No. 2-11-0452

IN THE
APPELLATE COURT OF ILLINOIS
SECOND JUDICIAL DISTRICT

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

BRIEF OF AMICI CURIAE AABB'S PATIENT AND DONOR SAFETY CENTER, ALLIANCE FOR PATIENT MEDICATION SAFETY, ANESTHESIA QUALITY INSTITUTE, CVS CAREMARK CORPORATION, INSTITUTE FOR SAFE MEDICATION PRACTICES, KENTUCKY INSTITUTE FOR PATIENT SAFETY AND QUALITY, MEDNAX PSO, LLC, NORTHERN METROPOLITAN PATIENT SAFETY INSTITUTE, QUALITY CIRCLE FOR HEALTHCARE, INC., TENNESSEE CENTER FOR PATIENT SAFETY, AND UNIVERSITY PATIENT SAFETY ORGANIZATION, LLC IN SUPPORT OF APPELLEE, WALGREEN CO.

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I. STATEMENT OF INTEREST

The subject matter of this appeal is the scope of the privilege afforded to incident reports defined as Patient Safety Work Product under the Patient Safety and Quality Improvement Act of 2005 (hereinafter the "PSQIA" or the "Act"). *See* Patient Safety and Quality Improvement Act, 42 U.S.C. §§ 299b-21, *et seq.* (2010).

The amici curiae are ten Patient Safety Organizations (hereinafter "PSO") and one provider.[1] The vast majority of the amici curiae are federally-certified PSOs whose existence, purpose, and continued viability are contingent upon preservation of the privilege and confidentiality protections of the PSQIA. Federally-listed PSOs are the only entities through which health care providers can obtain the privilege protections found under the PSQIA. 42 U.S.C. § 299b-21(7).

Allowing for the discovery of privileged incident reports created as part of a Patient Safety Evaluation System and provided to a PSO for the purpose of analyzing trends and errors in an effort to improve the quality of health care will strip PSOs of their ability to perform their review and analysis in a privileged setting deemed vital by Congress to improve patient safety and the quality of healthcare. Without such protection, the purpose of PSOs is wholly undermined.

This matter presents the first case in which a court will consider whether the materials the Department of Financial and Professional Regulation (hereinafter

[1] The amici curiae include AABB's Patient and Donor Safety Center; Alliance for Patient Medication Safety; Anesthesia Quality Institute; CVS Caremark Corporation; Institute for Safe Medication Practices; Kentucky Institute for Patient Safety and Quality; MEDNAX PSO, LLC; Northern Metropolitan Patient Safety Institute; Quality Circle for Healthcare, Inc.; Tennessee Center for Patient Safety; and University Patient Safety Organization, LLC.

"Department") seeks are privileged and confidential Patient Safety Work Product.[2] This lack of precedent makes the amici curiae's view all the more important as it offers a perspective different from an enforcement agency such as the Department and different from a provider such as Walgreen Co. (hereinafter "Walgreen"). In fact, the amici curiae are the only entities whose purpose will be abrogated in the event this Court overturns the trial court's decision.

[2] While no courts have yet addressed the privilege protections of the PSQIA substantively, several courts have touched upon the Act generally. *See Lee Medical, Inc. v. Beecher*, 312 S.W. 3d 515, 534-535 (Tenn. 2010) (questioning, but not deciding, whether PSQIA preempts state privilege); *KD ex. rel. Dieffenbach v. United States*, 82 Fed. R. Evid. Serv. 862, 2010 WL 2077002, *6 (D. Del. 2010) (recognizing PSQIA constituted a "shift in congressional policy" towards a federal peer review privilege); *Schlegel v. Kaiser Foundation Health Plan*, 2008 WL 4570619, *2-3 (E.D. Cal. 2008) (rejecting privilege claim under PSQIA); *Massi v. Walgreen Co.*, 2006 U.S. Dist. LEXIS 77893, *14-16 (E.D. Tenn. 2006) (same).

II. NATURE OF CASE

Petitioner-Appellant, the Department, issued three (3) subpoenas against Appellee Walgreen seeking "[a]ll incident reports of medication error" involving three named pharmacists. Walgreen objected based upon the privileges found under the PSQIA placing patient safety work product beyond the compulsion of administrative subpoena. The Department filed a petition in the Circuit Court, Lake County seeking to compel enforcement of the subpoenas. Walgreen successfully moved to dismiss the Department's petition under both the PSQIA and the Illinois Medical Studies Act. This appeal followed.

III. ISSUES PRESENTED FOR REVIEW

1. Whether the PSQIA (42 U.S.C. § 299b-21, *et seq*.) extends its privilege protections to pharmacy incident reports prepared by Walgreen for transfer to a federally-listed PSO rendering them immune from compelled disclosure through administrative subpoenas issued by the Department.

2. Whether the Department impermissibly seeks to expand the scope of the material sought in its subpoenas by asserting that employment performance records fall within the meaning of the phrase "incident reports of medication error."

3. Whether this Court need reach the trial court's ruling regarding the Illinois Medical Studies Act (735 ILSC 5/8-2101 (2010)) when the decision is controlled by the federal PSQIA.

IV. JURISDICTIONAL STATEMENT

On April 7, 2011, the circuit court issued an order granting Walgreen's Motion to Dismiss the Department's petition seeking to enforce compliance with its subpoenas. C00275. The Department timely filed its Notice of Appeal. This Court has jurisdiction to decide this appeal. Ill. Sup. Ct., R 301 (eff. February 1, 1994).

V. STATUTES INVOLVED

In relevant part, the Federal Patient Safety and Quality Improvement Act, 42 U.S.C. § 299b-22(a) (2010) provides:

> (a) Privilege
>
> > Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be privileged and shall not be –
> >
> > (1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;
> >
> > * * *
> >
> > (4) admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a 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. § 299b-21(7) (2010) provides:

> (7) Patient Safety Work Product.
>
> > (A) In general. Except as provided in subparagraph (B), the term "patient safety work product" means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—
> >
> > > (i) which—
> > >
> > > > (I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or
> > > >
> > > > (II) are developed by a patient safety organization for the

conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or

(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

(B) Clarification

(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

(ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

(iii) Nothing in this part shall be construed to limit—

(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

The Illinois Medical Studies Act, 735 ILCS 5/8-2101 (2010), provides, in relevant part:

> All information, interviews, reports, statements, memoranda, recommendations, letters of reference or other third party confidential assessments of a health care practitioner's professional competence … used in the course of internal quality control or of medical study for the purpose of reducing morbidity or mortality, or for

improving patient care or increasing organ and tissue donation, shall be privileged, strictly confidential and shall be used only for medical research, increasing organ and tissue donation, the evaluation and improvement of quality care, or granting, limiting or revoking staff privileges or agreements for services, except that in any health maintenance organization proceeding to decide upon a physician's services or any hospital or ambulatory surgical treatment center proceeding to decide upon a physician's staff privileges, or in any judicial review of either, the claim of confidentiality shall not be invoked to deny such physician access to or use of data upon which such a decision was based.

VI. STATEMENT OF FACTS

Pursuant to its statutory powers to license pharmacists and regulate the practice of pharmacy within the state, the Department issued three subpoenas on July 1, 2010 to Walgreen requiring the production of "[a]ll incident reports of medication error" involving three named pharmacists. C00006-C00010. On August 11, 2010, Walgreen objected to compliance with the subpoenas asserting that the requested materials were patient safety work product immune from compelled disclosure under the PSQIA. The Department overruled Walgreen's objections at the administrative level. C00003. Walgreen again refused to comply. *Id*.

The Department filed a Petition to Enforce the subpoenas in the Nineteenth Judicial Circuit, Lake County. C00001. Walgreen moved to dismiss the Petition because the responsive incident reports constituted patient safety work product under the PSQIA and, therefore, were privileged and protected from compelled disclosure by way of administrative subpoena. C00025. Walgreen further contended that the incident reports were protected under the Illinois Medical Studies Act. *Id*.

In support of its motion, Walgreen filed an affidavit and later a supplemental affidavit of Suzanne Hansen, Vice-President of Pharmacy Services at the company. C00115-C00119; C00179-C00180. In her affidavits, Ms. Hansen indicated that Walgreen did not maintain documents entitled "incident reports" pertaining to "medication errors." C00115 at ¶13. She swore, however, that Walgreen maintained a proprietary Strategic Tracking and Analytical Reporting System (hereinafter "STARS") to track and report improperly processed or filled prescriptions dispensed to customers. C00116 at ¶5. These STARS reports are forwarded to a federally-certified component

patient safety organization, The Patient Safety Research Foundation, Inc. Id. at ¶¶6, 7.

Appended to Ms. Hansen's original affidavit as an Exhibit was an exemplar of a STARS report form. C00119. The completed form includes information identifying the patient involved, detailing the prescription and describing the error. *Id.* The report includes a root cause analysis section and identifies factors contributing to the error. *Id.* The form calls for an "Improvement Plan" and "Suggestions for Improvement." *Id.* There can be no doubt that a STARS report is a report, including a root cause analysis, with the potential to improve patient safety which is developed by a provider to transfer to a patient safety organization. *See* 42 U.S.C. § 299b-21(7)(A)(i). In other words, STARS reports are patient safety work product under the PSQIA.

The Department filed an affidavit of Scott Golden, a Department agent, in opposition to the motion stating that, based upon his review of documents filed by Walgreen in an unrelated litigated employment matter, he believed that the company possessed materials other than the STARS reports responsive to the subpoena. C00222-C00224.

In granting Walgreen's motion to dismiss with prejudice, Judge Hall stated,

> Congress sought to encourage the reporting and analysis of medical errors in that one of its intentions was to help create a culture of safety by providing peer review protection for information reported on health carriers for the purpose of quality improvement and patient safety. The goal was that the Federal privilege that touches the PSQIA will provide protections that will enable all healthcare systems, including multi-facility healthcare systems, to share data within the protected legal environment.

Tr. 00026-00027. This appeal followed.

VII. STANDARD OF REVIEW

When ruling on a section 2–619 motion to dismiss, a court must interpret all pleadings and supporting documents in the light most favorable to the nonmoving party. *In re Marriage of Streur*, 2011 IL App (1st) 082326, ¶27 (citing *In re Chicago Flood Litigation*, 176 Ill. 2d 179, 189 (1997)). "This court's standard of review of a trial court's grant of a motion to dismiss pursuant to section 2–619 is de novo." *Id.* (citing *Parks v. Kownacki*, 193 Ill. 2d 164, 175, (2000)). However, "[a] dismissal order may be affirmed 'if it is justified in the law for any reason or ground appearing in the record regardless of whether the particular reasons given by the trial court, or its specific findings, are correct or sound.'" *Id.* (citing *BDO Seidman, LLP v. Harris*, 379 Ill. App. 3d 918, 923 (2008), quoting *Natural Gas Pipeline Co. of America v. Phillips Petroleum Co.*, 163 Ill. App. 3d 136, 142 (1987)).

VIII. ARGUMENT

A. The History, Enactment and Operation of the PSQIA

1. The History and Enactment of the PSQIA

In 1999 the Institute of Medicine (hereinafter "IOM") published its seminal work *To Err is Human*. Extrapolating from two studies examining error rates in hospitals, the IOM estimated that between 44,000 and 98,000 patients die in hospitals each year due to medical errors. Institute of Medicine, *To Err is Human: Building A Safer Health System,* p. 1 (National Academy Press 1999). The IOM intended the report "to stimulate a national effort to improve patient safety" through expanded reporting of adverse events and errors, the development of safety protocols within various health care organizations and "intensified efforts" by health care professionals. L. Leape, M.D., *Institute of Medical Error Figures Are Not Exaggerated*, Journal of the American Medical Association, Vol. 284, No. 1., p. 95 (2000). Within two weeks of the IOM report's publication, Congress began hearings in order to determine the best ways to implement the IOM's recommendations. *Id*. These hearings culminated in the passage and enactment of the PSQIA.

Based upon the IOM report, Congress concluded that state mandatory reporting systems, focusing upon sanctions, had failed to promote patient safety. S. 544, 109th Cong. § 2(a), (6), (9) (2005) (enacted). In passing the PSQIA, Congress intended to improve the quality of patient care by creating a "culture of safety" by providing peer review protections for a wide variety of health care providers on a national basis. H.R. Rep. No. 109-197, at 9; S. 544, 109th Cong. §§ 2(b)(1), (b)(2).

In arriving at its solution, Congress had to balance at least three competing interests. First was the desire of Congress itself to create a "learning environment" in which health care professionals would be encouraged to 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 (2003). Second was the need on the part of patients harmed through medical negligence to have access to health care information equal to that which they possessed before PSQIA in order to seek redress for their injuries. S. Rep. No. 108-196, at 7. Third was the long-recognized, legitimate interest on the part of states to regulate health care professionals practicing within their borders. H.R. Rep. No. 109-197, at 14, 16-17; S. Rep. No. 108-196, at 8.

2. Operation of the Privilege and Confidentiality Protections of PSQIA

Throughout the legislative process in enacting PSQIA, Congress sought to achieve its goals by creating a "system and process – separate from, and parallel to, complementary state, federal and local laws and regulations designed to ensure accountability." S. Rep. No. 108-196, at 3. This philosophy was carried through the PSQIA and its regulations. *See* The Patient Safety and Quality Improvement Act, 73 Fed. Reg. 70,732, 70,742 (November 21, 2008) ("The Patient Safety Act establishes protected space or system that is separate, distinct, and resides alongside but does not replace other information collection activities mandated by laws, regulations and accrediting and licensing requirements as well as voluntary reporting activities that occur for the purposes of maintaining accountability in the health care system."). At the core of this system are three elements: patient safety work product, patient safety organizations,

and privilege and confidentiality protections. Under the PSQIA, patient safety work product is subject to strong privilege and confidentiality provisions prohibiting compelled and voluntary disclosures, with narrow exceptions. Among those protections is the freedom of patient safety work product from compelled disclosure through administrative subpoenas, such as those issued by the Department here. 42 U.S.C. § 299b-22(a)(1).

"Patient Safety Work Product" is broadly defined[3] but essentially means any information, data or report, whether in written or verbal form, which has the potential to improve patient safety, and, with few exceptions,[4] is transferred, whether physically, electronically, or "functionally",[5] to a patient safety organization. Falling outside the definition, and therefore ineligible for protection as patient safety work product, are original patient and provider records [6] and "information which is collected, maintained or developed, or exists separately, from a patient safety evaluation system."[7] 42 U.S.C. § 299-21(7)(B)(ii).

The exclusion of original patient and provider records fulfills Congress's promise to maintain access to the evidence patients injured through professional negligence need to support their allegations. Congress's intent has always been to ensure that the statute's protections "do not extend backward to the underlying factual information contained

[3] 42 U.S.C. § 299b-21(7) set forth in Section V *supra*.
[4] *Id.* § 299b-21(7)(A)(ii) (There is no statutory or regulatory requirement that documents, data and the like which "identify or constitute the deliberations or analysis of or identify the fact of reporting pursuant to, a patient safety evaluation system" need be transferred to a PSO in order to receive the statutory benefits.).
[5] Neither the statute nor the regulations dictate that a particular method of reporting be used. They are broadly written to permit alternative methods of reporting. *See* The Patient Safety and Quality Improvement Act, 73 Fed. Reg. at 70,741 ("Functional reporting" means authorizing a PSO access to specific patient safety work product with the ability to process and analyze the information "comparable to the authority a PSO would have if the information were physically transferred to a PSO."). PSOs employing functional reporting are still required to maintain adequate security control over the information to which they are granted access. 42 C.F.R. § 3.106(b)(4)(ii) (2008).
[6] 42 U.S.C. § 299b-21(7)(B)(i).
[7] A "patient safety evaluation system" is simply "the collection, management, or analysis of information for reporting to or by a patient safety organization." 42 U.S.C. § 299b-21(6).

within or referred to in the patient safety data reported to a PSO." S. Rep. No. 108-196, at 5. The medical error is not privileged; the analysis of it by or for the provider in collaboration with the PSO receives the statutory protections. H.R. Rep. No. 109-197, at 15; S. Rep. No. 108-196, at 5; *See* The Patient Safety and Quality Improvement Act, 73 Fed. Reg. at 70,743. Plaintiffs retain the panoply of rights which they had before the passage of PSQIA. H.R. Rep. No. 109-197, at 9; *See* The Patient Safety and Quality Improvement Act, 73 Fed. Reg. at 70,732.

PSOs are entities, listed as qualified by the Secretary of the United States Department of Health and Human Resources, made up of medical and other professionals whose mission and primary activity are to conduct activities designed to improve patient safety and the quality of health care delivery. 42 U.S.C. § 299b-24(b)(1)(A). PSOs must utilize patient safety work product to advise and assist health care providers to minimize patient risk. *Id*. § 299b-24(b)(1)(G). They are to offer "expert advice in analyzing patient safety events … to provide feedback and recommendations to providers." The Patient Safety and Quality Improvement Act, 73 Fed. Reg. at 70,733. It is only through association with a PSO that a health care provider can obtain the privilege and confidentiality protections of the PSQIA. 42 U.S.C. § 299b-21(7).

In regard to privilege, PSQIA places patient safety work product beyond federal, state, or local civil, criminal, and administrative agency subpoena power. *Id*. § 299b-22(a)(1). The privilege excludes such materials from discovery in any civil, criminal, or administrative proceedings, including disciplinary proceedings against a provider. *Id*. § 299b-22(a)(2). The privilege removes patient safety work product from the ambit of the Freedom of Information Act and any other similar federal, state, or local law. *Id*. § 299b-

22(a)(3). It excludes materials sheltered under its umbrella from admission as evidence in any civil, criminal, or administrative rulemaking or adjudicatory proceeding. *Id.* § 299b-22(a)(4). Finally, the privilege excludes patient safety work product from admission before disciplinary bodies existing pursuant to state law. *Id.* § 299b-22(a)(5). The confidentiality provision prohibits disclosure of patient safety work product unless the release of information falls within one of the enumerated exceptions. *Id.* § 299b-22(b)(1), (b)(2).

Once disclosed, whether permissibly or impermissibly, patient safety work product retains its privileged and confidential nature with two notable exceptions. 42 C.F.R. § 3.208(a). Those exceptions are when patient safety work product is disclosed for use in a criminal proceeding as set forth in PSQIA or when non-identifiable patient safety work product is disclosed. *Id.* § 3.208(b)(1), (2). The statute is explicit that "the privileged and confidential nature of [the disclosed] work product" continues to "apply to such work product in the possession or control of a person to whom such work product is disclosed." 42 U.S.C. § 299b-22(d)(1). Unlike waiver of the attorney-client privilege in the litigation context where disclosure of a single communication can waive the privilege as to all communications on the same subject matter,[8] only the protection applicable to the work product actually disclosed is lost or limited under PSQIA. *Id.* § 299b-22(d)(3).

It is against this legislative backdrop that the Department issued its subpoenas.

B. The Patient Safety and Quality Improvement Act of 2005 Preempts the State of Illinois Subpoena Power When Seeking Patient Safety Work Product

In accordance with the Supremacy Clause of the United States Constitution, a

[8] *Goldman, Sachs & Co. v. Blondis*, 412 F. Supp. 286, 288 (N.D. Ill. 1976); *Newton v. Meissner*, 76 Ill. App. 3d 479, 498-99 (1979); WEINSTEIN & BERGEN, WEINSTEIN'S FEDERAL EVIDENCE § 503.41(1) (Joseph M. McLaughlin ed., 2010) (collecting cases).

state law that conflicts with a federal statute is preempted. U.S. Const. Art. VI cl. 2. There are two types of federal preemption: express and implied. *Altria Group, Inc. v. Good*, 555 U.S. 70, 76-77, 129 S. Ct. 538, 543, 172 L. Ed. 2d 398, 405 (2008). Express preemption occurs when the federal statute indicates by its terms that state law is superseded. *Id*. Where the Congressional act contains an express preemption clause, the court must still discern its meaning and define its scope. *Id.*

The preemptive language of PSQIA is found within its privilege and confidentiality provisions. 42 U.S.C. §§ 299b-22(a), (b). Both the privilege and confidentiality provisions begin with the preamble: "Notwithstanding any federal, state or local law, and subject to [the exceptions of] subsection (c)," patient safety work product is declared privileged or confidential as the case may be. *Id*. This preemptory language clearly indicates that the provisions which follow supersede all other sources of law as they relate to the discoverability, using the broad sense of the word, of patient safety work product. If there is to be any room for state regulation, at least as it relates to patient safety work product, Congress would have to insert provisions salvaging the states' powers to do so. The state regulators' salvation is found in the definition of patient safety work product itself, excluding certain information from its protective confines, and 42 U.S.C. 299b-22(g), preserving state laws affording patient safety work product greater privilege and confidentiality protections than the PSQIA.

The PSQIA expressly places patient safety work product beyond the reach of Illinois' administrative subpoena power. 42 U.S.C. §§ 299b-22(a)(1). The record shows that the STARS reports were created by Walgreen to transfer to a PSO, were transferred to a PSO, and have the potential to improve patient safety, health care quality or health

care outcomes. *See* C00115-C00119, C00179-C00180. Therefore, they constitute patient safety work product under the PSQIA. *See* 42 U.S.C. § 299b-21(7)(A)(i).

C. Walgreen's STARS Reports are Privileged Patient Safety Work Product Under the Patient Safety and Quality Improvement Act of 2005, (42 U.S.C. § 299b-21 (2010)) Immune from Compelled Discovery Through Administrative Subpoena

The Department asserts that patient safety work product "*also* maintained separately from a patient safety evaluation system" loses its privileged status. Brief of Petitioner/Appellant at p. 26 (emphasis added). The Department contends that Walgreen's STARS reports are not patient safety work product because "a document used for multiple purposes and appearing in multiple locations is not patient safety work product." *Id*. Unless "quarantined" from other provider records, the Department argues, either the protections never attach or are waived. *Id*. Further, the Department claims that the record "does not show that [the STARS reports] are maintained and utilized for the sole purpose of reporting events to a PSO." Brief of Petitioner/Appellant, p. 27.[9] Such arguments reflect a fundamental misunderstanding of the definition of patient safety work product and the concept of waiver under the PSQIA.

The statutory language relied upon by the Department declaring information which is "collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system" as being outside the definition of patient safety work

[9] The Department asserts that "an incident report of medication error" must be reported to a PSO in order to be subject to the privilege and confidentiality protections under the PSQIA. Brief of Petitioner/Appellant, pp. 25-26. While undoubtedly true for information falling within 42 U.S.C. § 299b-21(7)(A)(i), no such transfer requirement exists for information described in 42 U.S.C. § 299b-21(7)(A)(ii). The two clauses are joined by the conjunction "or." Thus, reports identifying or constituting the deliberations or analysis of a provider's patient safety evaluation system need not be reported to a PSO in order to be protected from disclosure under the PSQIA. Given the Department's argument for a broad interpretation of the phrase "[a]ll incident reports of medication error" appearing in its subpoenas, the distinction is worth noting.

product does not, and was never intended to, mean that patient safety work product located outside a patient safety evaluation system is no longer protected. The information referred to in the quoted passage is information which never was patient safety work product in the first place, as made clear by the second sentence of the subpart. 42 U.S.C. § 299b-21(7)(B)(ii) ("*Such separate information* or copy thereof reported to a PSO shall not by reason of its reporting be considered patient safety work product.") (emphasis added). Nowhere does the statute or regulation suggest that patient safety work product "also" kept outside a patient safety evaluation system loses its privileged nature. From the outset, Congress intended this language to preserve state reporting requirements. Sen. R. 108-196, p. 9 (November 17, 2003) ("Conversely, information covered under state reporting laws falls outside the definition of patient safety data because such information is 'collected or developed separately from and that exists separately from patient safety data * * *.'")

The focus is upon the *purpose* for which the information is collected, not the place wherein the information is stored. When considering the meaning of a statute or regulation, a reviewing court must give substantial weight and deference to the interpretation placed on a statute or regulation by the agency charged with its administration and enforcement. *McDougall v. White*, 355 Ill. App. 3d 483, 486 (2005). The Department of Health and Human Services, the agency charged with the administration of the PSQIA, makes clear in its official comments to the statute and regulations that the purpose for which the information is created or collected is the central concern. *See* The Patient Safety and Quality Improvement Act, 73 Fed. Reg. at 70,739 (In order to be patient safety work product "[a]ny information must be collected or

developed for the purpose of reporting to a PSO."); *see also id.* at 70,742-743 ("Information is not patient safety work product if it is collected to comply with external obligations, such as: state incident reporting requirements, adverse drug event reporting to the Food and Drug Administration (FDA); certification or licensing records for compliance with health oversight agency requirements …"). A patient safety evaluation system is merely "the mechanism through which information can be collected, maintained, analyzed and communicated." Id. at 70,738. The system need not be documented or formalized but "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*. While documentation of a patient safety evaluation system is considered a "best practice," it was not mandated by the Secretary or Congress. *Id.*

The Department's position that patient safety work product located outside a patient safety evaluation system loses its privileged and confidential nature would turn the notion of "disclosure" on its head. A "disclosure" is the release or transfer of information from the holder of the patient safety work product to an outside person or legally separate entity. 42 C.F.R. § 3.20. Once the material is sent to a third person or entity other than the PSO, the information is no longer within the provider's patient safety evaluation system. Yet both the statute and regulations indisputably extend the PSQIA's privilege and confidentiality protections to the patient safety work product in the hands of the party to whom the information was disclosed. 42 U.S.C. § 299b-22(d)(1); 42 C.F.R. § 3.208(a); *see also* 42 C.F.R. § 3.20 (extending statute's

confidentiality obligations to a "responsible person," an individual, other than the provider or PSO, having custody of the patient safety work product.)

Nothing in the PSQIA requires that information created, collected and maintained for reporting to a PSO be segregated from information used to satisfy state reporting requirements. The official comments to the regulations prove that segregation of patient safety work product from other information is not mandated under the statute.

> Information may also become patient safety work product upon collection within a patient safety evaluation system. Such information may be voluntarily removed from a patient safety evaluation system if it has not been reported and would no longer be patient safety work product. **As a result, providers need not maintain duplicate systems to separate information to be reported to a PSO from information that may be required to fulfill state reporting obligations.** All of this information, collected in one patient safety evaluation system, is protected as patient safety work product unless the provider determines that certain information must be removed from the patient safety evaluation system for reporting to the state.

The Patient Safety and Quality Improvement Act, 73 Fed. Reg. at 70,742 (emphasis supplied).[10]

The privileged nature of the patient safety work product is not vitiated because it is used internally for purposes other than patient safety activities. Only "disclosures" to outside entities are regulated under the PSQIA. Internal sharing of information, termed a "use" by the Secretary, is unregulated. *Id.* at 70,736. Providers are simply admonished "to prudently manage the internal sharing of sensitive patient safety work product." *Id.*

[10] The regulations do require that patient safety work product maintained by component patient safety organizations, such as the Patient Safety Research Foundation, be segregated from the records of its parent organization and that any disclosures to the parent fall within one of the statutory confidentiality exceptions. 42 C.F.R. § 3.102(c)(2)(i),(ii). Here only Walgreen's handling of the patient safety work product is at issue, not the practices of its component PSO.

Finally, the Department's position regarding waiver of the privilege is simply wrong. The penalty for an improper disclosure is financial, not waiver of the privilege. 42 U.S.C. § 299b-22(f)(1). Whether patient safety work product is disclosed properly or improperly, the privilege and confidentiality protections remain. 42 C.F.R. § 3.208(a). Assuming, without conceding, that Walgreen improperly disclosed or maintained the STARS reports, they would still be beyond the subpoena power of the Department.

The affidavits submitted by Vice-President Hansen are not inadequate because they unequivocally establish that the STARS reports are patient safety work product. The conditions the Department seeks to place upon such materials in order to maintain their privileged nature simply do not exist under the PSQIA. The production of the STARS reports cannot be compelled by subpoena. 42 U.S.C. § 299b-22(a)(1).

D. The Department Impermissibly Seeks to Extend the Scope of Its Subpoena by Urging a Broad Interpretation of the Phrase "Incident Reports of Medication Error"

A subpoena must fairly describe the material it seeks. *People v. Smith*, 237 Ill. App. 3d. 901, 906 (1992). A subpoena that is too general in its terms and overly broad in its demand is improper. *People v. Lurie*, 39 Ill. 2d 331, 335 (1968). The subpoenas at issue called for "*certain* documents and records" to be produced which were described as "[a]ll incident reports of medication error involving" three pharmacists. (emphasis added). They sought no other materials. By statute, the Department's subpoena power is to be exercised "in the same manner as prescribed by law in judicial proceedings in civil cases in circuit courts of this State." Illinois Pharmacy Practice Act, 225 ILCS 85/35.5 (2011). In judicial proceedings, subpoenas must be "*limited* to the production of

specified documents, objects, or tangible things." Ill. 19th J. Cir. R. 3.09(A) (emphasis added); *see also* Ill. R. Civ. P. 204(a)(4).

In the affidavit supporting Walgreen's Motion to Dismiss, Suanne Hansen, Vice-President of Pharmacy Services, clearly states that the only "incident reports" responsive to the subpoenas are the STARS reports. C00129-C00130 ¶¶3, 5; C00179 ¶12. In opposition, the Department filed an affidavit of Scott Golden, an agent for the Department, who reviewed certain documents filed by Walgreen in 2009 in a litigated employment action, *Lindsey v. Walgreen Co.* C00222-C00224. Mr. Golden implies that the *Lindsey* documents were of a type responsive to the subpoena. Id. In a supplemental affidavit, Ms. Hansen noted that no STARS reports were produced in *Lindsey*. C00180.

Rather than issue additional subpoenas calling for the production of materials of the type filed in *Lindsey*, the Department chose to contend that this type of material falls within the scope of the phrase "incident reports of medication error." Even a cursory examination of the *Lindsey* materials shows them not to constitute incident reports as that term is understood in the practice of pharmacy. Such reports typically seek the name of the pharmacy, staff members involved, type of medication error, cause of injury and nature of injury. *See* 247 Mass. Code. Regs. 6.14, 6.14(1)(c) ("Pharmacy Report of Improper Drug Dispensing Resulting in Serious Injury or Death"); 21 N.C. Admin. Code. 46.2502(l) ("Incident Report"); 22 Tex. Admin. Code. § 281.18 ("Board of Pharmacy Professional Liability Claim Report Form"); *see also* N.Y. Comp. Codes R. & Regs. tit. 10, § 405.8(b)(1) (2010). Instead, these documents relate to the employee pharmacist's job performance.

The first document is a "Pharmacy Manager Performance Review" which, as the title suggests, contains an evaluation of the subject pharmacist's work performance. C00225-C00229. Included in the evaluation is the pharmacist's success in achieving sales growth, overseeing pharmacy staff, providing customer service and supporting community relations goals. C00225-C00226. The preparation of two peer review reports is referenced but no incidents are described anywhere in the document. C00225.

The next document entitled "Case Inquiry Report" does not deal with a medication error but the failure of the pharmacist to adhere to store policies. C00230-C00233. The document is a summary of written statements prepared by pharmacy staff members about Pharmacist Lindsey. This document describes Lindsey's failure to adhere to Walgreen's policies by neglecting to document emergency refills, modifying prices and substituting one form of medication for another. Admittedly, the summary contains references to the pharmacist committing errors and not completing a STARS report in violation of Walgreen's policies but such an assertion verifies the absence of a report. Neither the summary nor any of the handwritten statements provide detail with regards to any of the alleged medication errors, as is typically found in pharmacy incident reports. *See*, C00233-C00243.

In short, none of the *Lindsey* documents are of the type describing and/or analyzing a medication error typically seen in pharmacy incident reports. They cannot be fairly characterized as "incident reports of medication error" responsive to the subpoenas. The Department should be required to issue new subpoenas describing the documents it actually seeks while permitting Walgreen to meet the demand with any appropriate objection.

E. This Court Need Not Render a Decision Regarding the Illinois Medical Studies Act Because the Case is Controlled by the Federal PSQIA

An appellate court may affirm a trial court's decision on any basis, even one upon which the trial court did not rely in rendering its decision. *Leonardi v. University of Chicago*, 168 Ill. 2d 83, 97 (1995); *Bell v. Louisville & Nashville R.R. Co.*, 106 Ill. 2d 135, 148 (1985); *see Werner v. Botti, Marinaccio & DeSalvo*, 205 Ill. App. 3d 673, 679 (1990). Because the PSQIA applies and controls, this Court can affirm on that ground alone. The trial court created no binding precedent in ruling upon the Medical Studies Act.

The PSQIA preempts any state law providing lesser protection for patient safety work product. 42 U.S.C. § 299b-22(g)(1). If the Medical Studies Act applies, but provides lesser protection than the PSQIA, the PSQIA preempts the Medical Studies Act and the subpoenaed materials remain beyond the reach of the Department. If the Medical Studies Act provides greater protection than the PSQIA, then the subpoenaed materials remain beyond the reach of the Department. In order to prevail, the Department must first carry the day on the PSQIA.

Should the Court believe it necessary to render a decision on the Medical Studies Act, the *amici curiae* adopt the arguments raised by Walgreen in its brief.

IX. CONCLUSION

For the reasons set forth, the *amici curiae* respectfully request that the trial court's order granting Walgreen Co.'s Motion to Dismiss be **AFFIRMED**.

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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 pages containing the Rule 341(d) cover, the Rule 341(h)(1) statement of points and authorities, the Rule 341(c) certificate of compliance, and the certificate of service, is 26 pages.

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STATE OF ILLINOIS)
) SS.
COUNTY OF COOK)

PROOF OF SERVICE

The undersigned, being first duly sworn upon oath, deposes and states that three (3) copies of the foregoing **BRIEF OF AMICI CURIAE AABB'S PATIENT AND DONOR SAFETY CENTER, ALLIANCE FOR PATIENT MEDICATION SAFETY, ANESTHESIA QUALITY INSTITUTE, CVS CAREMARK CORPORATION, INSTITUTE FOR SAFE MEDICATION PRACTICES, KENTUCKY INSTITUTE FOR PATIENT SAFETY AND QUALITY, MEDNAX PSO, LLC, NORTHERN METROPOLITAN PATIENT SAFETY INSTITUTE, QUALITY CIRCLE FOR HEALTHCARE, INC., TENNESSEE CENTER FOR PATIENT SAFETY, AND UNIVERSITY PATIENT SAFETY ORGANIZATION, LLC** were served on the below-named individuals on September 12, 2011, by depositing such copies in the United States mail at 225 W. Wacker Drive, Chicago, Illinois, before 5:00 p.m., in envelopes bearing sufficient postage.

Edward D. Rickert Mark W. Bina KRIEG DeVAULT LLP 30 North LaSalle Street, #3516 Chicago, IL 60602 Attorney for Respondent-Appellee Walgreen Co.	Lisa Madigan Attorney General State of Illinois Michael A. Scodro Solicitor General Clifford W. Berlow Illinois Assistant Attorney General 100 W. Randolph Street, 12th Floor Chicago, IL 60601 Attorneys for Petitioner-Appellant Illinois Department of Financial and Professional Regulation.

SUBSCRIBED and SWORN to before
me this 12th day of September, 2011.

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NOTARY PUBLIC

APPENDIX

TABLE OF CONTENTS TO APPENDIX

DESCRIPTION OF AMICI CURIAE

1. AABB Patient and Donor Safety Center
8101 Glenbrook Road; Bethesda, MD 20814-2749

AABB's Patient and Donor Safety Center is a component PSO of the American Association of Blood Banks, a 501(c)(3) organization and is not publicly traded.

AABB's Patient and Donor Safety Center (PDSC) is dedicated to confidentially analyzing data on adverse reactions and incidents associated with blood transfusions. The mission of the PDSC is to foster a culture of safety and quality in the practice of transfusion medicine and cellular and related biological therapies that advances evidence-based medicine and enhances outcomes nationwide.

2. Alliance for Patient Medication Safety
2530 Professional Road, Suite 202; Richmond, VA 23235

The mission of the Alliance for Patient Medication Safety (APMS) is to foster a culture of quality within the profession of pharmacy that promotes a continuous systems analysis to develop best practices that will reduce medication errors, improve medication use and enhance patient care. APMS is a Patient Safety Organization that provides a variety of patient safety services to healthcare providers, but most specifically to pharmacists working in community pharmacy practice settings.

3. Anesthesia Quality Institute
520 North Northwest Highway; Park Ridge, IL 60068

The Anesthesia Quality Institute (AQI) is a non-profit related-organization of the American Society of Anesthesiologists, created to improve patient safety in the perioperative period. The AQI maintains the National Anesthesia Clinical Outcomes Registry and the Anesthesia Incident Reporting System. Both of these nationwide registries capture information about anesthesia care on an ongoing basis. The AQI uses data from these registries to provide benchmarked quality management reports to participating practices, to identify common trends in anesthesia adverse events, and to create educational materials based on unique cases and unusual events. The AQI has been a Patient Safety Organization since September 2010, and could not perform its mission without this important certification.

4. CVS Caremark Corporation
One CVS Drive; Woonsocket, RI 02895

CVS Caremark Corporation is a publicly-traded holding company whose subsidiaries operate more than seven thousand retail pharmacies across the United States. These subsidiaries have contracted with patient safety organizations in order to improve patient safety and the quality of the delivery of care.

5. Institute for Safe Medication Practices
200 Lakeside Drive, Suite 200; Horsham, PA 19044

The Institute for Safe Medication Practices (ISMP) is a 501(c)(3) organization formed to educate healthcare practitioners and institutions, regulatory agencies, professional organizations, consumers and industry professionals about adverse drug events and their prevention. Its multidisciplinary staff of pharmacists, nurses, pharmacy technicians and physician medical director review all medication error reports submitted by practitioners to the ISMP National Medication Errors Reporting Program (MERP). ISMP is an FDA MEDWATCH partner and regularly communicates with the FDA to help to prevent medication errors. ISMP is a federally-certified Patient Safety Organization (PSO).

6. Kentucky Institute for Patient Safety and Quality
2501 Nelson Miller Parkway; Louisville, KY 40223

The Kentucky Institute for Patient Safety and Quality (KIPSQ) is a component entity of the Kentucky Hospital Association and serves as a certified Patient Safety Organization to hospitals, health systems, and their related organizations.

7. MEDNAX PSO, LLC
1301 Concord Terrace; Sunrise, FL 33323

MEDNAX PSO, LLC is a federally-listed PSO. MEDNAX PSO, L.L.C. is affiliated with a publicly traded company, MEDNAX, Inc.

8. Northern Metropolitan Patient Safety Institute
400 Stony Brook Court; Newburgh, NY 12550

The Northern Metropolitan Patient Safety Institute works with 22 hospitals in the seven counties north of New York City to support their steadfast commitment to safe, high quality and effective care for the nearly 3 million residents of the region. Each safety initiative has a working group/committee co-chaired by a medical director and nurse specialist. The focus is on analysis of work patterns to identify vulnerabilities to patient safety and high quality care, and specific areas needing change in order to achieve the improvement goals and then developing tool kits for hospital use in implementing change, and measuring outcomes.

9. Quality Circle for Healthcare, Inc.
111 North Orlando Avenue; Winter Park, FL 32789

Quality Circle for Healthcare, Inc. is a federally-listed component Patient Safety Organization staffed by five professionals who are assisted by qualified shared staff exclusively serving the hospitals and other healthcare providers of Adventist Health System. Quality Circle for Healthcare, Inc. is a not-for-profit 501(c)(3) entity and is not owned or controlled by a publicly traded entity.

10. Tennessee Center for Patient Safety
500 Interstate Blvd. South; Nashville, TN 37210

The Tennessee Center for Patient Safety, through its federally-listed Patient Safety Organization, assists Tennessee hospitals and health systems in providing the safest, highest quality healthcare to patients. The PSO is designed to encourage collaboration among hospitals by providing secure methods for the hospitals to share, analyze and learn from patient safety events and near misses to reduce or eliminate patient harm on a wide-scale basis throughout the state.

11. University Patient Safety Organization, LLC

University Patient Safety Organization is an independent privately held Patient Safety Organization located in Providence, Rhode Island with a primary focus on medication error management for retail, specialty, mail order, long term care and hospital pharmacy providers. University Patient Safety Organization is a privately held limited liability company.