No. SU-15-0212

IN THE
SUPREME COURT OF THE STATE OF RHODE ISLAND
AND PROVIDENCE PLANTATION

RANDALL ROSENTHAL, M.D.,
NEWPORT OB-GYN ASSOCIATES, LTD.,
AND NEWPORT HOSPITAL,

Defendants-Appellants,

– v. –

KATHERINE CARRON AND
RYAN CARRON, INDIVIDUALLY AND AS
CO-ADMINISTRATORS OF THE ESTATE
OF KENNETH H. CARRON,

Plaintiffs-Appellees.

On Appeal from the Newport County Superior Court
(C.A. NO. NC-2013-0479)

BRIEF OF VIZIENT® PSO, THE AMERICAN MEDICAL ASSOCIATION, AND THE RHODE ISLAND MEDICAL SOCIETY AS *AMICI CURIAE* SUPPORTING APPELLANTS AND REVERSAL

GEORGE E. LIEBERMAN
Counsel of Record
GIANFRANCESCO & FRIEDEMANN LLP
214 Broadway
Providence, RI 02903
george@gianfrancescolaw.com
(401) 270-0070

MICHAEL R. CALLAHAN
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661
michael.callahan@kattenlaw.com
(312) 902-5634
Pro Hac Vice pending

ROBERT T. SMITH
KATTEN MUCHIN ROSENMAN LLP
2900 K Street NW
North Tower – Suite 200
Washington, DC 20007
robert.smith1@kattenlaw.com
(202) 625-3616
Pro Hac Vice pending

Counsel for Amici Curiae

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES:

STATUTES:

REGULATIONS:

OTHER AUTHORITIES:

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") (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. The information included in these databases is available for analysis by healthcare professionals to improve medical outcomes and patient safety. 42 U.S.C. § 299b-23.

Critically, 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). Setting aside for the moment these exceptions, which are not applicable here, patient safety work product is defined to include, among other things, "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" that are "assembled or developed by a provider for reporting" to a PSO and could be used to improve "patient safety, health care quality, or health care outcomes." *Id.* § 299b-21(7)(A).

The lead *amicus*, the Vizient® PSO, is a PSO within the meaning of the Patient Safety Act. *Id.* § 299b-21(4). Notably, it is the PSO with which Newport Hospital has currently

contracted[1] and has 230 participating academic medical centers, hospitals, and other licensed provider facilities as members from around the country.

The remaining *amici* are the American Medical Association ("AMA") and the Rhode Island Medical Society ("RIMS"). These professional associations represent tens of thousands of physicians in Rhode Island and around the country, including many who participate in and provide information to PSOs.[2]

In addition to *amici*, twenty-nine other PSOs and two hospital systems have expressed support for the positions espoused here by *amici*, and those statements of support are on file with counsel for *amici*. Though not formally seeking leave to participate as *amici*, these twenty-nine supporting PSOs share Vizient's interests in the outcome of these proceedings. They collect patient safety information from thousands of healthcare providers across the country in order to conduct various patient safety analyses and studies to understand why certain errors occurred as well as how to improve the quality of health care services and reduce patient risk.[3] The supporting hospital systems participate in at least one of the supporting PSOs.[4]

---

[1] At the time when Newport Hospital submitted the two Medical Event Reporting System (MERS) reports at issue in this case, it was participating in the GE-MERS National Patient Safety Organization (GEPSO), which voluntarily withdrew as a certified PSO. Newport Hospital subsequently contracted with Vizient® PSO on August 2, 2013, and it is now sending these and other reports to Vizient® PSO.

[2] The AMA and RIMS join in their own right and as representatives of the Litigation Center of the AMA and 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.

[3] The twenty nine supporting PSOs are: The American Data Network PSO; The American Medical Foundation PSO Center; QA to QI LLC Organization; Society for NeuroInterventional Surgery PSO; 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 Keystone Center 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., PsychSafe; Quality Circle for Healthcare, Inc.; Quantros Patient Safety Center; Strategic Radiology Patient Safety Organization LLC; The

Collectively, the *amici* and their supporters represent all sides of the collection, submission, and use of "patient safety work product." Accordingly, they share a common interest in the proper interpretation of the privilege provided under the Patient Safety Act.

Because the Superior Court's decision in this case would render meaningless the protections afforded by the Act and conflicts with the full scope of the privilege established by Congress, *amici* and their supporters file this brief in support of the Appellants. For the reasons that follow, this Court should reverse the decision of the Superior Court.

SUMMARY OF ARGUMENT

The Superior Court's decision threatens to significantly undermine and limit the scope of the privilege afforded under the Patient Safety Act, thereby gutting the nationwide protections that Congress envisioned. This erroneous decision will, in turn, 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.[5]

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

---

PSO Advisory, LLC; UHS Acute Care PSO; MCIC Vermont, Inc. PSO; Kentucky Institute for Patient Safety and Quality Virginia PSO; Tennessee Center for Patient Safety PSO; Mid-Atlantic PSO; AABB Center for Patient Safety; the New Jersey Association Health, Research & Educational Trust Institute for Quality & Patient Safety; and Quality Alliance PSO.

[4] The supporting hospitals are: 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); and the Regents of the University of California on behalf of its hospitals at UC Davis, UCSF, UC Irvine, UCLA and UC San Diego Health Systems.

[5] Although the Rhode Island General Assembly established a near-identical privilege under the Rhode Island Patient Safety Act of 2008 (codified at Rhode Island General Laws, Ch. 23-17.21), this *amici* brief focuses exclusively on the federal Patient Safety Act.

that participating licensed providers 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 patient 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").

Contrary to the scope of the federal privilege, the Superior Court held that the plaintiffs were "entitled to the records here," Tr. 6/1/15 at 5—specifically, records that were prepared exclusively for submission to a PSO and unquestionably constituted "patient safety work product." Instead of honoring the policy judgment reached by Congress, the Superior Court erroneously offered its own:

> If at all possible, I'd like to see as much open discovery as possible. To say, well, there is a federal statute or state statute, how that applies in this particular case gives me great concern. And I don't like the idea of the hospital using these kinds of statutes to avoid discovery for something that is this traumatic to the mother and child.

Id. at 5-6.

In so ruling, the Superior Court ignored the clear legislative intent of Congress as well as specific statutory language which protects from discovery and admissibility into evidence patient safety information collected in a licensed provider's patient safety evaluation system ("PSES") for the purpose of reporting to a PSO, and that is ultimately reported to a PSO. *See* 42 U.S.C.

§ 299b-22(a). Such information qualifies as privileged patient safety work product, *id.*, which is defined in the Patient Safety Act, in pertinent part, as follows:

> "Patient safety work product" means 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 assumed or developed by a provider for reporting to a PSO and are reported to a PSO . . . or
>
> (B) Are developed by a PSO for the conduct of patient safety activities; or
>
> (ii) Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system...

42 C.F.R. § 3.20; *see also* 42 U.S.C. § 299b-21(7)(A).

The Superior Court record clearly demonstrated that Newport Hospital had established and implemented a PSES, which prompted the creation and collection of the two Medical Event Reporting System (MERS) reports at issue in this case. These reports were intended to be used for efforts to improve patient safety and were, in fact, reported to a PSO.

Despite the fact that Newport Hospital met its burden of establishing compliance with the Act, and produced other non-privileged records and information that concerned the unfortunate incident at the center of the parties' dispute, the Superior Court essentially ignored the Act because the judge believed the two privileged MERS reports might have relevant information to support the plaintiffs' malpractice action. Respectfully, that was not a policy judgment that the Superior Court was entitled to make.

The Superior Court's decision will, in turn, 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 Superior Court's decision also will have a significant chilling effect on whether hospitals, physicians, physician groups, nursing homes, surgical centers and all other licensed providers choose to 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.

Additionally, the reduced reporting of adverse events and other patient quality information to PSOs will significantly erode and therefore limit, if not eliminate, the ability of PSOs to evaluate this information in order to create individual provider and aggregate patient safety analyses, and benchmark and comparative studies; identify best practices; and provide safety alerts and other related studies—key components and benefits of the Act.

ARGUMENT

I. The Superior Court's Decision Conflicts with and Undermines the Statutory Duties and Responsibilities of PSOs Under the Patient Safety Act.

The Superior Court's ruling conflicts with what should have been a straightforward application of the patient safety work product privilege under the Patient Safety Act. *See* 42 U.S.C. § 299b-22(a). The MERS reports at issue were created exclusively for Newport Hospital's PSES and were submitted to Newport Hospital's Patient Safety Organization. As the U.S. Department of Health and Human Services recently clarified, these types of records falls squarely within the disclosure privilege created under the Patient Safety Act. *See* Dep't of Health & Human Servs., *Patient Safety and Quality Improvement Act of 2005 – HHS Guidance*

Regarding Patient Safety Work Product and Providers' External Obligations, 81 Fed. Reg. 32,655, 32,656 (May 24, 2016). By ordering the production of clearly privileged documents, the Superior Court's ruling undermines the responsibilities of PSO's under the Patient Safety Act, and threatens to disrupt the valuable information-sharing services that PSOs provide their members.

PSOs are heavily regulated entities. 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 has delegated these responsibilities to the Agency for Healthcare Research and Quality ("AHRQ"), is required to ensure that, among other things, the PSOs' "mission and primary activity . . are to conduct activities that are to improve patient safety and the quality of health care delivery." *Id.* § 299b-24(b)(1). AHRQ describes a PSO's primary activity 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 and hazards 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 February 22, 2017). In order to be certified 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)(i)(A). PSOs also have multiple statutory duties, including an obligation to conduct

patient safety activities on their own and for the benefit of the participating providers. *See, e.g.*, 42 U.S.C. § 299b-21(5).

PSOs that cannot demonstrate compliance are subject to a fine and loss of certification. *See* 42 C.F.R. §§ 3.304-3.552. Accordingly, AHRQ published a "Compliance Self-Assessment Guide" ("Guide") to assist PSOs with the certification and recertification processes and meet their obligations under the Patient Safety Act and the rules promulgated thereunder. *See generally* AHRQ, Patient Safety Organizations: A Compliance Self-Assessment Guide (Sept. 2009), *available at* https://www.pso.ahrq.gov/sites/default/files/wysiwyg/saguide.pdf. 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—requirements that are necessary to obtain and maintain certification. *Id.*

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 February 22, 2017).

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

> PSOs serve as independent, external experts who can assist providers in analyzing data that a provider voluntarily chooses to report to the PSO. . . .
>
> The Patient Safety Act and Rule provide protections that are designed to allay fears of providers of increased risk of liability if they voluntarily participate in the collection and analysis of patient safety events. The uniform Federal protections that apply to a provider's relationship with a PSO are expected to remove significant barriers that can deter the participation of health care providers in patient safety and quality improvement initiatives, such as fear of legal liability or professional sanctions.

AHRQ, Patient Safety Organization (PSO) Program, Frequently Asked Questions, www.pso.ahrq.gov/faq#BenefitstoMedicareProviders (last visited February 22, 2017).

- 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 visited February 22, 2017).

PSOs enter into contracts with 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." 42 C.F.R. § 3.102(b)(2)(i)(F), (G).

In addition to the regulations governing PSOs, providers must meet separate requirements to have records qualify as privileged patient safety work product. The Patient Safety Act requires providers to 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 id.* §§ 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, so long as the provider did not collect and assemble the patient safety information to satisfy other state or federal reporting obligations, *see* 81 Fed. Reg. at 32,657.

Thus, as the Patient Safety Act and the accompanying regulations and agency guidance make clear, PSOs are not "black-box" receptacles for patient medical records. They are heavily regulated entities that collect, analyze, and provide direct feedback to providers to improve quality and reduce risk. And providers who participate in a PSO must satisfy their own requirements to qualify for the privilege protections under the Patient Safety Act.

In the end, a PSO and its national database are only as useful as the information that the database contains and providers will not generate the additional information contemplated by the Act 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 and privileged basis to their respective PSOs. The information submitted by providers to PSOs around the country includes sensitive patient incident reports, such as the MERS reports at issue in this case, root cause analyses, peer review evaluations, and other patient safety information that providers are not otherwise obligated to collect.

The submission of patient safety information by providers has enabled Vizient® PSO 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 benefited 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.[6]

---

[6] 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 Vizient® PSO has produced a number of "Applied Learnings" reports based on patient safety event data received from its participating providers. The purpose of these reports, which cover Health IT-related patient safety events, surgical pathology specimen errors, patient violence, retained sponges and guidewires and an analysis of suicide-related events, is to identify specific safety events, conduct analyses and make recommendations designed to improve the quality of patient care and reduce risk. *See* Vizient PSO, Aggregate Analyses and Leading Safety Practices (Dec. 2016), *available at* http://www.advansiv.net/clients/vizient/docs/2016-PSO-Summary-Analyses.pdf.

ECRI Institute PSO distributes information regarding the top patient safety concerns they have identified through the PSO and on HIT, pressure ulcers, medication safety, and other patient-care related issues. *See* Press Release, ECRI Institute PSO, Partnership for Health IT Patient Safety Issues Recommendations for the Safe Use of Health IT for Patient Identification (Feb. 20, 2017), *available* https://www.ecri.org/press/Pages/HITPS-Issues-Recommendations-for-Patient-Identification.aspx; ECRI Institute PSO, Key Learning from ECRI Institute PSO, https://www.ecri.org/resource-center/Pages/Key-Learnings-from-ECRI-Institute-Patient-Safety-Organization.aspx (last visited Feb. 22, 2017). ECRI has its own PSO and also provides analyses, benchmarking reports, and other patient care studies under contractual agreements with PSOs around the country.

Child Health Patient Safety Organization, which has 50 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, *see* Child Health Patient Safety Organization, Patient Safety Action Alerts, http://www.childrenshospitals.org/Quality-and-Performance/Patient-Safety/Patient-Safety-Action-Alerts (last visited Feb. 22, 2017), and educates providers at conferences to help eliminate patient harm, *see* Child Health Patient Safety Organization, 2017 Quality and Safety in Children's Health Conference, https://www.childrenshospitals.org/Events/2017/03/19/2017-Quality-and-Safety-in-Childrens-Health-Conference/Sessions/Saving-One-Child-A-Vision-to-Eliminate-All-Repeat-Harm/23C44B66CC2E40E9B1A12E229D9053AA (last visited Feb. 22, 2017).

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/

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.[7] The simple reality is that this safety information will no longer be reported by hospitals, physicians, and other providers if it is not given protection under the Patient Safety Act.

The Superior Court, however, refused to acknowledge the importance of patient safety work product, or the privilege afforded to such work product under the Patient Safety Act. Rejecting the policy judgment of Congress, the Superior Court opined that it did not "like the idea of the hospital using these kinds of statutes to avoid discovery for something that is traumatic to the mother and child." Tr. 6/1/15 at 5-6. This ruling runs contrary to the mandate of the Patient Safety Act, which clearly protects patient safety work product in federal, state or local government civil proceedings. *See* 42 U.S.C. § 299b-22(a).[8]

Nor can the Superior Court find support to drastically limit the privilege under the Patient Safety Act in prior court decisions or recent guidance from the U.S. Department of Health and Human Services. These authorities only provide that reports are not privileged

---

clarity-patient-safety-organization/learning-library/pso-learning-series (last visited Feb. 22, 2017).

[7] 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.

[8] Contrary to the Superior Court's suggestion, patient safety work product is not always harmful to a defendant in a malpractice lawsuit. The work product could very well include information helpful to the defense, but the Act does not provide an exception to allow a defendant to selectively waive the privilege once such work product is reported. In other words, the Act does not allow a defendant provider to admit into evidence information that is privileged patient safety work product. Thus, the Act would prohibit Newport Hospital from introducing the MERS report to support its defense.

under the Patient Safety Act when a provider was otherwise required to prepare that report under separate state or federal law. *See Baptist Health Richmond, Inc. v. Clouse*, 497 S.W.3d 759, 766 (Ky. 2016) (holding that the Patient Safety Act privilege did not cover information that should have been collected and maintained pursuant to a state obligation); *Tibbs v. Brunnel*, 448 S.W.3d 796, 809 (Ky. 2014) (same); *Charles v Southern Baptist of Florida Inc.*, No. SC15-2180, 2017 WL 411333 (Fla. Jan. 31, 2017) (holding that the privilege did not cover a report that a provider was obligated to disclose under state law); *see also* 81 Fed. Reg. at 32,657 (explaining that privilege does not cover reports prepared to satisfy other reporting obligations).

The case at hand is readily distinguishable from those decisions and the guidance from the Department of Health and Human Services because the MERs reports at issue were *not* created to satisfy any state-reporting obligations. In fact, Newport Hospital met its state-mandated reporting obligations through *separate* incident reports it submitted to the Rhode Island Department of Health. By contrast, Newport Hospital voluntarily prepared the MERS reports at issue as part of its patient safety program, entered those reports into a PSES, and submitted those reports to its PSO, in accordance with recent guidance issued by the U.S. Department of Health and Human Services. *See* 81 Fed. Reg. at 32,659 (advising providers to maintain separate systems for voluntary PSO reporting and state-reporting obligations). Thus, the Superior Court's ruling misapplied the law to a class of materials that is entitled to clear protection under the Patient Safety Act. *See id.*

The Superior Court's ruling, if left to stand, will necessarily discourage providers from compiling and submitting patient safety information, thereby undermining the ability of PSOs

to review and analyze adverse patient incidents, and perversely impacting their efforts to improve quality and reduce risk to patient health.

II. The Superior 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—were meant to further the paradigm 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.

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), and 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

- The final CMS rule for implementation of the Medicare Access and CHIP Reauthorization Act (MACRA), an historic Medicare reform law, which was issued on November 4, 2016 to implement a Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models as part of CMS' Quality Payment Program for physicians. *See generally* Dep't of Health & Human Servs., *Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models*, 81 Fed. Reg. 77,008 (Nov. 4, 2016). Under this program, physicians who satisfy identified quality measures can receive certain incentivized payments. *Id.*

CMS estimates that from January 2012 to December 2013, these programs saved 50,000 lives and $12 billion in spending, and resulted in 150,000 fewer readmissions. Press Release, Dep't of Health & Human Servs., 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* https://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html.

In order to meet these 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. This ensures that the provider's compliance can be tracked and monitored, and remedial efforts may be 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 to correct substandard practices. These same materials also are reported to PSOs for further evaluation and analysis, all of which are considered patient safety work product.

The privilege and confidentiality protections afforded to providers and PSOs under the Patient Safety Act, therefore, are essential to meeting federal quality standards because they facilitate frank and robust discussions and evaluations about medical errors and other adverse events. An affirmance of the Superior Court's ruling by this Court will significantly undermine the efforts of providers and PSOs in Rhode Island and around the country to meet these quality and value objectives if plaintiffs and other third parties have free access to protected patient safety work product. 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.

CONCLUSION

For the foregoing reasons, the *amici curiae* and supporters respectfully request that this Court reverse the Superior Court's decision and hold that the MERS reports prepared by Newport Hospital be treated as privileged patient safety work product under the Patient Safety Act.

Respectfully submitted.

MICHAEL R. CALLAHAN
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661
michael.callahan@kattenlaw.com
(312) 902-5634
Pro Hac Vice Pending

GEORGE E. LIEBERMAN
Counsel of Record
GIANFRANCESCO & FRIEDEMANN LLP
214 Broadway
Providence, RI 02903
george@gianfrancescolaw.com
(401) 270-0070

ROBERT T. SMITH
KATTEN MUCHIN ROSENMAN LLP
2900 K Street NW
North Tower – Suite 200
Washington, DC 20007
robert.smith1@kattenlaw.com
(202) 625-3616
Pro Hac Vice Pending

February 27, 2017

Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that on the 27th day of February 2017, I caused this document to be mailed via First Class Mail, postage prepaid, to the attorneys for the parties to this matter whose names and addresses are as follows:

George Wakeman, Esq.
Timothy M. Zabbo, LLP
ADLER, COHEN, HARVEY, WAKEMAN & GUEKGUEZIAN
170 Westminster Street, 10th Floor, Suite 1000
Providence, RI 02903

Jason C. Preciphs, Esq.
ROBERTS, CARROLL, FELDSTEIN & PEIRCE
Ten Weybosset Street
Providence, RI 02903

Mark Mandell, Esq.
Yvette M. Boisclair, Esq.
Heather M. Bonnet-Hebert, Esq
MANDELL, SCHWARTZ & BOISCLAIR, LTD.
One Park Row, Suite 2C
Providence, RI 02903-1293

George Lieberman
Counsel for Amici-Curiae