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 Kentucky Supreme Court

MOTION FOR LEAVE TO FILE AND BRIEF OF *AMICUS CURIAE* ALLIANCE FOR QUALITY IMPROVEMENT AND PATIENT SAFETY IN SUPPORT OF PETITIONERS

PEGGY BINZER
POLSINELLI PC
1401 I Street, N.W., Suite 800
Washington, D.C. 20005
202-783-3300

BENNETT L. COHEN
Counsel of Record
SEAN R. GALLAGHER
POLSINELLI PC
1515 Wynkoop Street, Suite 600
Denver, CO 80202
303-572-9300
BCohen@Polsinelli.com

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

MOTION FOR LEAVE TO FILE *AMICUS* BRIEF

Pursuant to Supreme Court Rule 37.2(b), the Alliance for Quality Improvement and Patient Safety ("AQIPS") requests leave to file this *amicus* brief. Counsel for AQIPS notified counsel of record for all parties of its intention to file this brief more than ten days prior to the due date. AQIPS obtained consent to file from all parties save Respondent, the Estate of Luvetta Goff. As noted above, as the national organization for Patient Safety Organizations that implement the Patient Safety and Quality Improvement Act of 2005, AQIPS has a strong interest in insuring uniform interpretation of the Act's privilege provisions, and is uniquely positioned to provide insight to the Court regarding the Act's intent and operation.

Respectfully submitted,

PEGGY BINZER
POLSINELLI PC
1401 I Street, N.W., Suite 800
Washington, D.C. 20005
202-783-3300

BENNETT L. COHEN
Counsel of Record
SEAN R. GALLAGHER
POLSINELLI PC
1515 Wynkoop Street,
Suite 600
Denver, CO 80202
303-572-9300
BCohen@Polsinelli.com

April 20, 2015

TABLE OF CONTENTS

Page

MOTION FOR LEAVE TO FILE *AMICUS* BRIEF 1

TABLE OF AUTHORITIES ii

INTEREST OF *AMICUS CURIAE* 1

SUMMARY OF THE ARGUMENT 2

ARGUMENT 3

I. A nationally uniform privilege for reports to PSOs is necessary to allow providers to learn from mistakes to improve patient safety, patient outcomes, and the quality of patient care 3

II. Operation of the Patient Safety Act's privilege provision 6

III. Operation of the Patient Safety Act learning system 9

IV. Review is warranted because the Kentucky Supreme Court's decision is upsetting the carefully constructed balance Congress developed between confidential provider self-driven quality improvement and accountability through regulatory agencies, and the tort system 16

CONCLUSION 19

TABLE OF AUTHORITIES

Page

STATUTES

Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §§ 299b-21, *et seq.* .....*passim*

42 U.S.C. § 299b-22(g)(1).....5

42 U.S.C. § 299b-23(c) 15

OTHER AUTHORITIES

42 C.F.R. 3.206(b)(4)(iv)(A).....6, 17

73 Fed. Reg. 8112 (February 12, 2008).....5

73 Fed. Reg. 70732 (November 21, 2008) 8, 9, 19

H.R. Rep. No. 109-197 (2005).....*passim*

S. Rep. No. 108-196 (2003) .....*passim*

Institute of Medicine, Committee on Quality of Health Care in America, *To Err Is Human: Building a Safer Health System* (1999) 4, 16

A National Survey of Medical Error Reporting Laws," Yale J. Health Policy, Law, and Ethics IX:1, 243 (2008).....18

INTEREST OF *AMICUS CURIAE*[1]

The Alliance for Quality Improvement and Patient Safety ("AQIPS") is a not-for-profit, national professional organization composed of over 20 Patient Safety Organizations ("PSOs") and their member providers, including hospitals and other providers throughout the health care continuum and throughout the United States. The Alliance's mission is to foster the ability of PSOs to improve the patient safety, health care quality and health care outcomes through the privilege and confidentiality protections afforded in the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §§ 299b-21, *et seq*. ("Patient Safety Act"). As an organization that is at the forefront of fostering high reliability of the quality of patient care for every patient in every health care organization across the nation, AQIPS is uniquely positioned to provide this Court with insight into how PSOs employ what is intended to be a nationally uniform privilege to create a national learning system that permits the confidential and privileged sharing of incident reports, lessons learned and best practices

[1] No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to its preparation or submission. Counsel for AQIPS notified counsel of record for all parties of its intention to file this brief more than ten days prior to the due date. AQIPS obtained consent to file from all parties save Respondent, the Estate of Luvetta Goff.

to prevent medical errors from occurring over and over again in every health care organization across the nation. Accordingly, AQIPS has a great stake in ensuring that the federal privilege for patient safety work product is not eroded by a State court determination that a state regulation effectively trumps the federal privilege, lest the resultant breakdown of the national learning system cause health care providers in that State to be precluded from learning from the mistakes of others, ultimately causing patients to be harmed by preventable medical errors contrary to the federal scheme. Lives may literally be at stake.

SUMMARY OF THE ARGUMENT

Given the grave implication of the matters before this Court, it is important that the Court understand how the Patient Safety Act was intended to provide nationally uniform protections to information collected and developed by providers and reported to a PSO for purposes of improving patient safety, patient outcomes and the quality of patient care. Congress designed the Patient Safety Act to foster a "learning system" through a voluntary reporting process with strong privilege and confidentiality protections that would allow health care providers to assess medical errors free from liability and reputational harm. The Patient Safety Act was intended to break the silos that had been created due to the erosion of state peer review laws, and thereby create a national system of

sharing and learning with the goal of improving the quality and safety of patient care.

Allowing the Kentucky regulation to effectively trump the federal privilege will undermine Congress's intent and national uniformity. This approach will predictably lead to a breakdown of the national learning system. Without the broad privilege and confidentiality protections expressly written into the Patient Safety Act, the lessons learned from harm inflicted on a patient when a medical error occurs will once again be kept carefully guarded within individual institutions, even among hospitals within the same health system, due to the fear of discoverability in legal actions. As a result, the same mistakes and the same patient harms will be unnecessarily repeated in hospitals (especially in states like Kentucky that have no peer review protections), and the cycle of patient harm will return.

ARGUMENT

I. A nationally uniform privilege for reports to PSOs is necessary to allow providers to learn from mistakes to improve patient safety, patient outcomes, and the quality of patient care.

The case before the Court has grave ramifications for the ability of health care providers to improve patient outcomes across the nation. Deaths due to preventable medical errors exceed the deaths

attributable to motor vehicle accidents, breast cancer and AIDS combined. Institute of Medicine, Committee on Quality of Health Care in America, *To Err is Human: Building a Safer Health System*, 26 (1999). The Patient Safety Act was enacted as the cornerstone of the federal effort to reduce preventable injuries and deaths in the United States' health care system. By passing the legislation, Congress intended to improve the quality of patient care by creating a "culture of safety" through a non-punitive confidential voluntary reporting system, and to ensure accountability by raising standards for continuous improvements in health care. H.R. Rep. No. 109-197, at 9.

Congress designed the Patient Safety Act to foster a "learning environment" that would allow health care providers to assess their errors without fear that their data and analyses will be subject to discovery in medical malpractice actions. H.R. Rep. 109-197, at 9; S. Rep. No. 108-196, at 3. The privilege was intended to eliminate the fear of personal liability from individual health care professionals, eliminating the incentive to hide errors affecting patient safety and unsafe conditions. *See To Err is Human: Building a Safer Health System*, 9. Congress viewed such protections as necessary to encourage health care providers to report medical errors. H.R. Rep. No. 109-197, at 9 (2005). These protections are critical to creating a learning environment in which patient safety events are seen as opportunities for learning and improvement. Progress toward creating a culture

of patient safety requires empowering health care providers to point out errors, defects, and systems failures that could cause patient harm.[2]

The success of the Patient Safety Act depends on national uniformity in its implementation and interpretation. The Patient Safety Act was intended to provide a uniform privilege to permit health care providers to employ proven practices to evaluate and share how to make patient care safer throughout the entire healthcare continuum. 42 U.S.C. § 299b-22(g)(1). For example, the privilege allows providers, such as ambulatory care providers, to collect incident reports and conduct peer review within the "patient safety evaluation system." Such quality improvement and risk management activities were not typically being conducted in many ambulatory care settings because many states did not provide any protection or privilege for these quality improvement practices.

The Patient Safety Act was designed "to accelerate the development of new, voluntary provider-driven opportunities for improvement" and to "set the stage for breakthroughs in our understanding of how best to improve patient safety." Patient Safety and Quality Improvement, Proposed Rule, 73 Fed. Reg. 8112, 8113 (February 12, 2008). One way the Patient

---

[2] *See* The Joint Commission: Comprehensive Accreditation Manual for Hospitals: The Patient Safety Systems Chapter, http://www.jointcommission.org/assets/1/6/PSC_for_Web.pdf. (All websites visited April 14, 2015.)

Safety Act does this is through the national and uniform scope of its privilege, which allows providers who have extensive experience in patient safety, such as hospitals, to share their reports and evidence-based solutions with providers less experienced in employing such safety practices. *See* 42 C.F.R. 3.206(b)(4)(iv)(A). This nationwide sharing of information accelerates quality improvement. *Id.* Through a uniform and national privilege, innovative programs developed by health care providers and PSOs can thus promote transformational change in the quality of health care provided to patients.

II. Operation of the Patient Safety Act's privilege provisions

Providers who voluntarily participate in a PSO do so with the primary aim of improving patient safety and the quality of health care delivery. 42 U.S.C. § 299b-21(5). Hospitals develop a "patient safety evaluation system" under the Patient Safety Act to collect, analyze, manage and maintain information for reporting to or by a PSO. 42 U.S.C. § 299b-21(6).

There are several ways that information becomes privileged patient safety work product. First, information that is collected in the patient safety evaluation system for the purpose of reporting to a PSO and that is reported to a PSO is designated under the law as privileged and confidential "patient safety work product." 42 U.S.C. § 299b-21(7)(A)(i)(I). The privilege for patient safety work product applies to information

to the extent that it was collected for the purpose of reporting to a PSO and is reported to a PSO. 42 U.S.C. §§ 299b-21(5)(B). However, original records, such as an x-ray or an entire medical record, are not patient safety work product. 42 U.S.C. § 299b-21(7)(B)(i).

Second, if a PSO develops information, such as through an investigation by the PSO workforce, or if it develops feedback from the providers reported patient safety work product, the feedback is patient safety work product. 42 U.S.C. § 299b-21(7)(A)(i)(II).

Finally, if information collected identifies the deliberations or analysis of, or the fact of reporting to, a patient safety evaluation system, then such information is patient safety work product. 42 U.S.C. § 299b-21(7)(A)(ii). For example, suppose a hospital collects records developed separately from the patient safety evaluation system to investigate how to better prevent infections after surgery. These collected records, which would not otherwise be protected under the Patient Safety Act by reason of being reported to a PSO, are nonetheless patient safety work product because they identify the analysis, deliberations and the fact of reporting to the patient safety evaluation system. *Id.* This section was specifically added to the Patient Safety Act to prevent plaintiffs' lawyers from indirectly defeating the federal privilege by accessing the road map created by the PSO's collection of reports or copies of records. S. Rep. No. 108-196 at 5, 7. The Patient Safety Act effectively requires plaintiffs' lawyers to collect their own information, rather than build their malpractice

cases through information that is privileged under the Patient Safety Act.

Congress excluded from the privilege information found in original patient provider records, such as medical and discharge records necessary for plaintiffs to seek redress for their injuries. H.R. Rep. No. 109-197 at 9; S. Rep. No. 108-196 at 2, 7. Thus, the Patient Safety Act does not prevent malpractice lawsuits. However, the Patient Safety Act prevents a plaintiff from being enriched by collecting information from the provider's patient safety evaluation system or the PSO that would not otherwise have been created by healthcare providers but for the promise of the Patient Safety Act's privilege and confidentiality protections.

The collection and analysis of incident reports is the centerpiece of hospitals' patient safety evaluation systems. Under the Patient Safety Act, continuous reporting of adverse events allows hospitals to analyze these events, conduct a root cause analysis, change the process or system to improve safety, and disseminate clinical solutions, clinical protocols or lessons learned to all of the affiliated providers within the organization (*e.g.*, hospitals and other facilities in a health system). To prevent duplication of hospital reporting systems, which would unnecessarily increase health care costs, the Department of Health and Human Services does not require providers to maintain duplicate systems to separate information to be reported to a PSO from information that may be required to fulfill state reporting obligations. *See*

Patient Safety and Quality Improvement Final Rule, 73 Fed. Reg. 70732, 70742 (November 21, 2008). As a result, it is common practice among hospitals to combine their incident reporting system and their patient safety evaluation system, consistent with this federal regulation. Information reported to the PSO cannot be used to fulfill state reporting obligations and must be reported to the State before reporting a copy to the PSO. If the information reported to the PSO is needed for State reporting, it must be reproduced outside of the patient safety evaluation system. *Id.* at 70773 ("Further, as original medical and other records are expressly excepted from the definition of patient safety work product, providers always have the option of using those records to generate the reports necessary for their mandatory reporting obligations to federal, state, and local agencies.").

III. Operation of the Patient Safety Act learning system

State reporting systems typically collect information concerning "what" happened during the incident to hold the provider accountable. In contrast, the patient safety evaluation system is the only system designed to permit health care providers to investigate "how" and "why" the incident occurred, in a safety culture that reinforces professionalism and learning, to benefit patients. The patient safety evaluation system allows providers to methodically evaluate systems and processes to determine what actually caused the systems to fail and prevent the

reoccurrence of the failure without fear of litigation or harm to professional reputation. The protections encourage candid dialog, which permits the exposure of underlying causes that may not be evident in an incident report.

To illustrate by example, in a case where a patient died due to complications secondary to a medical error during surgery, the surgeon reportedly received a call from a laboratory technician during the operation warning the surgeon of a mismatch of blood types after it was too late for the patient.[3] In this instance, the patient safety evaluation system would thoroughly evaluate the failures in the system. First, the investigation could include peer review in the patient safety evaluation system to conduct a root cause analysis and to create an action plan, which would include such things as revising clinical protocols to include redundant checks to minimize risk. Second, the hospital could analyze its system of blood collection from laboratories to correct any critical gaps in the system that could allow potentially life-saving information to slip through the cracks and cause patient harm. The systems analysis would identify the failures in the system beginning with the

[3] The incident discussed herein was reported in the public press in 2003 and is not actual patient safety work product. *See* www.cbsnews.com/news/anatomy-of-a-mistake-16-03-2003. In addition, the patient safety evaluation system analysis is an illustration of what is currently occurring and is permissible under the Patient Safety Act.

laboratory for providing organs without checking for the blood type, the hospital accepting the organs without checking for the blood type match, as well as other surgical checklists and procedures requiring checks within the system to catch such an error. In this instance, upon review it was discovered that more than a dozen healthcare providers who were caring for this patient never communicated to the surgeon that the record indicated that the laboratory test clearly identified a mismatch of blood type. The patient safety evaluation system would analyze why the safety culture was not followed. The hospital could conduct a comprehensive analysis of all reports collected concerning laboratory events and produce reports to determine if information failed to be communicated in other cases to develop solutions to minimize risk. Further, the patient safety evaluation system would evaluate the system of communicating critical clinical information to health care providers who need to know this information. The patient safety evaluation system could investigate whether the institution suffers from a "shame and blame culture" in which providers feared to raise potential patient safety issues to the surgeon because they could be punished or fired as the messenger of the bad news, or if the providers were simply overconfident that the meticulous surgeon would catch the problem on his own, and thus, failed to employ a safety culture. To promote a safety culture, all health care providers in the hospital would be encouraged to confidentially report patient safety concerns to the patient safety evaluation system if they are afraid to

raise them to the health care providers responsible for the patient to ensure that the next error is a "near miss" and no harm befalls a patient.[4]

This is the very heart of the Patient Safety Act: the collection, analysis and distribution of life-saving information that would not otherwise be collected or shared with other providers without strong privilege and confidentiality protections. And this discussion provides only an example of the types of analyses that might be performed in the patient safety evaluation system.

Under the Patient Safety Act, the incident, root cause analysis, contributing factors and process solutions are voluntarily reported to a PSO. PSOs certified under the Patient Safety Act are an expert patient safety resource to health care providers, helping organizations develop systems and processes to enhance the safety of care, treatment, and services to patients. PSOs must conduct patient safety activities, which are efforts to improve patient safety and the quality of health care delivery that include, among other things: 1) the collection and analyses of patient safety work product; 2) the development and dissemination of best practices, clinical solutions, or other feedback to minimize risk; and 3) the evaluation

[4] Near misses are events that do not occur because the potential mistake is identified and corrected before harm to the patient occurs. Analysis of near miss data permits health care providers to prevent harm that is about to happen.

of how the best practices were implemented by the health care provider and if the practices were effective in minimizing risk and encouraging a safety culture. 42 U.S.C. § 299b-21(5). In the above example, the PSO could evaluate whether other nonaffiliated hospitals were experiencing the same or similar errors as the one reported in the example.

The PSO could also evaluate "near miss" data to assess why a similar event was not happening at other hospitals and what barriers the other providers have adopted to prevent the incident from happening. Surgeons from other hospitals could assemble in the PSO to discuss a case study for the purpose of learning and sharing clinical practices in a confidential forum. The PSO could also evaluate the clinical literature for evidenced-based solutions developed by other experts in the field. Following the evaluation, the PSO would then disseminate the lessons learned to other health care providers, hospitals and laboratories; and encourage them to implement processes to avoid the same or similar mistakes and thereby hold these providers accountable for improvement.

PSOs have many different programs to analyze patient safety work product in order to accelerate the identification, understanding, and implementation of evidence-based solutions for preventable harm that may occur in the increasingly complex systems of healthcare delivery. For example, one PSO collected and analyzed over 300,000 event reports, research requests and root cause analysis over an approximate five-year period from a wide range of health care

organizations to develop a list of the top ten patient safety concerns confronting health care organizations along with suggested strategies to improve patient safety.[5] Another PSO collects root cause analysis developed from peer review that is conducted in the hospital's patient safety evaluation system and brings together top experts in the field to allow broader inspection and investigation of the events. To provide a specific example, this PSO convened leaders in emergency medicine to share their expertise and opinions regarding patient safety issues in emergency departments. Participants discussed case studies, as well as emerging technologies and new strategies that are now available to complement existing patient safety protocols aimed at reducing adverse events, specifically those associated with delayed diagnosis.[6] These are just two of a multitude of examples that

---

[5] ECRI Institute, "Top 10 Patient Safety Concerns for Healthcare Organizations" (3/24/2014), https://www.ecri.org/components/hrc/pages/RMRep0414_Focus.aspx. These patient safety concerns are: 1) Data integrity failures with health information technology systems; 2) Poor care coordination with patient's next level of care; 3) Test results reporting errors; 4) Drug shortages; 5) Failure to adequately manage behavioral health patients in acute care settings; 6) Mislabeled specimens; 7) Retained devices and unretrieved fragments; 8) Patient falls while toileting; 9) Inadequate monitoring for respiratory depression in patients taking opioids; 10) Inadequate reprocessing of endoscopes and surgical instruments. The report also discusses strategies to address each category of error.

[6] https://www.rmf.harvard.edu/About-CRICO/Our-Community/AMC-PSO-home-page/AMCPSO-newsletters.

illustrate PSOs' activities in promoting patient safety and contributing to the learning system.

But the Patient Safety Act goes further than the learning system established by the health care providers and the PSOs, by putting this system of quality improvement to work on a national level. Incident report information is "de-identified" of provider and patient information, and is then reported to a network of patient safety databases, created by the Federal Department of Health and Human Services, "to be used to analyze national and regional statistics, including trends and patterns of health care errors." 42 U.S.C. § 299b-23(c). The trends and statistics can spur improvement in regions that are lagging behind to promote a nationally uniform highly reliable quality health care system. This way patients receiving care in the Pacific Northwest can be assured of receiving the same quality of care as patients on the Atlantic Northeast and vice versa.

None of this patient safety improvement work can be effectively performed if the reporting to PSOs is not confidential. The protection of patient safety work product is essential to enable PSOs to collect enough data to perform core patient safety activities such as "undertak[ing] broader statistical pattern analysis" across multiple providers. S. Rep. No. 108-196, at 10. Congress intended for patients to benefit from the rich bodies of quality data collected by PSOs; and Congress also intended that plaintiffs' lawyers not be permitted to invade PSOs' reporting systems,

lest the use of such confidential information in malpractice lawsuits lead to an end of the voluntary reporting that underlies the entire Patient Safety Act. S. Rep. No. 108-196 at 5, 7. *See also To Err is Human: Building a Safer Health System*, 113 ("The committee notes that protecting data in a reporting system as recommended in this chapter does not mean that the plaintiff in a lawsuit could not try to obtain such information through other avenues if it is important in securing redress for harm; it just means that the plaintiff would not be assisted by the presence of a reporting system designed specifically for other purposes beneficial to society.").

IV. Review is warranted because the Kentucky Supreme Court's decision is upsetting the carefully constructed balance Congress developed between confidential provider self-driven quality improvement and accountability through regulatory agencies, and the tort system.

Congress carefully constructed the Patient Safety Act to balance the need for providers to have confidentiality protections for self-critical analysis, and the need for accountability. Importantly, the Patient Safety Act privilege does not keep information from regulators, patients or the public, and does not hide health care providers who consistently provide substandard care. In the aforementioned example of a blood type mismatching error, the health care providers who did not follow proper hospital procedure

could be subject to immediate summary suspension or other disciplinary action, as appropriate. In that example, State regulators conducted their own investigation of the incident and cited the hospital for deficiencies in its procedures. The patient and the family were also immediately informed about the error.

The Patient Safety Act does not prohibit disclosure of medical errors to patients by their health care providers. To the contrary, the Patient Safety Act encourages transparency among health care providers under the protection of the privilege for patient safety work product so that lives can be saved by sharing critical information to ensure that incidents are not repeated to harm other patients in other hospitals. 42 C.F.R. 3.206(b)(4)(iv)(A). Moreover, the Patient Safety Act encourages transparency of best practices and clinical solutions across the entire health care continuum. This transparency between health care providers will likely disappear if the privilege guaranteed to providers is breached by state courts.

Here, the Kentucky Supreme Court misconstrued the Patient Safety Act in part through its failure to appreciate the difference between state record-keeping requirements versus affirmative reporting requirements. The Kentucky regulations at issue are record-keeping requirements. Pet.App. 24a-25a, discussing 902 KAR 20:016 § 3(3)(a). The State regulations do not constitute affirmative reporting requirements – *i.e.*, a directive that hospitals provide

specific records to State regulators.[7] The Kentucky Supreme Court erroneously treated this State record-keeping requirement as an affirmative reporting requirement, which in turn meant that those records subject to reporting to State regulators would necessarily be discoverable by plaintiffs' counsel in this action, since Kentucky has no State privilege, even for peer review materials. Pet.App. 14a-15a, 25a.

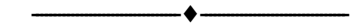
Any public or even *in camera* inspection of incident reports drawn from reports in a patient safety evaluation system, as ordered by the Kentucky Supreme Court in this case, undermines the entire structure of the federal Patient Safety Act. The Kentucky Supreme Court's misconstruction of the federal Patient Safety Act privilege may result in federally protected patient safety work product being reviewed by persons other than PSOs, and eventually provided to the Respondent's medical malpractice attorney for use in this lawsuit. Simply put, providers will stop voluntarily submitting incident reports to patient safety evaluation systems and PSOs if there is any possibility that those reports can be used against them in later medical malpractice litigation. As discussed above, to the extent that State law

---

[7] Indeed, Kentucky has no affirmative medial error reporting requirements. *See "A National Survey of Medical Error Reporting Laws,"* Yale J. Health Policy, Law, and Ethics IX:1, 243 (2008), citing October 21, 2008 letter from Dr. J. Thomas Badgett, Chief Medical Officer of the Kentucky Cabinet for Health & Family Services.

might require a hospital to comply with a State reporting requirement, that compliance can be accomplished with medical records and other information that is not patient safety work product. 73 Fed. Reg. 70732, 70773.

The Kentucky Supreme Court's misconstruction of the federal Patient Safety Act privilege will also have the perverse effect of punishing good hospitals that are reporting to a PSO by making them look worse. A high reliability, high performing hospital fostering a strong safety culture that encourages incident reporting will have more events to analyze and evaluate than hospitals that are not reporting to a PSO and are not focused on safety culture and learning. Hospitals with weaker safety cultures will have a lower number of events not because events are not occurring, but because these incidents are not being reported. As a result, health care consumers in our data-driven culture may mistakenly be led to believe that the high performing hospitals that invest heavily in safe systems and safety culture provide lower quality and value of care – which then punishes the high performing hospitals and correspondingly punishes patients.



CONCLUSION

All patient safety improvements begin with the reporting of an incident by a provider to a patient safety evaluation system and to a PSO. Allowing the

Kentucky Supreme Court decision for State requirements to override the uniform federal privilege established by Congress in the Patient Safety Act will inevitably lead to a breakdown of the national learning system and patients being harmed.

If the ruling from the Kentucky Supreme Court is permitted to allow courts or private attorneys to sift through a health care provider's most sensitive confidential information, it will upset Congress's carefully constructed "learning environment" in which health care professionals report errors and near misses free from fear that their communications would land in the possession of litigants and disciplinary boards. H.R. Rep. No. 109-197 at 9; S. Rep. No. 108-196 at 2.

Without the broad privilege and confidentiality protections created in the Patient Safety Act, events and the lessons learned from harm inflicted on a patient when a medical error occurs will again be held in silos within individual hospitals in Kentucky. As a result, the same mistakes and harm to patients will be unnecessarily repeated by providers in other hospitals. Indeed, as the dissent below aptly observed, the likely result of such a decision is the wholesale dismantling of the safety culture system Congress intended to create. "It is hard to imagine a holding more at odds with Congress's clear intent to foster provider trust in the patient safety system" . . . than permitting a trial court to "rummage through the provider's patient safety evaluation system and PSO submissions" in search of state-mandated records;

and which "would completely undermine Congress's assurance to providers that they may participate in the patient safety system without fear of liability or harm to reputation." Pet.App. 37a-38a (Abramson, J., dissenting). A collapse of voluntary reporting would inevitably diminish the ability of health care systems to improve patient safety by identifying and correcting "faulty systems, processes, and conditions." *Id.* at 7a. This, in turn, would "undercut the [Patient Safety] Act's effectiveness in advancing patient safety" and may lead to increased patient injuries and deaths. *Id.* at 26a.

For these reasons, *amicus curiae* AQIPS urges this Court to grant the petition for writ of certiorari.

Respectfully submitted,

PEGGY BINZER
POLSINELLI PC
1401 I Street, N.W., Suite 800
Washington, D.C. 20005
202-783-3300

BENNETT L. COHEN
Counsel of Record
SEAN R. GALLAGHER
POLSINELLI PC
1515 Wynkoop Street,
Suite 600
Denver, CO 80202
303-572-9300
BCohen@Polsinelli.com

April 20, 2015