ANN MARIE VENOSH,	:	IN THE COURT OF COMMON PLEAS
	:	OF LACKAWANNA COUNTY
Plaintiff	:	
vs.	:	CIVIL ACTION - LAW
JACK HENZES, M.D., CINDY S. ANDERSON, PA-C, SCRANTON ORTHOPEDIC SPECIALISTS, P.C., and MOSES TAYLOR HOSPITAL,	:	NO. 11 CV 3058
Defendants	:	

MEMORANDUM AND ORDER

NEALON, J.

The defendant hospital in this malpractice action has appealed the Special Trial Master's discovery order directing it to produce two incident or "event" reports pertaining to plaintiff's medical treatment which serves as the basis for this suit. The hospital contends that the event reports are privileged and protected from discovery by Section 4 of the Peer Review Protection Act ("PRPA"), 63 P.S. § 425.4, Section 311 of the Medical Care Availability and Reduction of Error ("MCARE") Act, 40 P.S. § 1303.311, and Section 299b-22 of the federal Patient Safety Quality Improvement Act of 2005 ("PSQIA"), 42 U.S.C. § 299b-22.

The hospital's "Event Reporting" policy that was in effect at the time that the two event reports were prepared, and the language of the hospital's "Event Report" form that was utilized, do not indicate that those reports were generated by or for a peer review committee as part of a quality assurance assessment, and as such, they do not qualify for peer review protection under the PRPA. Similarly, since the available record does not reflect that the event reports "arise out of matters reviewed by" the hospital's patient safety committee or governing board pursuant to its statutory responsibility to review, evaluate and report "serious events and incidents," they are not immune from discovery under the patient safety provisions of the MCARE Act. Finally, the two event reports do not constitute "patient safety work product" subject to a "federal medical peer review privilege" under the PSQIA in that there is no indication in the record that the reports were provided to a duly certified patient safety organization or a comparable patient safety committee. Consequently, the event reports are discoverable and the hospital's discovery appeal will be denied.

I. FACTUAL BACKGROUND

Plaintiff, Ann Marie Venosh ("Venosh"), has instituted this medical negligence suit against her orthopedic surgeon, Jack Henzes, M.D. ("Dr. Henzes"), his surgical assistant, Cindy S. Anderson, PA-C, and his orthopedic group, Scranton Orthopedic Specialists, P.C., as well as Moses Taylor Hospital ("Moses Taylor"), based upon a left total knee replacement surgery that Dr. Henzes performed on Venosh at Moses Taylor on June 11, 2009. (Docket Entry No. 47 at ¶¶ 1-3; Docket Entry No. 48 at ¶¶ 1-3). Venosh contends that Dr. Henzes negligently injured her arteries and nerves during the surgery, as

a result of which "a vascular surgeon was summoned to repair the arterial injury." (Docket Entry No. 1 at ¶¶ 12-13). Venosh further alleges that she continued to exhibit "signs and symptoms of vascular and neurologic injury" post-operatively, but that Dr. Henzes and Moses Taylor personnel "negligently delayed in recognizing" those symptoms and caused her to develop "occlusion of the left popliteal artery." (Id. at ¶¶ 14-15). Venosh was reportedly "returned to the operating room where a vascular surgeon performed exploration of the left popliteal artery with repair of intimal flap and patch angioplasty," and she allegedly continues "to suffer left foot drop, peroneal neuropathy, claudication, sensory and motor nerve dysfunction" and other damage to her left leg. (Id. at ¶¶ 16-17).

During the course of discovery, Venosh served a request upon Moses Taylor for the production of any "incident or event" reports "which in any way reference facts surrounding the medical care of [Venosh]." (Docket Entry Nos. 47, 48 at ¶ 4). Although Moses Taylor acknowledged the existence of two "event" reports "relative to Ms. Venosh's admission of June 11, 2009," (Id. at ¶ 6), it objected to Venosh's discovery request "to the extent that it seeks information that may be protected from discovery by Pennsylvania's Peer Review Protection Act, 63 P.S. § 425.1." (Docket Entry No. 48, Exhibit B at ¶ 21).

On March 25, 2013, Venosh presented a discovery motion to the Special Trial Master pursuant to Lacka. Co. R.C.P. 4000.1(a), and on that date, the Master issued an order granting the motion and directing Moses Taylor to produce the event reports within twenty days. (Docket Entry No. 42). On April 3, 2013, Moses Taylor filed a timely *de novo* appeal of that order in accordance with Lacka. Co. R.C.P. 4000.1(b). (Docket Entry

No. 47). Moses Taylor contends that the events reports "in question are immune from discovery pursuant to 40 P.S. § 1303.311(a) and 42 U.S.C. § 299b-22 as they were prepared exclusively and solely for the use of Moses Taylor's Patient Safety Improvement and Management Committee and are not provided or shared with any other entity, person, or state agency." (Id. at ¶ 11).

At the time of Venosh's surgery, Moses Taylor had an "Event Reporting" policy, "Operating Policy 50-85-1," in effect which had a stated purpose of prescribing "the standard procedure for the reporting of any unusual occurrence or event which takes place at Moses Taylor Hospital." (Docket Entry No. 48, Exhibit J at p. 1). As per its express language, Operating Policy 50-85-1 was designed "to: (1) improve the management of patient care and treatment...and to assure the prevention of recurrences; (2) provide a data base for the facility so that trends can be identified...; (3) provide a record of the occurrence for legal purposes; and (4) comply with the requirements of state and/or federal laws and regulations." (Id.). Under the "Event Reporting" protocol established by that policy, the "initial investigation" of the event "should be conducted by the Department Head/Supervisor/Manager as soon as possible," although that person will "not necessarily prepare the report." (Id. at pp. 2-3). "The Investigative Analyst will follow up with the Department Head/Supervisor/Manager as to the cause of the event and measures taken to prevent recurrence when indicated." (Id.). All event reports must "be reviewed and analyzed by the Investigative Analyst for any developing trends," and those results are to be "reviewed by the Patient Safety Improvement and Management Committee." (Id. at p. 3).

Operating Policy 50-85-1 contains specific reporting requirements for "Patient Events," which require (a) the patient's physician to be promptly notified, (b) "the patient examined as soon as possible," and (c) the examining physician's "findings or comments" to be documented in the "the patient's medical record." (Id. at p. 2). The event "report should be sent to the Investigative Analyst within twenty-four (24) hours of completion," but "**[n]o report should be maintained on the patient's chart.**" (Id.) (emphasis in original). Furthermore, "[i]f the Investigative Analyst determines that the event falls within the scope of Pennsylvania's Act 13, the appropriate information will be forwarded to the Patient Safety Officer."[1] (Id.).

In the event that the Investigative Analyst "determines that a particular event requires more specific documented follow-up, the Department Head/Manager/Supervisor will be asked to complete an 'Event Report Investigation and Follow-up' (Form 1654, attached) within five (5) days." (Id. at p. 3). "The completed report shall be forwarded to the department's Vice-President or President" and following review, "the signed original will be forwarded to the Investigative Analyst who will review the form with the Vice President of Corporate Development." (Id.). Moreover, the policy directs that the completed "Event Report Investigation and Follow-up" Form is not to "be faxed or sent through the carrier," and "should be hand-delivered to the intended recipient." (Id.). Finally, "[d]ocumentation of all factual patient-related information regarding the event shall appear in the medical record (nurses notes) without mention that an Event Report

[1] The MCARE Act, Act of March 20, 2002, P.L. 154, No. 13, 40 P.S. §§ 1303.101-1303.1115, is often referred to as Act 13. *See* Clifford A. Rieders, *Pennsylvania's Patient Safety Authority: An Overview*, 76 Pa. Bar.Q. 54, 56 (April 2005).

was completed or an investigation and follow-up was (*sic*) conducted." (Id. at p. 4) (emphasis in original).

Following Moses Taylor's acquisition by Community Health Systems and its corresponding affiliation with the Commonwealth Health network, Moses Taylor revised its Event Reporting policy ("the Commonwealth Health Policy"). In contrast to the former policy, the stated purpose of the Commonwealth Health Policy is to prescribe "the standard procedure for reporting to the Patient Safety Improvement and Management Committee any unusual occurrence or event" at Moses Taylor. (Docket Entry No. 48, Exhibit I at p. 1). The current policy also states that "[e]vents that compromise patient safety or quality of care will be used to facilitate safe conditions and serve as a source of trending information for the Patient Safety Improvement and Management Committee." (Id.). The amended policy distinctly references "the Federal Privilege and Confidentiality Protections Act, 42 U.S.C. § 299(b)" and "the requirements of Act 13 and the Patient Safety Authority," and confirms "that the document utilized to report events to the Patient Safety Improvement and Management Committee will not be utilized for reporting to any other agency or party, nor utilized for any other purpose." (Id.). To that end, the Event Reporting policy no longer indicates that it is designed to "provide a record of the occurrence for legal purposes." (Id. at p. 2).

The Commonwealth Health Policy reflects that "[a]ll event reports should be completed within twenty-four (24) hours or next business day per hospital policy in accordance with the Pennsylvania Patient Safety Authority guidelines." (Id. at p. 5). It further mandates that "[t]he information contained in the event reports is confidential and may not be disclosed or released except by written authority of the Chairman of the

hospital's Patient Safety Improvement and Management Committee." Id. More importantly, the present policy states that "[t]he event report form will be used for reporting events and for review by the Patient Safety Improvement and Management Committee and for no other purpose." (Id.).

In its brief in support of its discovery appeal, Moses Taylor asserts that the two event reports are immune from discovery under Section 311of the MCARE Act, 40 P.S. § 1303.311, inasmuch as they were allegedly prepared solely for the purpose of (1) fulfilling the patient safety committee's statutory responsibilities under 40 P.S. § 1303.310(b), (2) satisfying Moses Taylor's obligation to report "serious events" to the Patient Safety Authority and the Pennsylvania Department of Health under 40 P.S. §§ 1303.304 and 1303.306, or (3) complying with the MCARE Act's requirements concerning (a) Moses Taylor's development of a patient safety plan and the (b) reporting of serious events by health care workers, patient safety officers and patient safety committees in accordance with 40 P.S. §§ 1303.307-1303.313. (Docket Entry No. 46 at pp. 3-4). Moses Taylor also maintains that Section 299b-22 of the federal PSQIA, 42 U.S.C. § 299b-22, "mandates that documentation, like the type requested by [Venosh], be free from discovery to protect the intended benefit of the Act." (Id. at p. 4). In that respect, Moses Taylor submits that Venosh's discovery request is governed by the current Commonwealth Health Policy, and that there is "no appellate authority" addressing "how a new federal statute, 42 U.S.C. § 299b-22, interacts with the discovery parameters of the MCARE Act found at 40 P.S. § 1303.311." (Id. at p. 5).

Venosh argues that the discoverability of the event reports is subject to former Operating Policy 50-85-1, and that those reports are not protected from discovery by the

Peer Review Protection Act, the MCARE Act or the PSQIA. Citing a series of unpublished Lackawanna County court rulings, Venosh contends that the event reports are discoverable under the Pennsylvania statutes since the two reports were not part of an analysis conducted by a peer review committee and were not prepared solely for the purpose of complying with statutory reporting requirements. (Docket Entry No. 48 at pp. 4-9). Venosh posits that the event reports are likewise not protected from discovery by the federal PSQIA in that they "do not pertain to deliberations or analysis of the incident," and instead "are the initial reports which are produced and provided to a safety evaluation system thereby initiating an analysis." (Id. at p. 10).

On June 18, 2013, oral argument was conducted on the instant discovery appeal, and pursuant to an Order dated July 9, 2013, the two event reports were submitted for an *in camera* review on July 12, 2013. (Docket Entry No. 51). Following that *in camera* review, Moses Taylor's *de novo* appeal became ripe for resolution.

II. DISCUSSION

(A) STANDARD OF REVIEW

Under Pa.R.C.P. 4003.1, "discovery is liberally allowed with respect to any matter, not privileged, which is relevant to the cause being tried." Berg v. Nationwide Mutual Insurance Company, Inc., 44 A.3d 1164, 1178 n. 8 (Pa. Super. 2012). Any limitations or restrictions upon discovery should be construed narrowly. Ferguson v. Ghigiarelli, 2012 WL 5376702, at * 4 (Lacka. Co. 2012); McAndrew v. Donegal Mutual Insurance Company, 56 Pa. D. & C. 4th 1, 7 (Lacka. Co. 2002).

Pennsylvania law does not favor evidentiary privileges since "they are in derogation of the search for truth." Joe v. Prison Health Services, Inc., 782 A.2d 24, 31

(Pa. Cmwlth. 2001) (quoting Com. v. Stewart, 547 Pa. 277, 282, 690 A.2d 195, 197 (1997)). Except in those instances where a party objects to discovery based upon the attorney-client privilege, the party opposing discovery bears the burden of establishing that the requested material is privileged and shielded from discovery. Yadouga v. Cruciani, 66 Pa. D. & C. 4th 164, 168 & n. 1 (Lacka. Co. 2004); Taylor v. Pars Manufacturing Co., 13 Phila. Co. Rptr. 132, 135 (Phila. Co. 1985). All doubts regarding the discoverability of information should be resolved in favor of permitting discovery. McAndrew, supra; Fitt v. General Motors Corp., 13 Pa. D. & C. 4th 336, 338 (Lacka. Co. 1992).

(B) APPLICABLE "EVENT REPORTING" POLICY

A threshold determination must be made as to whether the instant discovery dispute is governed by Moses Taylor's Operating Policy 50-85-1 or the more recent Commonwealth Health Policy. Moses Taylor contends that the Commonwealth Health policy is applicable since it was in effect at the time that Venosh demanded production of the event reports. (Docket Entry No. 47 at ¶ 17). Venosh counters that Moses Taylor's "new event reporting policy cannot prevent disclosure of the incident reports, as [Venosh's] injuries occurred prior to the policy taking effect." (Docket Entry No. 48 at p. 8). Neither party has cited any authority in support of their respective positions, nor has our own research revealed any direct precedent.

As the Commonwealth Court has observed, "no document should be accorded a privilege unless it was prepared with the expectation that it would be kept confidential, and has in fact been kept confidential." Joe, 782 A.2d at 34 (citing Dowling v. American Hawaii Cruises, Inc., 971 F.2d 423 (9th Cir. 1992)). At the time that the event reports in

question were prepared by Moses Taylor, only Operating Policy 50-85-1 was in effect. That policy directed that the initial investigation of the reportable events was to be conducted by the appropriate Department Head, and that the patient's treating physician was to be promptly notified so that [s]he could examine the patient and report the attending physician's findings in the patient's chart. Within twenty-four hours of its completion, the event report was to be transmitted to the Investigative Analyst or risk manager who would then determine whether it was to be forwarded to the patient safety officer. If the Investigative Analyst concluded that further investigation was warranted, the Department Head was to complete a "follow-up" report that was to be delivered to the Department's Vice-President or President, as well as to the Investigative Analyst who would thereafter review it with the Vice-President of Corporate Development. The Investigative Analyst was also required to analyze all event reports "for any developing trends," and the results of that analysis were to be reviewed by the Patient Safety Improvement and Management Committee. As a result, the sole involvement of the Patient Safety Improvement and Management Committee vis-a-vis event reports was its review of the results of the "developing trends" analysis that was conducted by the Investigative Analyst.[2]

When the event reports at issue were drafted and circulated, Moses Taylor

[2] Under the Commonwealth Health Policy, the Patient Safety Improvement and Management Committee has assumed a larger role with respect to event reports and now receives and reviews all reports regarding any unusual occurrences or events at Moses Taylor, not simply the Investigative Analyst's "developing trends" analysis. The current policy expressly establishes "the standard procedure for reporting to the Patient Safety Improvement and Management Committee any unusual occurrence or event," and mandates that any "document utilized to report events to the Patient Safety Improvement and Management Committee will not be utilized...for any other purpose." The Commonwealth Health Policy clarifies that the event report form may only "be used for reporting events and for review by the Patient Safety Improvement and Management Committee."

personnel acted pursuant to Operating Policy 50-85-1. The protocols described in the Commonwealth Health Policy were implemented years later and were not considered by Moses Taylor personnel when the two event reports were generated in June 2009. As a matter of logic, the confidentiality to be accorded to those event reports, and Moses Taylor's expectations of confidentiality at the time that the event reports were prepared, may only be determined by Moses Taylor's event reporting policy which was in effect in June 2009.[3] Therefore, the instant discovery dispute is governed by Operating Policy 50-85-1 rather than the Commonwealth Health Policy.

(C) PEER REVIEW PROTECTION ACT

Moses Taylor originally objected to Venosh's request for production of any

[3] By way of analogy, a statute or rule may be applied retroactively to antecedent events only where it is merely procedural and does not alter any substantive rights. Giant Eagle, Inc. v. WCAB (Weigand), 764 A.2d 663, 666 (Pa. Cmwlth. 2000), *app. denied*, 566 Pa. 651, 781 A.2d 149 (2001). In determining whether a law may be applied retroactively, "the court must ask whether the new provision attaches new legal consequences to events completed before its enactment." Warren v. Folk, 886 A.2d 305, 308 (Pa. Super. 2005) (quoting Landgraf v. U.S.I. Film Products, 511 U.S. 244, 269-270 (1994)). Where a statute or rule relates to a party's substantive rights, courts must apply the law that was in effect at the time that the cause of action arose. McDonald v. Redevelopment Authority of Allegheny County, 952 A.2d 713, 716-717 (Pa. Cmwlth. 2008), *app. denied*, 600 Pa. 772, 968 A.2d 234 (2009). The application of evidentiary privileges is considered to be a matter of substantive law, *see* Lebovitz v. Hartford Inland Company of the Midwest, 2013 WL 150717, at * 2 (W.D. Pa. 2013) ("...the Court must examine Pennsylvania substantive law to determine whether there is an evidentiary privilege that applies here."), and for that reason, the Pennsylvania Peer Review Protection Act applies in federal actions premised upon diversity jurisdiction. *See, e.g.*, Corrigan v. Methodist Hospital, 885 F.Supp. 127, 128-129 (E.D. Pa. 1995); Garber v. Abington Memorial Hospital, 1993 WL 209542, at * 2 (E.D. Pa. 1993), *aff'd*, 22 F.3d 301 (3d Cir. 1994). Moses Taylor has not articulated a plausible reason why the Commonwealth Health policy should be applied retroactively to arguably afford greater confidentiality and discovery immunity to a pre-existing report which had been authored in accordance with Operating Policy 50-85-1. *Cf.* Warren, supra ("Retroactive application occurs only when the statute or rule 'relates back and gives a previous transaction a legal effect different from that which it had under the law in effect when it transpired.'" (quoting In re R. T, 778 A.2d 670, 679 (Pa. Super. 2001), *app. denied*, 568 Pa. 618, 792 A.2d 1254 (2001)). Any discovery protection or evidentiary privilege to be granted to the subject "event reports" affects the parties' substantive rights and should be determined by the policy that was in effect at the time that Venosh's cause of action arose and the event reports were drafted. *See* Salt Lake Child and Family Therapy Clinic, Inc. v. Frederick, 890 P.2d 1017, 1020 (Utah 1995) (more recent statute, under which communications between plaintiff and mental health therapists would not be privileged and confidential, did not apply retroactively to communications which pre-dated new statute, even though statute was in effect at the time of discovery request for mental health records).

incident or event reports based upon the PRPA, 63 P.S. §§ 425.1 – 425.4. The PRPA grants qualified immunity for health care providers participating in a peer review process and establishes an evidentiary privilege applicable to peer review proceedings. *See* 63 P.S. §§ 425.3 – 425.4. Section 4 of the Act governs the confidentiality of peer review materials and states, in relevant part:

> 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...: Provided, however, that information, documents or records otherwise available from original sources are not to be construed as immune from discovery or use in any civil action merely because they were presented during proceedings of such committee....

63 P.S. § 425.4. Under the statute and decisional precedent, a "review committee" is "an entity or an individual engaged in peer review." Troescher v. Grody, 869 A.2d 1014, 1022 (Pa. Super. 2005). The phrase "peer review" is defined by the PRPA 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, including practice analysis, inpatient hospital and extended care facility utilization review,... and the compliance of a hospital...with the standards set by an association of health care providers and with applicable laws, rules and regulations." 63 P.S. § 425.2.

The PRPA was enacted to facilitate self-policing in the health care industry, Dodson v. DeLeo, 872 A.2d 1237, 1242 (Pa. Super. 2005), and to maintain "high professional standards in the medical practice for the protection of patients and the general public." Piroli v. Lodico, 909 A.2d 846, 850 (Pa. Super. 2006) (quoting Troescher, 869 A.2d at 1020-21). It represents a legislative determination "that, because of the expertise and level of skill required in the practice of medicine, the medical profession itself is in

the best position to police its own activities." McClellan v. Health Maintenance Organization of PA, 546 Pa. 463, 472, 686 A.2d 801, 805 (1996) (per Newman, J., with one Justice concurring and one Justice concurring in the result). The Act is designed to encourage "comprehensive, honest, and potentially critical evaluations of medical professionals by their peers." Dodson, supra (citing Young v. The Western Pennsylvania Hospital, 722 A.2d 153, 156 (Pa. Super. 1998)).

"The PRPA does not, however, protect non-peer review business records, even if those records eventually are used by a peer review committee." Dodson, 872 A.2d at 1242. For example, in Atkins v. Pottstown Memorial Medical Center, 430 Pa. Super. 279, 634 A.2d 258 (1993), the trial court excluded evidence of an incident report that the defendant hospital had prepared following the plaintiff's injury. "This report had been prepared for use by a risk manager (who sometimes reviewed incident reports with a Quality Assurance Committee), was marked 'confidential' and was not made part of the patient's hospital records." Id. at 282, 634 A.2d at 260. After the "trial court ruled that the report was inadmissible under the provisions of the Peer Review Protection Act," Id., the Superior Court reversed and held:

> This document contained information "otherwise available from original sources." It was not derived from nor part of an evaluation or review by a peer review committee. It was, rather, a report of an incident based on information also available to plaintiffs. As such, the report did not come within the need for confidentiality which the statute was intended to provide. Indeed, it is questionable whether a risk manager is a "review organization" to whom the protection of the statute extends. The report, therefore, was a business record not subject to the confidentiality safeguards of the statute.

Id. at 283, 634 A.2d at 260. *Accord*, Ellison v. Women and Children's Hospital of Buffalo, 2010 WL 5139030, at * 2 (W.D. Pa. 2010) (holding that document was akin to an

incident report and discoverable, and stating that "[t]his conclusion is supported by the fact that no peer review committee was ever convened in this matter and, therefore, the note was never utilized in conjunction with a quality assurance function."); Litvin & McHugh, 3 West's Pa. Practice, *Torts: Law and Advocacy* § 7.40 (2012 ed.) ("...incident reports prepared on behalf of a hospital's department of risk management are not privileged, as their purpose is to facilitate the investigation of claims, not improve the quality of medical care.").

"Atkins makes clear that general business records do not become privileged merely because they are sent to a peer review department." Dodson, 872 A.2d at 1243. Conversely, "documents generated by a peer review committee specifically for use in the peer review process are not discoverable simply because some of the information contained therein is available elsewhere." Id. at 1244 (citing Young, supra.). Thus, the critical inquiry in addressing the discoverability of Moses Taylor's event reports under the PRPA is whether those reports were prepared by Moses Taylor's 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. *See* Treible v. Lehigh Valley Hospital, Inc., 75 Pa. D. & C. 4th 22, 27-28 (Lehigh Co. 2005) ("Therefore, to sustain its claim of peer review privilege, LVH had the burden of demonstrating that the documents at issue were in fact utilized by a peer review committee. Unless the [Quality Assurance Review] forms were part of the proceedings or records of a review committee, the Act by its terms does not apply.... Whether or not the

documents *might* be used at sometime in the future by a review committee is irrelevant.") (emphasis in original).

In compliance with the Order of July 9, 2013, Moses Taylor submitted the two event reports for an *in camera* review. The first report relates to Venosh's knee replacement surgery that was performed by Dr. Henzes, and the ensuing surgical intervention and participation by a vascular surgeon, Dr. Michael Sunday. The second event report concerns the subsequent surgery that was performed by another vascular surgeon, Dr. James Roche, on the evening of June 11, 2009, involving exploration of the left popliteal artery and repair of the intimal flap with graft angioplasty.

Both event reports are dated June 11, 2009, and contain blocks to be completed to identify the "[n]ame of attending physician," "[d]iagnosis and/or procedure at time of event," any "[w]itness(es)" to the event, the "[p]ractitioners Involved," the "[r]eporting Department," and "[h]ow was this event discovered." The person preparing the report is also directed to "[d]escribe the Event" and "[p]rovide as much detail as necessary to convey the facts (who, what, when, where, how)."

In addition, the form requires the individual preparing the report to characterize the event as either an "Incident" or a "Serious Event." Under the "Harm Score" portion of the form, an "incident" is described as either an unsafe condition "that could cause adverse events (e.g., look alike medications, confusing equipment, etc.)," or an event that caused "No Harm." An incident is characterized as a "No Harm" event if an event occurred (1) but did not reach the individual (i.e., a "near miss") because of "chance alone" or "active recovery efforts by caregivers," or (2) did "reach the individual but did not cause harm" and either did or did not require monitoring to confirm the absence of harm.

A "serious event" references an event that caused harm or death. Specifically, an "Event, Harm" classification is defined as any event "that contributed to or resulted in" a "near-death event," "permanent harm," or "temporary harm" that required treatment, intervention, or initial or prolonged hospitalization. An "Event, Death" is identified as an event "that contributed to or resulted in death." After characterizing the event as an "Incident" or a "Serious Event," the person preparing the form must check one of the foregoing categories under the "Harm Score" section.

Besides indicating whether the "Incident" or "Serious Event" had a "Harm Score" of "Unsafe Condition," "Events, No Harm," "Event, Harm" or "Event, Death," the individual must state the "Likelihood of Event Recurrence" and the "Severity of Effect Resulting from Recurrence of Event." The "Event Report" form also obligates the reporter to identify the "Type of Injury," the individuals who received "Notification of the event," and the "Immediate Action Taken" in response to the event. However, no portion of the event report form directs the reporter to evaluate the quality of the care provided or to opine whether malpractice was involved. Finally, the form must be signed by the "[i]ndividual preparing report" and the "Department Head/Supervisor," thereby confirming that the Department Head/Supervisor had reviewed the "Event Report."

Nothing contained in Moses Taylor's "Event Report" form indicates that the report is generated in conjunction with an evaluation of medical care conducted by a peer review committee. The two event reports in question were prepared by attending nurses and co-signed by the Department Head, rather than by a representative of a peer review committee. Although the form contains sixteen possible choices from which to select the appropriate individuals or departments that are to receive "Notification" of the event,

Moses Taylor's "Patient Safety Improvement and Management Committee" or other peer review committee is not listed as a potential choice. Moreover, despite the fact that twenty options are provided on the form for a description of the "Immediate Action Taken" following the reportable event, referral to the Patient Safety Improvement and Management Committee or some other peer review committee is not designated as a prospective response to that inquiry. The *de novo* appeal record submitted for review is likewise devoid of any suggestion that a peer review of Venosh's care was ever initiated by a "review organization," as that phrase is defined by 63 P.S. § 425.2, to evaluate the quality of the treatment that was provided to Venosh.

Nor does Operating Policy 50-85-1 reflect that Moses Taylor's "Event Reporting" policy was intended to establish a standard procedure for reporting an "Event" to Moses Taylor's peer review committee. While it is true that one of the stated purposes of Operating Policy 50-85-1 was the improved management of patient care, the other expressed purposes of that policy were the creation of a record of the occurrence for litigation purposes and the collection of data for the evaluation of event trends. The primary participant in the "Event Reporting" process under Operating Policy 50-85-1 was the Investigative Analyst or risk manager, not the Patient Safety Improvement and Management Committee or comparable peer review committee.

Based upon the foregoing language of Operating Policy 50-85-1 and Moses Taylor's "Event Report" form, the two event reports are not protected from discovery by the PRPA since they constitute incident reports that were prepared on behalf of Moses Taylor's risk management department to document or investigate an event or potential claim. The event reports were not generated by or for a peer review committee in

assessing the quality of the medical care that the treating health care providers furnished to Venosh. As such, they are not shielded from discovery by 63 P.S. § 425.4. *See* Atkins, supra.

(D) SECTION 311 OF THE MCARE ACT

Moses Taylor alternatively contends that the two event reports dated June 11, 2009, are immune from discovery by Section 311 of the MCARE Act which states, in pertinent part, that:

> Any documents, materials or information solely prepared or created for the purpose of compliance with section 310(b) or of reporting under section 304(a)(5) or (b), 306(a)(2) or (3), 307(b)(3), 308(a), 309(4), 310(b)(5) or 313 which arise out of matters reviewed by the patient safety committee pursuant to section 310(b) or the governing board of a medical facility pursuant to section 310(b) are confidential and shall not be discoverable or admissible as evidence in any civil or administrative action or proceeding.

40 P.S. § 1303.311(a).[4] Not unlike the PRPA, Section 311(a) contains an "original source" exception and provides that any materials "that would otherwise be available from original sources shall not be construed as immune from discovery...merely because they were presented to the patient safety committee or governing board of a medical facility." Id. Section 311(c) clarifies that the confidentiality protections contained in Section 311(a) "only apply to the documents...prepared or created pursuant to the responsibilities of the patient safety committee or governing board of a medical facility set forth in Section 310(b)." 40 P.S. § 1303.311(c).

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[4]Section 310(b) addresses the responsibility of a hospital's patient safety committee, including receipt and review of reports from the patient safety officer and disclosure of "serious events and incidents" to the hospital's "administrative officer and governing body." 40 P.S. § 1303.310(b). Sections 304 and 306 concern the reporting of "serious events" to the Patient Safety Authority and the Pennsylvania Department of Health. *See* 40 P.S. §§ 1303.304, 1303.306. Section 307 of the Act addresses a hospital's development of a patient safety plan, whereas sections 308, 309, 310 and 313 relate to the reporting of "serious events" by health care workers, patient safety officers and patient safety committees. *See* 40 P.S. §§ 1303.307-1303.313.

Under the plain language of section 311(a), documents are protected from discovery only if: (1) they were "solely prepared or created for the purpose of compliance with" the MCARE Act's "serious events" reporting requirements or the patient safety committee's responsibilities under section 310(b); (2) they "arise out of matters reviewed by the patient safety committee...or the governing board" pursuant to section 310(b); and (3) they are not otherwise available "from original sources." As a consequence, if the investigation of an incident by the defendant hospital was not "commenced at the request of or by the defendant's Patient Safety Committee," the confidentiality protections afforded by Section 311(a) are inapplicable. Forrest v. St. Luke's Hospital, 73 Pa. D. & C. 4th 353, 355 (Lehigh Co. 2005), *app. quashed*, 903 A.2d 56 (Pa. Super. 2006), *app. denied*, 591 Pa. 684, 917 A.2d 315 (2007). Similarly, absent proof "that the [Quality Assurance Review] forms were reviewed by a patient safety committee or by the hospital's governing board," the confidentiality provisions of section 311(a) have no application. Treible, 75 Pa. D. & C. 4th at 28.

Three Lackawanna County rulings have previously held that incident or event reports generated pursuant to Operating Policy 50-85-1 are not shielded from discovery by Section 311 of the MCARE Act. In Davis v. Voyce, No. 05 CV 4126 (Lacka. Co. June 17, 2009), Judge Carmen D. Minora concluded that the Moses Taylor event report was discoverable since it "contains information readily discernible from non-confidential, unprotected sources," including the "[d]ates, event description, witnesses, every action

taken such as a remedial medical procedure..., bills and notes." Id. at p. 5.[5] Less than two months later, visiting Senior Judge Harold A. Thomson, Jr., likewise deemed Moses Taylor's event reports to be discoverable, and held that Section 311 only protects documents "prepared solely for compliance with the Patient Safety Act," 40 P.S. §§ 1303.301-1303.315, whereas Moses Taylor's event reports were generated pursuant to Operating Policy 50-85-1 which had stated purposes other than compliance with the patient safety provisions of the MCARE Act. Kersavage v. Chiavacci, No. 08 CV 4555 at pp. 10-11 (Lacka. Co. Aug. 6, 2009). Additionally, in Santracroce v. Moses Taylor Hospital, No. 08 CV 3352 (Lacka. Co. June 28, 2010), visiting Senior Judge John Leete found that since Section 311 clearly states that documents "must be solely prepared for compliance with the Patient Safety Act" to be considered confidential, Moses Taylor's event reports pursuant to Operating Policy 50-85-1 are discoverable inasmuch as they are not prepared "solely for compliance with the Patient Safety Act." (Id. at p. 4) (emphasis in original).

The materials submitted for review do not establish that the two event reports were generated solely for the purpose of complying with the patient safety reporting requirements contained in Sections 304, 306-310 or 313 of the MCARE Act. Rather, as indicated in Section II(C) above, the reports were created pursuant to Operating Policy 50-85-1 to, *inter alia*, make a record of the incident for litigation purposes and compile data to evaluate event trends. Nor does the available record reflect that the reports "arise out of

[5] On August 20, 2009, Judge Minora certified his Order for an interlocutory appeal under 42 Pa. C.S. § 702(b) and Pa.R.A.P. 1311. *See* Davis v. Voyce, No. 05 CV 4126 at Docket Entry No. 125. However, the parties settled that malpractice action and discontinued the litigation before the Superior Court of Pennsylvania had an opportunity to consider the merits of that appeal. Id. at No. 190.

matters reviewed by" Moses Taylor's patient safety committee or Board of Trustees in fulfillment of their statutory responsibilities under Section 310(b).[6] There simply is no suggestion in the record that Venosh's care was ever reviewed by the patient safety committee or the Board of Trustees in compliance with 40 P.S. § 1303.310(b). Thus, Moses Taylor's two event reports are not protected from discovery by Section 311 of the MCARE Act. *See* 40 P.S. § 1303.311(c).

(E) "PATIENT SAFETY WORK PRODUCT" PRIVILEGE UNDER PSQIA

Last, Moses Taylor asserts that the event reports are privileged and protected from discovery as "patient safety work product" under the PSQIA. The PSQIA was enacted in response to the 2000 report of the Institute of Medicine's Committee on Quality of Healthcare in America, which concluded "that preventable medical error causes between 44,000 and 98,000 deaths per year," "that medical errors were the eighth leading cause of death in the United States," "that the cost of preventable medical errors was approximately $17 billion per year and that most of the errors were not the result of personal recklessness but rather resulted from faulty systems, processes, and conditions." Lee Medical, Inc. v. Beecher, 312 S.W.3d 515, 534-535 (Tenn. 2010). "In contrast to the [Health Care Quality Improvement Act of 1986, 42 U.S.C. 1101 *et seq.*], which was motivated by the particular need 'to restrict the ability of incompetent physicians to move

[6] Section 310(b) of the MCARE Act states that a hospital's patient safety committee must (1) "[r]eceive reports from the patient safety officer," (2) "[e]valuate investigations and actions of the patient safety officer on all reports," (3) "[r]eview and evaluate the quality of patient safety measures," including "[a] review...of reports made" under Sections 304, 307 and 308, (4) "[m]ake recommendations to eliminate future serious events," and "report to the administrative officer and governing body of the medical facility on a quarterly basis regarding the number of serious events and incidents and its recommendations to eliminate future serious events and incidents." 40 P.S. § 1303.310(b)(1)-(5).

from State to State without disclosure or discovery of the physician's previous damaging or incompetent performance,' the PSQIA tackled the larger problem of systemic weaknesses in the delivery of health care resulting in preventable adverse events." Dieffenbach v. United States, 715 F.Supp.2d 587, 595 (D. Del. 2010) (quoting 42 U.S.C. § 11101(2)).

The PSQIA creates "a federal medical peer review privilege," Francis v. Untied States, 2011 WL 2224509, at * 6 (S.D.N.Y. 2011), for "patient safety work product." Dieffenbach, 715 F.Supp.2d at 596. *See also* 42 U.S.C. § 299b-22(a)-(b). Section 299b-21(7) of the Act defines "patient safety work product" as meaning any data, reports or records:

> (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)(i)-(ii). A "patient safety organization" is defined by Section 299b-21(4) as meaning "a private or public entity or component thereof that is listed by the Secretary [of the Department of Health and Human Services] pursuant to section 299b-24(d) of this title." 42 U.S.C. § 299b-21(4). Section 299b-24(d) sets forth the procedures for a patient safety organization ("PSO") to obtain PSO certification by the Secretary of HHS and thereby be officially listed as a PSO that has achieved such certification. *See* 42 U.S.C. § 299b-24.

The PSQIA is intended to "encourage a culture of safety and quality" in health care by providing confidentiality and legal protection for information that is "collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety." Department of Financial and Professional Regulation v. Walgreen Company, 361 Ill. Dec. 186, 191, 970 N.E.2d 552, 557 (2012) (quoting S. Rep. No. 108-196, at 3 (2003)). The "patient safety work product" privilege applies only to the reports, analyses and data that are developed by a health care provider for reporting to a PSO *and* which are, in fact, reported to a PSO. Id. (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 privilege is inapplicable if the patient safety work product materials are not actually furnished to a PSO. *See* Lee Medical, Inc., 312 S.W.3d at 535 n. 70 ("Patient safety work product that is not actually reported to a patient safety organization is not privileged under the PSQIA."); Francis, supra ("The quality assurance review documents at issue in this action are not protected under the PSQIA, since they were not provided to a PSO.").

"To qualify as a patient safety organization, the entity must submit certification to the Secretary of the Department of Health and Human Services and must meet specific criteria." Schlegal v. Kaiser Foundation Health Plan, 2008 WL 4570619, at * 3 (E.D. Cal. 2008). As noted above, PSOs are "organizations that collect and analyze patient safety work product and provide feedback to providers on strategies to improve patient safety and qualify of care, and that have been listed by the Department of Health and Human Services as such." Dieffenbach, 917 F.Supp.2d at 596. However, the record presented by the parties does not reflect that Moses Taylor had a PSO in June 2009 that had obtained

the requisite certification from the Secretary of HHS and was listed as a PSO pursuant to 42 U.S.C. § 299b-24.

Assuming *arguendo* that Moses Taylor did have a PSO in June 2009 which had attained such certification, the privilege and confidentiality protections of 42 U.S.C. § 299b-22 are nonetheless inapplicable. There is no indication in the record that the two event reports were generated by or reported to a PSO, Moses Taylor's patient safety committee, (*see* Section II(D) above), or its peer review committee, (*see* Section II(C) above). Absent proof that the event reports were reported to a PSO, those reports are not protected by the "patient safety work product" privilege created by the PSQIA. *See* Lee Medical, Inc., 312 S.W.3d at 535 ("The PSQIA creates a tightly crafted federal privilege for 'patient safety work product' actually reported to a 'patient safety organization.'"); Schlegel, supra ("This statute carves out a narrow peer review privilege for work product prepared by a patient safety organization or prepared for, and reported to, a patient safety organization."). Accordingly, the two event reports are not immune from discovery under the federal PSQIA or the state PRPA or MCARE Act, and as a result, Moses Taylor's discovery appeal will be denied.

ANN MARIE VENOSH, Plaintiff vs. JACK HENZES, M.D., CINDY S. ANDERSON, PA-C, SCRANTON ORTHOPEDIC SPECIALISTS, P.C., and MOSES TAYLOR HOSPITAL, Defendants	:	IN THE COURT OF COMMON PLEAS OF LACKAWANNA COUNTY CIVIL ACTION - LAW NO. 11 CV 3058

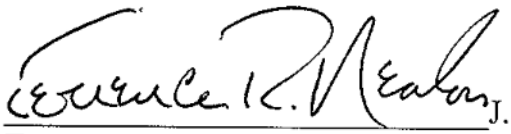
ORDER

AND NOW, this 17th day of July, 2013, upon consideration of the "Motion for Appeal *De Novo* by Defendant, Moses Taylor Hospital, from the Order of the Special Trial Master of March 25, 2013, Pursuant to Lackawanna County R.C.P. 4000.1(b)," the exhibits and memoranda of law submitted by the parties, the oral argument of counsel on June 18, 2013, and the *in camera* review of the subject event reports on July 12, 2013, and based upon the reasoning set forth in the foregoing Memorandum, it is hereby ORDERED and DECREED that:

1. The *de novo* discovery appeal filed by Defendant, Moses Taylor Hospital, pursuant to Lacka. Co. R.C.P. 4000.1(b) is DENIED and DISMISSED, and the Special Trial Master's discovery order dated March 25, 2013, is AFFIRMED; and

2. Within twenty (20) days of the date of this Order, Defendant, Moses Taylor Hospital, shall produce the two event reports dated June 11, 2009, pertaining to the treatment received by Plaintiff, Ann Marie Venosh, at Moses Taylor Hospital on June 11, 2009.

BY THE COURT:



J.

Terrence R. Nealon

cc: *Written notice of the entry of the foregoing Memorandum and Order has been provided to each party pursuant to Pa. R. Civ. P. 236 (a) and (d) by transmitting time-stamped copies via electronic mail to:*

Gary Solomon, Esquire — kornblau@kornblau&kornblau.com
Justin L. Groen, Esquire
Kornblau, Kornblau & Solomon
610 Harper Avenue
Jenkintown, PA 19046
Counsel for Plaintiff

Eugene P. Feeney, Esquire — efeeney@wglaw.com
Noah E. Katz, Esquire — nkatz@wglaw.com
Weber, Gallagher, Simpson, Stapleton,
Fires & Newby, LLP
201 Penn Avenue, Suite 400
Scranton, PA 18503
Counsel for Defendants Jack Henzes, M.D., and Scranton Orthopedic Specialists, P.C.

James A. Doherty, Jr., Esquire — jadoherty@shdlawfirm.com
Scanlon, Howley & Doherty, P.C.
321 Spruce Street, Suite 1000
Scranton, PA 18503
Counsel for Defendant Cindy S. Anderson, PA-C

Timothy E. Foley, Esquire — timefoley@comcast.net
Foley, Comerford & Cummins
507 Linden Street, Suite 700
Scranton, PA 18503
Counsel for Defendant Moses Taylor Hospital