctors, nurses and other caregivers working in hospitals are taking steps to create a "culture of safety," an environment that focuses on protecting patients from harm. The AHA, through its strategic initiative, "Hospitals in Pursuit of Excellence, is assisting hospitals by providing the field-tested practices, tools, education and other networking resources that support hospital efforts to meet the Institute of Medicine's Six Aims for Improvement – care that is safe, timely, effective, efficient, equitable and patient-centered."

On behalf of their members, the KHA and the AHA submit that the issue before the Court is of vital important to hospital, health systems and the progress of health care in Kentucky. Hospitals and health systems across the Commonwealth have invested significant resources in restructuring and adapting patient safety systems to comply with the Patient Safety Act. The members of the KHA and the AHA have an interest in assuring that Kentucky's courts understand and implement the federal health care construct established by the Patient Safety Act. The KHA and the AHA offer the following arguments to supplement and support the arguments raise by Appellant and as a means of helping the Court consider the implications of the issues on appeal.

Argument

The Patient Safety Act Implements a Comprehensive Framework for Health Care Providers to Improve Patient Safety and Quality within a Protected Learning Environment

A. Congressional Intent for the Patient Safety Act

The Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 42 U.S.C. §299b-21 *et seq.*, ("Patient Safety Act" or the "Act"), implemented a nationwide initiative to improve patient safety and quality. Over a period of nearly six years and after numerous hearings, Congress developed and enacted bipartisan legislation intended to address the impediments to patient safety and quality. Passed unanimously by the Senate and nearly unanimously by the House (428 Yeas to 3 Nays) and signed by the President on July 29, 2005, the Patient Safety Act represented a significant moment of political agreement on the best method to achieve advances in patient safety and quality.

The Patient Safety Act rests on the foundation of two significant findings. First, Congress found that safety and quality improvements in health care require health care providers to report, analyze and share lessons learned from medical errors. H.R. Rep. No.

197, 109th Cong., 1st Sess., at 9 (2005). Just as advances in medical care rely upon data developed from evidence-based practices, advances in safety and quality require accumulated data that can be analyzed to determine the cause and ultimately the prevention of medical errors. As Congress noted, "...most human errors are triggered by system failures."[1] S. Rep. No. 196, 108th Cong., 1st Sess., at 2 (2003).[2]

Secondly, Congress recognized that the threat of malpractice litigation discourages health care professionals and organizations from reporting, analyzing and sharing data related to patient safety and quality. Id. Patient safety initiatives that focus on blame and punishment fail to accomplish improvements in patient safety. Id. at 3. By enacting the Patient Safety Act, Congress intended to "shift the current focus from culpability to a new paradigm of error reduction and quality improvement." Id. A "critical component" of the Patient Safety Act "is to create an environment that encourages organizations to identify errors, evaluate causes and design systems to prevent future errors from occurring." Id. at 2. The non-punitive environment created by the Patient Safety Act "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." Id. at 5.

B. Operational Construct of the Patient Safety Act

The Patient Safety Act creates a health care framework that promotes a "culture of safety" focusing on information sharing. H.R. Rep. No. 197, 109th Cong., 1st Sess., at 9 (2005). Congress authorized the creation of patient safety organizations, or PSOs, to collect and analyze patient safety and quality information and provide feedback to providers on trends, patterns and strategies to improve patient safety and quality. 42 U.S.C. §299b-21(4).

[1] Congress cites the seminal report published by the Institute of Medicine, To Err is Human, (1999), as an authoritative source for identifying the impediments to patient safety and quality.

[2] H.R. 3205 was the bill from the 109th Congress that ultimately resulted in Public Law 109-41. H.R. 3205 was itself a re-introduction of S. 720 from the 108th Congress in 2003.

Providers and PSOs form a symbiotic relationship whereby the PSOs need providers to supply patient safety information and providers need PSOs to aggregate and analyze patient safety information to establish the evidentiary foundation for patient safety solutions. The federal Department for Health and Human Services ("DHHS") governs the certification and oversight of PSOs. 42 U.S.C. §299b-23. As the Patient Safety Act becomes fully implemented, it is expected that PSOs will work cooperatively with the federal government and other PSOs to develop a nationwide network of patient safety databases to increase the aggregation and analyses of patient safety evidence.

Congress recognized that the Patient Safety Act's goal of information sharing could only be accomplished if the information is shared in a protected environment. Within this framework,Congress established a category of protected information called "patient safety work product," ("PSWP"). 42 U.S.C. §299b-21(7). Information designated as PSWP is subject to broad privilege and confidentiality protections under the Patient Safety Act. 42 U.S.C. §299b-22. Generally, any information exchanged between provider and PSO may qualify as PSWP subject to the boundaries and limitations expressly set out within the definition of PSWP. Id. "The final rule permits any data, which is a term that is broadly defined and would include retrospective analyses, to become [PSWP]." 73 Fed. Reg. 70732, 70744 (Nov. 21, 2008)(Commentary to Final Rule).

Although the definition of PSWP is intentionally broad, the privilege is not intended to extend to "underlying factual information contained within or referred to in patient safety data reported to a PSO." S. Rep. No. 196, 108th Cong., 1st Sess., at 5 (2003). Hence, as reflected in the definition of PSWP, medical records, billing and discharge information, or other provider records separately maintained are not privileged. 42 U.S.C. §299b-21(7)(B)(i). Accordingly, the Patient Safety Act does not affect a patient's access to his or her medical

records or prevent such medical records from being discovered in the event of a subsequent malpractice action. Id.

Contrary to the ruling by the Kentucky Court of Appeals, however, the Patient Safety Act's definition of PSWP does not limit the privilege to information required for "self-examining analysis." Although self-critical analyses are activities which the Act intends to protect, the Court of Appeals is without authority to arbitrarily re-define PSWP by imposing the "self-examining analysis" requirement on information before it qualifies for the Act's privilege protections. The Patient Safety Act does not restrict its privilege protections only to information that proves to be "self-examining." To qualify information as privileged, the Act requires that the information be assembled or developed by providers for reporting to a PSO. 42 U.S.C. §299b-21(7)(A)(i)(I). No where does the Act condition the privilege upon a subjective evaluation of whether the information is self-examining. The Act expressly states that the information gains privilege protections by the mere act of the provider assembling and developing the information for reporting to a PSO. The further requirement imposed by the Court of Appeals, writes language into the Patient Safety Act that defies a plain reading of the words and intent fixed by Congress. "When a statute is as clear as a glass slipper and fits without strain, courts should not approve an interpretation that requires a shoehorn." City of Bowling Green v. Helbig, 2012 Ky. App. LEXIS 195, *8 (September 28, 2012)(citations omitted.)

C. The Broad Privilege Protections of the Patient Safety Act

The patient safety framework established by the Patient Safety Act permits health care providers to analyze and share patient safety information within a protected

environment "without fear that these reports will become public or be used in litigation." S.Rep. No. 196, 108th Cong., 1st Sess., at 5 (2003). DHHS emphasized the importance of the Patient Safety Act's privilege protections within commentary to its regulations implementing the Act:

> 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.

73 Fed. Reg. 70732, 70741 (Nov. 21, 2008)(Commentary to Final Rule).

The Patient Safety Act contains comprehensive privilege provisions prohibiting compelled disclosure of PSWP, with very narrow exceptions. The privilege protections of the Patient Safety Act apply, "[n]otwithstanding any other provider of Federal, State or local law...." 42 U.S.C. §299b-22(a). Specifically, and as appropriate to the case *sub judice*, PSWP cannot be subject to discovery in a State civil proceeding or subject to compelled disclosure through a State civil subpoena or order. 42 U.S.C. §299b-22(a)(1) and (2). And, PSWP cannot be admitted as evidence in a state civil proceeding. 42 U.S.C. §299b-22(a)(4).

The Court of Appeals' addition of "self-examining analysis" to the definition of PSWP abrogates the Act's privilege protections by re-defining and restricting the information that qualifies for the privilege. Neither the Court of Appeals nor the trial court is permitted to promulgate orders that conflict with federal law. In general terms, the doctrine of federal preemption provides that "a state law that conflicts with federal law is without effect." Wright v. General Electric Co., 242 S.W.3d 674, 678 (Ky. App. 2007) (citing McCulloch v. Maryland, 17 U.S. (4 Wheat.) 316, 4 L.Ed. 579 (1819)). Congress' power to preempt state law is rooted in the Supremacy Clause of the United States

Constitution (Article VI, Clause 2). DirecTV, Inc. v. Treesh, 290 S.W.3d 638, 641 (Ky. 2009). Under the Supremacy Clause, a state law that interferes with or is contrary to federal law is "without effect." Id. (citing Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992)). ""The purpose of Congress is the ultimate touchstone' in every pre-emption case." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1997); see also Wright, 242 S.W.3d at 678. The preemptive effect of the Patient Safety Act was articulated and understood well before passage of the Act. H.R. Rep. No. 197, 109th Cong., 1st Sess., at 12 (2005).

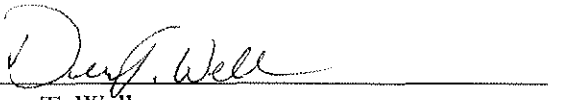
By limiting the Patient Safety Act privilege to only information containing "self-examining analysis," the Court of Appeals thwarts the Congressional purpose behind the Act. Congress intended the Act's privilege to be an application of law; not to allow courts to apply the privilege only after a subjective, qualitative analysis of the information.

Hospitals and health care systems in Kentucky that participate in the Patient Safety Act framework comply with the Act in anticipation of receiving the protections that the Act assures. Kentucky state courts should not be permitted to lessen the promises made by Congress. Hospitals and health systems have invested considerable time and resources to promote the patient safety goals of the Act. Should the Court of Appeals' "self-examining analysis" criteria be permitted by the Court, the scope and purpose of the Act will be fundamentally altered and the foundation of work by Congress and health care providers across the nation, over a decade in the making, will be undermined. The Patient Safety Act is "intended to encourage the reporting and analysis of medical errors...." H.R. Rep. No. 197, 109th Cong., 1st Sess., at 9 (2005). Any construction of the Patient Safety Act by Kentucky courts that discourages reporting is fundamentally contrary to the Act.

Conclusion

For the foregoing reasons, *amicus curiae* the Kentucky Hospital Association and the American Hospital Association respectfully request that the Court affirm the Court of Appeal's grant of the writ of prohibitions on the finding that the trial court's order was preempted by the Patient Safety Act, but reverse and remand only that portion of the Court of Appeals' order remanding to the trial court with instructions that restrict the Act's privilege protections only to information containing "self-examining analysis."

Respectfully submitted,



Dean T. Wellman
WELLMAN, NICHOLS & SMITH, PLLC
444 Lewis Hargett Circle, Suite 170
Lexington, KY 40502
Tel. 859-368-8116
COUNSEL FOR *AMICUS CURIAE*