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

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

APPEAL FROM
KENTUCKY COURT OF APPEALS
v. ORIGINAL ACTION NO. 2012-CA-916-OA

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

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

BRIEF AMICUS CURIAE OF UNIVERSITY HEALTHSYSTEM CONSORTIUM PERFORMANCE IMPROVEMENT PSO, THE AMERICAN MEDICAL ASSOCIATION, THE KENTUCKY MEDICAL ASSOCIATION, AABB's PATIENT AND DONOR SAFETY CENTER, ANESTHESIA QUALITY INSTITUTE, CALIFORNIA HOSPITAL PATIENT SAFETY ORGANIZATION, CAROLINAS HEALTHCARE SYSTEM PATIENT SAFETY ORGANIZATION, CAROLINAS REHABILITATION – PATIENT SAFETY ORGANIZATION, CHILD HEALTH PSO, CHS PSO, LLC, CLARITY PSO, ECRI INSTITUTE PSO, HEALTHCARE IMPROVEMENT PATIENT SAFETY ORGANIZATION OF ALABAMA, INC., INSTITUTE FOR SAFE MEDICATION PRACTICES, MEDNAX PSO, LLC, MISSOURI CENTER FOR PATIENT SAFETY, NC QUALITY CENTER PSO, PSYCHSAFE, QA TO QI LLC, QUANTROS PATIENT SAFETY CENTER, SCHUMACHER GROUP PATIENT SAFETY ORGANIZATION, INC., SOCIETY OF HOSPITAL MEDICINE PSO, THE MIDWEST ALLIANCE FOR PATIENT SAFETY, WAKE UP SAFE, THE ILLINOIS HOSPITAL ASSOCIATION, THE METROPOLITAN CHICAGO HEALTHCARE COUNCIL, SOCIETY FOR VASCULAR SURGERY PATIENT SAFETY ORGANIZATION, LLC, QUALITY CIRCLE FOR HEALTHCARE

Martin A. Arnett
Phillips Parker Orberson & Arnett, PLC
716 W. Main Street, Suite 300
Louisville, Kentucky 40202
Counsel for *Amici Curiae*

I hereby certify that signed originals of this brief have been served via First Class U.S. Mail on the 29th day of October, 2012, on the persons listed on the following page.

Counsel to the *Amici Curiae*

CERTIFICATE OF SERVICE

I hereby certify that signed originals of this brief have been served via First Class United States Mail on this the 29th day of October 2012, to the following persons:

The Honorable Kimberly N. Bunnell,
Judge, Fayette Circuit Court
Robert F. Stephens Courthouse,
120 North Limestone
Lexington, Kentucky 40507

Michael Lucas
Carter & Lucas
151 Main Street, P. O. Box 852
Pikeville, Kentucky 41502

Wesley R. Butler
Bradley J. Sayles
Barnett Benvenuti & Butler, PLLC
489 East Main Street, Suite 300
Lexington, Kentucky 40507

Peggy Binzer
McDermott Will & Emery, LLP
500 North Capitol Street N.W.
Washington, DC 20001

Dean T. Wellman
Wellman Nichols & Smith, PLLC
444 Lewis Hargett Circle, Suite 170
Lexington, Kentucky 40502

James M. Bolus, Jr.
Bolus Law Offices
600 West Main Street, Suite 500
Louisville, Kentucky 40202

Brad A. Case
Stephen J. Mattingly
Dinsmore & Shohl, LLP
101 South Fifth Street, Suite 2500
Louisville, Kentucky 40202

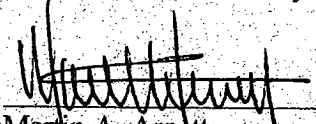
Charles E. Monarch
Bryce L. Cotton
Blackburn Domene & Burchett, PLLC
3000 West Main Street, Suite 3000
Louisville, Kentucky 40202

Lee E. Sitlinger
Sitlinger McGlincy & Theiler
455 South 4th Avenue, Suite 370
Louisville, Kentucky 40202

Paul E. Dwyer, Jr.
Edwards Wildman Palmer, LLP
2800 Financial Plaza
Providence, RI 02903

Samuel P. Givens, Jr.
Clerk, Court of Appeals
360 Democrat Drive
Frankfort, Kentucky 40601

Albert N. Naiser
Naiser Law Office
600 West Main Street, Suite 500
Louisville, Kentucky 40202



Martin A. Arnett
Phillips Parker Orberson & Arnett, PLC
716 W. Main Street, Suite 300
Louisville, Kentucky 40202
Counsel to the *Amici Curiae*

POINTS AND AUTHORITIES

STATEMENT OF INTEREST

The University HealthSystem Consortium Performance Improvement PSO ("UHC") is the patient safety organization for the University of Kentucky Hospital ("U of K"), where the incident occurred that is at issue in Phillip Tibbs, et al. v. Hon. Kimberly N. Bunnell, Judge, and Estate of Luvetta Goff and Clyde Goff, Supreme Court No. 2012-SC-000603. UHC understands that this appeal and the appeal in the Tibbs case are being heard concurrently. UHC has submitted an Amicus Brief in both cases because both involve efforts by plaintiffs to discover information that was gathered and reported to patient safety organizations on a privileged and confidential basis pursuant to the Patient Safety and Quality Improvement Act of 2005 ("Patient Safety Act" or "Act"). 42 U.S.C. § 299b-21 et seq.

The other amicus parties include 22 patient safety organizations ("PSOs") from around the country which, like UHC, have obtained and maintained certifications from the Agency for Healthcare Research and Quality, along with the Kentucky Medical Association ("KMA") and American Medical Association ("AMA"), and the Illinois Hospital Association and the Metropolitan Chicago Healthcare Council, which organized the Midwest Alliance for Patient Safety, one of the PSOs joining in this brief.

UHC and the other PSOs operate under the strict requirements of the Patient Safety Act. The KMA and AMA have thousands of hospital and physician members who rely on the Act for the protection of information gathered and reported to their respective PSOs for the improvement of patient outcomes pursuant to the Act. The KMA and AMA join this brief in their own persons and as representatives of the Litigation Center of the AMA and the State Medical Societies, which is a coalition of the AMA and the medical societies of each state and the District of Columbia whose purpose is to

represent the viewpoint of organized medicine in the courts.

The Patient Safety Act allows hospitals, physicians and other providers to collect documents, incident reports, analyses and other materials relating to patient safety activities and report them to a certified PSO without fear that the information will be disclosed. Under the Act, such information, known as "patient safety work product," is strictly privileged and not subject to discovery or admission into evidence in court proceedings. (42 U.S.C. § 299b-22(a) (2010).) UHC and the other amicus parties submit this brief because this Court will be the first state supreme court to interpret and apply the Act's confidentiality and privilege protections to the patient safety activities of PSOs and participating providers.[1]

The Court of Appeals' decision seeks to significantly limit the broad scope of the protections provided by the Act. Unless that portion of the decision is reversed, Congress' goal of preempting conflicting state law and encouraging PSOs and providers to engage in the candid analysis and exchange of patient safety information will be defeated in Kentucky. Whereas fellow physicians and other health care personnel are essential to the process of gathering, assessing and reporting patient safety information to a PSO, the Court of Appeals concluded that only "self-examining analysis," i.e., analysis prepared by the provider in question, is protected by the Act. Analyses, reports and information prepared by any other person involved in the quality improvement process would remain discoverable, even if gathered and reported in strict accordance with the Patient Safety Act. Such a stunning result is wholly contrary to the clear provisions of

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1 "Provider" is broadly defined to include "an individual or entity licensed or otherwise authorized under state law to provide health care services . . . " and includes hospitals, nursing facilities, home health agencies, hospice programs, ambulatory surgical centers, pharmacies, physicians and nurses. 42 U.S.C. § 299b-21(8).

the Act and would make it impossible for PSOs, hospitals, physicians, nursing homes, pharmacies and other health care providers to coordinate their efforts to improve patient health care throughout the country, as contemplated by the Act. The interest of UHC and the other amicus parties is to prevent such an adverse and unintended outcome.

NATURE OF THE CASE

Norton Hospital, Aasim Kazmi, M.D., Community Medical Associates and Keller Reide, M.D., were sued for wrongful death after Jacob Hill died at Norton Hospital on June 10, 2010. Plaintiff requested in discovery that Norton Hospital produce certain patient safety and quality improvement information created by the hospital following Mr. Hill's death. After Norton Hospital objected and plaintiffs filed a motion to compel, the trial court ruled that Norton Hospital must produce the documents.

The defendants/appellants' Motion for Writ of Prohibition was granted with instructions from the Appellate Court regarding the scope of the privilege to be applied by the trial court under the Patient Safety Act. Defendants/appellants then filed an appeal to this Court as a matter of right.

ARGUMENT

The Patient Safety Act protects information gathered and reported in accordance with its requirements, and, as the Court of Appeals found, preempts state law. It was adopted to encourage candid and effective reporting and sharing of information concerning adverse patient outcomes and efforts directed toward patient safety activities, and to provide the confidential environment required for such reporting and sharing to occur.

The protections of the Act are broad and not limited merely to information constituting "self-examining" analysis. Indeed, the Act contains no such qualifier, and

much of the information reported and shared among providers pursuant to the Act is created by someone **other** than the provider in question, based on their review and assessment of what occurred. After an incident or occurrence report is prepared, the event is typically evaluated by numerous health care personnel, including fellow physicians who serve on quality, performance, risk management and peer review committees. This evaluative process and the open and frank dialogue associated with it are critical to local, state and national efforts to improve patient care and to help contain skyrocketing costs. The principle purpose behind the Patient Safety and Quality Improvement Act of 2005 was to promote, support and protect such efforts.

The Court of Appeals apparently got distracted by a lone opinion from a New York federal court in a case construing a privilege different from the one arising under the Patient Safety Act. In Francis v. United States, No. 09-Civ. 4004, 2011 WL 2224509 (S.D.N.Y. May 31, 2011), the court was applying a medical peer review privilege in a case arising under the Federal Tort Claims Act ("FTCA"), not the Patient Safety Act. In fact, the court observed that the documents in question were not covered by the Patient Safety Act. The Francis court held that in the context of claims arising under the FTCA, the medical peer review privilege should be limited to information containing so-called "self-examining analysis." The Francis court offered dictum regarding additional matters, including the Patient Safety Act, but it is not good authority with respect to the scope of the privilege provided by Act.

The law of preemption requires that the Patient Safety Act be enforced in accordance with its provisions, without limitation or alteration by reference to state law, so as to protect information generated by providers for purposes of improving patient

care. And, contrary to plaintiffs' contentions, a decision to acknowledge the preemptive effect of the Act and enforce it according to its language will in no way hinder the ability of injured parties to obtain original medical records needed for malpractice cases. Under the Act, those remain available.

A. Overview of the Patient Safety Act and Patient Safety Rule

One of the principal motivating factors behind the passage of the Patient Safety Act was a scathing report prepared in 1999 by the Institute of Medicine ("IOM"), which estimated that every year between 44,000 and 98,000 people die from preventable medical errors. (Institute of Medicine, "To Err is Human: Building a Safer Health Care System," Nat'l Acad. Press, 1999). The IOM concluded that these deaths mostly were attributable to medication administration errors and gaps in system communication networks and information exchanges that caused delays in treatment. These industry-wide problems had systematically led to mistakes in care, yet little was done to address them. Id. at 49-66. At the same time, the IOM report recognized that in order to foster an effective, voluntary system for gathering and sharing the information needed to identify and address errors in patient care, strict protections for such information were required. Indeed, Chapter 6 of the report is entitled "Protecting Voluntary Reporting Systems from Legal Discovery." (Id. at 109.)

The Patient Safety Act was adopted to help combat the disastrous health results reported by the IOM and to provide the needed confidentiality for information gathered in connection with quality improvement and patient safety activities. Specifically, to facilitate the candid and effective collection and analysis of information required to improve patient outcomes, the Act provides strict confidentiality for such information.

The overarching purpose of the Patient Safety Act was succinctly summarized in

The Ill. Dep't of Fin. and Prof'l Regulation v. Walgreen Co., 2012 IL App. (2d) 100452-U (May 29, 2012). There, an Illinois Appellate Court affirmed the dismissal of a suit filed by the Illinois Department of Financial and Professional Regulation to try to force Walgreens to disclose "reports of medication error" involving three pharmacists. Walgreens had collected and transmitted these reports to its PSO in accordance with the Patient Safety Act and therefore refused to produce them. As observed by the Illinois Appellate Court:

> The Patient Safety Act "announces a more general approval of the medical peer review process and more sweeping evidentiary protections for materials used therein." KD ex rel. Dieffenbach v. United States, 715 F. Supp. 2d 587, 595 (D. Del. 2010). According to Senate Report No. 108-196 (2003), the purpose of the Patient Safety Act is to encourage a "culture of safety" and quality in the United States 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." S. Rep. No. 108-196, at 3 (2003). The Patient Safety Act provides that "patient safety work product shall be privileged and shall not be ***subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding." 42 U.S.C. § 299b-22(a) (2006). Patient safety work product includes any data, reports, records, memoranda, analyses, or written or oral statements that are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization. 42 U.S.C. § 299b-21(7) (2006). Excluded as patient safety work product is "information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system." 42 U.S.C. § 299b-21(7)(B)(ii) (2006).

(Id. at 8-9.)

The privilege and confidentiality protection provided by the Patient Safety Act is known as the "Patient Safety Rule," and the Preamble to the Patient Safety Rule convincingly explains the need for the protection:

> As compared to other high-risk industries, the health care system is behind in its attention to ensuring basic safety [Citation omitted]. The reasons for this lag are complex and varied. Providers are often reluctant to participate in quality review activities for fear of liability, professional sanctions, or injury to their reputations. Traditional state-based legal protections for such health care quality improvement activities, collectively known as peer review protections, are limited in scope: they do not exist in all States; typically they only apply to peer review in hospitals and do not cover other health care settings, and seldom enable health care systems to pool data or share experience between facilities. If peer review protected information is transmitted outside of an individual hospital, the peer review privilege for that information is generally considered to be waived. This limits the potential for aggregation of a sufficient number of patient safety events to permit the identification of patterns that could suggest the underlying causes of risks and hazards that then can be used to improve patient safety.

73 Federal Register 8113.

The final Patient Safety Rule, which took effect in January 2009, was adopted at a critical time when increasing expectations and legal obligations were being placed on providers through numerous and comprehensive state and federal requirements, detailed accreditation standards, and other legal mandates to monitor, evaluate and track patient outcomes, determine the initial and ongoing qualifications of healthcare providers, and conduct various analyses to determine individual and systematic deficiencies.[2] The failure to adhere to these standards can result in loss of licensure, accreditation and loss of reimbursement and eligibility to treat Medicare and Medicaid patients.[3] It can also cause increased exposure to professional liability actions under the doctrines of apparent

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2 See generally KRS Chapter 216B; Medicare/Medicaid Conditions of Participation for Hospitals, 42 CFR Part 482; and see, The Joint Commission Comprehensive Accreditation for Hospitals 2012.

3 Under the Patient Protection and Affordable Care Act, (42 U.S.C. § 300gg-11), and the Hospital Inpatient Value – Based Purchasing Program, 76 FR 26489-26547(2011), failure to monitor and achieve specified quality outcome metrics will result in reduced reimbursement.

agency and corporate negligence.[4] See, e.g., Paintsville Hosp. Co. v. Rose, 683 S.W. 2d 255 (Ky. 1995). Thus, it has become essential to exchange and evaluate patient safety information, and to protect such information from harmful disclosure.

Providers seeking the protections of the Patient Safety Act are expected to develop a patient safety evaluation system ("PSES") to manage the collection, analysis and reporting of information to a PSO. 42 U.S.C. § 299b-21(b) (2010). The PSES typically identifies the types of patient safety activities and the reports, data, root cause analyses, committee minutes and other materials designed to improve patient care. Information collected through the PSES and reported to a PSO is known as patient safety work product ("PSWP") and is strictly privileged, confidential and not subject to discovery or admission into evidence in state or federal proceedings. Id. at 299b-21(7) (2010), 299b-22(a) (2010).

UHC, the PSO for the University of Kentucky Hospital, collects such information from U of K and other participating medical centers, so that the information can be aggregated, analyzed and shared with all of UHC's members in a collective effort to improve patient care.

B. The Patient Safety Act Preempts State Law

As previously noted, the drafters of the Patient Safety Act recognized that state

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4 This doctrine requires hospitals to make reasonable efforts to make sure that new and current physicians are trained, educated and qualified to provide patient care services. If not, and if patients are injured, the hospital can be held separately liable. See, e.g., Darling, II v. Charleston Cmty Mem'l Hosp., 33 Ill. 2d 326 (1965). Although the doctrine has not yet been formally adopted in Kentucky as applied to hospitals, forty other states have enforced this common law standard. Moreover, Kentucky courts have applied similar theories such as negligent supervision (McDonald's Corp. v. Ogborn, 309 S.W. 3d 274 (Ky. App. 2009) and negligent retention in other industries. See, e.g., Oakley v. Flor-Shin, Inc., 964 S.W.2d 438 (Ky. App. 1998).

laws on confidentiality and privilege were inconsistent and limited in scope, both with respect to the categories of providers covered and the breadth of patient safety information that is protected from disclosure. For example, KRS 311.377(2) provides that materials generated in peer reviews "shall be confidential and privileged and shall not be subject to discovery [, subpoena, or introduction] into evidence in any action in any court." But, in Sisters of Charity Health Sys., Inc. v. Raikes, 984 S.W.2d 464, 469 (Ky. 1999), this Court held that the protections do not apply to medical malpractice defendants. In Florida, the peer review confidentiality statute was essentially eliminated through Constitutional Amendment 7 as a trade-off for adopting a statutory limitation on compensatory damages in medical malpractice lawsuits. See Fla Hosp. Waterman, Inc. v. Buster, 984 So. 2d 478 (Fla. 2008).

Congress recognized the need to implement a uniform, broad framework for the protection of information generated in connection with health care quality and improvement activities by (i) passing the Patient Safety Act, and (ii) expressly preempting state law that might otherwise require the disclosure of protected information. On the subject of preemption, the Preamble stated:

> While the Patient Safety Act does not preempt state laws that require providers to report information that is not patient safety work product, **a state may not require that patient safety work product be disclosed.**

73 Federal Register at 70743, 70744. (Emphasis added.)

Likewise, in response to comments and questions concerning preemption, the Agency for Healthcare Research and Quality and the Office for Civil Rights stated that:

> Thus, the patient safety work product protections provided under the [Patient Safety Act] generally preempt state or other laws that would permit or require disclosures of information contained within patient safety work product. However, state laws that provide for greater protection of patient safety work product are not preempted and continue

to apply.

Id. at 70774. In summary, as the Court of Appeals held, it is clear that the Patient Safety Act preempts conflicting state law.

C. The Patient Safety Act Provides Broad Protection For Patient Safety Work Product Which Is Not Limited To Information Constituting So-Called "Self-Examining Analysis."

Although the Court of Appeals correctly ruled that the Patient Safety Act preempts state law, it then imposed an enormous limitation on the scope of the Act's confidentiality that does not appear in the Act itself or in regulations promulgated thereunder, thereby creating state common law that conflicts with the federal legislation. It is therefore important to examine the scope of the protection provided by the Act.

"Patient safety work product" is defined as:

> 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, healthcare quality, or healthcare 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 of the information entered the patient safety evaluation systems; or
>
> (B) are developed by a PSO for the conduct of patient safety activity; or
>
> (ii) which identifies or constitutes the deliberations or analyses of, or identify the fact of reporting pursuant to a patient safety evaluation system.

42 U.S.C. § 299b-21(7) (2010).

Information which qualifies as patient safety work product is, in turn, **strictly privileged**. In this regard, the Act provides:

(a) *Privilege*. Notwithstanding any other provision of the Federal, State, local, or Tribal law and subject to paragraph (c) of this Section and § 3.28 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, criminal, or administrative subpoena or order, including in a Federal, State, local, or Tribal, civil or administrative proceeding against the provider;

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

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

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

The importance of these protections is reflected in the preamble to the Patient Safety Rule:

> Proposed Subpart C sought to balance key objectives of the Patient Safety Act. First, the proposal sought to address provider concerns about the potential for damage from unauthorized release of information, including the potential for the information to serve as road map for provider liability from negative patient outcomes. It also promoted the sharing of information about adverse patient safety events among providers and PSOs for the purpose of learning from those events to improve patient

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5 (42 U.S.C. § 299b-22(a) (2010)). Certain limited exceptions to these protections are not applicable here, i.e., criminal proceedings; disclosures which are authorized by the provider; where patient safety work product has been fully de-identified; and where disclosure is necessary to implement enforcement procedures by the secretary of CMS. Id. at § 299b-22(c) (2010).

> safety and quality of care. To achieve these objectives, Subpart C [which was not amended and became final], proposed that patient safety work product would be privileged and confidential, except in the certain limited circumstances identified by the Patient Safety Act and as needed by the Department to implement and enforce the Patient Safety Act.

73 Federal Register at 70770.

The physician defendants/appellants have documented that the information requested by plaintiffs was collected through defendants' patient safety evaluation systems and reported to their PSO in accordance with the Patient Safety Act. See, e.g., Affidavit of Brenda Runner, Brief of Appellants at 12-13 and App. Tab 7.

Once such compliance with the Act is established, the information is strictly privileged and inadmissible. Contrary to the holding of the Court of Appeals, there is no additional requirement that the information constitute "self-examining" or "self-critical" analysis. Indeed, much of the information gathered and reported in accordance with the Patient Safety Act will not be "self-examining," but will instead be generated by someone **other than** the physician, nurse or other health care worker who actually treated the patient in question. To limit the privilege and confidentiality protections of the Patient Safety Act to the self-evaluation and criticisms generated by the particular physician or other provider, as the Court of Appeals proposes, would render the Act largely meaningless, because the assessments, reports, findings and evaluations of everyone else involved in the improvement process would be discoverable. The chilling effect that this would have on efforts to candidly investigate, assess, discuss and learn from adverse outcomes needs no further explanation.

In closing, it is important to keep in mind that a decision to enforce the Patient Safety Act as written (as required by the law of preemption) will in no way deprive injured plaintiffs of the evidence that has traditionally been available to them in medical

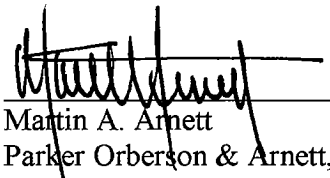
malpractice cases. The Patient Safety Act protects information generated through a patient safety evaluation system for the purpose of improving future outcomes. The original medical records, charts, reports and other information generated in the course of the treatment itself — i.e., the evidence used by counsel and experts to show that the standard of care was or was not met in a given case — remain available just as they were before the Act was adopted.

CONCLUSION

UHC and the other participating PSOs, associations and parties who join in this amicus brief respectfully request that the Court embrace that portion of the Court of Appeals' decision which holds that the Patient Safety Act preempts state law, as other courts have found, reject that portion of the decision which seeks to improperly limit the protection of the Act to only those reports and documents constituting "self-examining analysis," and remand the case to the trial court to determine whether the information in question was gathered and reported to the PSOs in accordance with the Patient Safety Act. To hold otherwise will not only undermine clear Congressional intent, it will significantly erode the collective efforts of health care providers across the country to engage in necessary and protected patient safety activities designed to improve health care services for all.

Date: October 29, 2012

Respectfully submitted,



Martin A. Arnett
Parker Orberson & Arnett, PLC
716 W. Main Street, Suite 300
Louisville, Kentucky 40202
Counsel to the *Amici Curiae*