**No. 2-11-0452**

IN THE
APPELLATE COURT OF ILLINOIS
SECOND DISTRICT

| | | |
|---|---|---|
| ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION,<br><br>Petitioner-Appellant.<br><br>v.<br><br>WALGREEN CO.<br><br>.<br><br>Respondent-Appellee. | ) | On Appeal from the Circuit Court of the Nineteenth Judicial Circuit, Lake County, Illinois<br><br>Case No. 10 MR 1760<br><br>The Honorable DAVID M. HALL, Judge Presiding |

**BRIEF AMICUS CURIAE OF CLARITY PSO, SOCIETY FOR VASCULAR SURGERY PATIENT SAFETY ORGANIZATION, THE MIDWEST ALLIANCE FOR PATIENT SAFETY, UHC PERFORMANCE IMPROVEMENT PSO, NC CENTER FOR HOSPITAL QUALITY & PATIENT SAFETY, MHA PATIENT SAFETY ORGANIZATION, CALIFORNIA HOSPITAL PATIENT SAFETY ORGANIZATION, AND CHILD HEALTH PATIENT SAFETY ORGANIZATION, INC. ("PATIENT SAFETY ORGANIZATIONS") IN SUPPORT OF DEFENDANT-APPELLEE WALGREEN CO.**

Michael R. Callahan
James W. Hutchison
**KATTEN MUCHIN ROSENMAN LLP**
525 West Monroe Street
Chicago, IL 60661
(312) 902-5200
*Counsel for Amicus Curiae*

## POINTS AND AUTHORITIES

## Statement of Interest

As set forth in the motion for leave to file this brief, the *Amicus Curiae* include eight separate AHRQ certified Patient Safety Organizations ("PSOs"), including four PSOs located in Illinois, which were established pursuant to the Patient Safety and Quality Improvement Act of 2005 ("Patient Safety Act") (42 USC Section 299b1-21 et seq.). The decision in this case will directly affect all PSOs and their provider members in Illinois and around the country. A reversal of the trial court's decision that the Walgreen's medication error incident reports are protected from disclosure under the Patient Safety Act would significantly impair the ability of PSOs and providers to improve the quality of patient care services because it would destroy the privilege and confidentiality protections that have proven so critical to the candid and complete exchange and analysis of patient information used to assess and improve patient outcomes.

The Preamble to the final rules to implement the Patient Safety Act ("Patient Safety Rule") provides a good summary of the Act's purposes:

> 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 without fear of liability and creates PSOs to receive this protected information and analyze patient safety events. These protections will enable all 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 providers.[1]

The Patient Safety Rule has been in effect for over two and a half years and provides protections for patient safety information, referred to as "patient safety work

[1] 73 Federal Register 70732 (November 21, 2008). The final rule became effective January 19, 2009.

product", which are far broader than those granted under most state statutes, including the Illinois Medical Studies Act (735 ILCS 5/8-2101 et seq. (2010)). Yet, many providers remain reluctant to create a PSO or to contract with an existing one for a number of reasons.

First, a provider must expend significant time and expense to establish patient safety procedures and policies, known as a "patient safety evaluation system." Second, there must be a coordinated decision among multiple personnel concerning which patient safety, quality, peer review and risk management information to include in their patient safety evaluation system, for once it is collected and reported to a PSO, the information becomes strictly privileged and confidential under state and federal law. Once protected, it can be used for internal patient safety activities but cannot be disclosed for other purposes, and an impermissible disclosure can result in civil penalties imposed by the Office of Civil Rights. Third, many providers have not previously been covered by a state confidentiality statute and are not familiar with the manner and method of maintaining these protections. Fourth, because the Patient Safety Act and Patient Safety Rule provide broader protections than most existing state laws and have yet to be interpreted by an appellate court, providers fear that efforts to improve patient care and promote organizational learning will be undermined if the Patient Safety Rule is struck down or its protections not upheld in a court of law.

This will be one of the first, if not the first time a state or federal appellate court has addressed the Patient Safety Rule issues identified in this appeal.[2] The Appellate

[2] Illinois courts, as well as courts in other jurisdictions, however, have addressed and interpreted state confidentiality protections for peer review materials on numerous occasions Therefore, the confidentiality and privilege protection principles underlying these statutes and their judicial enforcement are not new. See, e.g., Anderson v. Rush Copley Medical Center, 385 Ill. App. 3d

Court's decision will not only have a binding and precedential impact on all Illinois health care providers and Illinois-based PSOs, but will likely influence the rulings of state and federal courts around the country as they address similar challenges to the Patient Safety Act.

The PSO's who join in this brief and all other PSOs certified by AHRQ have contracted with thousands of health care providers who can now seek the protections that the Patient Safety Act and Patient Safety Rule provide. While this case involves pharmacies, which are specifically referenced under the Patient Safety Rule, the Amicus PSOs and their respective members represent a broad cross section of covered heath care providers, all of whom will be affected by this Court's decision.[3]

The Amicus PSOs respecfully submit that this brief will assist the Court in understanding how the myriad legal responsibilities placed on providers, as well as the health care reform measures demanded by private and public payors to improve the quality of health care services and reduce costs, make the affirmance of the trial court's decision to protect patient safety information crucial to the success of the patient safety activities of all health care personnel.

## Nature of the Case

Walgreen Company ("Walgreens") was served with three subpoenas by the Department to produce "[a]ll incident reports of medication error" ("medication error reports") relating to three Walgreens pharmacists. Walgreens refused to produce these

---

167 (2d Dist. 2008); Berry v. West Suburban Hospital Medical Center, 338 Ill. App. 3d 49 (1st Dist. 2003).

[3] A provider is broadly defined to include "an individual or entity licensed or otherwise authorized under State law to provide health care services...." Providers include, but are not limited to "[a] hospital, nursing facility, home health agency, hospice program,... ambulatory surgical center, pharmacy...physician,... registered nurse... [and] pharmacist...." (42 U.S.C. Section 299b1-21(8))

reports on the ground that they were prepared as part of its established patient safety evaluation system, and were collected and transmitted to its patient safety organization, The Patient Safety Research Foundation, Inc. ("PSRF"), pursuant to the Patient Safety Act. Therefore, the medication error reports were strictly privileged and protected from disclosure under the Patient Safety Act and under the Illinois Medical Studies Act (735 ILCS 5/8-2101 et seq. (2010)).[4] The Department filed suit in the Circuit Court of Lake County, Illinois, seeking to enforce the three subpoenas despite these federal and state protections. The trial court granted Walgreens' Motion to Dismiss, holding that the Walgreens medication error reports were privileged and not subject to disclosure. The Department then filed this appeal.

## ARGUMENT

### I. The Walgreens' Medication Error Reports Subpoenaed by the Department Are Strictly Privileged and Not Subject to Discovery Under the Patient Safety Act.

#### A. Summary of Arguments

The Department concedes that the Patient Safety Act governs the disclosure of patient safety work product as defined therein, and this brief will further demonstrate that the Department lacks the authority to force the disclosure of the protected patient work product. The Walgreens medication error reports are precisely the type of information that is protected by the Act, and Walgreens submitted evidence to show that the reports were collected and submitted to the PSO in accordance with the Act, thus maintaining the protection from disclosure. The Department submitted no evidence to support its argument that Walgreens separately maintained other responsive documents that are not

[4] Because Walgreens is asserting arguments related to the Illinois Medical Studies Act and a number of the Amicus PSOs are not based in Illinois, they do not to address the Illinois Medical Studies Act issue on appeal.

protected by the Patient Safety Act. The Department merely points to *other types* of documents that were produced by Walgreens in an unrelated case, and it is easily shown that those documents have nothing to do with the medication error reports at issue here. Finally, the Department suggests that its subpoenas should not be limited to the language used therein, but instead should be read to include information beyond what was actually requested. The documents that were requested, however, are protected from disclosure under the Patient Safety Act.

**B. Overview of the Patient Safety Act and Patient Safety Rule**

The Department has have acknowledged that one of the principal motivating factors behind the passage of the Patient Safety Act was a scathing report prepared in 1999 by the Institute of Medicine ("IOM") which estimated that between 44,000 and 98,000 people die every year due to preventable medical errors (Institute of Medicine, "To Err is Human: Building a Safer Health Care System", 1999). The IOM concluded that these deaths mostly were attributable to human error and faulty systems such as treatment administration defects, the failure to provide indicated tests and delays in treatment. These industry-wide problems systematically led caregivers to commit mistakes and to do little to address their causes. (Id. at 49-66.)

In order to help effectively confront these disastrous results, Congress implemented a broad privilege and confidentiality protection to prevent the disclosure of information derived from patient safety activities, because such protections directly facilitate the collection and analysis of necessary data and ensure candid and effective discussions and efforts to improve patient outcomes. Without these protections, such efforts will be adversely affected and patients will suffer. The privilege and

confidentiality protection granted under the Patient Safety Act is known as the "Patient Safety Rule".

The Preamble to the Patient Safety Rule convincingly explains the clear need for these protections:

> As compared to high-risk industries, the health care system is behind in its attention to ensuring basic safety [Citation omitted]. The reasons for this lag are complex and varied. Providers are often reluctant to participate in quality review activities for fear of liability, professional sanctions, or injury to their reputations. Traditional state-based legal protections for such health care quality improvement activities, collectively known as peer review protections, are limited in scope: They do not exist in all States; typically they only apply to peer review in hospitals and do not cover other health care settings, and seldom enable health care systems to pull data or share experience between facilities. If peer review protected information is transmitted outside of an individual hospital, the peer review privilege for that information is generally considered to be waived. This limits the potential for aggregation of a sufficient number of patient safety events to permit the identification of patterns that could suggest the underlying causes of risks and hazards that then can be used to improve patient safety (Volume 73 Federal Register 8113 (February 12, 2008)).

Although the Patient Safety Act was adopted in 2005, the final Patient Safety Rule did not take effect until January 19, 2009. This legislation was adopted at a critical time given the ever-increasing expectations and legal obligations placed on providers through numerous and comprehensive state and federal requirements, detailed accreditation standards, and other legal mandates to monitor, evaluate and track patient outcomes, determine the initial and ongoing qualifications of health-care providers, and conduct various analyses to determine individual and systematic deficiencies. The failure to adhere to these standards can result in loss of licensure[5], loss of reimbursement and eligibility to treat Medicare and Medicaid patients[6] and loss of accreditation.[7] It can also

---

5 See, e.g., Illinois Hospital Licensing Act, 210 ILCS 85/1 et seq. (2010).

6 42 C.F.R. § 482.

cause increased exposure to professional liability actions under the doctrines of corporate negligence[8] and apparent agency.[9]

### C. The Patient Safety Act Preempts Conflicting Illinois Law and Provides a Broad Privilege for Patient Safety Work Product.

As previously discussed, the drafters of the Patient Safety Rule clearly understood that current state confidentiality and privilege statutes are limited in scope with respect to the categories of health care providers covered, as well as the breadth of patient safety activities and information which can be protected from disclosure. In some states, such as Florida, the peer review confidentiality statute was essentially eliminated as a trade off for the adoption of a statutory limitation on compensatory damages in medical malpractice lawsuits. (See discussion on Florida Hospital – Waterman, Inc. v. Buster, 984 So. 2d 478 (Fla. 2008).)

Congress recognized the need to implement more uniform broad protections for all health care providers when it passed the Patient Safety Act, by specifically preempting any state law that would require disclosure of patient safety work product or that does not otherwise provide the same level of protections available under the Patient Safety Rule.

The Department concedes in its brief that the Patient Safety Act provides comprehensive protection for patient safety work product and preempts any conflicting state law:

> The Department acknowledges that to the extent the confidentiality provision of the [Patient Safety Act] conflicts with state law allowing the

---

7 See generally The Joint Commission Comprehensive Accreditation Manual for Hospitals (2011).

8 See, e.g., Darling v. Charleston Community Memorial Hospital, 33 Ill. 2d 326 (1965), Frigo v. Silver Cross Hospital and Medical Center, 377 Ill. App. 3d 43 (1st Dist. 2007).

9 See, e.g., Spiegelman v. Victory Memorial Hospital 392 Ill. App. 3d 826 (1st Dist. 2009), Churkey v. Rustica, 329 Ill. App. 3d (2nd Dist. 2002).

> Department to subpoena pharmacy records, the Federal law preempts the state law (Appellant's brief at page 24, footnote 5).

Despite this admission, the Department attempts to limit the intended breadth of the preemption. It is therefore important to examine the scope of protection provided under the Patient Safety Act.

Privileged and confidential patient safety work product is defined in the Patient Safety Act as:

> any data, reports, records, memoranda, analyses, (such as root cause analyses) or written or oral statements (or copies of any of this material)
>
> (i) which could improve patient safety, healthcare quality, or healthcare outcomes and
>
> > (A) Which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a patient safety evaluation system for reporting to a PSO, and such documentation includes the date of the information entered the patient safety evaluation systems; or
> >
> > (B) are developed by a PSO for the conduct of patient safety activity; or
>
> (ii) which identifies or constitutes the deliberations or analyses of, or identify the fact of reporting in pursuant to a patient safety evaluation system (42 U.S.C. Section 299b-21(7) (2010)).

A patient safety evaluation system is defined, in part, as the "collection, management or analysis of information for reporting to or by a PSO" (Id. at 299b-21(6) (2010)).

Information which qualifies as patient safety work product *is strictly privileged and not subject to a subpoena*. The Patient Safety Act provides:

> (a) *Privilege.* Notwithstanding any other provision of the Federal, State, local, or Tribal law and subject to paragraph (c) of this Section and § 3.28 of this subpart, Patient Safety Work Product shall be privileged and shall not be:

> (1) Subject to a Federal, State, local, or Tribal, civil, criminal or administrative subpoena or order, including in a Federal, State, local or Tribal, civil, criminal, or administrative subpoena or order, including in a Federal, State, local, or Tribal, civil or administrative proceeding against the provider;
>
> (2) Subject to discovery in connection with the Federal, State, local, or Tribal, civil, criminal or administrative proceeding, including in a Federal, State, local, or Tribal, civil or administrative disciplinary proceeding against the provider;
>
> (3) Subject to disclosure pursuant to section 552 of Title 5, United States Code (commonly known as the Freedom of Information Act), or any other similar Federal, State, local, or Title law;
>
> (4) Admitted as evidence in a Federal, State, local or Tribal governmental civil proceeding, criminal proceeding, administrative rule making proceeding, or administrative adjudicatory proceeding, including any such proceeding against the provider; or
>
> (5) Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under state law (42 U.S.C. Section 299b1-22(a) (2010)).[10]

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

> Proposed Subpart C sought to balance key objectives of the Patient Safety Act. First, the proposal sought to address provides concerns about the potential for damage from unauthorized release of information, including the potential for the information to serve as road map for provider liability from negative patient outcomes. It also promoted the sharing of information about adverse patient safety events among providers and PSOs for the purpose of learning from those events to improve patient safety and quality of care. To achieve these objectives, Subpart C [which was not amended and became final], proposed patient safety work product would be privileged and confidential, except in the certain limited circumstances identified by the Patient Safety Act and as needed by the Department to implement and enforce the Patient Safety Act... (73 Federal Register at 70770)... [w]e anticipate that the tribunals, agencies or professional disciplinary bodies before whom the proceedings take place

[10] Certain limited exceptions to these protections are not applicable here, i.e., criminal proceedings; disclosures which are authorized by the provider; where patient safety work product has been fully de-identified; and where disclosure is necessary to implement enforcement procedures by the secretary of CMS. Id. at Section 299b1-22(c) (2010).

> and before which patient safety work product is sought would adjudicate the application of the privilege protections of the Patient Safety Act [and that] the privileged protections will be enforced through the court systems....(73 Federal Register at 70771).
>
> On the subject of Preemption, the Preamble specifically states:
>
> While the Patient Safety Act does not preempt state laws that require providers to report information that is not patient safety work product, a state may not require that patient safety work product be disclosed (Id. at 70743, 70744). (Emphasis added).

Furthermore, in response to comments and questions concerning preemption, AHRQ and OCR stated that:

> Thus, the patient safety work product protections provided under the [Patient Safety Act] generally preempt state or other laws that would permit or require disclosures of information contained within patient safety work product. However, state laws that provide for greater protection of patient safety work product are not preempted and continue to apply (Id. at 70774).

In summary, the Patient Safety Rule preempts conflicting state law and specifically bars the Department's effort to force disclosure of Walgreens' medication error reports because they constitute protected patient safety work product.

### D. The Department's Additional Arguments that Walgreens' Medication Error Reports Are Not Protected Patient Safety Work Product Misinterpret the Patient Safety Rule.

To circumvent the Patient Safety Act, the Department claims that its subpoena encompassed a broader set of documents that are not protected patient safety information. The subpoena, however, only seeks reports concerning "incidents of medication error." The evidence presented by Walgreens in its Motion to Dismiss under Section 2-619 of the Code establishes that its medication error reports were collected as part of Walgreens' patient safety evaluation system and reported to The Patient Safety Research Foundation

pursuant to the Patient Safety Act. This is precisely the type of information and activity that the Patient Safety Act protects.

The Department next contends that Walgreens failed to show that the medication error reports, which are collected in the STARS reporting system, were "not created or used for any purpose other than reporting to a PSO" (Appellant's Brief at page 27). While the Department accurately notes that information "that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system" is not considered protected safety work product (Notice of Proposed Rule at 73 Federal Reporter at 8123, February 12, 2008), this rule has no application to this case. Walgreens' affidavits establish that (1) the STARS reports containing the subpoenaed medication error reports were collected as part of its patient safety evaluation system and transmitted to The Patient Safety Research Foundation; (2) Walgreens has no medication error reports beyond what is collected in the STARS system and reported to The Patient Safety Research Foundation; and (3) there are no such reports collected or maintained separately from the STARS reporting system. On these points, Ms. Hansen, Walgreens' Vice President, Pharmacy Services at Walgreens, certified that:

* * *

> 2. Walgreen's does not create, maintain, or otherwise have in its possession incident reports pertaining to medication error other than the STARS reports referenced in my original affidavit. There are no other incident reports pertaining to medication error that are collected or maintained separately from the STARS reporting system.
>
> 3. As previously stated, STARS reports generated by Walgreens pharmacies in Illinois are maintained for one year from the date they are reported to the Patient Safety Research Foundation, Inc. ("PSRF"). All existing STARS reports that are responsive to the Department's subpoena were reported to PSRF after the date of

certification (January 9, 2009) (See Supplemental Affidavit of Suzanne Hansen at A21 of Appellant's Brief).

The Department argues that Walgreens has not definitively proven that there are no other incident reports maintained outside of its patient safety evaluation system and that the STARS reports are used for other purposes and are therefore not protected under the Patient Safety Rule. The Department, however, submitted no competent evidence to rebut Ms. Hansen's sworn statements, and mere allegations and speculation are insufficient to defeat a Section 2-619 motion that is supported by competent evidence.[11]

The preamble to the final Patient Safety Rule also specifically states that while documentation of the patient safety evaluation system and what is considered patient safety work product may be useful for different purposes, AHRQ concluded that "we have not modified the proposed decision *to not require documentation*" (See Supplemental Affidavit of Suzanne Hansen at A21 of Appellant's Brief). According to AHRQ, a patient safety evaluation system does not need to be documented because it "exists whenever a provider engages in patient safety activities for the purpose of reporting to a PSO or a PSO engages in these activities with respect to information for patient safety purposes" (Id.).

The Department also asserts that if information is not "quarantined" in the Walgreens' patient safety evaluation system, or if it somehow appears in an employee's personnel file then it is not protected. (Appellant's Brief at page 28.) This ignores the clear language of the Patient Safety Rule. While patient safety work product must be used in a manner consistent with efforts to improve patient care, it need not be

[11] The Patient Safety Research Foundation "analyzes the information contained within the STARS reports to improve the quality of the prescription dispensing process." (Notice of Proposed Rule at 73 Federal Reporter at 8123, February 12, 2008.)

quarantined. In fact, the expectation is that medication error reports and other protected patient safety information will be analyzed, evaluated and discussed by and among employers and employees and the PSO so that the cause of an adverse patient event is better understood and future problems avoided. To prohibit the use of such information by and between a provider, its employees, consultants and others within Walgreens and The Patient Safety Research Foundation would completely undermine the intended purpose of the Patient Safety Act. Disclosure of patient safety work product for patient safety activities is specifically authorized under the Patient Safety Rule for, among other things, internal uses and business operations as well as between a provider and the PSO. (See Section 3.206(b)(4)). Thus, the Department's argument that patient safety work product must be quarantined to remain protected must fail.

The Department has presented no evidence to support its suggestion that Walgreens has disseminated the information beyond the bounds set by the Patient Safety Act. But, even if the STARS report had been placed in an employment file, this would be permissible under the Patient Safety Rule because the expectation is that the reports would lead to a pro-active learning opportunity for a pharmacist. Moreover, the Patient Safety Rule specifically provides that once a document is protected as patient safety work product, such as the STARS report, the protection cannot be waived (Section 3.208(a)).

Lastly, the Department argues that Walgreens must have responsive documents or information that is not protected by the Patient Safety Rule because in the case of Lindsay v. Walgreen Co., (No. 08- C-3547 (N.D. Ill. Aug. 19, 2009)), which involved an age discrimination complaint brought by a former Walgreens employee who was

terminated for poor performance, Walgreens introduced into evidence certain documents that detailed Ms. Lindsay's various performance problems, including medication errors.

This argument is misplaced. First, the documents produced in the Lindsay case were prepared in 2006, three years before The Patient Safety Research Foundation became certified in 2009. Second, even if Walgreens retained the documents produced in the Lindsay case until August 2009, there is no evidence that Walgreens still continues to maintain such reports for any of its employees, much less the three pharmacists in question. Third, the subpoena issued by the Department in this case requested only medication error reports, and not the types of documents introduced by Walgreens in the Lindsay case. Fourth, the affidavit of Suzanne Hansen specifically states that the only medication error reports Walgreens collects are the STARS reporting forms. (Id.) These reports were collected and reported to PSRF as part of Walgreens patient safety evaluation system, and are therefore privileged and protected patient safety work product.[12]

## II. Other Recent Health Care Legislation Bolsters The Need To Protect Patient Safety Information Such As The Medication Error Reports.

Health care services are unlikely to improve, and rapidly escalating costs are unlikely to be contained, unless all providers are able to engage in privileged and confidential analyses, debates and discussions designed to identify and remedy the causes of adverse patient outcomes *without* the "fear of liability, professional sanctions, or injury to their reputations." (73 Federal Register 70732 (November 21, 2008).) The Patient

[12] The Patient Safety Rule also contains a very detailed enforcement program to monitor compliance and to investigate complaints that violations of the confidentiality provisions have occurred, and includes extensive procedures which govern the administrative hearing procedures A confirmed violation can lead to the imposition of a civil monetary penalty. These provisions reflect the seriousness and importance that Congress placed on keeping patient safety work product protected.

Safety Act and the Patient Safety Rule provide the needed protections for patient safety information and are thus key elements in the effort to achieve quality outcomes and reduce costs, to meet the high expectations of patients and their families, and to comply with all legal obligations imposed on providers.

The importance of enforcing these protections is further demonstrated by recent health care reform legislation, such as the Patient Protection and Affordable Care Act ("Affordable Care Act"). This legislation represents the federal government's comprehensive mandate to expand health coverage and consumer choice for all citizens, enhance access to fundamental and necessary health care services and, most importantly, improve the quality and efficiency of these services. (42 U.S.C. Section 18001 et seq. (2011).) The Affordable Care Act is just one of the many examples of payors, be they private or public, requiring providers to improve care through the achievement of established quality benchmarks, as a condition of reimbursement.[13]

Congress has determined that the need to protect information used in a provider's patient safety evaluation system, so as to encourage and promote comprehensive patient safety activities, improve care and reduce adverse events, outweighs the Department's

[13] Under the Affordable Care Act, participating providers are expected to participate in a CMS certified accountable care organization ("ACO") in order to provide the complete continuum of health care services to an assigned Medicare patient organization. There are sixty-five quality measures set forth in the proposed ACO rules. These include, for example, whether appropriate discharge instructions have been given to patients who suffered heart failure or whether a certain drug was given to a patient suffering a heart attack within ninety minutes of their arrival to a hospital. To track and report on whether these measures and standards are achieved, providers will need to expand their existing quality assurance, performance improvement, risk management and peer review policies, treatment procedures and systems. These efforts, in turn, will generate a significant volume of highly sensitive patient safety information, much of which can be protected under the Patient Safety Act. ACOs, in fact, will be obligated to participate in PSOs when negotiating with the state insurance exchanges that are being set up to cover individuals and small employer groups.

desire to subpoena Walgreens' medication error incident reports. The Patient Safety Rule covers and protects all providers and PSOs who take advantage of the Rule.

The PSOs who join in this Amicus brief, as well as all other PSOs and their participating providers, will be affected by the ruling of this Court. A decision that does not hold that the Patient Safety Rule preempts conflicting state laws, or which determines that the scope of protection does not extend to the STARS reports collected within Walgreens' patient safety evaluation system, will seriously undermine provider efforts to improve health care services.

## Conclusion

For all of the foregoing reasons, this Court should affirm the trial court's decision.

Date: September 16, 2011

Respectfully submitted,

By: _____
One of the Attorneys for Amicus Curiae Clarity PSO, Society for Vascular Surgery Patient Safety Organization, The Midwest Alliance for Patient Safety, UHC Performance Improvement PSO, NC Center for Hospital Quality & Patient Safety, MHA Patient Safety Organization, California Hospital Patient Safety Organization, and Child Health Patient Safety Organization, Inc.

Michael R. Callahan
James W. Hutchison
**KATTEN MUCHIN ROSENMAN LLP**
525 West Monroe Street
Chicago, Illinois 60661
Tele: (312) 902-5200
Fax: (312) 902-1061
Firm ID 41832

## CERTIFICATE OF COMPLIANCE

I certify that this brief conforms to the requirements of Rules 341(a) and (b). The length of this brief, excluding the points and authorities, is 17 pages.

James W. Hutchison

60910636v1