No. 14-1140

IN THE
Supreme Court of the United States

PHILLIP TIBBS, *et al.*,

Petitioners,

v.

KIMBERLY BUNNELL, Judge,
Circuit Court of Kentucky, Fayette County, *et al.*,

Respondents.

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

MOTION FOR LEAVE TO FILE AND BRIEF OF UNIVERSITY HEALTHSYSTEM SAFETY INTELLIGENCE® PSO AND THE AMERICAN MEDICAL ASSOCIATION, *ET AL.*, AS *AMICI CURIAE* SUPPORTING PETITIONERS*

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ADDITIONAL *AMICI CURIAE*

Litigation Center of the American Medical Association and State Medical Societies; Kentucky Medical Association; American Data Network PSO; American Society for Radiation Oncology; Ascension Health Patient Safety Organization; California Hospital Patient Safety Organization; Child Health Patient Safety Organization, Inc.; CHS PSO, LLC; Clarity PSO; ECRI Institute PSO; MEDNAX PSO, LLC; MHA Patient Safety Organization; Midwest Alliance for Patient Safety; Missouri Center for Patient Safety d/b/a Center for Patient Safety; NC Quality Center PSO; Pascal Metrics Inc., Patient Safety Organization of Florida (PSO Florida); PsychSafe; Quality Alliance Patient Safety Organization; Quality Circle for Healthcare, Inc.; Quantros Patient Safety Center; Schumacher Group Patient Safety Organization, Inc.; Society of NeuroInterventional Surgery PSO; Strategic Radiology Patient Safety Organization LLC; The PSO Advisory, LLC; Tennessee Center for Patient Safety; UHS Acute Care PSO; Verge Patient Safety Organization; MCIC Vermont, Inc. PSO; The Johns Hopkins Hospital; Johns Hopkins Bayview Medical Center, Inc.; All Children's Hospital, Inc.; Suburban Hospital, Inc.; The Lucy Webb Hayes National Training School for Deaconesses and Missionaries d/b/a Sibley Memorial Hospital; Howard County General Hospital, Inc.; Yale New Haven Health System (Yale-New Haven Hospital, Bridgeport Hospital, Greenwich Hospital, Northeast Medical Group, and the Yale Medical Group, an affiliate of Yale University); Strong Memorial Hospital, a division of the University of Rochester; George Washington University Hospital; Tampa General Hospital; and The Regents of the University of California on behalf of its UC Davis, UCSF, UC Irvine, UCLA and UC San Diego Health Systems.

MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE*

Pursuant to Supreme Court Rule 37.2(b), the University HealthSystem Consortium Safety Intelligence® ("UHC"), the American Medical Association, and the other proposed *amici* respectfully move for leave to file the accompanying brief as *amici curiae* supporting the Petition for a Writ of Certiorari filed in this case. Consistent with Rule 37.1(a), the proposed *amici* provided timely notice to the Petitioners and Respondents of the proposed *amici*'s intent to file this brief. Petitioners and Respondent Kimberly N. Bunnell have consented to the filing of this brief, and those consents are on file with the Clerk. Respondent Estate of Luvetta Goff has not responded substantively to the proposed *amici*'s requests for consent, despite several attempts at securing a response.

This case involves the scope of a federal privilege provided under the Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (the "Patient Safety Act," which is codified at 42 U.S.C. §§ 299b-21, *et seq.*). The proposed lead *amici*, UHC, is a "patient safety organization" (PSO) within the meaning of the Patient Safety Act. 42 U.S.C. § 299b-21(4). Notably, UHC is the PSO with which the Petitioner contracted and to which the Petitioner reported the patient post-incident report that is the subject of the underlying dispute between the parties regarding the scope of the privilege provided under the Act. The remaining *amici* are other PSOs, organizations that submit protected "patient safety work product" to these PSOs, and associations that advo-

cate on their behalf, including the American Medical Association.

The *amici* have a substantial interest in the outcome of this case: The decision below threatens to destroy the nationwide privilege established by Congress and thereby discourage healthcare providers from voluntarily contributing information to patient-safety databases for review and analysis, and to improve patient-safety outcomes, as contemplated by Congress through the enactment of the Patient Safety Act.

The proposed *amici* believe that the attached brief sheds additional light on the intended operation of the Patient Safety Act and the need for this Court to preserve the nationwide "patient safety work product" privilege contemplated by Congress. In light of their unique perspectives—from all sides of the collection, submission, and use of "patient safety work product"—the proposed *amici* respectfully request that the Court grant them leave to participate as *amici curiae* by filing the accompanying brief in support of the Petition for a Writ of Certiorari.

Respectfully submitted.

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INTERESTS OF *AMICI CURIAE*

Congress enacted the federal statute at issue in this case, the Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (the "Patient Safety Act," which is codified at 42 U.S.C. §§ 299b-21, *et seq.*), to improve patient safety, health care quality, and health care outcomes by facilitating the sharing and analysis of patient-safety information. The Act achieves these laudable goals by, among other things, establishing federally-certified "patient safety organizations" (PSOs) that are charged with maintaining a network of patient-safety databases, where medical outcomes can be analyzed by healthcare professionals. 42 U.S.C. § 299b-23. To ensure that useful information is voluntarily contributed to these databases, the Act also establishes a nationwide privilege that attaches to "patient safety work product" reported by healthcare providers to these databases, shielding this work product from disclosure or use in a federal, State, or local civil, criminal, or administrative proceeding unless certain narrow exceptions are met. *Id.* § 299b-22(a).[1]

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[1] No counsel for a party in this case authored this brief in whole or in part. No person or entity—other than *amici*, their members, or their counsel—made a monetary contribution specifically for the preparation or submission of this brief. Consistent with Supreme Court Rule 37.1(a), the *amici* provided timely notice to the Petitioners and Respondents of the *amici*'s intent to file this brief. Petitioners and Respondent Kimberly N. Bunnell have consented to the filing of this brief, and those consents are on file with the Clerk. Respondent Estate of Luvetta Goff has not responded substantively to the *amici*'s requests for con-

Broadly categorized, the *amici curiae* are organizations that collect patient safety work product, organizations that submit this work product, and associations that advocate on their behalf, including the American Medical Association. The *amici* have a substantial interest in the outcome of this case: The decision below threatens to destroy the nationwide privilege established by Congress and thereby discourage healthcare providers from voluntarily contributing information to patient-safety databases for review and analysis, and to improve patient-safety outcomes, as contemplated by Congress through the enactment of the Patient Safety Act. This Court's review is urgently needed to ensure that healthcare providers will continue to voluntarily submit information to these databases.

The lead *amicus*, the University HealthSystem Consortium Safety Intelligence® ("UHC"), is a PSO within the meaning of the Patient Safety Act. *Id.* § 299b-21(4). Notably, it is the PSO with which the Petitioner contracted and to which the Petitioner reported the patient post-incident report that is the subject of the underlying dispute between the parties over the scope of the privilege. Like all PSOs, UHC is subject to a civil penalty of up to $10,000 if it "discloses identifiable patient safety work product" in violation of the Patient Safety Act. *Id.* § 299-22(f)(1).

UHC is joined by twenty-six other certified PSOs from around the country that have contracted with thousands of participating hospitals, physicians, and other licensed providers (collectively, "the PSO *Ami-*

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sent, despite several attempts at securing a response. As a result, *amici* have filed a motion for leave to file this brief.

ci"). These PSOs collect patient-safety information from healthcare providers in order to conduct various patient-safety analyses and studies to understand why certain errors occurred, improve the quality of health care services, and reduce patient risk.

The American Medical Association ("AMA"), the Kentucky Medical Association ("KMA"), and the American Society for Radiation Oncology (collectively, the "Association *Amici*") are professional associations representing tens of thousands of physicians around the country, including many who participate in and provide information to PSOs. The AMA and KMA join in their own right 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 Johns Hopkins Hospital; Johns Hopkins Bayview Medical Center, Inc.; All Children's Hospital, Inc.; Suburban Hospital, Inc.; The Lucy Webb Hayes National Training School for Deaconesses and Missionaries d/b/a Sibley Memorial Hospital; Howard County General Hospital, Inc.; Yale New Haven Health System (Yale-New Haven Hospital, Bridgeport Hospital, Greenwich Hospital, Northeast Medical Group, and the Yale Medical Group, an affiliate of Yale University); Strong Memorial Hospital, a division of the University of Rochester; George Washington University Hospital; Tampa General Hospital and the Regents of the University of California on behalf of its UC Davis, UCSF, UC Irvine, UCLA and UC San Diego Health Systems are hospitals (collec-

tively, the "Hospital *Amici*"). Each of these hospitals participates in one of the PSO *Amici*.

Collectively, the *Amici* represent all sides of the collection, submission, and use of "patient safety work product" under the Patient Safety Act. They are filing this brief in support of the Petition for a Writ of Certiorari filed in this case.

SUMMARY OF ARGUMENT

The Kentucky Supreme Court's decision in *Tibbs* v. *Bunnell*, 448 S.W.3d 796 (Ky. 2014) (Pet. App. 1a-41a), threatens to significantly undermine and limit the scope of the privilege afforded under the Patient Safety Act, thereby gutting the nationwide confidentiality protections that Congress envisioned. This, in turn, will stifle the collection and use of "patient safety work product," and frustrate one of the fundamental purposes of the Act—to provide a nationwide repository where adverse healthcare outcomes can be studied and corrected beyond the reach of the "culture of blame," which, Congress found, actively discourages the sharing of patient-safety information.

Indeed, the clear intent of the Patient Safety Act, as set forth in the preamble to the implementing regulation, was to encourage the sharing of patient-safety information by ensuring that contributors could not be held liable based on the information that they voluntarily report:

> The Patient Safety Act focuses on creating a voluntary program through which health care providers can share information relating to pa-

> tient safety events with PSOs, with the aim of improving patient safety and the quality of care nationwide. The statute attaches privilege and confidentiality protections to this information, termed "patient safety work product," to encourage providers to share this information without fear of liability and creates PSOs to receive this protected information and analyze patient safety events. These protections *will enable all health care providers, including multi-facility health care systems, to share data within a protected legal environment, both within and across states, without the threat that the information will be used against the subject providers.*

Dep't of Health & Human Servs., *Patient Safety and Quality Improvement – Final Rule*, 73 Fed. Reg. 70,732, 70,732 (Nov. 21, 2008) (emphasis added) (hereinafter "Final Rule").

The Kentucky Supreme Court's decision misinterprets the Patient Safety Act by ordering the Petitioner to produce clearly protected documents simply because, under that court's view, the Petitioner was required to develop, collect, and maintain similar reports under State law. Because most quality, performance-improvement, peer-review, risk-management, and other patient-safety-activity records that are kept by providers can be traced back to some State, federal, accreditation, or other similar record-keeping requirement, the effect of the Kentucky Supreme Court's decision is to effectively nullify the privilege and confidentiality protections afforded under the Patient Safety Act. This, in turn will dramatically reduce the reporting of such information to

PSOs. Unless the scope of the privilege is clarified immediately, the result will be to frustrate—if not completely undermine—the contribution, analysis, and use of patient safety work product, depriving healthcare providers of information that they can use to improve care and reduce patient risk.

The *Tibbs* decision also will have a significant chilling effect on whether a provider will participate in a PSO in the first place and take full advantage of the privilege and confidentiality protections clearly afforded to patient-safety activities under the Patient Safety Act. Hospitals, physicians, and all other providers will not run the risk of generating patient-safety and related reports that track the cause and effect of adverse patient events if this information can be accessed by a plaintiff's attorney for use in a malpractice action.

Moreover, if the decision is embraced in other jurisdictions, as occurred in *Charles* v. *Southern Baptist Hospital of Florida, Inc.*, No. 12-CA-002677 (Fla. Cir. Ct. July 30, 2014), it will adversely affect the efforts of all providers to achieve required quality outcomes for patient care established by Medicare, Medicaid, and private payors under health care reform measures thus hampering the important and uniform goal of controlling runaway health care costs and reducing patient deaths. This Court's review is therefore urgently needed to restore the nationwide scope of the privilege as intended by Congress.

ARGUMENT

I. The Kentucky Supreme Court's Decision Conflicts with and Undermines the Statutory Duties and Responsibilities of PSOs Under the Patient Safety Act, Requiring this Court's Immediate Review.

Under the Patient Safety Act, a PSO must obtain certification from the Secretary of the Department of Health and Human Services to serve as a repository for information within the patient-safety network established under the Act. 42 U.S.C. §§ 299b-21(4), 299b-24(a)(1). The Secretary, who in turn has delegated these responsibilities to the Agency for Healthcare Research and Quality ("AHRQ"), is required to ensure that, among other things, the PSO's "mission and primary activity . . are to conduct activities that are to improve patient safety and the quality of health care deliver." *Id.* § 299b-24(b)(1). AHRQ describes a PSO under the Act as follows:

> The primary activity of an entity or component organization seeking to be listed as a PSO must be to conduct activities to improve patient safety and health care quality. A PSO's workforce must have expertise in analyzing patient safety events, such as the identification, analysis, prevention and reduction or elimination of the risks associated with the delivery of patient care.

AHRQ, Patient Safety Organization (PSO) Program, Frequently Asked Questions, http://www.pso.ahrq.gov/faq#WhatisaPSO (last visited Apr. 19, 2015). In order to be certified and

recertified by AHRQ, a PSO must attest to satisfying eight specific patient safety activities and seven other additional operational criteria. *See* 42 C.F.R. § 3.102(b). These criteria include certifying compliance with certain "confidentiality provisions" and "security measures." *Id.* § 3.102(b)(1)(A).

AHRQ further describes PSOs and their role in improving patient care and reducing risk in a series of frequently asked questions under the heading "PSO General Information," which not only defines their activities and benefits, but also touches upon the scope of confidentiality afforded under the Patient Safety Act:

- What are patient safety activities?

  * * *

  > The term 'safety' refers to reducing risk from harm and injury, while the term 'quality' suggests striving for excellence and value. By addressing common, preventable adverse events, a health care setting can become safer, thereby enhancing the quality of care delivered. PSOs create a secure environment where clinicians and health care organizations can collect, aggregate, and analyze data, thus identifying and reducing the risks and hazards associated with patient car and improving quality.

AHRQ, Patient Safety Organization (PSO) Program, Frequently Asked Questions, www.pso.ahrq.gov/faq#WhatArePatientSafetyActivities (last visited Apr. 19, 2015).

- What are the benefits to health care providers who work with a PSO?

  PSOs serve as independent, external experts who can collect, analyze, and aggregate [patient safety work product] locally, regionally, and nationally to develop insights into the underlying causes of patient safety events. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

  The protections of the Patient Safety Rule enable PSOs that work with multiple providers to routinely aggregate the large number of patient safety events that are needed to understand the underlying causes of patient harm from adverse events and to develop more reliable information on how best to improve patient safety.

AHRQ, Patient Safety Organization (PSO) Program, Frequently Asked Questions, www.pso.ahrq.gov/faq#BenefitstoMedicareProviders (last visited Apr. 19, 2015).

- What is the importance of the privacy and confidentiality protections for [patient safety work product ("PSWP")]?

  The Patient Safety Act makes PSWP privileged and confidential. The Patient Safety Act and the Patient Safety Rule generally bar the use of PSWP in criminal, civil, administrative, or disciplinary proceedings except where specifically permitted. Strong

> privacy and confidentiality protections are intended to encourage greater participation by providers in the examination of patient safety events. By establishing strong protections, providers may engage in more detailed discussions about the causes of adverse events without the fear of liability from information and analyses generated from those discussions. Greater participation by health care providers will ultimately result in more opportunities to identify and address the causes of adverse events, thereby improving patient safety overall.

AHRQ, Patient Safety Organization (PSO) Program, Frequently Asked Questions, www.pso.ahrq.gov/faq#ImportanceofPrivacy (last viewed Apr. 19, 2015).

In order for providers to access the confidentiality and privilege protections of the Patient Safety Act, they must collect and assemble identified "data, reports, records, memoranda, [and] analyses (such as root cause analyses)" relating to patient safety activities within their respective patient safety evaluation systems for reporting to a PSO. *See generally* 42 C.F.R. §§ 3.20, 3.204, 3.206. Such information then qualifies as confidential patient safety work product, which is not subject to discovery in federal, State, or local proceedings. *Id.* §§ 3.20, 3.206. PSOs, in turn, have multiple statutory duties, including an obligation to conduct patient safety activities on their own and for the benefit of the participating providers.

PSOs enter into contracts with these providers to "collect patient safety work product. . . that permits valid comparisons of cases among similar providers,"

and to "utilize patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk." *Id.* § 3.102(b)(2)(F), (G). PSOs that cannot demonstrate compliance are subject to a fine and loss of certification. *See id.* §§ 3.304-3.552.

AHRQ published a "Compliance Self-assessment Guide" ("Guide") in September 2009 to assist PSOs with the certification and recertification processes as well as with their continued compliance with the requirements of the Patient Safety Act and the Final Rule promulgated thereunder. The Guide identifies what AHRQ will examine and what the PSO should be documenting to demonstrate compliance with these and other duties under the Patient Safety Act, which is necessary to obtain and maintain certification. AHRQ, Patient Safety Organization (PSO) Program, Compliance Self-Assessment Guide, www.pso.ahrq.gov/legislation/assessment (last visited Apr. 19, 2015).

The Patient Safety Act, the Final Rule, and the Guide make it very clear that PSOs are not merely "black-box" receptacles for privileged patient safety work product submitted by participating providers. PSOs, as noted above, are required to collect, analyze, and provide "direct feedback" to providers in order for them to utilize the information to improve quality and reduce patient risk.

But a database is only as useful as the information that it contains, and providers will not furnish information if they believe that it might ultimately be used against them in a civil, criminal, or administrative proceeding. Thus, PSOs cannot fulfill

their important responsibilities unless providers are able to submit patient-safety, data reports, and related information on a confidential basis to their respective PSOs. The information submitted by providers to PSOs around the country includes sensitive patient-incident reports, root-cause analyses, peer-review evaluations, and other patient-safety information that is not required to be reported externally and therefore should be treated as confidential patient safety work product under the Act.

And yet, under the Kentucky Supreme Court's reasoning, these documents are not protected, because there is an independent provision of Kentucky law requiring 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," including "incident investigation reports, peer review and credentialing records." Pet. App. 14a-15a (citing to 902 Ky. Admin. Regs. 20:016 § 3(3)(a)). Stated more plainly, the Kentucky Supreme Court reasoned that, because records of this sort are required to be created under State law, the Patient Safety Act did not furnish any protections to any information, meeting this description, that was submitted to a PSO under the Patient Safety Act. *See id.*

The *Tibbs* decision read an exception into the Patient Safety Act, nowhere contemplated by Congress, that would vitiate the nationwide privilege established therein. The Act establishes and encourages healthcare providers to collect adverse incident reports and other patient-safety information and report this protected patient safety work product to PSOs. The PSOs then serve as repositories for this privi-

leged and confidential information, which exists separate and apart from a provider's obligations under State law, and also analyze this information to improve patient-safety outcomes and reduce risk. And yet, the Kentucky Supreme Court held that this federal privilege does not attach where the same "information normally [would be] contained in" documents that a State requires a healthcare provider to create or maintain. Pet. App. 24a-25a. In the process, the court gave scant attention to the supremacy of federal law.

The fundamental purpose of the Patient Safety Act cannot be achieved without ensuring the confidentiality of patient-safety information. Indeed, the submission of such information by providers, such as the Hospital *Amici* pursuant to the Act, has enabled the PSO *Amici* and other PSOs around the country to provide safety alerts, identify best practices, and prepare comparative and benchmarking studies, as well as other confidential and public reports, that have greatly assisted providers and the entire health care industry in their collective efforts to reduce risk and improve care. For example, PSOs have provided vital feedback that has improved health information technology ("HIT") associated with identifying and tracking adverse events, reduced incidents of pressure ulcers, improved medication safety, reduced surgical errors and patient falls, and facilitated a host of other patient-safety improvements.[2]

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[2] There are numerous publicly-available examples of the important work being performed by PSOs across the nation to improve patient safety and health care quality. A few of these are recounted below in this footnote.

Amicus The University HealthSystem Consortium Safety Intelligence® PSO, to which the University of Kentucky submitted the post-incident patient report that is the subject of the underlying discovery dispute in this case, has provided a number of "Applied Learnings" reports based on patient safety event data received from its participating providers. The purpose of these reports is to identify specific safety events, conduct analyses and make recommendations designed to improve the quality of patient care and reduce risk. Some of the risks addressed, which include Health IT-related patient safety events, surgical pathology specimen errors, patient violence, retained sponges and guidewires and an analysis of suicide-related events, are available at https://www.uhc.edu/docs/5555-21-15331_SafetyIntelligenceAnalyses_Description.pdf (last visited Apr. 19, 2015).

Links to publically available materials from *Amicus* ECRI Institute PSO on the top patient safety concerns they have identified through the PSO and on HIT, pressure ulcers, medication safety, and other issues are available at https://www.ecri.org/resource-center/Pages/Key-Learnings-from-ECRI-Institute-Patient-Safety-Organization.aspx (last visited Apr. 19, 2015). ECRI has its own PSO and also provides analyses, benchmarking reports, and other patient care studies under contractual agreements with PSOs around the country.

Amicus Child Health Patient Safety Organization, which has fifty children's hospitals around the country as its members, has similarly published online "Patient Safety Action Alerts" in the areas of medication administration errors, fingertip amputation, cutaneous fungal outbreak, wrong-size tracheostomy selection, and blind pediatric NG tube placements, examples of which are available at http://www.childrenshospitals.org/Quality-and-Performance/Patient-Safety/Patient-Safety-Action-Alerts (last visited Apr. 19, 2015).

Amicus Clarity PSO has published materials on surgical errors, medication dosing omissions, fall prevention, HIT, and other issues, which are available at http://www.claritygrp.com/clarity-patient-safety-organization/learning-library/pso-learning-series (last visited Apr. 19, 2015).

These aggregated and de-identified studies would not be possible without the receipt of sensitive confidential patient safety work product currently being collected and reported to PSOs by their participating providers.[3] The simple reality is that this safety information will no longer be reported by hospitals, physicians, and other providers if it is not given nationwide protection under the Patient Safety Act.

Moreover, because this information may be protected under State law, a provider could be deemed to have waived these State-law protections by furnishing information to a PSO, because a PSO could be treated as a third-party under State law, thereby vitiating the confidentiality necessary to maintain the underlying State-law privilege. The recognition of a federal privilege is therefore critical to ensuring the continued exchange and analysis of patient-safety information between providers and PSOs.[4]

Quantros Patient Safety Center, along with the PSO Advisory, both of which are PSO *Amici*, recently collaborated on a Safety Advisory report relating to significant patient harm associated with the dispensing of the wrong disposable insulin pump devices, which is available at http://www.quantros.com/resources/quantros-perspective/safety-advisory-on-pharmacy-dispensing-of-insulin-device (last visited Apr. 19, 2015).

[3] In addition to these studies, which are publically available and based on aggregated data, PSOs also participate in reviews and analysis with individual providers and systems which are not publically shared but are treated as patient safety work product and utilized internally by the providers in their patient safety activities.

[4] Most States have confidentiality statutes as applied to peer review and quality reports and analyses. *See, e.g.*, Illinois Med-

The Kentucky Supreme Court's ruling therefore threatens to preclude the important analysis and study of shared information by and between providers and PSOs, thereby diminishing future efforts to improve quality and reduce risk to patient health. Indeed, unless reviewed and corrected by this Court, the decision below will effectively destroy the nationwide privilege envisioned by Congress.

II. The Kentucky Supreme Court's Decision Undermines Industry Reform Efforts, Contemplated by Congress, to Reduce Costs and the Number of Patient Deaths.

The all-important goals of the Patient Safety Act to improve the quality of patient services and to reduce medical errors was meant to further the para-

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ical Studies Act, 735 Ill. Comp. Stat. § 5/8-2101. Generally speaking, however, the scope of the protected activities under State law are not as broad as the protections afforded under the Patient Safety Act, the categories of providers which can seek protection are more limited, and the confidential information cannot be freely shared within a health care system without the risk of waiving the protections, which is contrary to the Patient Safety Act. Moreover, the State confidentiality protections apply only in State proceedings, whereas the Patient Safety Act protections can be asserted and sustained in federal, State, and local proceedings. Under many State confidentiality laws, a plaintiff's attorney could successfully argue that the protections applicable in State proceedings could be waived if disclosed to a third party, such as a PSO, because under the Kentucky Supreme Court's decision, peer review, incident reports, and other records collected and maintained under State law can never qualify as patient safety work product. It is for these reasons that providers are choosing the privilege and confidentiality protections of the Patient Safety Act over those provided under the more limited State statutes.

digm shift occurring in the health care industry, which increasingly conditions reimbursement on the quality of services provided as measured against established standards and quality metrics. Evidence of this "volume to value" movement has long been reflected in what is termed "pay for performance" standards implemented by private payers designed to increase quality and reduce costs. *See generally* Julia James, Health Policy Brief: Pay-for-Performance, Health Affairs (Oct. 11, 2012) (available at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_78.pdf) (last viewed Apr. 19, 2015).

In addition, the federal government, through the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), has implemented numerous program requirements that condition reimbursement and the imposition of payment penalties on meeting identified quality metrics as a means of reducing health care costs and improving care. Examples of such federal programs include:

- The Medicare Shared Savings Program for Participating Accountable Care Organizations, under which such entities must meet 33 established quality metrics in order to share in cost savings and avoid payment penalties. Examples of these metrics include preventative health measures for diabetes, hypertension and heart failure. 42 C.F.R. §§ 425.10 *et seq*.

- The Value-Based Purchasing Program, which applies to hospitals (ACA § 3001, 124 Stat. at 353-63), physicians (ACA § 3007, 124. Stat. at 373-76), skilled nursing facilities and home

health agencies (ACA § 3006, 124 Stat. at 372-73), imposes identified quality metrics that, if not met, will result in penalties and reductions in payment. Examples of these metrics include heart failure discharge instructions and medication given to heart attack patients within 90 minutes of hospital arrival.

- The Hospital-Acquired Conditions Reduction Program, which reduces Medicare payments to hospitals in the lowest quartile with respect to the number of hospital-acquired conditions. Examples include catheter infections and foreign bodies left in the patient after surgery. ACA § 3008, 124 Stat. at 376-78.

- The Hospital Readmissions Reduction Program, which penalizes hospitals whose readmission rates for admitted patients with heart attacks, pneumonia, or joint replacement exceed a certain ratio by up to a maximum of 3% of their Medicare payments. ACA § 3025, 124 Stat. at 408-13.

Most recently, the Centers for Medicare and Medicaid Services announced that the current 20% of Medicare payments tied to accountable care organizations and other similar programs based on quality outcomes will be increased to 50% by 2016. From January 2012 to December 2013, these programs have resulted in saving 50,000 lives, a cost reduction of $12 billion in spending, and 150,000 fewer readmissions. Dep't of Health & Human Servs., *Press Release: Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to*

value (Jan. 26, 2015) (available at http://www.hhs.gov/news/press/2015pres/01/20150126a.html) (last viewed Apr. 19, 2015).

In order to meet these private payer and governmental quality outcome standards and metrics, hospitals, physicians, and other providers must implement processes that incorporate these metrics into their quality, risk, peer-review and other patient-safety activities so that the provider's compliance can be tracked and monitored, and remedial efforts taken. Providers also engage in these patient-safety activities because they help reduce malpractice liability and the associated costs in defending against these claims. Indeed, the resulting internal evaluations and reviews are used precisely to correct substandard practices. These materials also are reported to PSOs for further evaluation and analysis all of which are considered patient safety work product.

The confidentiality protections afforded to providers and PSOs under the Patient Safety Act therefore become essential to meeting these federal quality standards, because they facilitate frank and robust discussions and evaluations about medical errors and other adverse events. In fact, the Affordable Care Act provides that all hospitals with more than 50 beds, and that have contracted with payers participating in State insurance exchanges, are required to establish or participate in a PSO by January 2015. ACA § 1311(h), 124 Stat. at 180 (codified at 42 U.S.C. § 18031(h)). Although this required participation in a PSO has been delayed for two years, the importance of PSOs in the health care industry's effort to improve care and to reduce unnecessary utilization and costs is obvious.

The Kentucky Supreme Court's decision, standing alone and especially if embraced by other courts, such as the *Southern Baptist* case, *supra*, No. 12-CA-002677 (Fla. Cir. Ct. July 30, 2014), will significantly undermine the efforts of providers and PSOs around the country to meet these quality and value mandates if plaintiffs and other third parties have free access to this information. Even worse, there is a very real prospect that providers will not participate in PSOs at all, thus making the Patient Safety Act a statutory relic. This Court's immediate review is therefore needed to clarify the scope of the privilege on a nationwide basis.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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