IN THE SUPREME COURT OF PENNSYLVANIA
MIDDLE DISTRICT

No. 418 MAL 2020, 419 MAL 2020, 420 MAL 2020, 421 MAL 2020, 422 MAL 2020

SUSAN UNGURIAN, individually and as guardian of JASON UNGURIAN, an incapacitated person
v.
ANDREW BEYZMAN, M.D., ROBERT CURRY, CRNA, NORTH AMERICAN PARTNERS IN ANESTHESIA (PENNSYLVANIA), INDIVIDUALLY and d/b/a NAPA, WILKES BARRE HOSPITAL COMPANY, LLC, INDIVIDUALLY and d/b/a WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTHCARE SYSTEM, COMMONWEALTH HEALTH AND/OR COMMONWEALTH HEALTH SYSTEM, COMMONWEALTH HEALTH SYSTEMS INC., INDIVIDUALLY and d/b/a WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTHCARE SYSTEM, COMMONWEALTH HEALTH AND/OR COMMONWEALTH HEALTH SYSTEM

BRIEF OF *AMICI CURIAE* ALLIANCE FOR QUALITY IMPROVEMENT AND PATIENT SAFETY, ECRI INSTITUTE PSO, CASSATT PATIENT SAFETY ORGANIZATION, THE GUTHRIE CLINIC PSO, MCIC VERMONT PSO, AND DAVITA PATIENT SAFETY ORGANIZATION IN SUPPORT OF THE PETITION FOR ALLOWANCE OF APPEAL

Petition for Allowance of Appeal from the Order of the Superior Court entered April 28, 2020 at Nos. 298 MDA 2019, 300 MDA 2019, 722 MDA 2019, 949 MDA 2019, and 950 MDA 2019

Robin Locke Nagele, Esq. (36992)
Elizabeth M. Hein, Esq. (314096)
Post & Schell, P.C.
1600 J.F.K. Blvd., Four Penn Center
Philadelphia, PA 19103-2808
Ph: (215) 587-1000/Fax: (215) 320-4702
Counsel for *Amici Curiae* Alliance for Quality Improvement and Patient Safety, ECRI Institute PSO, Cassatt Patient Safety Organization, The Guthrie Clinic PSO, MCIC Vermont PSO, and DaVita Patient Safety Organization

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B: Opinion issued by the Court of Common Pleas of Luzerne County dated August 14, 2019.

C: Statement of Interest of the United States, *Lawrence Brawley v. Donald A. Smith, M.D., et.al.*, Case No. 17-CA-000119 (Fla. 13th Cir. Ct.).

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I. INTRODUCTION

This case presents this Court with its first opportunity to interpret the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §§ 299b-21-26 ("PSQIA") and to correct an artificially constricted interpretation of the scope of the federal privilege for Patient Safety Work Product ("PSWP") articulated by the courts below. The PSQIA is a federal statute enacted to create a national learning system based on the voluntary sharing of information by providers, made possible by a privilege, so that providers and federally certified Patient Safety Organizations (PSOs) can share quality and safety information without fear that it will be used against providers in litigation. The PSQIA's strict, preemptive privilege for PSWP creates a protected zone where systemic, critical analysis of safety events can take place that will lead to better systems of care. The privilege is the foundation for the Congressional goal of transformational change in the quality of care provided to patients across the nation.

In the decision below, the Superior Court held that two documents – an Event Report and a Root Cause Analysis ("RCA") – were not privileged PSWP, despite the uncontroverted evidence that both documents fit squarely within the definition of PSWP, having been created and maintained within the Petitioner's Patient Safety Evaluation System

("PSES") for reporting to its PSO, and duly reported. The Event Report and RCA constitute quintessential PSWP, and the application of the PSQIA should have been straightforward. But, the Superior Court held otherwise, based on an apparent misreading of the factual record, and a misinterpretation of the key definitional provisions of the term "PSWP." The Court seemed to apply a "sole purpose" analysis, failing to appreciate that once a document is developed within a PSES and reported to a PSO it does not lose its status as PSWP, regardless of subsequent uses or disclosures. The lower court also failed to recognize that a provider's own internal analysis, such as the analysis that is performed as part of a RCA, is PSWP from inception and irrespective of reporting to the PSO or any other use to which it is put.

The Superior Court's interpretation of the PSQIA was unsupported by the statute and its regulations. If allowed to stand, it would engender an unduly restrictive interpretation of the PSQIA by Pennsylvania lower courts that would, in effect, eviscerate this important federal privilege protection in the Commonwealth. In this case of first impression, this Court should intervene to correct the Superior Court's error and provide much needed guidance regarding the scope of the federal privilege for PSWP. *See* Pa.R.A.P. 1114(b)(3). Recognition of the full scope of the PSQIA privilege

is a matter of substantial public importance. Pa.R.A.P. 1114(b)(4). The success and feasibility of the national learning system envisioned by Congress depends on the privilege.

II. IDENTIFICATION AND INTEREST OF *AMICI CURIAE*

The Alliance for Quality Improvement and Patient Safety ("AQIPS") is a not-for-profit, national professional organization composed of over 50 federally certified PSOs. AQIPS' mission is to foster the ability of PSOs and providers to work collaboratively to improve patient safety, health care quality, and health care outcomes. ECRI Institute PSO, Cassatt Patient Safety Organization, The Guthrie Clinic PSO, MCIC Vermont PSO, and DaVita Patient Safety Organization are federally certified PSOs[1] that work with providers in Pennsylvania to collect, aggregate and analyze patient safety information, to develop learnings that will improve the safety and quality of care for patients in Pennsylvania and across the nation.

This patient safety mission can only be accomplished through the privilege and confidentiality protections afforded by the PSQIA. As

[1] The above-stated names are the names listed with the Agency for Healthcare Research and Quality (AHRQ). The corporate names of these entities are, respectively: Emergency Care Research Institute d/b/a ECRI Institute PSO, Cassatt RRG Holding Company d/b/a Cassatt Patient Safety Organization, The Guthrie Clinic PSO, MCIC Vermont, Inc. d/b/a MCIC Vermont PSO and DaVita Institute for Patient Safety, Inc. d/b/a DaVita Patient Safety Organization.

organizations that are at the forefront of fostering safer care for patients, AQIPS and the PSOs are uniquely positioned to provide this Court with insight into how PSOs and providers employ the privilege for PSWP to create a national healthcare learning system.

AQIPS and the PSOs are submitting this *Amicus Curiae* Brief in support of the Petition for Allowance of Appeal. The issues of the proper interpretation of the PSQIA and its privilege for PSWP, and of the Pennsylvania peer review privilege, are vital to all Pennsylvania patients, Pennsylvania providers and all PSOs that work with them, and to all of the national patient safety initiatives created by the PSQIA.

No party's counsel authored the brief in whole or in part. No person contributed money to the preparation of this brief other than the *Amici Curiae*, their members, or their counsel.

III. STATEMENT OF QUESTIONS PRESENTED

The *Amici Curiae* adopt the Questions Presented as set forth by the Petitioner.

IV. REASONS RELIED UPON FOR ALLOWANCE OF APPEAL

A. The Superior Court's Erroneous Interpretation of the PSQIA Statute Presents a Case of First Impression

1. The PSWP Privilege

The PSQIA provides a strict privilege for PSWP. Using the language of express federal preemption, the PSQIA provides "[n]otwithstanding any other provision of Federal, State or local law . . . [PSWP] shall be privileged and shall not be . . . subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding . . . against a provider." 42 U.S.C. § 299b-22(a)(2).

The PSQIA defines PWSP as follows:

> **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 [PSO] and are reported to a [PSO]; or
>
> (II) are developed by a [PSO] 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 [PSES].[2]

42 U.S.C. § 299b-21(7)(A) (emphasis supplied). The PSQIA excludes from the definition of PSWP "a patient's medical record, billing, and discharge information, or any other original patient or provider record," 42 U.S.C. § 299b-21(7)(B)(i), and "information that is collected, maintained, or developed separately, or exists separately, from a [PSES]," 42 U.S.C. § 299b-21(7)(B)(ii).

As discussed in Section IV.A.3, below, the Hospital's Event Report and Root Cause Analysis fit squarely into the definition of PSWP and are entitled to federal PSQIA privilege protection. A state court's duty in interpreting a federal statute is to give effect to Congress's intent by examining the statutory language, design, and purposes. *Council 13 v. Commonwealth*, 986 A.2d 63, 80-81 (Pa. 2009). However, the Superior Court failed to apply the plain terms of the statute and regulations, and instead engrafted onto the regulatory framework a "sole purpose" test that does not exist.

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[2] Pursuant to the PSQIA, providers may develop a PSES to collect, analyze, and manage information for reporting to or by a PSO. 42 U.S.C. § 299b-21(6).

2. The Superior Court Implied a "Sole Purpose" Requirement That Does Not Exist in the PSQIA

The Superior Court held that the Hospital failed to establish that the Event Report and RCA were PWSP in part because it failed to show that either document was prepared "for the purpose of reporting to a PSO." *Ungurian v. Beyzman*, 2020 Pa. Super. LEXIS 355, *14 (Pa. Super. April 28, 2020) (Addendum "A"). It agreed with the trial court's analysis that because the averments in the Affidavit of Joan DeRocco-DeLessio ("Affidavit") (R.523a-540a) implied that the Event Report could have been used for a purpose other than reporting to a PSO and still exist in the Hospital's Event Reporting System ("ERS") (which was where the Hospital maintained documents within its PSES), the Hospital could not satisfy its burden of establishing that the Event Report had in fact been prepared for reporting to a PSO. *Id.* at *14. Similarly, the Superior Court agreed with the trial court's analysis that because the RCA had been prepared for multiple purposes (including evaluating the care provided to Mr. Ungurian on March 5, 2018 and improving patient safety and quality of care), that it could not also have been prepared for reporting to a PSO. *Id.* at *15; August 14, 2019 Trial Court Op. at 19 (Addendum "B"). Inherent in this analysis was an assumption that information cannot be both prepared for

reporting to a PSO and used for any other purpose. This assumption is at odds with the plain language and logic of the PSQIA statute and regulation.

Nothing in the PSQIA requires that information be prepared solely or exclusively for reporting to a PSO in order to qualify as PSWP. *Rumsey v. Guthrie Med. Group, P.C.*, 2019 U.S. Dist. LEXIS 164731, at *5-6 (M.D. Pa. Sept. 26, 2019). Not only does the word "solely" not appear in 42 U.S.C. § 299b-21(7)(A)(i)(I), the "reporting pathway" prong of the privilege protection, but the PSQIA provides a separate prong for information to qualify for PSWP in 42 U.S.C. § 299b-21(7)(A)(ii) -- the "deliberations and analyses" prong. Under this provision, the definition of PSWP also encompasses "data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements . . . which identify or constitute the deliberations or analysis of . . . a [PSES]." 42 U.S.C. § 299b-21(7)(A)(ii). There is no requirement here that such "deliberations and analyses" be prepared for any purpose nor reported to a PSO to qualify as PSWP. *Rumsey*, 2019 U.S. Dist. LEXIS 164731, at *7.

The PSQIA Final Rule issued in 2008 further clarifies that PSWP can be used for many purposes within a PSES and does not need to be created or collected solely or exclusively for reporting to a PSO. First, the Final Rule provides that information becomes PSWP <u>when it is collected within a</u>

PSES, not when it is reported to a PSO. 42 C.F.R. § 3.20 (Patient Safety Work Product) at (1)(i)(A); *Patient Safety and Quality Improvement, Final Rule*, 73 Fed. Reg. 70732, 70741 (Nov. 21, 2008) ("PSQIA Final Rule"). The U.S. Department of Health and Human Services ("HHS") implemented this regulation expressly to allow providers to investigate events and conduct analysis regarding causes of the event in a protected environment before deciding whether the information created to do so would be reported to a PSO. PSQIA Final Rule, 73 Fed. Reg. 70740. Rather than forcing providers to choose between designating information as PWSP or using it to comply with regulatory obligations, HHS clarified:

> [P]roviders 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 [PSES], is protected as [PSWP] unless the provider determines that certain information must be removed from the [PSES] for reporting to the state. Once removed from the [PSES], this information is no longer [PSWP].

73 Fed. Reg. 70742.

The regulations also underscore the fact that once information is designated as PSWP, it can (and should) be used for multiple purposes. The Preamble to the PSQIA Final Rule emphasizes that the PSQIA "does

not regulate uses of [PSWP] within a single legal entity." 73 Fed. Reg. 70778. HHS explained:

> We have made this policy clear in the final rule by modifying the definition of disclosure to apply only to the release, transfer, provision of access to, or divulging in any other manner [PSWP] by: (1) an entity or natural person holding the [PSWP] to another legally separate entity or natural person outside the entity holding the [PSWP]; or (2) a component PSO to another entity or natural person outside the component organization."

Id.

Sharing PSWP internally for educational purposes, or to prevent or ameliorate patient harm is the whole point of the PSQIA. It would be nonsensical for PSWP to lose privilege protection when providers engage in the very activities the statute was enacted to encourage.

The idea that information must be prepared "solely" for reporting to a PSO in order to qualify as PSWP derives from "supplemental guidance" offered by HHS in 2016. *See HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations*, 81 Fed. Reg. 32655 (May 24, 2016) ("2016 Guidance"). The 2016 Guidance contradicted HHS's formal rulemaking by suggesting that information must be prepared "solely" for reporting to a PSO to be PSWP, *see* 81 Fed. Reg. 32657, 32658, and that providers were required to maintain dual systems for

information that may be used to fulfill external reporting requirements, rather than recognizing that HHS had expressly determined that doing so was not necessary.

Throughout their briefing before the Superior Court, Respondents referred to the 2016 Guidance as if it were law. It is not. The 2016 Guidance was sub-regulatory commentary, not derived through notice-and-comment rulemaking. To the extent the 2016 Guidance articulates a requirement that PSWP must be prepared "for the sole purpose" of reporting to a PSO, courts should not credit it, because it is erroneous and inconsistent with existing regulations. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2411 (2019); *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945). HHS has, itself, departed from the "sole purpose" discussion in the 2016 Guidance and, instead, has re-affirmed that the PSQIA regulations expressly permit providers to maintain privileged PSWP within a PSES for more than just reporting to a PSO. *See* Statement of Interest of the United States, at 11, *Lawrence Brawley v. Donald A. Smith, M.D., et.al.*, Case No. 17-CA-000119 (Fla. 13th Cir. Ct.) (citing 73 Fed. Reg. at 70,742) (Addendum "C").

This Court has not had the opportunity to address the interpretation of the PSQIA or scope of the privilege for PSWP. Pennsylvania lower court

opinions interpreting the PSQIA have wrongly held that documents must be assembled/developed for the sole purpose of reporting to a PSO to qualify for the privilege, underscoring how important this Court's guidance is in this area. *See, e.g., Morgan v. Cmty. Med. Ctr. Healthcare Sys.,* 2011 WL 12672148, *4 (Lacka. C.C.P. 2011); *Brink v. Mallick*, 2015 WL 1387936 (Lacka. C.C.P. 2015). This Court should grant *allocator* to clarify that neither the PSQIA nor its implementing regulations require that information be prepared solely for the purpose of reporting to a PSO to qualify as PSWP.

3. The Event Report and Root Cause Analysis Are Privileged & Confidential PWSP Under the Plain Terms of the Statute and Regulations.

a. Event Report

The Event Report is a straightforward example of PSWP. The Superior Court erred in concluding otherwise. According to the PSQIA, PSWP includes "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 [PSO] and are reported to a [PSO] . . . ." 42 U.S.C. § 299b-21(7)(A)(i)(I). The Affidavit clearly established that (i) the Event Report was maintained within the

Hospital's ERS for reporting to the PSO, and (ii) the Event Report was in fact reported to the PSO. (Affidavit ¶¶ 6, 17, R.524a-525a).[3]

The Superior Court held that the Event Report was not PSWP because the Affidavit also stated that (i) the Hospital prepared the Event Report "for the express purpose of improving patient safety and quality" and (ii) the Hospital maintained the Event Report in the Hospital's ERS, which is used to manage information that may be reported to the PSO. *Ungurian*, 2020 Pa. Super. 355, *13-14. Since, in the Superior Court's view, information must be prepared for the purpose of reporting to a PSO, and not for any other purpose, to qualify as PSWP, it found the Event Report did not qualify.

The Superior Court got it wrong. First, as argued above, there is no requirement in the PSQIA statute or regulation that information be collected or prepared exclusively or solely for the purpose of reporting to a PSO in order to qualify as PSWP. *See supra* 7-12. To the extent that the Hospital's Affidavit states that its ERS is its "internal mechanism for collecting, managing, and analyzing information that may be reported to CHS PSO, LLC," (Affidavit, ¶ 4, R.524a) (emphasis supplied), this is

[3] The Opinion below states that there was no record evidence that the Event Report had actually been reported to the Hospital's PSO, but the DeRocco Affidavit presents uncontradicted evidence that it was reported. *Ungurian*, 2020 Pa. Super. 355 at *14 n. 11; Affidavit, ¶ 17, R.525a.

consistent with the PSQIA Final Rule, which recognizes that some information collected in the PSES may need to be removed to use for external reporting. Such information is privileged PSWP unless removed prior to reporting to the PSO. 73 Fed. Reg. 70742. Once reported to the PSO, its status as PSWP cannot be undone. 73 Fed. Reg.70743. In this case, however, there is no evidence that the Event Report was ever removed from the PSES, either before or after reporting to the PSO. Instead, the Affidavit is clear that it was not required to be publicly disclosed or reported, does not exist outside of the PSES, and was in fact reported to the PSO. (Affidavit, ¶¶ 8, 17, R.524a-525a). It qualified as PSWP under 42 U.S.C. § 299b-21(7)(A)(i)(I).

To the extent that the Superior Court found that the statement in the Affidavit that the Event Report was also prepared "for the express purpose of improving patient safety and quality" disqualified it as PSWP, this was clear error. The fundamental purpose of the PSQIA is to improve patient safety and quality. S. Rep. 108-196 at 3. Providers are encouraged to use PSWP to improve patient safety and quality. 73 Fed. Reg. 70778. The notion that, by using PSWP to further the Congressional purpose of improving patient safety and quality, a provider disqualifies that same

information for the federal privilege protection turns the statutory protection on its head.

Once information becomes PSWP, it can be used for any purpose within the organization. *See* 73 Fed. Reg. 70778 ("we emphasize that the rule does not regulate uses of [PSWP] within a single legal entity"); *Taylor v. Hy-Vee, Inc.*, 2016 U.S. Dist. LEXIS 177764, *8-9 (D. Kan. Dec. 22, 2016). In *Hy-Vee*, the court rejected plaintiff's argument that incident reports that were saved in an Error Log Book to comply with Kansas record-keeping laws applicable to pharmacies and logged in Hy-Vee Connect, an internal record-keeping website, could not be PSWP. The court noted that "what a pharmacy ultimately does with data collected and reported to a PSO is irrelevant." *Hy-Vee*, 2016 U.S. Dist. LEXIS 177764, at *8. Once information is designated as PSWP, "there is nothing in the PSQIA to suggest that data can lose that designation." *Id.* at *9.

b. Root Cause Analysis

The RCA presents another straightforward application of the definition of PSWP. As stated in the Affidavit, the RCA was (i) maintained within the Hospital's PSES for reporting to the PSO, and (ii) was reported to the PSO. (Affidavit, ¶¶ 30-31, R.527a). This is sufficient to establish that it was PSWP under 42 U.S.C. § 299-21(7)(A)(i)(I).

In addition, the RCA qualifies as PSWP under 42 U.S.C. § 299-21(7)(A)(ii), which includes in the definition of PSWP the "deliberations or analyses of . . . a [PSES]." According to the statute, such "deliberations and analyses" constitute PSWP regardless of whether the information is reported to the PSO. *Id.*; *see also Rumsey*, 2019 U.S. Dist. LEXIS 174631, at *6; *Lewis v. Upadhyay*, 90 Va. Cir. 81, 82-84 (Va. Cir. Ct. 2015). Both the trial court and the appeals court erred in analyzing the RCA's privilege protection only as a "reporting pathway" protection and failing to acknowledge that the RCA was separately privileged under the "deliberations or analysis" prong of the statute. 42 U.S.C. § 299-21(7)(A)(ii).

The Superior Court held that the RCA was not PSWP for the additional reason that it "was not contained solely in the PSES." *Ungurian*, 2020 Pa. Super. LEXIS 355, *15 (citing Hospital counsel's admission that an email between Joan Keis and Dr. Thomas Jane specifically references the RCA). The cited correspondence indicates that some information from the RCA (but not the RCA itself) was shared with the patient's health insurer. (R.319a-322a). There are a variety of ways that could have come about, but none would impact the privilege attached to the RCA. The shared information could have been reconstructed outside of the PSES, in

which case it would not be PSWP. *Patient Safety and Quality Improvement Notice of Proposed Rulemaking*, 73 Fed. Reg. 8112, 8124 (Feb. 12, 2008). Or, it could have constituted a permissible disclosure of PSWP made under the business operations disclosure permission. 42 C.F.R. § 206(b)(9). It could have been PSWP disclosed with provider consent. 42 C.F.R. § 206(b)(3). Or, it might have constituted an impermissible disclosure. 42 C.F.R. § 3.20 (Disclosure). Regardless of the circumstances under which the information was shared with the health insurer, and contrary to the conclusion reached by the Superior Court, such disclosure did not waive the PSWP privilege attached to the RCA. The privilege for PSWP cannot be waived. 42 C.F.R. § 3.208(a) (providing that identifiable PSWP retains its privileged and confidential character even after disclosure as provided in the statute and regulations, or impermissibly). As HHS explained in the Preamble to the PSQIA Final Rule, "[t]o encourage provider reporting of sensitive patient safety information, Congress saw a need for strong privilege and confidentiality protections that continue to apply downstream even after disclosure . . . ." 73 Fed. Reg. 70787 (emphasis supplied). The lower court seemed to apply a common law waiver concept, but any such state law doctrine is superseded by PSQIA's preemptive privilege protections. *Quimbey v. Cmty Health Sys. Prof'l Servs. Corp*, 222 F. Supp.

3d 1038 (D.N.M. 2016) (recognizing the preemptive effect of the PSQIA); *Shulick v. Painewebber, Inc.* 722 A.2d 148, 150 (Pa. 1998) ("preemption is no less of an issue where common law requirements, rather than statutory ones, are concerned").

B. Recognizing the Strict, Preemptive Privilege for PSWP is a Matter of Substantial Public Importance because the Privilege is Essential to the PSQIA Policy Goals

The privilege for PSWP set forth in the PSQIA is the foundation for the national learning system envisioned by Congress when it enacted the PSQIA. Proper interpretation of the privilege is a matter of substantial public importance because without the privilege, the entire structure created by the PSQIA to encourage reporting and learning from patient safety events cannot survive.

The PSQIA was enacted in response to a seminal report of the Institute of Medicine (IOM) finding that preventable medical errors were responsible for tens of thousands of deaths each year, costing the country tens of billions of dollars annually, and proposing a "national agenda for reducing errors in health care." IOM, *To Err is Human: Building a Safer Health System* (1999). One of the IOM's most important findings was that most medical errors are the result of human factors that are systemic,

meaning that they are due to breakdowns in the systems that deliver care. *To Err is Human: Building a Safer Health System*, at 51-53.

In response to the IOM's findings, Congress enacted the PSQIA, establishing a system under which individual healthcare providers are encouraged to come forward and report patient safety events to their institutional leadership so that those events can be fully analyzed. Healthcare entities are, in turn, incentivized to voluntarily report both the events and their analysis to federally certified PSOs that can aggregate this data with the aim of improving patient safety and the quality of care nationwide. Congress intended to improve the quality of patient care by creating a non-punitive, confidential, voluntary reporting system, and to ensure accountability by raising standards for continuous improvements in health care. H.R. Rep. No. 109-197, at 9. The goal was to improve the safety and quality of the delivery of patient care on a national scale.

The privilege provided for PSWP lies at the core of the learning environment that Congress created in enacting the PSQIA. H.R. Rep. 109-197, at 9; S. Rep. No. 108-196, at 3. The system was designed to allow health care providers to assess their errors without fear that their data and analyses would be subject to discovery in litigation. The privilege was intended to eliminate the fear of personal liability among individual health

care professionals, eliminating the incentive to hide errors affecting patient safety and unsafe conditions. *See To Err is Human: Building a Safer Health System*, 9. Congress viewed such protections as necessary to encourage health care providers to report medical errors. H.R. Rep. No. 109-197, at 9.

Opinions like the Superior Court's undermine the policy goals of the PSQIA. Unless overturned, the decision so limits the scope of the PSQIA privilege that it will, as a practical matter, eliminate the protected space that providers need to fully analyze and learn from safety events. The HHS Office of Inspector General ("OIG") recently found that PSOs are effective in reducing patient harm and recommended that more hospitals work with PSOs but acknowledged that uncertainty over the PSQIA's legal protections for PSWP is a "major challenge" for nearly a quarter of hospitals that work with PSOs. HHS, OIG, Patient Safety Organizations: Hospital Participation, Value, and Challenges, Report No. OEI-01-17-00420 at 12 (Sept. 2019). Uncertainty over the status of the PSWP privilege has far-reaching negative implications. Lessons learned from harm inflicted on a patient when medical errors or systemic breakdowns occur will once again be carefully guarded, and PSOs will not have the same ability to aggregate and generate learnings from the safety analysis submitted by

their participating providers. As a result, the same mistakes will unnecessarily be repeated and the cycle of patient harm will return.

C. Granting *Allocator* is Necessary to Clarify the Status of Credentialing Files Post-*Reginelli*

The *Amici Curiae* join in the arguments of Petitioner as to why the Superior Court erred in determining that peer review information in credentials files is not privileged under the Pennsylvania Peer Review Protection Act, 63 P.S. §§ 425.1-425.4. As Justice Wecht foresaw in his concurrence in *Estate of Krappa v. Lyons*, 222 A.3d 372, 374 (Pa. 2019), the post-*Reginelli* line of Superior decisions denying privilege protection to peer evaluations in credentials files reflects "a substantial difficulty that lurks in the shadows cast by our bright line" distinction between a "review committee" and "review organization" in *Reginelli v. Boggs*, 181 A.3d 293 (Pa. 2018). *Amici* urge this court to follow Justice Wecht's sound advice that this Court "avail itself of any future opportunity to further hone the law in this challenging, consequential area of statutory interpretation" by granting review in this case. *Krappa*, 222 A.3d at 375.

V. CONCLUSION

For the reasons set forth above, this Court should grant the Petition

for Allowance of Appeal.

Respectfully submitted,

POST & SCHELL, P.C.

By: */s/ Robin Locke Nagele*

Robin Locke Nagele (PA Bar No. 36992)
Elizabeth M. Hein (PA Bar No. 314096)
1600 John F. Kennedy Boulevard, 13th Fl.
Four Penn Center
Philadelphia, PA 19103
215-587-1000 (Phone)
215-320-4702 (Facsimile)
rnagele@postschell.com
ehein@postschell.com

Counsel for Amici Curiae Alliance for Quality Improvement and Patient Safety (AQIPS); ECRI Institute PSO; Cassatt Patient Safety Organization; The Guthrie Clinic PSO; MCIC Vermont PSO, and DaVita Patient Safety Organization

Date: July 30, 2020

CERTIFICATE OF WORD COUNT

I certify that this brief contains 4,490 words and therefore complies with Pa.R.A.P. 531(b)(3).

By: */s/Robin Locke Nagele*
Robin Locke Nagele

Date: July 30, 2020

CERTIFICATE OF COMPLIANCE

I certify that this filing complies with the *Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts* that require filing confidential information and documents differently than non-confidential information and documents.

By: */s/Robin Locke Nagele*
Robin Locke Nagele

Date: July 30, 2020

ADDENDUM A

Ungurian v. Beyzman

Superior Court of Pennsylvania

January 23, 2020, Argued; April 28, 2020, Decided; April 28, 2020, Filed

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Reporter
2020 Pa. Super. LEXIS 355 *; 2020 PA Super 105

SUSAN UNGURIAN, INDIVIDUALLY AND AS GUARDIAN OF JASON UNGURIAN, AN INCAPACITATED PERSON v. ANDREW BEYZMAN, M.D.; ROBERT BURRY, CRNA; NORTH AMERICAN PARTNERS IN ANESTHESIA (PENNSYLVANIA), LLC, INDIVIDUALLY AND D/B/A NAPA; NORTH AMERICAN PARTNERS IN ANESTHESIA, LLP, INDIVIDUALLY AND D/B/A NAPA; WILKES-BARRE HOSPITAL COMPANY, LLC, INDIVIDUALLY AND D/B/A WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTH CARE SYSTEM, COMMONWEALTH HEALTH AND/OR COMMONWEALTH HEALTH SYSTEMS, INC.; COMMUNITY HEALTH SYSTEMS, INC., INDIVIDUALLY AND D/B/A WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTH CARE SYSTEM, COMMONWEALTH HEALTH AND/OR COMMONWEALTH HEALTH SYSTEM. APPEAL OF: WILKES-BARRE HOSPITAL COMPANY, LLC D/B/A WILKES BARRE GENERAL HOSPITAL;SUSAN UNGURIAN, INDIVIDUALLY AND AS GUARDIAN OF JASON UNGURIAN, AN INCAPACITATED PERSON v. ANDREW BEYZMAN, M.D.; ROBERT BURRY, CRNA; NORTH AMERICAN PARTNERS IN ANESTHESIA (PENNSYLVANIA), LLC, INDIVIDUALLY AND D/B/A NAPA; NORTH AMERICAN PARTNERS IN ANESTHESIA, LLP, INDIVIDUALLY AND D/B/A NAPA; WILKES-BARRE HOSPITAL COMPANY, LLC, INDIVIDUALLY AND D/B/A WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTH CARE SYSTEM, COMMONWEALTH HEALTH AND/OR COMMONWEALTH HEALTH SYSTEMS, INC.; COMMUNITY HEALTH SYSTEMS, INC., INDIVIDUALLY AND D/B/A WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTH CARE SYSTEM, COMMONWEALTH HEALTH AND/OR COMMONWEALTH HEALTH SYSTEM. APPEAL OF: WILKES-BARRE HOSPITAL COMPANY, LLC, INDIVIDUALLY AND D/B/A WILKES-BARRE GENERAL HOSPITAL;SUSAN UNGURIAN, INDIVIDUALLY AND AS GUARDIAN OF JASON UNGURIAN, AN INCAPACITATED PERSON v. ANDREW BEYZMAN, M.D.; ROBERT BURRY, CRNA; NORTH AMERICAN PARTNERS IN ANESTHESIA (PENNSYLVANIA) LLC, INDIVIDUALLY AND D/B/A NAPA; NORTH AMERICAN PARTNERS IN ANESTHESIA LLP, INDIVIDUALLY AND D/B/A NAPA; WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEATHCARE SYSTEM, COMMONWEALTH HEALTH AND/OR COMMONWEALTH HEALTH SYSTEM, INC. INDIVIDUALLY AND D/B/A WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTHCARE SYSTEM, COMMONWEALTH HEALTH AND/OR COMMONWEALTH HEALTH SYSTEMS. APPEAL OF: WILKES-BARRE HOSPITAL COMPANY, LLC D/B/A WILKES-BARRE GENERAL HOSPITAL;SUSAN UNGURIAN, INDIVIDUALLY AND AS GUARDIAN OF JASON UNGURIAN, AN INCAPACITATED PERSON v. ANDREW BEYZMAN, M.D.; ROBERT BURRY, CRNA; NORTH AMERICAN PARTNERS IN ANESTHESIA (PENNSYLVANIA), LLC, INDIVIDUALLY AND D/B/A NAPA; NORTH AMERICAN PARTNERS IN ANESTHESIA, LLP, INDIVIDUALLY AND D/B/A NAPA; WILKES-BARRE HOSPITAL COMPANY, LLC, INDIVIDUALLY AND D/B/A WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTH CARE SYSTEM, COMMONWEALTH HEALTH AND/OR COMMONWEALTH HEALTH SYSTEMS, INC.; COMMUNITY HEALTH SYSTEMS, INC., INDIVIDUALLY AND D/B/A WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTH CARE SYSTEM, COMMONWEALTH HEALTH AND/OR COMMONWEALTH HEALTH SYSTEM. APPEAL OF: WILKES-BARRE HOSPITAL COMPANY, LLC D/B/A WILKES-BARRE GENERAL HOSPITAL

Subsequent History: Rehearing denied by *Ungurian v. Beyzman, 2020 Pa. Super. LEXIS 542 (Pa. Super. Ct., June 30, 2020)*

Prior History: [*1] Appeal from the Order Entered February 1, 2019. In the Court of Common Pleas of Luzerne County Civil Division at No(s): 2018-08789.

Appeal from the Order Entered February 6, 2019. In the Court of Common Pleas of Luzerne County Civil Division at No(s): 2018-08789.

Appeal from the Order Entered April 24, 2019. In the Court of Common Pleas of Luzerne County Civil Division at No(s): 08789-2018.

Appeal from the Order Entered June 6, 2019. In the Court of Common Pleas of Luzerne County Civil Division at No(s): 08789-2018.

Appeal from the Order Entered June 6, 2019. In the Court of Common Pleas of Luzerne County Civil Division at No(s): 08789-2018. Before LESA GELB, J.

Core Terms

peer, patient, Root, credentialing, healthcare, Minutes, Staff, discovery, Log, licensed

Case Summary

Overview

HOLDINGS: [1]-In a medical malpractice action, the trial court did not err in directing the Hospital to produce various documents to the guardian because credentialing review was not entitled to protection from disclosure under the Peer Review Protection Act (PRPA), *63 Pa. Stat. Ann. § 425.4* as the PRPA's protections did not extend to the credentialing committee's materials since that entity did not qualify as a review committee.

Outcome
Orders affirmed.

LexisNexis® Headnotes

Civil Procedure > Appeals > Appellate Jurisdiction > Collateral Order Doctrine

Civil Procedure > Appeals > Appellate Jurisdiction > Interlocutory Orders

Civil Procedure > Discovery & Disclosure > Disclosure

HN1 **Appellate Jurisdiction, Collateral Order Doctrine**

Most discovery orders are deemed interlocutory and not immediately appealable because they do not dispose of the litigation. Nevertheless, an appeal may be taken as of right from a collateral order of a lower court. *Pa.R.A.P. 313(a)*. A collateral order is an order separable from and collateral to the main cause of action where the right involved is too important to be denied review and the question presented is such that if review is postponed until final judgment in the case, the claim will be irreparably lost. *Pa.R.A.P. 313(b)*. When a party is ordered to produce materials purportedly subject to a privilege, we have jurisdiction under *Pa.R.A.P. 313*.

Civil Procedure > Appeals > Standards of Review > De Novo Review

Governments > Legislation > Interpretation

HN2 **Standards of Review, De Novo Review**

Where the issue is the proper interpretation of a statute, it poses a question of law; thus, the appellate court's standard of review is de novo, and the scope of our review is plenary. Generally, courts disfavor evidentiary privileges.

Evidence > Privileges

HN3 **Evidence, Privileges**

Generally, courts disfavor evidentiary privileges.

Healthcare Law > Business Administration & Organization > Peer Review > Peer Review Statutes

Healthcare Law > Business Administration & Organization > Hospital Privileges > Professional Review

HN4 **Peer Review, Peer Review Statutes**

The Patient Safety Quality Improvement Act (PSQIA), 42 U.S.C.S. § 299b-22(a), provides, generally, that patient safety work product shall be privileged. 42 U.S.C.S. § 299b-22(a). The Act defines patient safety work product as any data, reports, memoranda, analyses (such as root cause analyses), or written or oral statements which are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization. 42 U.S.C.S. § 299b-21(7)(A)(i)(I). Relevantly, patient safety work product excludes information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. § 299b-21(7)(B)(ii). 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.

Civil Procedure > Discovery & Disclosure > Discovery > Privileged Communications

Evidence > Privileges

HN5 **Discovery, Privileged Communications**

The party asserting a privilege bears the burden of producing facts establishing proper invocation of the privilege. Then the burden shifts to the party seeking disclosure to set forth facts showing that disclosure will not violate the privilege. Absent a sufficient showing of facts to support a privilege the communications are not protected.

Healthcare Law > Business Administration & Organization > Peer Review > Peer Review Statutes

Healthcare Law > Business Administration & Organization > Hospital Privileges > Professional Review

HN6 **Peer Review, Peer Review Statutes**

The Superior Court of Pennsylvania agrees with the trial court's analysis that the Patient Safety Quality Improvement Act (PSQIA), 42 U.S.C.S. § 299b-22(a), requires that, in order to be considered patient safety work product, a hospital has the burden of initially producing sufficient facts to show that it properly invoked the privilege.

Healthcare Law > Business Administration & Organization > Peer Review > Peer Review Statutes

Healthcare Law > Business Administration & Organization > Hospital Privileges > Professional Review

HN7 **Peer Review, Peer Review Statutes**

The Peer Review Protection Act, 63 Pa. Stat. Ann. § 425.4, provides an evidentiary privilege for peer review documents.

Healthcare Law > Business Administration & Organization > Peer Review > Peer Review Statutes

Healthcare Law > Business Administration & Organization > Hospital Privileges > Professional Review

HN8 **Peer Review, Peer Review Statutes**

Under the Peer Review Protection Act (PRPA), 63 Pa. Stat. Ann. § 425.4, a professional health care provider includes individuals who are approved, licensed, or otherwise regulated to practice or operate in the health care field under the laws of the Commonwealth. 63 P.S. § 425.2(1). The PRPA defines a peer review organization as any committee engaging in peer review to gather and review information relating to the care and treatment of patients for the purposes of (i) evaluating and improving the quality of health care rendered; (ii) reducing morbidity and mortality; or (iii) establishing and enforcing guidelines designed to keep within reasonable

bounds the cost of health care. 63 Pa. Stat. Ann. § 425.2. In contrast, hospital incident and event reports are business records of a hospital and not the records of a peer review committee. Incident reports are, therefore, not entitled to the confidentiality safeguards of the PRPA. Additionally, the PRPA does not protect documents available from other sources or documents that have been shared outside of the peer review committee. 63 Pa. Stat. Ann. § 425.4.

Healthcare Law > Business Administration & Organization > Peer Review > Peer Review Statutes

Healthcare Law > Business Administration & Organization > Hospital Privileges > Professional Review

HN9 **Peer Review, Peer Review Statutes**

Under the Peer Review Protection Act, 63 Pa. Stat. Ann. § 425.4, a professional health care provider includes individuals who are approved, licensed, or otherwise regulated to practice or operate in the health care field under the laws of the Commonwealth. 63 Pa. Stat. Ann. § 425.2(1).

Healthcare Law > Business Administration & Organization > Peer Review > Peer Review Statutes

Healthcare Law > Business Administration & Organization > Hospital Privileges > Professional Review

HN10 **Peer Review, Peer Review Statutes**

Credentialing review is not entitled to protection from disclosure under the Peer Review Protection Act (PRPA), 63 P.S. § 425.4. The PRPA's protections do not extend to the credentialing committee's materials, because that entity does not qualify as a review committee.

Healthcare Law > Business Administration & Organization > Peer Review > Peer Review Statutes

Healthcare Law > Business Administration & Organization > Hospital Privileges > Professional Review

HN11 **Peer Review, Peer Review Statutes**

Credentialing committees are not review committees under the Peer Review Protection Act, 63 Pa. Stat. Ann. § 425.4, whose materials are entitled to its statutory privilege.

Counsel: Ira L. Podheiser, Pittsburgh, for Appellant.

Joseph A. Quinn Jr., Kingston, for Appellee.

Judges: BEFORE: LAZARUS, J., STABILE, J., and DUBOW, J. OPINION BY DUBOW, J.

Opinion by: DUBOW

Opinion

OPINION BY DUBOW, J.:

Appellant, Wilkes-Barre Hospital Company, LLC d/b/a Wilkes-Barre General Hospital ("Hospital"), appeals from five Orders entered in the trial court compelling production of documents that Hospital alleges are privileged by the Patient Safety Quality Improvement Act ("PSQIA"), 42 U.S.C. § 299b-22(a), and the Peer Review Protection Act ("PRPA"), 63 P.S. § 425.4. After careful review, we affirm.

Briefly, this matter arises in the context of a medical malpractice action brought by plaintiff, Susan Ungurian, **[*2]** against multiple corporate and individual defendants. Mrs. Ungurian alleges that, on March 5, 2018, the negligence of defendants caused the total and permanent incapacity of her son, Jason Ungurian, who was undergoing a cystoscopy[1] at Hospital. In the course

[1] A cystoscopy is an endoscopy of the bladder via the urethra.

of discovery, on August 7, 2018, August 17, 2018, and September 13, 2018, Mrs. Ungurian propounded requests for production of documents and interrogatories on all defendants, including Hospital.

On October 8, 2018, and October 10, 2018, Hospital served Mrs. Ungurian with responses and objections to her First and Second Requests for Production of Documents, and responded and objected to her First Set of Interrogatories. Hospital asserted that these documents were privileged pursuant to, *inter alia*, the PRPA and the PSQIA, and served Mrs. Ungurian with a privilege log, listing five documents Hospital was withholding. Relevantly, Hospital's privilege log identified the following documents as privileged:

> 1. Event Report completed on March 5, 2018[,] by Robert Burry, CRNA [("Burry Event Report")] for event date of March 5, 2018[,] relating to "Surgery, Treatment, Test, Invasive Procedure" reviewed by Jacqueline Curley, R.N., Clinical Leader, **[*3]** on March 21, 2018[,] and Elizabeth Trzcinski, R.N., Risk Coordinator, on March 8, 2018;
> 2. The SSER (Serious Safety Event Rating) Meeting Summary dated April 12, 2018[,] prepared by Elizabeth Trzcinski, R.N., Risk Coordinator;
> 3. Meeting Minutes from the Patient Safety Committee held on May 15, 2018[,] prepared by Joan DeRocco, R.N., Director Patient Safety Services, and Elizabeth Trzcinski, R.N., Risk Coordinator;
> 4. Root Cause Analysis Report dated April 12, 2018; and
> 5. [Hospital's] Quality Improvement Staff Peer Review completed by Dale A. Anderson, M.D. on April 15, 2018.

Privilege Log, 10/8/18, at 2-3.

On December 3, 2018, Mrs. Ungurian filed a Motion to Strike Objections and Compel Responses to her First and Second Requests for the Production of Documents and First Set of Interrogatories Propounded upon Hospital. In her Motion, Mrs. Ungurian argued that Hospital had failed to establish that PSQIA and PRPA privileges applied to the documents in Hospital's privilege log.

Hospital filed a Response to the Motion, claiming that two documents—the Burry Event Report and the Root Cause Analysis—were patient safety work product privileged by the PSQIA. Hospital also asserted that the PRPA Privilege **[*4]** protected it from producing the Burry Event Report and the Root Cause Analysis along with other documents, including the Quality Improvement Peer Review Meeting minutes, the Serious Safety Event Rating Meeting, minutes from the Patient Safety Committee, and certain credentialing files. Hospital supported its privilege claims with an affidavit from Joan DeRocco-DeLessio, Director of Patient Safety Services ("Affidavit").[2] In addition to baldly asserting that each of the requested documents were "specifically designated as privileged peer review information[,]" the Affidavit describes the relevant documents as follows.

The Burry Event Report

Hospital described the Burry Event Report as a two-page document "completed on March 5, 2018," which was the day of the incident that gave rise to this action. Privilege Log, 10/8/18, at 2. CRNA Robert Burry completed the Report in compliance with Hospital's "Event Reporting Policy."[3] Affidavit, 12/18/18, at ¶ 10.

The Root Cause Analysis Report

Hospital's Root Cause Analysis Committee produced the Root Cause Analysis Report on April 12, 2018, ostensibly "during the course of a peer review concerning [Jason] Ungurian's medical care on March 5, 2018." Affidavit **[*5]** at ¶ 26. Hospital purports that it prepared the Root Cause Analysis Report to evaluate Jason Ungurian's care and to improve patient safety and quality of care. ***Id.*** at ¶¶ 27-28. Hospital stated that it maintains the Root Cause Analysis Report within its ERS[4] for reporting to CHS PSO, LLC,[5] and that it electronically submitted the Root Cause Analysis Report to CHS PSO, LLC. ***Id.*** at ¶¶ 30-31.

The Quality Improvement Peer Review

Hospital referred to the Quality Improvement Peer Review as the "initiating part of the peer review

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Jason Ungurian underwent a cystoscopy to remove kidney stones.

[2] The Affidavit is the only evidence Hospital provided to the court in support of its assertions of privilege.

[3] Hospital attached a copy of its "Event Reporting Policy" to the Affidavit.

[4] An "ERS" is an "event reporting system."

[5] A "PSO" is a "patient safety organization."

process." Affidavit at ¶ 21. Dr. Dale Anderson was the physician reviewer of the Quality Improvement Medical Staff Peer Review Form. ***Id.*** at ¶ 20. According to Hospital's Privilege Log, Dr. Anderson completed the Quality Improvement Peer Review on April 15, 2018, more than one month after the incident in question. Privilege Log at 3.

The Serious Safety Event Meeting Summary

Hospital asserted that Elizabeth Trzcinski, R.N., Risk Coordinator, prepared the Serious Safety Event Meeting dated April 12, 2018, to summarize the meeting of Hospital's Serious Safety Event Committee. Privilege Log at 2; Affidavit at ¶ 23. In its Affidavit, Hospital does not provide the date the Committee met or who comprised the committee.

The Patient Safety Committee Meeting [*6] Minutes

Hospital held the relevant Patient Safety Committee Meeting on May 15, 2018. Affidavit at ¶ 34. The Affidavit describes the Committee as "a multidisciplinary group whose membership is representative of both the hospital and community it serves." ***Id.*** at ¶ 36.

The January 30, 2019 Order

The court held a hearing on Appellee's Motion after which, on January 30, 2019, it issued an Order ("January 30, 2019 Order") directing Hospital to produce the Burry Event Report, the Root Cause Analysis, and the Quality Improvement Peer Review. The court found that neither the PSQIA nor the PRPA privileges protected any of these documents.[6]

The February 5, 2019 Order

On February 5, 2019, the court amended the January 30, 2019 Order directing Hospital to produce, within 15 days, Dr. Andrew Beyzman's and CRNA Robert Burry's complete credentialing files and the National Practitioner Data Bank Query Response[7] ("February 5, 2019 Order").

On February 22, 2019, Mrs. Ungurian filed a Motion to Compel production of the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes.

The April 24, 2019 Order

On April 16, 2019, the court held a hearing on the Motion to Compel. **[*7]** [8] Following the hearing, on April 24, 2019, the court issued an Order ("April 24, 2019 Order") directing Hospital to produce the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes .

On June 3, 2019, Mrs. Ungurian filed an Emergency Motion to Strike Objections and Compel Discovery Responses from Defendants Andrew Beyzman, M.D., Robert Burry, CRNA, North American Partners In Anesthesia (Pennsylvania), LLC, Individually and d/b/a NAPA ("NAPA PA"), and North American Partners In Anesthesia, LLP, Individually and d/b/a ("NAPA LLP") (collectively, the "NAPA Defendants"). Mrs. Ungurian also moved for sanctions against those defendants. Relevantly, she averred that through supplemental discovery responses from the NAPA Defendants, she learned that the NAPA Defendants also possessed the Quality Improvement Peer Review, which, despite Hospital's privilege assertion, the court had previously ordered Hospital to produce.

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[6] The January 30, 2019 Order also directed Hospital to provide the court within fifteen days with information about Serious Safety Event Rating Meeting and the Patient Safety Committee Meeting Minutes to help it determine whether a privilege attached to these documents. This information included: (1) the author of the document; (2) the purpose of the document; (3) the attendees at the meeting; and (4) any other recipients of the document.

[7] The National Practitioner Data Bank is a "web-based repository of reports containing information on medical malpractice payments and certain adverse actions related to health care practitioners, providers, and suppliers." About US, National Practitioner Data Bank, https://www.npdb.hrsa.gov/topNavigation/aboutUs.jsp (last visited April 9, 2020). Congress established the data bank as a "tool that prevents practitioners from moving state to state without disclosure of discovery of previous damaging performance." ***Id.***

[8] At this hearing, Hospital asserted that in its January 30, 2019 Order the court had ordered an *in camera* review of the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes. The court rejected this contention, emphasizing that it ordered Hospital to provide it with information about those documents to assist it in determining whether the documents were privileged, **not** because it intended to review the documents *in camera*.

The court held a hearing on Mrs. Ungurian's Emergency Motion. Mrs. Ungurian argued at the hearing that the PRPA did not protect the Quality Improvement Peer Review because Dr. Anderson prepared it and he was not a licensed **[*8]** medical professional. Hospital and the NAPA Defendants argued that the privilege applied because Dr. Anderson had conducted the review at Hospital's request.

At the hearing, the parties also discussed the production of the credentialing files for Hospital employees involved in Jason Ungurian's care[9] and of correspondence between Joan Keis, Hospital's chief quality officer, and Dr. Thomas James, the senior medical director for Hospital's insurer, Highmark, about the substance of the Root Cause Analysis. Mrs. Ungurian argued that Hospital's asserted privileges over the Root Cause Analysis were inapplicable. Hospital countered with the policy argument that an insured should be freely able to discuss certain events with its insurer in an effort to maintain coverage. With respect to the credentialing files, Hospital claimed that it withheld production because it believed the files were either peer review protected or irrelevant.

The June 6, 2019 Orders

On June 6, 2019, the court ordered NAPA PA to produce a complete copy of the Quality Improvement Peer Review ("June 6, 2019 QIPR Order"). The court concluded that the PRPA privilege did not apply to the Quality Improvement Peer Review because: **[*9]** (1) Dr. Anderson was not licensed to practice medicine in Pennsylvania when he prepared the Quality Improvement Peer Review; (2) he was a managing partner of NAPA LLP, a non-healthcare provider; (3) the contract between Hospital and NAPA LLP did not provide for the provision of peer review services; and (4) NAPA LLP, an original source, also possessed the Quality Improvement Peer Review.

That same day the court entered a separate Order directing Hospital to produce the requested credentialing files, excluding limited personal information and any National Practitioner Data Bank Query Responses ("June 6, 2019 Credentialing Order").

Hospital filed appeals from each of these Orders, which this court consolidated.[10] Both Hospital and the trial court have complied with *Pa.R.A.P. 1925*.

Hospital raises the following issues on appeal:

> 1. Whether the [t]rial [c]ourt erred in holding that the [Burry] Event Report prepared by CRNA Burry and the Root Cause Analysis are not protected from discovery by virtue of the PSQIA?
> 2. Whether the [Burry] Event Report is privileged pursuant to the PRPA?
>
> 3. Whether the [t]rial [c]ourt erred in holding that the Root Cause Analysis is not protected from discovery by virtue of the **[*10]** PRPA?
> 4. Whether the [t]rial [c]ourt erred in holding that the Quality Improvement Peer Review performed by Dr. Dale Anderson is not protected from discovery by virtue of the PRPA?
> 5. Whether the [t]rial [c]ourt erred in holding that the Serious Safety Event Rating and Patient Safety Committee Minutes are not protected by virtue of the PRPA?
> 6. Whether the [t]rial [c]ourt erred in holding that the complete, unredacted credentialing files for Dr. Andrew Beyzman and CRNA Robert Burry are not protected from discovery by virtue of the PRPA?
> 7. Whether the [t]rial [c]ourt erred in holding that the unredacted personnel and/or credentialing files of Katelyn Farrell, RN, JoAnn Thomas, RN, Kristen Yavorski, RN, Kayla Barber, ST, Kimberly Barron, ST, Lisa Cernera, RNFA, BSN, Calvin Dysinger, MD, Shay Robinson, MD, John Amico, CRNA, Jason McDade, RN, and Daniel Walton, RN are not protected from discovery by virtue of the PRPA?

Hospital's Brief at 4-5.

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[9] These people included Katelyn Farrell, RN, JoAnn Thomas, RN, Kristen Yavorski, RN, Kayla Barber, ST, Kimberly Barron, ST, Lisa Cernera, RNFA, BSN, Calvin Dysinger, MD, Shay Robinson, MD, John Amico, CRNA, Jason McDade, RN, and Daniel Walton, RN.

[10] ***HN1***[↑] "[M]ost discovery orders are deemed interlocutory and not immediately appealable because they do not dispose of the litigation." ***Veloric v. Doe***, *2015 PA Super 194, 123 A.3d 781, 784 (Pa. Super. 2015)* (quotation marks and citation omitted). Nevertheless, "[a]n appeal may be taken as of right from a collateral order of [a] . . . lower court." ***Pa.R.A.P. 313(a)***. "A collateral order is an order separable from and collateral to the main cause of action where the right involved is too important to be denied review and the question presented is such that if review is postponed until final judgment in the case, the claim will be irreparably lost." ***Pa.R.A.P. 313(b)***. "When a party is ordered to produce materials purportedly subject to a privilege, we have jurisdiction under ***Pa.R.A.P. 313*** . . . ." ***Yocabet v. UPMC Presbyterian***, *2015 PA Super 132, 119 A.3d 1012, 1016 n.1 (Pa. Super. 2015)* (citation omitted).

PSQIA Claim

Issue 1 - The Burry Event Report and the Root Cause Analysis

In its first issue, Hospital claims that the trial court erred when it determined that the PSQIA did not privilege from discovery the Burry Event Report and the Root Cause Analysis. **[*11]**

In order to evaluate the argument of Hospital, we must analyze the language of PSQIA. We start with general principles of statutory construction. HN2[] "Where the issue is the proper interpretation of a statute, it poses a question of law; thus, our standard of review is *de novo*, and the scope of our review is plenary." ***Yocabet v. UPMC Presbyterian***, *2015 PA Super 132, 119 A.3d. 1012, 1019 (Pa. Super. 2015)* (quotation marks and citations omitted). HN3[] Generally, courts disfavor evidentiary privileges. ***Leadbitter v. Keystone Anesthesia Consultants, Ltd.***, *A.3d , 2020 PA Super 36, 2020 WL 702486 *3 (Pa. Super. 2020)*.

HN4[] The PSQIA provides, generally, that "patient safety work product shall be privileged[.]" *42 U.S.C. § 299b-22(a)*. The Act defines "patient safety work product" as "any data, reports, memoranda, analyses (such as root cause analyses), or written or oral statements . . . which . . . are assembled or developed by a provider for reporting to a patient safety organization **and** are reported to a patient safety organization[.]" ***Id.*** at *§ 299b-21(7)(A)(i)(I)* (emphasis added).

Relevantly, "patient safety work product" excludes "information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system." ***Id.*** at *§ 299b-21(7)(B)(ii)*. "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." ***Id.***

[*12] HN5[] The party asserting a privilege bears the burden of producing facts establishing proper invocation of the privilege. ***Custom Designs & Mfg. Co. v. Sherwin-Williams Co.***, *2012 PA Super 33, 39 A.3d 372, 376 (Pa. Super. 2012)*. "[T]hen the burden shifts to the party seeking disclosure to set forth facts showing that disclosure will not violate the [] privilege." ***Id.*** (citation omitted). "Absent a sufficient showing of facts to support [a] privilege . . . the communications are not protected." ***Ford-Bey v. Professional Anesthesia Services of North America, LLC***, *A.3d , 2020 PA Super 42, 2020 WL 830016 *5 (Pa. Super. 2020)*.

The Burry Event Report

Hospital argues it met its burden to establish that the Burry Event Report is protected by the PSQIA privilege because it asserted in the Affidavit that:

> 1. Hospital has maintained a relationship with a patient safety organization ("PSO") (CHS PSO, LLC) since 2012;
> 2. the purpose of the relationship with the PSO is to allow the confidential and protected exchange of patient safety and quality information in the conduct of patient safety activities;
> 3. Hospital has maintained a patient safety evaluation system ("PSES"), facilitated by the use of an event reporting system ("ERS"), as its internal process for collecting, managing, and analyzing information that may be reported to its PSO;
> 4. the PSES encompasses information assembled, developed, deliberated upon, or analyzed from patient safety and quality activities and includes information that may result in documents such as occurrence reports, cause analyses, and root cause analyses;
>
> 5. Hospital prepares the documents sought by Mrs. Ungurian for the express purpose of improving patient safety and **[*13]** care quality and are maintained within Hospital's PSES for reporting to the PSO
> 6. Hospital did not collect, maintain, or develop the Burry Event Report separately from its PSES, did not disclose the Burry Event Report and the Burry Event report is not required to be publicly disclosed or reported.

Hospital's Brief at 24-25.

The trial court determined that Hospital failed to meet its burden to establish that the Burry Event Report was "patient safety work product" under the PSQIA because Hospital failed to allege in the Affidavit that it developed the Burry Event Report for reporting to or by a PSO. Trial Ct. Op., 8/14/19, at 17-18. The court found Hospital's assertions that it: (1) prepared the Burry Event Report "for the express purpose of improving patient safety and quality;" (2) maintained the Burry Event Report "within [Hospital's] ERS for reporting to CHS PSO, LLC;" and (3) the "ERS is used to manage

information that only MAY be reported to the PSO" were insufficient to establish that Hospital developed the Burry Event Report for the purpose of reporting to the PSO. ***Id.*** at 18. It noted that the averments in the Affidavit only "confirm that the [Burry] Event Report **could have** been developed **[*14]** for a purpose other than reporting to a PSO and still be managed within the ERS." ***Id.*** (emphasis added).

The trial court interpreted PSQIA as "requir[ing] that, to be considered patient safety work product, a document **must** be developed for the purpose of reporting to a PSO." ***Id.*** (emphasis added). The trial court concluded, therefore, that because Hospital failed to assert that Hospital developed the Burry Event Report for the purpose of reporting to a PSO, the Burry Event Report was not patient safety work product entitled to the protection of the PSQIA privilege. ***Id.***

We agree with the trial court's analysis that ***HN6***[↑] the PSQIA requires that, in order to be considered patient safety work product, Hospital had the burden of initially producing sufficient facts to show that it properly invoked the privilege. Stated another way, Hospital had to allege that it prepared the Burry Event Report for reporting to a PSO **and** actually reported them to a PSO. Because Hospital did not so allege,[11] it did not meet its burden to establish that the Burry Event Report was entitled to protection under the PSQIA's patient safety work product privilege.

The Root Cause Analysis

With respect to the Root Cause Analysis, **[*15]** the court found Hospital's failure to proffer in the Affidavit that the Root Cause Analysis was "developed for the purpose of reporting to the PSO" was fatal to its PSQIA privilege claim. ***Id.*** at 19. The court also found that Hospital admitted that the information contained in the Root Cause Analysis "is not contained solely in the PSES." ***Id.*** at 19-20 (citing Hospital's counsel's admission that an email between Joan Keis and Dr. Thomas James specifically references the Root Cause Analysis). The court found that Hospital's admission that the Root Cause Analysis existed outside of the PSES defeated its claim that the Root Cause Analysis is privileged patient safety work product.

We agree with the trial court's analysis that the PSQIA imposed a burden on Hospital to proffer evidence that it developed the Root Cause Analysis for the purpose of reporting to a PSO. Hospital did not proffer such evidence. Moreover, Hospital admitted that the Root Cause Analysis exists outside of Hospital's patient safety evaluation system, also defeating its privilege claim. Therefore, Hospital failed to satisfy its burden of proving that the Root Cause Analysis was entitled to protection under the PSQIA's patient safety work product **[*16]** privilege.

PRPA

Issue 2 - the Burry Event Report

In its second issue, Hospital claims that the trial court erred in compelling it to produce the March 5, 2018 Burry Event Report. Hospital's Brief at 42-45. Hospital argues that the PRPA peer review privilege protects it from producing the Burry Event Report because: (1) Hospital is a "professional health care provider" under PRPA; and (2) the Burry Event Report was not in the nature of an "incident report." ***Id.***

HN7[↑] The PRPA provides an evidentiary privilege for "peer review" documents. *Section 425.4* provides, in relevant part, as follows:

> The proceedings and records of a review committee shall be held in confidence and shall not be subject to discovery or introduction into evidence in any civil action against a professional healthcare provider arising out of the matters which are the subject of evaluation and review[.]

63 P.S. § 425.3.

The PRPA defines "[p]eer review" as "the procedure for evaluation by professional health care providers of the quality and efficiency of services ordered or performed by other professional health care providers . . . ." *63 P.S. § 425.2*.

HN8[↑] Under the PRPA, a "[p]rofessional healthcare provider" includes "individuals who are approved, licensed[,] or otherwise **[*17]** regulated to practice or operate in the healthcare field under the laws of the

[11] Hospital asserts in its appellate Brief that it submitted the Burry Event Report to the PSO. Hospital's Brief at 27. As noted above, however, Hospital did not assert that it had submitted the Burry Event Report to the PSO in the Affidavit in support of its privilege claim and Hospital has not supported this assertion with citation to the record.

Commonwealth." 63 P.S. § 425.2(1).

The PRPA defines a peer "[r]eview organization" as "any committee engaging in peer review . . . to gather and review information relating to the care and treatment of patients for the purposes of (i) evaluating and improving the quality of health care rendered; (ii) reducing morbidity and mortality; or (iii) establishing and enforcing guidelines designed to keep within reasonable bounds the cost of healthcare." 63 P.S. § 425.2.

In contrast, hospital incident and event reports are business records of a hospital and not the records of a peer review committee. ***Atkins v. Pottstown Memorial Medical Center***, 430 Pa. Super. 279, 634 A.2d 258, 260 (Pa. Super. 1993). Incident reports are, therefore, not entitled to the confidentiality safeguards of the PRPA. ***Id.*** Additionally, the PRPA does not protect documents available from other sources or documents that have been shared outside of the peer review committee. 63 P.S. § 425.4.

Hospital argues that the Burry Event Report is privileged pursuant to the PRPA because it "was prepared for the express purpose of improving patient safety and quality of care . . . pursuant to Hospital's 'Policy/Procedure 8-2'"[12] and "was initiated by a professional healthcare provider under the Act, namely **[*18]** the Hospital." Hospital's Brief at 42-43. It disputes that the Burry Event Report is in the nature of an incident report. ***Id.*** at 43.

The trial court found that the PRPA peer review privilege did not apply to the Burry Event Report because Hospital failed to support its privilege claim with sufficient proof of the privilege's applicability, namely the identity of the members of the review committee. Trial Ct. Op. at 28. It also found that the PRPA privilege did not apply to the Burry Event Report because the Report was not generated in the context of a peer review and "is similar to the type of incident report that is not protected by the PRPA." ***Id.*** at 31. ***See also id.*** at 32-33 (where the court explained that "if the Burry Event Report was generated pursuant to [Hospital's] Event Reporting Policy as asserted in the Privilege Affidavit, it is an incident report that is not afforded the protections of the PRPA.").

Following our review of the record, we agree with the trial court that Hospital did not generate the Burry Event Report during the course of peer review. Instead, the Report, produced in accordance with Hospital's Event Reporting Policy, is in the nature of an incident report. It is, therefore, not entitled **[*19]** to the confidentiality safeguards of the PRPA. Moreover, even if the Burry Event Report was not merely an incident report, because the PRPA requires that peer review activities be conducted by professional healthcare providers, Hospital's failure to identify the members of its peer review committee is fatal to its claim that the PRPA privilege applies.

Issue 3 - The Root Cause Analysis

In its third issue, Hospital claims that the trial court erred in determining that the Root Cause Analysis is not privileged simply because Hospital did not provide a list of all individuals involved in the production of the Root Cause Analysis. Hospital's Brief at 46. Hospital argues that the privilege applies because "the peer review was initiated by a professional healthcare provider[.]" ***Id.*** Hospital also argues that the trial court erred when it held that the PRPA privilege does not apply to the Root Cause Analysis because the Root Cause Analysis was the subject of correspondence between Hospital and Highmark. ***Id.***

Hospital asserted in its Affidavit that its Root Cause Analysis Committee produced the April 12, 2018 Root Cause Analysis Report. Affidavit at ¶ 26. It did not, however, identify the members **[*20]** of the Root Cause Analysis Committee. Because the PRPA privilege only applies to the observations of and materials produced during an evaluation by "professional health care providers," Hospital's failure to identify the members of the Root Cause Analysis Committee as "professional healthcare providers" is, as the court concluded, fatal to their privilege claim. Hospital is, therefore, not entitled to relief.[13]

[12] Hospital appended a copy of its "Event Reporting Policy" to the Affidavit. The Policy's stated purpose is to: (1) "establish a standardized mechanism by which to report events internally and to the CHS PSO, LLC involving patients and/or visitors events of harm;" (2) "track and trend processes at risk that impact patient safety by using a Patient Safety Evaluation System, [ERS];" (3) "track and trend all severity levels of harm;" (4) "analyze trends to prevent harm, improve patient safety, healthcare quality[,] and healthcare outcomes;" and (5) "function as an organization[-]wide policy for [the] Event Report[.]" Policy, 6/2005, at § A-E. Nowhere in the Policy does Hospital refer to peer review or a peer review organization or committee.

[13] In light of our disposition, we do not address Hospital's alternate arguments.

Issue 4 - The Quality Improvement Medical Staff Peer Review

In its fourth issue, Hospital claims that the trial court erred in compelling NAPA to produce the Quality Improvement Medical Staff Peer Review performed on April 15, 2018, by Dr. Dale Anderson. Hospital's Brief at 47. Hospital asserts that the PRPA privilege applies because Dr. Anderson performed the review as the initiating part of the Hospital's peer review process expressly at Hospital's behest. ***Id.*** at 49.

HN9[] As mentioned above, under the PRPA, a "[p]rofessional healthcare provider" includes "individuals who are approved, licensed[,] or otherwise regulated to practice or operate in the healthcare field under the laws of the Commonwealth." 63 P.S. § 425.2(1).

Relying on the representations in Hospital's Affidavit and the testimony adduced at the January **[*21]** 23, 2019 hearing, the trial court determined that the PRPA privilege did not apply to the Quality Improvement Medical Staff Peer Review. The court based its conclusion on the fact that Dr. Anderson's Pennsylvania medical license expired in 2014 and, thus, he did not qualify as a "professional healthcare provider" under the PRPA at the time he performed the "peer review." Trial Ct. Op. at 25. The court also considered that Dr. Anderson was the managing partner of NAPA LLP, a non-healthcare provider, and, therefore, he could not have conducted peer review on NAPA's behalf.[14] ***Id.*** at 26.

In rejecting Hospital's argument that Dr. Anderson conducted peer review because he performed the Quality Improvement Medical Staff Peer Review at Hospital's behest, the court noted that neither Hospital nor the NAPA Defendants had presented the court with the contract between those parties to prove that Dr. Anderson performed the Quality Improvement Medical Staff Peer Review for Hospital. ***Id.*** at 27. Instead, the court noted that the only information of record regarding the relationship between Hospital and Dr. Anderson came from the argument of counsel. ***Id.*** Therefore, the court concluded that "the record lacks sufficient **[*22]** evidence that [Hospital] contracted with NAPA[] and/or Dr. Anderson for the provision of peer review services." ***Id.***

We agree with the trial court that, in order for the PRPA privilege to apply to the Quality Improvement Medical Staff Peer Review, Hospital had to prove that a "professional healthcare provider" conducted it. Neither Dr. Anderson nor the NAPA Defendants are "professional healthcare providers" under the PRPA, and, as noted by the trial court, Hospital did not proffer anything more than bald allegations to support its claim that Dr. Anderson performed the Quality Improvement Medical Staff Peer Review at its request. Accordingly, the trial court did not err in compelling Hospital to produce the Quality Improvement Medical Staff Peer Review.

Issue 5 - the Serious Safety Event Rating and Patient Safety Committee Meeting Minutes

In its fifth issue, Hospital claims that the trial court erred in concluding that the PRPA privilege does not apply to the April 12, 2018 Summary of its Serious Safety Event Rating Meeting because Hospital did not identify the members of the Serious Safety Event Rating committee. Hospital's Brief at 53. Hospital argues that the identity of the committee **[*23]** members is irrelevant because the members participate on behalf of and at the request of Hospital, which is a "professional healthcare provider" under the PRPA. ***Id.***

In its Affidavit in support of this particular claim of privilege, Hospital asserted only that: (1) "The Serious Safety Event Meeting Summary, dated April 12, 2018, was prepared to summarize the meeting of the Serious Safety Event Committee at [Hospital;]" (2) "This Committee meets for the purpose of reviewing and assessing the quality of patient care at [Hospital;]" and (3) "The Serious Safety Event Committee Summary is specifically designated as privileged peer review information." Affidavit at ¶¶ 23-25.

These bald claims, without more, do not satisfy Hospital's evidentiary burden of proving applicability of the PRPA privilege. Hospital's unilateral assertion that the Meeting Summary is "privileged peer review information" does not, without more, entitle this document to protection under the PRPA. Accordingly, the trial court did not err in ordering Hospital to produce to Mrs. Ungurian the Serious Safety Event Committee Meeting Summary.

The Patient Safety Committee Meeting Minutes

Hospital also argues that the court erred **[*24]** in

[14] Neither Hospital nor the Napa Defendants dispute that the NAPA Defendants are not "professional healthcare providers" as defined by the PRPA.

ordering it to produce the minutes from the May 15, 2018 Patient Safety Committee Meeting. Hospital's Brief at 58-64. Following our review of Hospital's Affidavit in support of this claim, we conclude that the trial court did not err. Notably, Hospital averred in its Affidavit that "[t]he Patient Safety Committee is a multidisciplinary group whose membership is representative of both the hospital and the community it serves." Affidavit at ¶ 36. Because the Patient Safety Committee includes members of the community served by Hospital, the Committee is not exclusively comprised of "professional healthcare providers." Accordingly, Hospital failed to satisfy its evidentiary burden of proving the applicability of the PRPA privilege to the Patient Safety Committee Meeting Minutes.

Issue 6 and 7—The Credentialing Files

Because Hospital's sixth and seventh issues are related, we address them together. In its sixth issue, Hospital claims that the trial court erred in compelling it to produce the complete unredacted credentialing files for Dr. Andrew Beyzman and CRNA Robert Burry.[15] Hospital's Brief at 58-64. In particular, Hospital claims that the doctors' performance reviews are privileged **[*25]** under the PRPA. ***Id.*** at 63. Hospital asserts that its own credentialing committee, staffed by physicians, evaluates the performance of other physicians. ***Id.*** at 62. It concludes, therefore, that its "[c]redentialing [c]ommittee falls within the PRPA's definition of qualifying 'review committee' as opposed to a non-qualifying 'review organization.'" ***Id.***

Similarly, in its seventh issue, Hospital claims that the trial court erred in compelling it to produce the "competency and performance evaluations" of certain of its staff members who participated in Jason Ungurian's care. ***Id.*** at 66. Hospital argues that Hospital itself conducted the performance evaluations of CRNA John Amico, registered nurses Katelyn Farrell, JoAnn Thomas, Kristin Yavorksy, Lisa Cernera, Daniel Walton, and Jason McDade, and surgical technicians Kayla Barber and Kimberly Barron to evaluate "the quality and efficiency of . . . services performed." ***Id.*** (citing 63 P.S. 425.2). It argues that the performance reviews within the credentialing files of doctors Calvin Dysinger and Shay Robinson are privileged under the PRPA because Hospital's "own credentialing committee initiates and executes its credentialing review, which implicitly is done for the purpose **[*26]** of ensuring quality of care in [] Hospital." ***Id.*** at 66-67. Thus, it concludes, "Hospital is itself 'a committee engaging in peer review.'" ***Id.*** at 67.

HN10[↑] Credentialing review is not entitled to protection from disclosure under the PRPA. ***Reginelli v. Boggs***, *645 Pa. 470, 181 A.3d 293, 306 n.13 (Pa. 2018)*. ***See also*** ***Estate of Krappa v. Lyons***, *2019 PA Super 168, 211 A.3d 869, 875 (Pa Super. 2019)*, *appeal denied*, *222 A.3d 372 (Pa. 2019)* (Table) (citation omitted) ("The PRPA's protections do not extend to the credentialing committee's materials, because this entity does not qualify as a 'review committee.'").

Hospital predicates its argument in support of the privilege attaching to the aforementioned credentialing files on its assertion that its credentialing committee is a PRPA-qualifying review committee. ***HN11***[↑] However, noted ***supra***, credentialing committees are not review committees under the PRPA, whose materials are entitled to its statutory privilege. ***Krappa***, *211 A.3d at 875*. Accordingly, the documents Hospital seeks to withhold are not protected by the PRPA privilege and the trial court did not err in directing Hospital to produce them to Mrs. Ungurian. Hospital is, therefore, not entitled to relief.

Orders affirmed.

Judgment Entered.

Date: 04/28/2020

End of Document

[15] Hospital produced a redacted version of the files. It noted in its Privilege Log that it had redacted from the credentialing files, "*inter alia*, malpractice insurance carrier questionnaires and credentialing reports, National Practitioner Data Bank Query Responses, Hospital Credentialing Risk Assessment Checklists, Claims Experience Reports, Ongoing Professional Practice Evaluations, letters from the malpractice insurance carrier, and department assessments and reports." ***Id.*** at 59 (referring to Hospital's Privilege Log).

ADDENDUM B

SUSAN UNGURIAN, Individually and as Guardian of Jason Ungurian, and Incapacitated Person **Plaintiff** **v.** **ANDREW BEYZMAN, M.D.; ROBERT BURRY, CRNA; NORTH AMERICAN PARTNERS IN ANESTHESIA (PENNSYLVANIA), LLC, Individually and d/b/a NAPA; NORTH AMERICAN PARTNERS IN ANESTHESIA, LLP, Individually and d/b/a NAPA; WILKES-BARRE HOSPITAL COMPANY, LLC, Individually and d/b/a WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTH CARE SYSTEM, COMMONWEALTH HEALTH and/or COMMONWEALTH HEALTH SYSTEMS, INC.; COMMUNITY HEALTH SYSTEMS, INC., Individually and d/b/a WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTH CARE SYSTEM, COMMONWEALTH HEALTH and/or COMMONWEALTH HEALTH SYSTEM** **Defendant(s)**	**IN THE COURT OF COMMON PLEAS OF LUZERNE COUNTY** **CIVIL ACTION MEDICAL MALPRACTICE** **No. 08789-2018** Copies Mailed 08/14/2019

OPINION

BACKGROUND

The above-captioned is a medical malpractice action filed against multiple corporate and individual Defendants. It involves a cystoscopy procedure on March 5, 2018, which Appellee alleges

rendered thirty-six year old Jason Ungurian totally and permanently incapacitated due to global hypoxic/anoxic brain damage. The five separate appeals currently pending before the Superior Court involve assertions of privilege by Appellant Wilkes-Barre Hospital Company, LLC, Individually and d/b/a Wilkes-Barre General Hospital, Wyoming Valley Health Care System, Commonwealth Health and/or Commonwealth Health System ("Appellant WBGH") over certain documents requested by Appellee during the discovery process. Because each of these matters are related, it is necessary to address them together in a consolidated Opinion. Procedurally, the pending appeals can be classified into three categories based upon the Orders from which they were taken: (1) the January 30, 2019 and February 5, 2019 Orders, (2) the April 24, 2019 Order, and (3) the June 6, 2019 Orders.

January 30, 2019 and February 5, 2019 Orders

On December 3, 2018, Appellee filed her "Motion to Strike Objections and Compel Responses to Plaintiff's First and Second Requests for the Production of Documents and First Set of Interrogatories Propounded Upon [Appellant WBGH]." (12/3/18 Motion to Compel.) In her Motion to Compel, Appellee argued that

Appellant WBGH failed to satisfy its burden of establishing that the asserted privileges, including, but not limited to the Peer Review Protection Act – 63 P.S. § 425.5 (the "PRPA") and the Patient Safety and Quality Improvement Act – 42 CFR Part 3 (the "PSQIA"), applied to five documents on its privilege log. (12/3/18 Brief, p. 9-10.) In its responsive brief, Appellant WBGH argued only that the Burry Event Report and the Root Cause Analysis are patient safety work product protected by the PSQIA, and that the Burry Event Report, the Root Cause Analysis, the Quality Improvement Peer Review, the Serious Safety Event Rating Meeting, the Patient Safety Committee Meeting Minutes, and certain credentialing files are protected by the PRPA. (12/19/18 Responsive Brief.) An oral argument on Appellee's Motion to Compel commenced before the Court on January 23, 2019.

After oral argument, the following occurred:

January 30, 2019 Order:

> 1. Defendant WBGH shall provide to Plaintiff the Burry Event Report, the Root Cause Analysis, and the Quality Improvement Peer Review. Defendant WBGH has failed to meet its burden that any of these documents are protected by a relevant privilege;
> 2. Defendant WBGH shall submit to the Court the following information about both the Serious Safety Event Rating Meeting and the Patient

Safety Committee Meeting Minutes: the author of the document, the purpose of the document, the attendees at the meeting, and any other recipients of the document; and,
3. All other matters have been resolved by the parties. (1/30/19 Order.)

January 31, 2019 Order: Imposed a deadline of fifteen days within which Appellant WBGH was required to provide the documents and information ordered produced in the January 30, 2019 Order. (1/31/19 Order.)

February 5, 2019 Order:

...the Court's Order dated January 30, 2019 related to Plaintiff's Motion to Strike Objections and Compel Response is amended by striking the word "and" from paragraph 2, striking paragraph 3, and adding the following language:
3. Defendant WBGH shall provide to Plaintiff the complete credentialing files for Dr. Beyzman and CRNA Burry, except for certain personal information which Plaintiff agreed could remain redacted and the National Practitioner Data Bank Query Response, within fifteen (15) days of the date of this Order; and,
4. All other matters have been resolved by the parties. (2/5/19 Order.)

February 14, 2019: Appellant WBGH filed Notices of Appeal to the Pennsylvania Superior Court from the January 30,

January 31,[1] and February 5 Orders. (Notices of Appeal.)

March 8, 2019: Concise Statement relative to the January 30, 2019 Order:

> 1) Whether the Trial Court erred in finding that Defendant/Appellant, Wilkes-Barre Hospital Company, LLC d/b/a Wilkes-Barre General Hospital, failed to meet its burden of demonstrating that the Event Report completed on March 5, 2018 by Robert Burry, CRNA, and the Root Cause Analysis Report dated April 12, 2018 are privileged patient safety work product precluded from discovery pursuant to the terms of the Patient Safety and Quality Improvement Act (PSQIA)?
> 2) Whether the Trial Court erred in finding that Defendant/Appellant, Wilkes-Barre Hospital Company, LLC d/b/a Wilkes-Barre General Hospital, failed to meet its burden of demonstrating that the Event Report completed on March 5, 2018 by Robert Burry, CRNA; the Root Cause Analysis Report dated April 12, 2018; and the Wilkes-Barre General Hospital Quality Improvement Medical Staff Peer Review completed by Dale A. Anderson, M.D., on April 15, 2018, are privileged documents precluded from discovery pursuant to the terms of the Pennsylvania Peer Review Protection Act?
> 3) Whether the Trial Court's ruling that Defendant/Appellant, Wilkes-Barre Hospital Company, LLC d/b/a Wilkes-Barre General Hospital, is to produce information for *in camera* review relating to the Serious Safety Event Rating Meeting Summary dated April 12, 2018, and the

[1] On or about May 13, 2019, Appellant filed a Praecipe to Discontinue its appeal of the January 31, 2019 Order with the Superior Court.

> Meeting Minutes from the Patient Safety Committee held on May 15, 2018, violates the privilege provisions of the Pennsylvania Peer Review Protection Act?" (3/8/19 Concise Statements.)

Appellant's Concise Statement relevant to the February 5, 2019 Order:

> 1) Whether the Trial Court erred in ordering Defendant/Appellant, Wilkes-Barre Hospital Company, LLC d/b/a Wilkes-Barre General Hospital, to produce to Plaintiff complete unredacted credentialing files for Andrew Beyzman, M.D., and Robert Burry, CRNA, (with the exception of certain personal information which Plaintiff agreed could remain redacted and the National Practitioner Data Bank Query Response), in violation of the Pennsylvania Peer Review Protection Act? (3/8/19 Concise Statement.)

April 24, 2019 Order

On February 22, 2019, Appellee filed her "Motion to Quash Defendant WBGH's Notice of Appeal with Respect to Paragraph 2 of the Court's January 30, 2019 and January 31, 2019 Orders; To Compel Production of the Serious Safety Event Rating Meeting Summary and Patient Safety Committee Meeting Minutes; and To Clarify the Court's February 15, 2019 Order." (2/22/19 Motion to Quash.) During a hearing regarding Appellee's Motion to Quash, the Court addressed

Appellant WBGH's assertions that an *in camera* review of the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes was ordered even though the January 30, 2019 Order required only that certain information about the creation of the documents be produced to aid the Court in determining whether they are privileged.

Following the April 16, 2019 hearing, by Order with attached Opinion dated April 24, 2019, the Court required Appellant WBGH to provide to Appellee the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes. (4/24/19 Order.) On April 29, 2019, Appellant WBGH filed a Notice of Appeal to the Superior Court from the April 24, 2019 Order. (4/29/19 Notice of Appeal.) Appellant WBGH filed its Concise Statement of Errors Complained of Appeal on May 21, 2019, raising one issue for review:

> Whether the Trial Court erred in ordering Defendant/Appellant, Wilkes-Barre Hospital Company, LLC d/b/a Wilkes-Barre General Hospital to produce both the Serious Safety Event Rating Meeting Summary dated April 12, 2018, and the Meeting Minutes from the Patient Safety Committee held on May 15, 2018, as said items are precluded from discovery pursuant to the privilege provisions of the Pennsylvania Peer Review Protection Act? (5/21/19 Concise Statement.)

June 6, 2019 Orders

In a separate, but related matter, on June 3, 2019, Appellee filed her "Emergency Motion to Strike Objections and Compel Discovery Responses and Documents from Defendants, Andrew Beyzman, M.D., Robert Burry, CRNA, North American Partners In Anesthesia (Pennsylvania), LLC, Individually and d/b/a NAPA and North American Partners in Anesthesia, LLP, Individually and d/b/a NAPA, and Motion for Sanctions Against Defendants, Andrew Beyzman, M.D., Robert Burry, CRNA, North American Partners In Anesthesia (Pennsylvania), LLC, Individually and d/b/a NAPA [("NAPA PA")] and North American Partners in Anesthesia, LLP, Individually and d/b/a NAPA [("NAPA LLP")]." (6/3/19 Emergency Motion.) Relevant to this appeal, Appellee stated in her Motion that, through the supplemental discovery responses of Defendant NAPA PA, she learned that Defendant NAPA PA was in possession of the Quality Improvement Peer Review, a document which this Court previously ordered produced over the privilege objections of Appellant WBGH.[2] (6/3/19 Emergency Motion, p. 11.)

[2] Although the Quality Improvement Peer Review appeared on a privilege log produced by NAPA PA, Appellee argued that it was really the privilege log of NAPA LLP. (EMH, p. 9.)

June 4, 2019 Emergency Motion Hearing:

At a hearing on Appellee's Emergency Motion, Appellee argued that, because Defendant NAPA LLP was in possession of the Quality Improvement Peer Review conducted by Dale Anderson, M.D., a managing partner of Defendant NAPA LLP, any claim that the document is protected by the PRPA fails because it is available from an original source, Defendant NAPA LLP. (EMH, p. 10, 35, 44, 46-47, 50, 52.)[3] Both Defendant NAPA LLP and Appellant WBGH countered that Dr. Anderson had simply retained a copy of the Quality Improvement Peer Review which he had personally conducted on behalf of Appellant WBGH, thus, no waiver of the peer review privilege had occurred. (EMH, p. 43-45, 47-50.)

Also during the Emergency Motion Hearing, the Court addressed Appellee's "Motion to Compel [Appellant WBGH] to Produce Documents Listed on WBGH's 3-14-19 Privilege Log and Unredacted Personnel and/or Credentialing Files of Katelyn

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Throughout the Emergency Motion Hearing, both Appellee and Defendant NAPA LLP referred to the document being in NAPA LLP's possession. (EMH, p. 45-48.)

[3] EMH refers to the Notes of Testimony from the Emergency Motion Hearing which occurred on June 4, 2019.

Farrell, RN, JoAnn Thomas, RN, Kristen Yavorski, RN, Kayla Barber, ST, Kimberly Barron, ST, Lisa Cernera, RNFA, BSN, Calvin Dysinger, MD, Shay Robinson, MD, John Amico, CRNA, Jason McDade, RN and Daniel Walton, RN." Appellee's Motion to Compel involved, in relevant part, the production of correspondence between the chief quality officer at Appellant WBGH and the senior medical director for Appellant WBGH's insurer, as well as the production of the credentialing files for certain individuals involved in the care of Jason Ungurian. (EMH, p. 68-70, 77-89.) During the Emergency Motion Hearing it became clear that Joan Kies, the chief quality officer at Appellant WBGH, had corresponded with Dr. Thomas James, the senior medical director at Highmark, about the substance of the Root Cause Analysis. (EMH, p. 68, 70, 72, 74.) In response to Appellee's argument that the correspondence is evidence that any privileges previously asserted over the Root Cause Analysis are inapplicable, Appellant WBGH made a policy argument that an insured should be able to freely communicate with its insurer about certain events in an effort to maintain coverage. (EMH, p. 69-77.) Regarding the credentialing files which Appellee sought to

compel, Appellant WBGH stated that it withheld certain information from the credentialing files produced which it believed was either peer review protected or irrelevant to the current matter. (EMH, p. 82-88.)

June 6, 2019 Orders:

(1) An Order compelling Defendant NAPA PA to produce a complete copy of the Quality Improvement Peer Review (the "Quality Improvement Peer Review Order"), and

(2) An Order requiring Appellant WBGH to produce the credentialing files identified in Appellee's Motion to Compel, with the exception of limited personal information and any National Practitioner Data Bank Query responses (the "Credentialing File Order"). (6/6/19 Quality Improvement Peer Review Order; 6/6/19 Credentialing File Order.)

Appeals of the June 6, 2019 Orders:

First, Appellant WBGH filed a Notice of Appeal from the Court's Quality Improvement Peer Review Order on June 10, 2019. (6/10/19 Notice of Appeal.) After receiving the Notice of Appeal, on June 10, 2019, the Court ordered Appellant WBGH to file a Concise Statement of Matters Complained of on Appeal

within twenty-one (21) days. (6/10/19 Concise Statement Order.) Appellant WBGH filed its Concise Statement late and subsequently filed an unopposed Motion for Leave to File the Concise Statement *Nunc Pro Tunc*. (7/9/19 Concise Statement; 7/10/19 NPT Motion.) Pursuant to the Court's Order granting its Motion, Appellant WBGH filed its Concise Statement on July 17, 2019, raising the following for appellate review:

> Whether the Trial Court erred in ordering Co-Defendant [NAPA PA], to produce a complete copy of the [WBGH] Quality Improvement Medical Staff Peer Review completed by Dale Anderson, M.D., and identified in Co-Defendant, NAPA PA's, Document Log as Bates 281-283, as said document is privileged and precluded from discovery pursuant to the terms of the Pennsylvania Peer Review Protection Act? Said document is also the subject of a separate appeal filed by Appellant [WBGH], assigned Superior Court of Pennsylvania Docket Number 298 MDA 2019. (7/12/19 Order; 7/17/19 Concise Statement.)

Next, Appellant WBGH filed a Notice of Appeal from the Court's Credentialing File Order on June 13, 2019. (6/13/19 Notice of Appeal.) By Order dated June 17, 2019, the Court required Appellant WBGH to file a Concise Statement within twenty-one (21) days. (6/17/19 Concise Statement Order.)

Again, Appellant WBGH filed its Concise Statement late and later filed an unopposed Motion for Leave to File the Concise Statement *Nunc Pro Tunc*. (7/9/19 Concise Statement; 7/10/19 NPT Motion.) After the Court granted its Motion, Appellant WBGH filed a timely Concise Statement on July 17, 2019. (7/12/19 Order; 7/17/19 Concise Statement.) In its Concise Statement, Appellant WBGH raised the following matters for review:

> 1) Whether the Trial Court erred in ordering [Appellant WBGH] to produce to Plaintiff complete unredacted credentialing and/or personnel files for Katelyn Farrell, RN, JoAnn Thomas, RN, Kristen Yavorski, RN, Kayla Barber, Surgical Technician, Lisa Cernera, RNFA, BSN, Calvin Dysinger, MD, Shay Robinson, MD, John Amico, CRNA, Jason McDade, RN, and Daniel Walton, RN, (with the exception of the limited personal information which Plaintiff agreed could remain redacted and any National Practitioner Data Bank Query Response), in violation of the Pennsylvania Peer Review Protection Act?
>
> 2) Whether the Trial Court erred in ordering [Appellant WBGH] to produce to Plaintiff complete unredacted credentialing and/or personnel files for Kimberly Barron, Surgical Technician, (with the exception of the limited personal information which Plaintiff agreed could remain redacted and any National Practitioner Data Bank Query Response), in violation of the Pennsylvania Peer Review Protection Act? (7/17/19 Concise Statement.)

STANDARD OF REVIEW

The Pennsylvania Superior Court has stated that, "[w]here 'the issue is the proper interpretation of a statute, it poses a question of law; thus, our standard of review is *de novo*, and the scope of our review is plenary." Yocabet v. UPMC Presbyterian, 119 A.3d 1012, 1019 (Pa. Super. 2015)(*citing* Phoenixville Hosp. v. Workers' Compensation Appeal Bd., 623 Pa. 25, 81 A.3d 830, 838 (Pa. 2013); *accord* In re Thirty–Third Statewide Investigating Grand Jury, 624 Pa. 361, 86 A.3d 204, 215 (Pa. 2014) (if an appellant invokes a statutory privilege, appellate review is plenary)).

ANALYSIS

Pursuant to Rule 4003.1 of the Pennsylvania Rules of Civil Procedure, "...a party may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action..." Pa. R.C.P. No. 4003.1 (2008). "As a general rule, Pennsylvania law does not favor evidentiary privileges, and any doubts regarding the discoverability of information or documents should be resolved in favor of permitting discovery." Brink v Mallick, 2015 WL 1387936 at *4 (Pa. Comm. Pl., 2015). It is well established by

the courts of the Commonwealth of Pennsylvania that "[t]he burden of establishing privilege is on the party seeking to prevent disclosure." Ario v. Deloitte & Touche LLP, 934 A.2d 1290, 1294 (Pa. Commw. Ct. 2007). In the event that the party seeking to prevent disclosure satisfies its burden, the burden then shifts to the opposing party to demonstrate that the privilege was waived or an exception applies. Custom Designs & Mfg. Co. v. Sherwin-Williams Co., 39 A.3d 372, 376 (Pa. Super. 2012). As will be discussed at length below, for each document which the Court ordered produced in discovery, Appellant WBGH either failed to meet its burden of establishing that a privilege applied, and/or waived the asserted privilege.

I. The Burry Event Report, the Root Cause Analysis, and the Quality Improvement Peer Review (January 30, 2019 Order)

First, this Opinion will address those documents which were ordered produced on January 30, 2019 in resolution of Appellee's original Motion to Compel, the Burry Event Report, the Root Cause Analysis, and the Quality Improvement Peer Review. This Motion was premised on blanket assertions of privilege by Appellant WBGH in a privilege log lacking any information to establish the applicability of the privileges. (12/3/18 Brief, p. 9-11, 16, 18-24.) The first time Appellant

WBGH provided additional information about the asserted privileges was in its Responsive Brief filed December 19, 2018. (12/19/18 Brief.) Appellant WBGH's Responsive Brief included an attached affidavit from Joan DeRocco-DeLessio, Director of Patient Safety Services at Appellant WBGH, which formed the entire factual basis for its privilege arguments (the "Privilege Affidavit"). Appellant WBGH provided no evidence to the Court other than the Privilege Affidavit to support its assertions of privilege.

PSQIA: the Burry Event Report and the Root Cause Analysis

The PSQIA provides, generally, that "...patient safety work product shall be privileged..." 42 U.S.C. § 299b-22(a) (2005). The Act defines "patient safety work product," in relevant part, as "...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..." 42 U.S.C.A. § 299b-21(7)(A). "Federal and state rulings interpreting the 'patient safety work product' privilege under the PSQIA have concluded that the privilege applies only to reports, analyses and data that (1) are developed by a health care provider for reporting to or by a PSO, and

(2) are actually reported to or by a PSO." Brink v Mallick, 2015 WL 1387936 at *4 (Pa. Comm. Pl., 2015)(*citing* Department of Financial and Professional Regulation v. Walgreen Company, 361 Ill. Dec. 186, 191, 970 N.E.2d 552, 557 (2012) (*citing* 42 U.S.C. § 299b-21(7)); Sevilla v. United States, 852 F. Supp. 2d 1057, 1068 (N.D. Ill. 2012) (citing 42 U.S.C. § 299b-22(a))).

The definitions section of the PSQIA further clarifies that patient safety work product "...does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system..." and that "...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." § 299b-21(7)(B).

A review of the Privilege Affidavit reveals that Appellant WBGH fell short of its burden to establish that the protections of the PSQIA apply to either the Burry Event Report or the Root Cause Analysis. First, nowhere in the Privilege Affidavit does Appellant WBGH even allege that the Burry Event Report was developed for reporting to or by a PSO, a critical element of the privilege. Indeed, the only statement in the Privilege Affidavit about the purpose of the Event Report is that:

"All such information and documents are prepared for the express purpose of improving patient safety and quality, and are maintained within [Appellant WBGH's] ERS for reporting to CHS PSO, LLC." (Privilege Affidavit, p. 2.) However, according to the Privilege Affidavit, the ERS is used to manage information that only *MAY* be reported to the PSO. (Privilege Affidavit, p. 2.) Thus, Appellant WBGH has failed to allege that the reason the document was developed was for reporting to the PSO and the fact that it is maintained in the ERS is of no consequence as that system holds information that may or may not be reported to the PSO. These statements in the Privilege Affidavit confirm that the Event Report could have been developed for a purpose other than reporting to a PSO and still be managed within the ERS. The statutory language of the PSQIA requires that, to be considered patient safety work product, a document must be developed for the purpose of reporting to a PSO. See 42 U.S.C. § 299b-21(7)(A)(2005). Consequently, Appellant WBGH has failed in its burden of establishing that the Burry Event Report is privileged patient safety work product.

Similar to the Burry Event Report, Appellant has failed to demonstrate that the Root Cause Analysis was created for the

purpose of reporting to the PSO. The Privilege Affidavit provided that the Root Cause Analysis was "...prepared for the express purpose of evaluation of the care provided to Mr. Ungarian on March 5, 2018 by a team of professional health care providers." (Privilege Affidavit, p. 4.) It added, "Root Cause Analyses are conducted for the express purpose of improving patient safety and quality of care." (Privilege Affidavit, p. 4.) While Appellant WBGH asserted that the Root Cause Analysis was maintained in the ERS and actually reported to the PSO, it again failed to even allege that it was developed for the purpose of reporting to the PSO. As discussed previously in relation to the Burry Event Report, such statements are insufficient for establishing the applicability of the privilege afforded by the PSQIA.

Appellant WBGH also initially failed in its burden of alleging that the Root Cause Analysis does not exist outside the PSES and has since admitted that the information is not contained solely in the PSES. When the Court issued its Order relative to the Root Cause Analysis on January 30, 2019, it did so on the basis that Appellant WBGH failed to demonstrate that the purpose of the document was for reporting to the PSO and failed to even allege that the information did not exist elsewhere. Since that time, Appellant WBGH has admitted that the

Root Cause Analysis exists separately from the PSES. When faced with the production of an email between Joan Kies, the chief quality officer at Appellant WBGH, and Dr. Thomas James, the senior medical director at Highmark, regarding the substance of the Root Cause Analysis, counsel for Appellant WBGH admitted: "There is a letter that we are withholding. It's addressed to Highmark and it specifically references the root cause analysis, ok." (EMH, p. 68, 70, 72, 74.) Counsel then went on to make a policy argument about why the information should not be produced in discovery. (EMH, p. 74.)

The PSQIA is clear that patient safety work product "...does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system..." See § 299b-21(7)(B). This is an essential element of the privilege that Appellant WBGH did not allege in its Privilege Affidavit because it knew that the information did exist separately, in an email correspondence between its chief quality officer and its insurer. For this reason, the Root Cause Analysis was never protected patient safety work product and never should have been presented as such.

Finally, Appellant WBGH appears to have either subsequently conceded this point and/or waived any further argument that the

Root Cause Analysis is protected by the PSQIA because it failed to appeal the Court's Order dated June 6, 2019 on the basis that it ordered the production of the Kies-Thomas correspondence, and, in turn, the substance of the Root Cause Analysis. (6/6/19 Credentialing File Order.) Although Appellant WBGH appealed the June 6, 2019 Order which also required the production of certain credentialing files, in its Concise Statement, it raised only the production of the credentialing files as the trial court's error. (7/17/19 Concise Statement.) Accordingly, Appellant WBGH should have already produced the Kies-Thomas correspondence and any further argument regarding the protection of the Root Cause Analysis by the PSQIA is waived.

PRPA: the Burry Event Report, the Root Cause Analysis, and the Quality Improvement Peer Review

Pursuant to the PRPA,

> The proceedings and *records of a review committee shall be held in confidence* and shall not be subject to discovery or introduction into evidence in any civil action against a professional health care provider arising out of the matters which are the subject of evaluation and review by such committee and no person who was in attendance at a meeting of such committee shall be permitted or required to

> testify in any such civil action as to any evidence or other matters produced or presented during the proceedings of such committee or as to any findings, recommendations, evaluations, opinions or other actions of such committee or any members thereof: *Provided, however, That information, documents or records otherwise available from original sources are not to be construed as immune from discovery* or used in any such civil action merely because they were presented during proceedings of such committee... 63 P.S. § 425.4 (1978)(emphasis added).

As defined by the statute, a "review organization" is "...any committee engaging in *peer review*." § 425.2 (1996)(emphasis added).

Further, "peer review" is "the procedure for evaluation *by professional health care providers* of the quality and efficiency of services ordered or performed by other professional health care providers, including practice analysis, inpatient hospital and extended care facility utilization review, medical audit, ambulatory care review, claims review, and the compliance of a hospital, nursing home or convalescent home or other health care facility operated by a professional health care provider with the standards set by an association of health care providers and with applicable laws, rules and regulations." Id. (emphasis added). The PRPA defines

"professional health care provider," as used in the definition of peer review, as "individuals or organizations who are approved, licensed or otherwise regulated to practice or operate in the health care field under the laws of the Commonwealth..." Id.

In Reginelli v. Boggs, the Pennsylvania Supreme Court clarified that protected "peer review" is only conducted by "professional healthcare providers." Reginelli v. Boggs, 181 A.3d 293 (Pa. 2018). As defined by the PRPA, "professional health care provider" means

> (1) individuals or organizations who are approved, licensed or otherwise regulated to practice or operate in the health care field under the laws of the Commonwealth, including, but not limited to, the following individuals or organizations:
>
> (i) a physician;
> (ii) a dentist;
> (iii) a podiatrist;
> (iv) a chiropractor;
> (v) an optometrist;
> (vi) a psychologist;
> (vii) a pharmacist;
> (viii) a registered or practical nurse;
> (ix) a physical therapist;
> (x) an administrator of a hospital, nursing or convalescent home or other health care facility; or
> (xi) a corporation or other organization operating a hospital, nursing or convalescent home or other health care facility; or

(2) individuals licensed to practice veterinary medicine under the laws of this Commonwealth. § 425.2.

The Reginelli Court reviewed a situation where a third party contractor of a hospital, UPMC Emergency Medicine, Inc. ("ERMI"), that provided administrative services to the hospital's emergency room claimed that the PRPA protected a "performance file" about the defendant doctor that was prepared by the director of the hospital's emergency department. Reginelli, 181 A.3d at 296. Notably, both the defendant doctor and the director of the emergency department, who maintained the file, were employees of ERMI, not the hospital. Id. While ERMI argued that the director had conducted a separate peer review outside of the hospital and that the documents were held exclusively by ERMI, the hospital contended that the director's peer review was on behalf of both ERMI and the hospital. Id. at 297-300. The Reginelli Court ultimately concluded that, because ERMI was not a professional healthcare provider, as defined by the PRPA, it was not entitled to the evidentiary protections of the Act. Id. at 304.

As demonstrated by the statutory language of the PRPA, as well as the case law interpreting such language, the identity of the

members of any committee engaging in a purported peer review is an essential element in determining whether the protections of the Act apply. Specifically, with regard to the Quality Improvement Peer Review, the Burry Event Report, and the Root Cause Analysis, Appellant WBGH failed in its burden of proving that the members of the "review organizations" for each document were professional health care providers, as required by the Act.

First, the Privilege Affidavit identified Dale A. Anderson, M.D. as the author of the Quality Improvement Peer Review. (Privilege Affidavit, p. 4.) Pursuant to the PRPA and the precedent set forth in Reginelli, protected peer review may only be conducted by "professional health care providers," defined as individuals or organizations licensed or otherwise regulated to practice or operate in the health care field under the laws of the Commonwealth. See Reginelli, 181 A.3d 293; 63 P.S. § 425.2 (1996). Dr. Anderson has not been licensed to practice medicine in Pennsylvania since 2014, and thus, did not qualify as a professional health care provider at the time of the relevant "peer review." (MTC[4], p. 31-32.) Further, at the time, Dr.

[4] MTC refers to the Notes of Testimony from the Oral Argument commencing on January 23, 2019.

Anderson was a managing partner of NAPA LLP, another non-healthcare provider, and, accordingly, could not have conducted an appropriate peer review on its behalf. (MTC, p. 36-37.)

In response to Appellee's arguments that neither Dr. Anderson nor NAPA LLP could conduct a protected peer review, Appellant WBGH asserted that Dr. Anderson's peer review was undertaken on its behalf even though Dr. Anderson's only connection to the hospital was through NAPA LLP. (MTC, p. 37.) While the Reginelli Court never resolved a similar argument made by the defendants, it provided guidance which is instructive. Reginelli, 181 A.3d at 306. Initially, the Court noted that both the hospital and ERMI had failed to preserve the issue for appeal; however, the Court went on to comment that, even if the argument were properly preserved, it lacked merit. Id. at 306-307. According to the Court, because there was no such contract for peer review services of record, "...the certified record here contains no conclusive documentary evidence to establish, one way or the other, whether [the hospital] contracted with ERMI to conduct peer review on its behalf." Id. at 308. The Reginelli Court ended its discussion by explaining that both the hospital and ERMI were relying on a "snippet" of testimony that the director acted on behalf of ERMI

and the hospital. Id. This was insufficient to establish that the performance file was developed on behalf of the hospital through a third party contract with ERMI for the provision of peer review services. See id.

Similar to the circumstances of Reginelli, the current record lacks sufficient evidence that Appellant WBGH contracted with NAPA LLP and/or Dr. Anderson for the provision of peer review services. The contract between Appellant WBGH and the NAPA entities has never been presented to the Court for this issue, nor have any of its relevant sections been argued as the basis for Appellant WBGH's assertions that the peer review was conducted on its behalf. In fact, the only information of record about the relationship between Appellant WBGH and Dr. Anderson comes from the arguments of counsel. During the Emergency Motion Hearing, counsel for the NAPA entities explained that, after the treatment of Jason Ungurian at WBGH, the chief medical officer for WBGH called his friend, Dr. Anderson, and asked for assistance in conducting the peer review. (EMH, p. 43-44.) This statement by counsel is wholly insufficient to carry Appellant WBGH's burden of demonstrating that the peer review was

conducted by a professional healthcare provider, such that it should be afforded the protections of the PRPA.

In contrast to Appellant WBGH's lengthy arguments about the ability of Dr. Anderson to conduct a peer review on its behalf, it has failed to even identify the members of the alleged peer review committee that produced the Burry Event Report and the Root Cause Analysis. Regarding the Burry Event Report, the Privilege Affidavit states only that, because it was created pursuant to the hospital's Event Reporting Policy, it would have been created by the reporting party, in this case Defendant Robert Burry, CRNA, reviewed by the Department Director/Designee, and later reviewed by either Joan DeRocco-DeLessio or Elizabeth Trzcinski, Appellant WBGH's Coordinator of Patient Safety Services and Department Director. (Privilege Affidavit, p. 3.) Likewise, with regard to the Root Cause Analysis, the only information provided about the individuals conducting the peer review was that it was produced by Appellant WBGH's Root Cause Analysis Committee. (Privilege Affidavit, p. 4.) The failure of Appellant WBGH to provide any information regarding the members of either alleged peer review committee is fatal to its argument that the documents are privileged. Pursuant to Reginelli,

protected peer review is conducted only by professional healthcare providers. Appellant WBGH's vague responses regarding the individuals involved in the peer reviews that produced the Burry Event Report and/or the Root Cause Analysis are insufficient to carry its burden of proving that these documents are afforded protection under the PRPA because it is impossible to determine if a proper review committee was even convened. Reginelli, 181 A.3d 293.

Additionally, for each of the three documents at issue, the Burry Event Report, the Quality Improvement Peer Review, and the Root Cause Analysis, circumstances independent of Appellant WBGH's failure to demonstrate that proper review committees were formed indicate that none of the documents are protected by the PRPA. First, both the Quality Improvement Peer Review and the Root Cause Analysis are available from independent sources. While the PRPA creates a limited privilege for the records of a properly convened review committee, it further provides that "... *information, documents or records otherwise available from original sources are not to be construed as immune from discovery...*" 63 P.S. § 425.4 (1978)(emphasis added). As explained previously, the content of the Root Cause Analysis is the subject of the Kies-Thomas

correspondence. See (EMH, p. 68, 70, 72, 74.) Because there is no allegation that the email between Kies and Thomas was a document generated by a review committee, this is an original source, outside of any peer review, from which the information in the Root Cause Analysis is available. Also, as noted previously, Appellant WBGH has failed to raise the production of the Kies-Thomas correspondence in its appeal, thereby conceding that the information is not protected and/or waiving any further privilege argument.

Likewise, the Quality Improvement Peer Review falls outside of the protections of the PRPA as it is in the possession of NAPA PA, an original source. See (6/3/19 Emergency Motion, p. 11.) If the arguments of both Appellant WBGH and Defendant NAPA LLP are correct that the Quality Improvement Peer Review was conducted for Appellant WBGH, there is no reason that the document should be in the possession of NAPA PA or NAPA LLP. While NAPA LLP argues that Dr. Anderson retained a copy for himself, not for NAPA LLP or NAPA PA, if that were true, then there is no reason that the document should be listed on a privilege log for either entity. (EMH, p. 48.) Clearly, either the NAPA entities and/or their counsel felt that the document was in the entities' possession, not solely the possession of Dr. Anderson, such

that it should be disclosed on a privilege log and thereby admitting that there is an original source of the alleged peer review materials.

Finally, while Appellant WBGH failed in its burden of establishing that the Burry Event Report was generated by a proper review committee, the document also is similar to the type of incident report that is not protected by the PRPA. Pennsylvania courts have consistently held that incident reports are business records of a hospital, not the records of a review committee. See generally Vaccaro v. Scranton Quincy Hospital Co., LLC, 2015 WL 13779743 (Pa. Com. Pl. 2015); Venosh v. Henzes, 2013 WL 9593953 (Pa. Com. Pl. 2013), amended, (Pa. Com. Pl. 2013), and aff'd, 105 A.3d 788 (Pa. Super. 2014); Atkins v. Pottstown Memorial Medical Center, 430 Pa. Super. 279, 634 A.2d 258 (Pa. Super. 1993). Most recently, in Vaccaro, Judge Nealon of the Lackawanna County Court of Common Pleas, relying on the Pennsylvania Superior Court's decision in Atkins, stated as follows: "...an incident report which documents or investigates an injury, unusual event or potential claim is not entitled to peer review protection since it is 'not derived from nor part of evaluation or review by a peer review committee.'" Vaccaro, 2015 WL 13779743 at *7 (*citing* Atkins, 634 A.2d at 260; Venosh, 31 Pa. D. & C. 5th at 426).

Judge Nealon also previously explained in Venosh that "...the critical inquiry in addressing the discoverability of...event reports under the PRPA is whether those reports were prepared by [the] peer review committee exclusively for the purpose of evaluating the quality of the care provided by the treating health care professionals, or instead, were produced by nursing staff, a Department supervisor or risk management personnel to document or investigate a potential claim." Venosh, 2013 WL 9593953 at *7 (internal citations omitted).

Although little is known about the Burry Event Report, from the limited facts of record and in accordance with the Venosh test, the Event Report is more akin to an incident report, rather than a peer review document. Importantly, the Report was created on the March 5, 2018, the day of Jason Ungurian's procedure, by Defendant Robert Burry, a CRNA involved in Mr. Ungurian's care. (Privilege Affidavit, p. 2; MTC, p. 45.) Further, if the Report was created pursuant to the hospital's Event Reporting Policy, as stated in the Privilege Affidavit, then it was reviewed by the Department head and given to those individuals in charge of patient safety at Appellant WBGH. (Privilege Affidavit, p. 3.) Although it is unclear to whom this Report was actually given, a document generated pursuant to Appellant WBGH's Event

Reporting Policy is clearly an incident report held as a business record of the hospital rather than as a protected peer review document. Accordingly, if the Burry Event Report was generated pursuant to the Event Reporting Policy, as asserted in the Privilege Affidavit, it is an incident report that is not afforded the protections of the PRPA.

II. The Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes (April 24, 2019 Order)

Next, the production of the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes are purportedly the subject of two Notices of Appeal in this matter; however, their production is only properly reviewable in one. As is discussed at length in the Court's April 24, 2019 Opinion, Appellant WBGH attempted to immediately appeal the Court's January 30, 2019 Order in relation to the Serious Safety Event Rating Meeting Minutes and the Patient Safety Committee Meeting Minutes under the guise that the Court had ordered an *in camera* review of such documents, which it had not. (4/24/19 Opinion; 3/8/19 Concise Statement.) Following a lengthy hearing on the matter and Appellant WBGH's repeated failures to provide the Court the information necessary to rule on the applicability of the PRPA to the Serious Safety Event Rating

Meeting Minutes and the Patient Safety Committee Meeting Minutes, the Court entered its April 24, 2019 Order requiring that the documents be produced. (4/24/19 Order.) Appellant WBGH then properly filed its Notice of Appeal on April 29, 2019. (4/29/19 Notice of Appeal.) Appellant's challenge to the April 24 Order on the basis of the PRPA is now at issue. Because all matters which Appellant WBGH challenges with regard to the Serious Safety Event Rating Meeting Minutes and the Patient Safety Committee Meeting Minutes are addressed in the Court's April 24, 2019 Opinion, a copy is attached as Exhibit A, incorporated with, and made part of, this Opinion.

III. The Credentialing Files (February 5, 2019 and June 6, 2019 Orders)

Finally, although the entirety of the credentialing files ordered produced in this case are the subject of two separate Orders and two separate Notices of Appeal, Appellant WBGH's arguments regarding protection by the PRPA are identical, thus, they will be addressed collectively. Specifically, Appellant WBGH argues that the PRPA protects the credentialing files of the following individuals: Andrew Beyzman, MD, Robert Burry, CRNA, Katelyn Farrell, RN, JoAnn Thomas, RN, Kristen Yavorski, RN, Kayla Barber, ST, Kimberly Barron, ST, Lisa

Cernera, RNFA, BSN, Calvin Dysinger, MD, Shay Robinson, MD, John Amico, CRNA, Jason McDade, RN and Daniel Walton, RN.

In Reginelli, the Pennsylvania Supreme Court explicitly held that a credentialing committee is not a "review committee," as defined by the PRPA and, thus, its records are not entitled to the privilege afforded by the Act. Reginelli, 181 A.3d 293. When faced with the argument that the director of the emergency department acted as her own peer review committee, the Court elaborated on the definition of a "review committee" versus a "review organization." Id. at 304-306. Only the first sentence of the definition of "review organization" defines a "review committee" entitled to the privilege afforded by the Act, namely, "any committee engaging in peer review." Id. at 305. To the contrary, it is a "review organization" that reviews "the professional qualifications or activities of its medical staff or applicants thereto" and does not involve peer review or the associated privilege. Id. at 305-306.

This holding by the Pennsylvania Supreme Court was recently ratified by the Superior Court's decision in Estate of Krappa v. Lyons. Estate of Krappa v. Lyons, 2019 PA Super 168, 2019 WL 2223329 (Pa. Super. 2019). In Krappa, the Superior Court affirmed a trial court order

requiring the un-redacted production of files from a hospital's credentialing committee for two doctors, one defendant and one non-defendant, based on the Supreme Court's decision in Reginelli. Id. at *1-*2. The Krappa Court explained, "...the Reginelli Court indicated that the PRPA does not extend its grant of an evidentiary privilege to materials that are generated and maintained by entities reviewing the professional qualifications or activities of medical staff i.e., credentials review." Id. at *5. Since the files in question were generated by the hospital's credentialing committee which does not qualify as a "review committee" the Krappa Court affirmed the order for their production. Id. In the current matter, Appellant WBGH has presented absolutely no evidence or argument to distinguish the credentialing files at issue here from those in Reginelli and Krappa. Both the Pennsylvania Supreme and Superior Courts have foreclosed this issue and held that credentialing files are not protected by the PRPA. Accordingly, the credentialing files requested by Appellee are discoverable.

EXHIBIT A

April 24, 2019 Opinion

SUSAN UNGURIAN, Individually and as Guardian of Jason Ungurian, and Incapacitated Person	:	**IN THE COURT OF COMMON PLEAS OF LUZERNE COUNTY**
Plaintiff	:	**CIVIL ACTION MEDICAL MALPRACTICE**
v.	:	
ANDREW BEYZMAN, M.D.; ROBERT BURRY, CRNA; NORTH AMERICAN PARTNERS IN ANESTHESIA (PENNSYLVANIA), LLC, Individually and d/b/a NAPA; NORTH AMERICAN PARTNERS IN ANESTHESIA, LLP, Individually and d/b/a NAPA; WILKES-BARRE HOSPITAL COMPANY, LLC, Individually and d/b/a WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTH CARE SYSTEM, COMMONWEALTH HEALTH and/or COMMONWEALTH HEALTH SYSTEMS, INC.; COMMUNITY HEALTH SYSTEMS, INC., Individually and d/b/a WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTH CARE SYSTEM, COMMONWEALTH HEALTH and/or COMMONWEALTH HEALTH SYSTEM	:	**No. 08789-2018**
Defendant(s)	:	

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PROTHONOTARY LUZERNE COUNTY

ORDER

AND NOW, this 24th day of April, 2019, upon consideration of Plaintiff's "Motion to Strike Objections and Compel Responses to Plaintiff's First and Second Requests for the Production of Documents and First Set of Interrogatories Propounded Upon Defendant, Wilkes-Barre Hospital Company, LLC, Individually and d/b/a Wilkes-Barre General Hospital, Wyoming Valley Health Care System, Commonwealth Health and/or Commonwealth Health System" ("Defendant

WBGH"), "Response of Defendant, Wilkes-Barre Hospital Company, LLC d/b/a Wilkes-Barre General Hospital, In Opposition to Plaintiff's Motion to Strike Objections and Compel Responses to Plaintiff's First and Second Requests for the Production of Documents and First Set of Interrogatories," "Plaintiff's Motion to Quash Defendant WBGH's Notice of Appeal with Respect to Paragraph 2 of the Court's January 30, 2019 and January 31, 2019 Orders; To Compel Production of the Serious Safety Event Rating Meeting Summary and Patient Safety Committee Meeting Minutes; and To Clarify the Court's February 15, 2019 Order," "Response in Opposition of Defendant, Wilkes-Barre Hospital Company, LLC d/b/s Wilkes-Barre General Hospital," briefs, and argument; and for the reasons set forth in the attached Opinion, it is hereby ORDERED as follows:

1. Plaintiff's Motion to Strike Objections and Compel Responses is GRANTED as it relates to the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes. Defendant WBGH shall provide to Plaintiff both the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes within five (5) days of the date of this Order; and,

2. Plaintiff's Motion to Quash is MOOT with regard to the request that the Court refuse to stay the entire case as Defendant WBGH agreed that it would not seek a stay of all proceedings, rather, it would expect only those matters on appeal be stayed.

The Office of Judicial Records/Prothonotary is directed to serve notice of the entry of this Order and attached Opinion pursuant to Pa. R.C.P. 236 to all Counsel of record and parties of record.

BY THE COURT:

LESA S. GELB, J.

cc:

Joseph A. Quinn, Jr., Esquire
Michelle M. Quinn, Esquire
Hourigan, Kluger and Quinn, P.C.
600 Third Ave.
Kingston, PA 18704

Melissa A. Dziak, Esquire
Cipriani & Werner
415 Wyoming Ave.
Scranton, PA 18503

Stuart O'Neal, Esquire
Burns White LLC
100 Four Falls, Suite 515
1001 Conshohocken State Road
West Conshohocken, PA 19428

SUSAN UNGURIAN, Individually and as Guardian of Jason Ungurian, and Incapacitated Person	:	**IN THE COURT OF COMMON PLEAS OF LUZERNE COUNTY**
Plaintiff	:	**CIVIL ACTION MEDICAL MALPRACTICE**
v.	:	
ANDREW BEYZMAN, M.D.; ROBERT BURRY, CRNA; NORTH AMERICAN PARTNERS IN ANESTHESIA (PENNSYLVANIA), LLC, Individually and d/b/a NAPA; NORTH AMERICAN PARTNERS IN ANESTHESIA, LLP, Individually and d/b/a NAPA; WILKES-BARRE HOSPITAL COMPANY, LLC, Individually and d/b/a WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTH CARE SYSTEM, COMMONWEALTH HEALTH and/or COMMONWEALTH HEALTH SYSTEMS, INC.; COMMUNITY HEALTH SYSTEMS, INC., Individually and d/b/a WILKES-BARRE GENERAL HOSPITAL, WYOMING VALLEY HEALTH CARE SYSTEM, COMMONWEALTH HEALTH and/or COMMONWEALTH HEALTH SYSTEM	:	**No. 08789-2018**
Defendant(s)	:	

Copies Mailed 04/25/2019

OPINION

Background

On December 3, 2018, Plaintiff filed her "Motion to Strike Objections and Compel Responses to Plaintiff's First and Second Requests for the Production of Documents and First Set of Interrogatories Propounded Upon Defendant, Wilkes-Barre Hospital Company, LLC, Individually and d/b/a Wilkes-Barre General Hospital, Wyoming Valley Health Care System, Commonwealth Health and/or Commonwealth

Health System" ("Defendant WBGH"). (12/3/18 Motion to Compel.) In her Motion to Compel, Plaintiff argued that Defendant WBGH failed to satisfy its burden of establishing that the asserted privileges ("Peer Review Protection Act – 63 P.S. § 425.5; Patient Safety and Quality Improvement Act – 42 CFR Part 3; Healthcare Quality Improvement Act; Quality Assurance and Improvement; Medical Care Availability & Reduction of Error (MCare) Act – Act 13 of 2002, P.L. 154, No. 13; Patient Safety and Quality Improvement Act of 2005 and its attendant regulations – 42 U.S.C. § 299b-21 *et seq.* and 42 CFP SEC 3.1 *et seq.*") applied to five documents on its privilege log, including, but not limited to, the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes. (12/3/18 Brief, p. 9-10.) Specifically, Plaintiff asserted that Defendant WBGH offered no more than a "boilerplate recitation" that the documents were privileged. (12/3/18 Brief, p. 9-10.)

In its responsive brief filed December 19, 2018, Defendant WBGH argued, in relevant part, that the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes were protected from discovery by the Peer Review Protection Act (the "PRPA"). (12/19/18 Brief, p. 12.) Regarding the Serious Safety Event Meeting Summary, Defendant WBGH explained only that the Serious Safety Event Committee "meets for purposes of reviewing and assessing quality of patient care" and that the summary is "specifically designated as privileged peer review information." (12/19/18 Brief, p. 15-16.) To establish that the Patient Safety Committee Meeting Minutes are protected by the PRPA, Defendant WBGH stated that the committee is "...a multidisciplinary group whose membership is representative of both the hospital and the community it serves" that "...reviews and evaluates patient safety and quality of care." (12/19/18 Brief, p. 16.) According to Defendant WBGH,

the Minutes, which are kept confidential, were prepared by Joan DeRocco, R.N., Director of Patient Safety Services, and Elizabeth Trzcinski, R.N., Risk Coordinator. (12/19/18 Brief, p. 16.) Together with its Answer in Opposition to Plaintiff's Motion to Compel, Defendant WBGH submitted the affidavit of Joan DeRocco-DeLessio, Director of Patient Safety Services at WBGH (the "DeRocco Affidavit"), which provided the information outlined above regarding the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes. (12/19/18 DeRocco Affidavit.) On January 22, 2019, Plaintiff filed a Reply Brief to Defendant WBGH's Opposition Brief, which highlighted that, because the DeRocco Affidavit noted that the Patient Safety Committee includes members of the community in general, then non-healthcare providers likely were part of the committee, such that the protections of the PRPA would not attach. (1/22/19 Reply Brief, p. 10.)

An oral argument on Plaintiff's Motion to Compel commenced before the Court on January 23, 2018. During the Argument, the parties essentially re-iterated the assertions in their briefs. (MTC Argument.) As a result, Defendant WBGH's repeated failure to identify the members of the committee allegedly conducting the relevant peer review was raised multiple times by both Plaintiff and the Court. (MTC Argument, p. 33, 34, 38-40, 42.) In fact, the Court specifically asked Defendant WBGH who was on the peer review committee and never received an answer. (MTC Argument, p. 33.) The Court made it clear to the parties throughout the Argument that, as part of establishing that the peer review privilege applies to the relevant documents, Defendant WBGH would have to reveal the members of the committee, as Plaintiff raised the argument that the committees were comprised on non-healthcare providers. The Court stated, "...you have to say who's on the committee." (MTC

Argument, p. 34.) Still, as will be discussed later, Defendant WBGH claims that it believes the Court's subsequent Order required an *in camera* review of the allegedly privileged document, not simply the additional information necessary for the Court to rule on whether the peer review privilege applies. The only mention of an *in camera* review during the Argument was in relation to credentialing files and completely unrelated to the current matter. (MTC Argument, p. 56-57.)

On January 30, 2019, the Court issued an Order which stated, in relevant part, as follows:

> 2. Defendant WBGH shall submit to the Court the following information about both the Serious Safety Event Rating Meeting and the Patient Safety Committee Meeting Minutes: the author of the document, the purpose of the document, the attendees at the meeting, and any other recipients of the document; and, (1/30/19 Order.)

The Court filed an additional Order on January 31, 2019, imposing a deadline of fifteen days within which Defendant WBGH was required to provide the additional information regarding the circumstances of the alleged peer review for the Serious Safety Event Rating Meeting and the Patient Safety Committee Meeting Minutes. (1/31/19 Order.) On February 14, 2019, Defendant WBGH filed Notices of Appeal to the Pennsylvania Superior Court for both the January 30 and January 31 Orders. (Notices of Appeal.) Pursuant to the Court's Order dated February 15, 2019, Defendant WBGH filed its Concise Statements of Matters Complained of on Appeal in relation to the January 30 and 31 Orders on March 8, 2019. The portion of the Concise Statement relevant to the current matter states:

> 3) Whether the Trial Court's ruling that Defendant/Appellant, Wilkes-Barre Hospital Company, LLC d/b/a Wilkes-Barre General Hospital, is to produce information for *in camera* review relating to the Serious

> Safety Event Rating Meeting Summary dated April 12, 2018, and the Meeting Minutes from the Patient Safety Committee held on May 15, 2018, violates the privilege provisions of the Pennsylvania Peer Review Protection Act?" (Concise Statement.)

On February 22, 2019, Plaintiff filed her "Motion to Quash Defendant WBGH's Notice of Appeal with Respect to Paragraph 2 of the Court's January 30, 2019 and January 31, 2019 Orders; To Compel Production of the Serious Safety Event Rating Meeting Summary and Patient Safety Committee Meeting Minutes; and To Clarify the Court's February 15, 2019 Order." (2/22/19 Motion to Quash.) In her Motion to Quash, Plaintiff requested that the Court require Defendant WBGH to produce the Serious Safety Event Rating Meeting Summary and Patient Safety Committee Meeting Minutes because Defendant WBGH failed to meet its initial burden of proving that the documents were privileged and failed to provide the additional information necessary for the Court to render its decision. (Motion to Quash Brief, p. 4.) The Motion also requested that the entire case not be stayed during the pending appeal. (Motion to Quash Brief, p. 4.) Plaintiff's theory that the Court should require the production of the information identified in Number 2 of its January 30 Order notwithstanding the pending appeal was premised on the idea that Number 2 is a non-appealable interlocutory order. (Motion to Quash Brief, p. 8-11.)

Defendant WBGH filed its Response in Opposition to Plaintiff's Motion to Quash on March 18, 2019. (Motion to Quash Response.) In its Response, Defendant WBGH initially clarified that it would not request a stay of the entire case during the pendency of the appeal and argued that the trial court is without authority to quash an appeal to the Superior Court. (Motion to Quash Response Brief, p. 5-8.) Further, Defendant WBGH specifically asserted that the Court's Order for an *in camera* review

of information relating to the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes violates the Peer Review Protection Act, and is thus, an immediately appealable collateral order. (Motion to Quash Response Brief, p. 8-9.) To support its contention, Defendant WBGH cited the analysis of the Pennsylvania Superior Court in Farrell v. Regola. (Motion to Quash Response Brief, p. 9.) In its brief, Defendant WBGH quoted the Farrell Court as stating "if materials are privileged, no one, not even a trial judge, may have access to them." (Motion to Quash Response Brief, p. 10.) Defendant WBGH ended its argument regarding the information requested by the Court in Number 2 of its January 30, 2019 Order, by stating, "[u]nder Farrell, even an *in camera* review of these documents would violate the asserted privilege." (Motion to Quash Response Brief, p. 10.)

Based on its review of Defendant WBGH's Concise Statements and Response to Plaintiff's Motion to Quash, on March 20, 2019, the Court ordered Defendant WBGH to be prepared to address at the previously scheduled April 16, 2019 hearing where in the record the Court ordered an *in camera* review of the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes. (3/20/19 Order.) Immediately prior to the April 16, 2019 hearing, Defendant WBGH provided its Response to the Court's March 20, 2019 Order. The Response indicated that Defendant WBGH's arguments regarding the alleged *in camera* review rest solely on Number 2 of the Court's January 30, 2019 Order. (4/16/19 Response.)

During the April 16, 2019 hearing, prior to argument on Plaintiff's Motion to Quash, the Court explained to counsel for Defendant WBGH that ordering an *in camera* review of allegedly privileged documents is far different from Number 2 of the Court's January 30, 2019 Order, which asked for the type of information that

would normally be included in an appropriate privilege log. (4/16/19 Argument, p. 95-101.) The Court stated, "[b]ut the Court never, never asked to do an *in camera* review..." (4/16/19 Argument, p. 96.) Still, counsel for Defendant WBGH insisted that it was the defense's reading that the January 30, 2019 Order required an *in camera* review of the "written material." (4/16/19 Argument, p. 96.) In the face of the Court's repeated declarations that the January 30 Order did not require an *in camera* review of the documents, counsel for Defendant WBGH persisted that an *in camera* review was ordered because Number 2 required that the information be sent to the Court and the Order did not use the words "privilege log." (4/16/19 Argument, p. 103, 105.) After explaining that some of the information requested in Number 2 of the January 30, 2019 Order had been supplied in a privilege log and the only outstanding information was the attendees at the meeting and the recipients of the documents, counsel for Defendant WBGH for the first time raised that such information itself is privileged. (4/16/19 Argument, p. 104.)

Following discussion of Defendant WBGH's misrepresentation to the Pennsylvania Superior Court that the trial court ordered an *in camera* review of privileged documents, the Court proceeded with the merits of Plaintiff's Motion to Quash. Plaintiff's counsel initially conceded that the trial court is unable to "quash" an appeal to the Superior Court, but requested that the Court act on Number 2 of its January 30 Order which is a non-appealable interlocutory order. (4/16/19 Hearing, p. 100-101.) Later, counsel for Defendant WBGH clarified that it would not request a stay of the entire case and only expects that the Court will not act further on those matters currently before the Superior Court. (4/16/19 Hearing, p. 107-108.)

Argument

Trial Court Jurisdiction

Pursuant to Rule 1701 of the Pennsylvania Rules of Appellate Procedure, once an appeal is taken, the trial court "...may no longer proceed further in the matter;" however, the same rule outlines certain actions a trial court may take while an appeal is pending. Pa. R.A.P. 1701 (2013). Notably, a trial court may "[p]roceed further in any matter in which a non-appealable interlocutory order has been entered, notwithstanding the filing of a notice of appeal or a petition for review of the order." Pa. R.A.P. 1701(b)(6). In the instant matter, the Court has jurisdiction to act on the matters set forth in Number 2 of its January 30, 2019 and January 31, 2019 Orders because they are non-appealable interlocutory orders.

While an appeal may be taken as of right from any order that disposes of all claims and of all parties, an appeal may only be taken as of right from an interlocutory order in certain circumstances, including those affecting judgments, attachments, change of criminal venue or venire, injunctions, peremptory judgment in mandamus, order for new trial, order directing partition, orders made final by rule or statute, order sustaining venue or jurisdiction, changes of venue, Commonwealth appeals in criminal cases, orders overruling preliminary objections in eminent domain cases, and administrative remands. Pa. R.A.P. 311 (2016); Pa. R.A.P 341 (a)&(b) (2016). Additionally, orders overruling asserted privileges and requiring that the document be produced are immediately appealable collateral orders. Custom Designs & Mfg. Co. v. Sherwin-Williams Co., 39 A.3d 372, 375 (Pa. Super. 2012). As Number 2 of the January 30 and 31 Orders is not a final order, nor fits the definition of an interlocutory order appealable as of right, there is no authority under those rules for Defendant

WBGH's appeal. Likewise, as Number 2 does not order the disclosure of any allegedly privileged information, it is not a collateral order which may be immediately appealed. Accordingly, for the reasons discussed at length below, no appeal can lie from the Court's interlocutory order in Number 2 of the January 30 or January 31 Orders.

Defendant WBGH appears to concede the point that Number 2 of the relevant orders are not the type of directives that are generally appealable as of right. As a consequence of this fact, Defendant WBGH misrepresents the nature of the Court's instructions in Number 2 of its January 30 Order. Knowing that orders requiring the production of privileged material are generally immediately appealable collateral orders, Defendant WBGH chose to frame Order Number 2 as such an order where clearly it is not. Number 2 of the Court's January 30 Order does not in any way require the production of privileged material. To the contrary, as will be discussed below, it requests information that is necessary for the Court to determine whether the peer review privilege applies to the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes. During the Court's first review of this issue upon the filing of Plaintiff's Motion to Compel, Defendant WBGH simply failed to satisfy its burden that the privilege afforded in the PRPA applies to either document. The Court directly addressed Defendant WBGH's failure to satisfy its burden of proof on this issue during the argument on Plaintiff's Motion to Compel. (MTC Argument, p. 33, 34, 38-40, 42.) Following the Argument, in its January 30 Order, Number 2, the Court gave Defendant WBGH another chance to satisfy its burden and provide the Court with the information necessary to rule on Plaintiff's Motion to Compel. (1/30/19 Order.) Instead of providing the information and

creating the record it should have created in response to the Motion to Compel, Defendant WBGH appealed Number 2 under the guise that the Court had ordered an *in camera* review of privileged material.

The notion that the Court ever ordered an *in camera* review of the allegedly privileged material is simply erroneous. There was never a discussion about the Court conducting an *in camera* review of the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes during the Argument on the Motion to Compel. (See MTC Argument.) More importantly, Number 2 of the January 30 Order neither uses the term *in camera* review, nor orders that the Serious Safety Event Rating Meeting Summary or the Patient Safety Committee Meeting Minutes be produced to anyone. If it were not already obvious that an *in camera* review had not been ordered, the Court directly addressed counsel for Defendant WBGH during the April 16, 2019 hearing, explaining that it considered the information ordered produced to be that which would be included in an appropriate privilege log and that it never intended that the allegedly privileged documents be turned over to anyone. (4/16/19 Argument, p. 95-101.)

After failing to convince the Court that its own intent in issuing the January 30 Order was for an *in camera* review, counsel for Defendant WBGH attempted yet another way to transform the order in Number 2 into an immediately appealable collateral order: the information itself is also privileged. (4/16/19 Argument, p. 104.) The record reflects that this was never counsel's argument previously, as Defendant WBGH's filings and representations at arguments reflect its assertion that Number 2 was appealable based solely on the Court allegedly having ordered an *in camera* review and the precedent set forth in Farrell v. Regola. More importantly, Defendant

WBGH provides absolutely no legal authority, statutory or case law, to support its contention that the members of a peer review committee or information regarding the dissemination of an allegedly privileged document is itself privileged.

Although Defendant WBGH attempts to divest this Court of jurisdiction relevant to the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes by redirecting the Superior Court to a legal analysis over the applicability of Farrell v. Regola, such analysis is unnecessary as no *in camera* review was ordered or will be ordered. Number 2 of the January 30, 2019 Order is a non-appealable interlocutory order because it does not require the production of privileged materials to anyone, including the Court for *in camera* review. Additionally, while Plaintiff notes that no *in camera* review was previously ordered, but now requests that the Court conduct an *in camera* review consistent with Yocabet v. UPMC Presbyterian, such review would be fruitless as it would not cure Defendant WBGH's failure to even assert the necessary elements to establish that privilege applies under the PRPA. (4/16/19 Argument, p. 109.) Unlike in the current matter, the Yocabet Court specifically found that the defendant "...made the appropriate proffer as to the applicability of the peer review privilege" prior to ordering an *in camera* review to determine whether all information was covered by the privilege facially asserted. Yocabet v. UPMC Presbyterian, 119 A.3d 1012, 1028-1029 (Pa. Super. 2015). Here, Defendant WBGH has not made the appropriate proffers and has not satisfied its burden of establishing that a privilege applies even facially. Further, a review of the substance of either document will not provide the information necessary to even facially establish the existence of the privilege. Consequently, the Court will not now order an *in camera* review or reach the issue of the applicability of Farrell v. Regola,

and, instead, proceeds to the merits of Plaintiff's Motion to Compel as it relates to the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes.

Peer Review Privilege

Defendant WBGH asserts that the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes are protected from discovery by the PRPA only. Pursuant to the PRPA,

> The proceedings and *records of a review committee shall be held in confidence* and shall not be subject to discovery or introduction into evidence in any civil action against a professional health care provider arising out of the matters which are the subject of evaluation and review by such committee and no person who was in attendance at a meeting of such committee shall be permitted or required to testify in any such civil action as to any evidence or other matters produced or presented during the proceedings of such committee or as to any findings, recommendations, evaluations, opinions or other actions of such committee or any members thereof: *Provided, however, That information, documents or records otherwise available from original sources are not to be construed as immune from discovery* or used in any such civil action merely because they were presented during proceedings of such committee... 63 P.S. § 425.4 (1978)(emphasis added).

As defined by the statute, a "review organization is "...any committee engaging in *peer review*." § 425.2 (1996)(emphasis added).

Further, "peer review" is "the procedure for evaluation *by professional health care providers* of the quality and efficiency of services ordered or performed by other professional health care providers, including practice analysis, inpatient hospital and extended care facility utilization review, medical audit, ambulatory care review, claims review, and the compliance of a hospital, nursing home or convalescent home or other health care facility operated by a professional health care provider with the

standards set by an association of health care providers and with applicable laws, rules and regulations." Id. (emphasis added). The PRPA defines "professional health care provider," as used in the definition of peer review, as "individuals or organizations who are approved, licensed or otherwise regulated to practice or operate in the health care field under the laws of the Commonwealth..." Id.

It is well established by the courts of the Commonwealth of Pennsylvania that "[t]he burden of establishing privilege is on the party seeking to prevent disclosure." Ario v. Deloitte & Touche LLP, 934 A.2d 1290, 1294 (Pa. Commw. Ct. 2007). In the event that the party seeking to prevent disclosure satisfies its burden, the burden then shifts to the opposing party to demonstrate that the privilege was waived or an exception applies. Custom Designs & Mfg. Co. v. Sherwin-Williams Co., 39 A.3d 372, 376 (Pa. Super. 2012). In the matter currently before the Court, Defendant WBGH failed to satisfy its initial burden that a privilege under the PRPA applies to the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes.

In support of its argument that the two documents are protected by the peer review privilege, Defendant WBGH provided only limited, general information regarding the process through which both documents were generated and failed to establish the necessary elements of the privilege pursuant to the PRPA. First, the only information about the Serious Safety Event Committee, which allegedly engaged in peer review, is that it assesses patient care and the summary of its meeting is designated as peer review. (12/19/18 Brief, p. 15-16.) Because the PRPA requires that peer review activities be conducted by professional healthcare providers, as defined by the statute, it is necessary to know the members of the committee.

Defendant WBGH also failed to even mention whether this document is kept in confidence or whether it may be available from another source. Similarly, regarding the Patient Safety Committee Meeting Minutes, Defendant WBGH merely stated that the committee is comprised of members of the community and hospital without naming those individuals or even claiming that they are professional healthcare providers. Although Defendant WBGH provided the purpose of the Committee and stated that the Minutes are kept confidential, it has totally failed to establish that the Committee is a proper review committee which may engage in protected peer review.

Finally, even after Defendant WBGH failed in its burden of establishing that the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes are privileged peer review documents, the Court provided it multiple additional opportunities to do so. Not only was Number 2 of the January 30, 2019 Order aimed at the Court gaining information necessary to make a proper ruling on the asserted privilege, but the relevant questions were again posed to Defendant WBGH by the Court during the April 16, 2019 oral argument. Instead of availing itself of the opportunities to satisfy its burden, Defendant WBGH misrepresented the nature of Number 2 of the Court's January 30 Order in an attempt to appeal a non-appealable interlocutory order. As a result, the Court is constrained to order the Serious Safety Event Rating Meeting Summary and the Patient Safety Committee Meeting Minutes produced based on an under-developed record regarding Defendant WBGH's claims that the documents are protected by the PRPA.

ADDENDUM C

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IN THE CIRCUIT COURT OF THE THIRTEENTH JUDICIAL CIRCUIT
IN AND FOR HILLSBOROUGH COUNTY, STATE OF FLORIDA
CIVIL DIVISION

LAWRENCE BRAWLEY,

Plaintiff,
v.

Case No. 17-CA-000119
Division: A

DONALD A. SMITH, M.D.,
UNIVERSITY OF SOUTH FLORIDA
BOARD OF TRUSTEES, and FLORIDA
HEALTH SCIENCES CENTER, INC.,
d/b/a TAMPA GENERAL HOSPITAL,

Defendants.
_____/

STATEMENT OF INTEREST OF THE UNITED STATES

It is in the interest of the United States that Patient Safety Work Product ("PSWP") is protected in this litigation, consistent with federal law, which requires that the Court analyze the purpose for which Tampa General Hospital ("TGH") created the documents that TGH seeks to protect as PSWP. The United States submits this statement of interest to address a matter of importance: reducing preventable medical errors by ensuring that PSWP created for the system of voluntary reporting established by the Patient Safety and Quality Improvement Act of 2005 ("Federal Act"), 42 U.S.C. 299b-21 *et seq*, will remain privileged and confidential. The privileged and confidential nature of PSWP lies at the heart of the system of reporting under which health care providers

voluntarily create PSWP to provide to Patient Safety Organizations (PSOs) with the aim of improving patient safety and the quality of care nationwide.

I. BACKGROUND

Federal Law

1. In 1999, the Institute of Medicine (IOM) issued a seminal report finding that preventable medical errors were responsible for tens of thousands of deaths each year, costing the country tens of billions of dollars annually, and proposing a "national agenda for reducing errors in health care." IOM, *To Err Is Human: Building a Safer Health System* (1999). One of the IOM's most important findings was that, although most medical errors are the result of human factors, most errors are systemic, meaning that they are due to breakdowns in the systems that deliver care. *Id.* at 51-53. To eliminate preventable medical errors and systemic breakdowns, the IOM endorsed voluntary reporting programs that encourage providers to share information about patient safety events so that those events can be analyzed. *Id.* at 9-10, 89-90. Further, because "fears about the legal discoverability of information" can discourage voluntary reporting, the IOM urged Congress to enact legislation protecting the confidentiality of information collected or shared "solely for purposes of improving safety and quality." *Id.* at 10.

2. In 2005, in response to the IOM's findings, Congress enacted the Federal Act, establishing a system under which health care providers can voluntarily report PSWP to PSOs with the aim of improving patient safety and the quality of care nationwide. *See* 42 U.S.C. §§ 299b-21 – § 299b-26.1; *see also* Patient Safety & Quality Improvement, 73 Fed. Reg. 70,732, 70,732 (Nov. 21, 2008). The PSOs aggregate and analyze PSWP and

provide feedback to health care providers with a goal to eliminate preventable medical errors. *See* H.R. Rep. No. 109-197 at 9. The providers receive broad privilege and confidentiality protections for PSWP, which alleviates concerns about PSWP being used against providers, such as in litigation. These broad protections are "intended to encourage the reporting and analysis of medical errors," H.R. Rep. No. 109-197 at 9, and are "required to encourage the reporting of errors and to create an environment in which errors became opportunities for learning and improvement," S. Rep. 108-196 at 3.

3. The Federal Act expressly provides that PSWP is both privileged and confidential "notwithstanding any other provision of Federal, State or local law." 42 U.S.C. §§ 299b-22(a), (b).

4. The Federal Act defines PSWP to mean "any data, reports, records, memoranda, 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." 42 U.S.C. § 299b-21(7)(A). PSWP "does not include a patient's medical record, billing and discharge information, or any other original patient or provider record," 42 U.S.C. § 299b-21(7)(B)(i), or "information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system," 42 U.S.C. § 299b-21(7)(B)(ii).

5. The Federal Act defines "patient safety evaluation system" to mean "the collection, management, or analysis of information for reporting to or by a [PSO]. 42 U.S.C. § 299b-21(6).

6. "Information may become [PSWP] 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 [PSWP]. 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 [PSWP] unless the provider determines that certain information must be removed from the patient safety evaluation system for reporting to the state. Once removed from the patient safety evaluation system, this information is no longer [PSWP]." 73 Fed. Reg. 70732, 70,742 (Nov. 21, 2008).

7. PSWP is confidential and is not subject to discovery in any administrative or judicial proceeding. 42 U.S.C. 299b-22(a), (b), and (c).

Florida Law

8. In 2004, Florida voters passed Amendment 7 — the "Patients' Right to Know About Adverse Medical Incidents" provision — which added Article X, Section 25 to the Florida Constitution. Art. X, § 25, Fla. Const. Amendment 7 provides that "patients have a right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident." *Id.* Further, Amendment 7 establishes that "[t]he phrase 'have access to any records' means, in

addition to any other procedure for producing such records provided by general law, making the records available for inspection and copying upon formal or informal request by the patient or a representative of the patient . . . ." *Id.*

9. In *Charles v. Southern Baptist Hospital of Florida, Inc. (Charles II)*, the Florida Supreme Court held that the Federal Act did not preempt Amendment 7. 209 So.3d 1199, 1212 (Fla. 2017). Even where the Federal Act and Amendment 7 overlap, a "mandatory disclosure law in [the] state constitution is not preempted by a health care provider's choice to participate in the Federal Act, coupled with its choice to place documents into a patient safety evaluation system." *Id.* at 1214. Further, the Florida Supreme Court held that "adverse medical incident reports" are not PSWP "because Florida statutes and administrative rules require providers to create and maintain these records." *Id.* at 1216. Specifically, the Court ruled that the documents fell within the Federal Act's exception for information that is "collected, maintained, or developed separately, or exists separately," from a patient safety system because "Amendment 7 provides patients with a constitutional right to access these records." *Id.* at 1211.

The Brawley Litigation

10. Tampa General Hospital (TGH) filed a Motion for Protective Order (MPO) requesting that this Court grant a limited protective order related to Plaintiff's Adverse Medical Incident Request to produce documents during the pendency of the Declaratory Action pending in the United States District Court for the Middle District of Florida and only as to the documents subject to that action. In the federal action, TGH asserts that the 248 documents that have been submitted to the Patient Safety Organization of Florida

and are responsive to Plaintiff Brawley's request are privileged and confidential pursuant to the Federal Act. *Florida Health Sciences Center, Inc. v. Azar*, No. 8:18-cv-00238 (M.D. Fla.), Dkt. 17 at ¶ 22. TGH further asserts that the Florida Supreme Court ruled in *Charles II* that these types of documents are not protected and the Florida Constitution mandates disclosure. *See id.* at ¶¶ 24, 34.

11. This Court denied TGH's Motion for Protective Order and ordered TGH to produce the documents to Plaintiff Brawley.

II. DISCUSSION

In its Motion for Protective Order, TGH asserts that some documents responsive to Plaintiff's discovery request, specifically those that have been submitted to PSO Florida, are privileged and confidential pursuant to the Federal Act. Dkt. 48, ¶ 3. TGH further asserts that the Florida Supreme Court decision in *Charles II* mandates the disclosure of these types of documents. Id. at ¶ 4. The United States takes no position as to whether the 248 documents are, in fact, PSWP. The United States' interest is in ensuring proper application of the Federal Act. To the extent the Florida Supreme Court decision in *Charles II* requires the disclosure of PSWP, the decision would conflict with the Federal Act and would be preempted by it. Therefore, in determining whether any of the documents are PSWP and thus may be upheld from production, the Court should apply the Federal Act and determine the purpose for which the documents were assembled or developed to decide whether they are bona-fide PSWP.

A. The Federal Act Preempts the Florida Supreme Court Decision in *Charles II* Insofar As It Requires the Production of PSWP.

"The Supremacy Clause of Art. VI of the Constitution provides Congress with the power to preempt state law." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 368 (1986). "State action may be foreclosed by express language in a congressional enactment . . . ." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001) (citations omitted).

Here, the Federal Act states that: "[n]otwithstanding any other provision of Federal, State, or local law . . . [PSWP] shall be confidential and shall not be disclosed." 42 U.S.C. § 299b–22(b). This express preemption clause in the Federal Act demonstrates Congress's intent to supersede any state law requiring the production of documents that meet the definition of PSWP. *See* 73 Fed. Reg. 70,732, 70,774 (Nov. 21, 2008) (stating that the Patient Safety Act "generally preempt[s] State or other laws that would permit or require disclosure of information contained within patient safety work product"). It is clear that the Court must apply the Federal Act to determine the confidentiality and privilege of the documents at issue.

In *Charles II*, the Florida Supreme Court concluded incorrectly that mandatory state disclosure laws were not preempted by the Federal Act. 209 So.3d 1199, 1212 (Fla. 2017). *Charles II* turns the Supremacy Clause on its head by allowing general Florida document disclosure laws to nullify the federal privilege and confidentiality protections for PSWP. States may not eliminate the privilege and confidentiality protections in the Federal Act—and gut the federal program designed to improve health outcomes through voluntary remediation of preventable errors—by foisting state disclosure requirements on providers. The potential programmatic impact is significant because *Charles II* has no

limiting principle. The scope of records covered by Amendment 7 is unbounded and could require the wholesale production of PSWP in litigation across Florida.

The Court should not automatically require the production of all documents that TGH turned over to the PSO, as such a categorical approach runs contrary to the Federal Act. Rather, the Court should conduct a review of the disputed documents to determine whether any PSWP exists among them, as well as ensure that any PSWP is protected consistent with federal law.

B. The Federal Act Sets the Standard for Reviewing TGH's Documents

The Federal Act is the standard for review of the documents subject to the Court's July 11, 2018 Order to determine whether they qualify as protected PSWP. In conducting its review, the Court must look to the broadly defined categories of material listed in the Federal Act: ". . . any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" which "could result in improved patient safety … quality, or … outcomes;" and are "assembled or developed" for the purpose of reporting to a PSO and in fact be reported to a PSO. 42 U.S.C. § 299b-21(7)(A). Application of any other standard may contravene Congress' intent to keep PSWP privileged and confidential.

1. The Court Should Determine the Purpose for Which the Documents Were Assembled or Developed.

The purpose for which the documents were assembled or developed must be known to determine with any accuracy whether the documents subject to the Court's July 11, 2018 Order qualify as PSWP.

The relevant portion of the definition of PSWP in the Federal Act states that PSWP is "data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" which "could result in improved patient safety … quality, or … outcomes" and are "assembled or developed by a provider for reporting to a [PSO] and are reported to a [PSO]." 42 U.S.C. § 299b-21(7)(A)(i). A common sense reading of this language is that it describes information that a provider assembles or develops for the purpose of reporting to a PSO—not information that must be created for some other purpose. As the Florida Supreme Court correctly stated, [PSWP] ''does not include a patient's medical record, billing and discharge information, or any other original patient or provider record." *Charles II*, 209 So.3d 1199, 1210 (Fla. 2017).

In May 2016, HHS issued guidance to "clarify what information that a provider creates or assembles can become [PSWP]." *HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations*, 81 Fed. Reg. 32655 (May 2016) ("HHS Guidance"). The guidance explains that "the reporting pathway is how providers generally create most of their PSWP." *Id.* at 32656. Accordingly, confidentiality and privilege determinations of PSWP are rooted in the purpose for which each document was assembled or developed and is a critical factor in determining whether information is bona-fide PSWP. Under the Federal Act, the Court must determine with specificity the purpose for which the documents were assembled or developed to determine with accuracy whether the documents are, indeed, PSWP.

The HHS guidance provides examples of determinations as to whether information is PSWP and makes clear that the answer depends squarely on the purpose

for which the information is assembled or developed. One example explains that "[a] list of provider staff who were present at the time a patient incident occurred" is not PSWP if prepared "[t]o ensure appropriate levels of clinician availability (e.g., routine personnel schedules), or for compliance purposes," but may be PSWP if "following the incident, the provider originally assembles the list for reporting to a PSO so the PSO can analyze the levels and types of staff involved in medication errors." *Id.* at 32656. Another example explains that "[w]ritten reports of witness accounts of what they observed at the time of a patient incident" is not PSWP if prepared "[f]or internal risk management (claims and liability purposes)," but may be PSWP if prepared "for reporting to a PSO so that the richness of the narrative can be mined for contributing factors." *Id.* These examples demonstrate the fact-specific nature of determining whether information is PSWP, as well as the fact that purpose is a key area of inquiry in making document-by-document privilege determinations.

2. *PSWP Does Not Include Information That is Separate From a Patient Safety Evaluation System.*

The Federal Act also excludes "information … collected, maintained, or developed separately, or [that] exists separately, from a patient safety evaluation system" from the definition of PSWP. 42 U.S.C. § 299b-21(7)(B)(ii). In *Charles II*, the Florida Supreme Court held that any document that may potentially be reported pursuant to state record keeping and reporting must exist separately from the patient safety evaluation system and therefore cannot be PSWP. This interpretation is incorrect; it contradicts the Federal Act, HHS regulations, and HHS clarifying guidance because it equates records "collected, maintained, or developed separately," with records "not created solely for the

purpose of submission to a patient safety evaluation system." In fact, "information … collected, maintained, or developed separately, or [that] exists separately, from a patient safety evaluation system" refers to where information is stored—either inside or outside the patient safety evaluation system. Further, this interpretation from *Charles II* runs contrary to the HHS' assurances that providers may place information into their patient safety evaluation system with the expectation of protection and may later remove the information if the provider later determines that it must be reported to the State. 73 Fed. Reg. at 70,732, 70,742 (Nov. 21, 2008). Privilege attaches to information created within the patient safety evaluation system immediately upon collection of the information and not at the time that the information is sent to a PSO. *Id.* at 70,741.

As indicated above, this overbroad interpretation subordinates the federal privilege and confidentiality provisions in the Federal Act to Florida law and fails to protect PSWP from state discovery laws. If the "exists separately" exception is read to cover information that "exists" in any part because of a state law requirement, it would defeat Congress's intent to preempt all state law requiring the production of documents that meet the definition of PSWP. The defeat of federal preemption would, in turn, defeat the main purpose of the Federal Act by gutting the incentive for health care providers to voluntarily report PSWP to PSOs and remediate preventable systemic medical errors.

The Court here should ask a straightforward and factual question to determine whether the documents qualify for this exception: Did TGH maintain the documents in its patient safety evaluation system for reporting to PSO Florida? If the answer to that

question is "yes," then the documents are not excluded from the definition of PSWP under the exception in 42 U.S.C. § 299b-21(7)(B)(ii).

III. CONCLUSION

The Court should apply the Federal Act in its review of the documents in a manner consistent with federal law as intended by Congress, and further explained in HHS guidance, to ensure that any PSWP that may be included in the disputed documents is protected from disclosure.

Respectfully submitted,

MARIA CHAPA LOPEZ
United States Attorney

By: */s/ Michael R. Kenneth*
MICHAEL R. KENNETH
Assistant United States Attorney
Florida Bar No. 44341
400 North Tampa Street, Suite 3200
Tampa, Florida 33602
Telephone: 813-274-6000
Facsimile: 813-274-6198
E-Mail: michael.kenneth@usdoj.gov

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing has been sent via E-mail on the 1st day of February 2019 to the following parties:

Chris M Limberopoulos
Kevin M Sparkman
Florida Law Group
407 N. Howard Avenue, Suite 100
Tampa, FL 33606
kevin@floridalawgroup.org

Derek M Daniels
Mason B Brinkley
McCumber, Daniels, Buntz, Hartig, Puig & Ross, P.A.
4401 West Kennedy Boulevard, Suite 200
Tampa, FL 33609
ddaniels@mccumberdaniels.com
mbinkley@mccumberdaniels.com

Derek B Alvarez
Genders Alvarez Diecidue
2307 West Cleveland Street
Tampa, FL 33609
GADeservice@gendersalvarez.com

Erin B Reynolds
Hughes Hamilton Rice
Bush Graziano Rice & Platter, P.A.
100 S. Ashley Drive, Suite 1400
Tampa, FL 33602
ereynolds@bgrplaw.com

Michael J Trentalage
Trentalange & Kelly, P.A.
218 N. Dale Mabry Highway
Tampa, FL 33609
mjt@tktampa.com

/s/ Michael R. Kenneth
Michael R. Kenneth
Assistant United States Attorney