IN THE COURT OF COMMON PLEAS OF MONTGOMERY COUNTY, PENNSYLVANIA
CIVIL ACTION – LAW

WAKEEM FORD-BEY, ADMINISTRATOR OF THE ESTATE OF WANETTA FORD-BEY	:	NO. 2017-02996 Superior Court No. 162 EDA 2022
vs.	:	
PROFESSIONAL ANESTHESIA SERVICES OF NORTH AMERICA, LLC, JOEL D. SOKOLOFF, M.D., THOMAS MADDALONI, CRNA, SCOTT WILSON, CRNA, PHYSICIAN'S CARE SURGICAL HOSPITAL LP ASSOCIATES	:	

OPINION

SALTZ, J. **March 23, 2022**

I. SUMMARY OF THE CASE

Section 311 of the Medical Care Availability and Reduction of Error (MCARE) Act, 40 P.S. §1303.311, provides for the confidentiality of documents and materials prepared or created pursuant to certain other provisions of the Act. In this medical malpractice case arising from the death of the Plaintiff's Decedent following surgery, Defendant Physician's Care Surgical Hospital, L.P. ("the Hospital"), objected under section 311 to the Plaintiff's discovery request for notes made by Lisa Gill, the Hospital's patient safety director, prepared during a root cause analysis of the incident. On motion of the Plaintiff, the Court rejected the Hospital's position and ordered the documents to be produced. From that determination, the Hospital has filed an appeal.

A. Background of the Motion to Compel

The action was commenced on February 13, 2017, by Plaintiff Wakeem Ford-Bey, Administrator of the Estate of the Decedent, Wanetta Ford-Bey, against the Hospital and several other Defendants, asserting claims for wrongful death and medical negligence. The claims arise

from surgery that was performed on Decedent at the Hospital on June 12, 2015. According to Plaintiff, immediately after the surgery was completed, Decedent was unresponsive and suffered an episode of bradycardia from respiratory depression, allegedly as a result of negligently administered anesthesia. Decedent was intubated and then transferred to Phoenixville Hospital. On July 2, 2015, Decedent, who had remained in a vegetative state, died.

On July 11, 2019, Plaintiff filed Plaintiff's Motion to Strike Objections and Compel Full and Complete Responses to Plaintiff's Supplemental Request for Production of Documents (Set X) Directed to Defendant, Physician's Care Surgical Hospital, LP ("the Motion to Compel") (Seq. 271). The Motion showed that on February 6, 2019, Plaintiff served Plaintiff's Supplemental Request for Production of Documents (Set X) Directed to Defendant, Physician's Care Surgical Hospital, LP ("the Document Request") (Mot. to Compel, Ex. C). The Document Request sought production by the Hospital and its management company, Nueterra Healthcare Management, LLC ("Nueterra"),[1] of a broad range of documents relating to Decedent's surgery and its aftermath.

The Motion to Compel further showed that on April 3, 2019, the Hospital served its Responses to the Document Request. (Mot. to Compel, Ex. D.) In addition to producing some documents, the Responses asserted various objections, including attorney-client privilege and "Chapter 3 of the MCARE Act."[2] The Motion to Compel sought to overrule the Hospital's

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[1] Nueterra Healthcare Management, LLC, is now known as NueHealth Management Services, LLC.

In the course of a prior discovery motion, the Court had ruled that documents in the possession of Nueterra could be obtained by a document request served on the Hospital, without service of a separate subpoena to the management company. That ruling is not at issue on the present appeal.

[2] Section 311 of the MCARE Act, as well as various other sections referred to in section 311, appears within chapter 3 of the Act.

objections and to compel production of the withheld documents. The Hospital filed its Response to the Motion to Compel on August 2, 2019. Oral argument on the Motion to Compel was held on September 17, 2021.[3]

B. Facts Established by the Motion to Compel and the Hospital's Response

Both the Motion and the Response included exhibits showing the process under which the root cause analysis relating to Decedent's treatment was developed. The record shows that on June 12, 2015, the same day the incident took place, Rebecca Wheeler, R.N., submitted an incident report in the Hospital's reporting system, which was reviewed by Pat McAnany, compliance officer of Nueterra. After the incident report was filed, it was referred to the Hospital's Director of Nursing, Thomas McLaughlin, and its Director of Quality, Lisa Gill. (Doyle Dep. at 42, 80.)[4] As a result, the Hospital's Sentinel Event Policy ("the Policy") was "triggered." (Doyle Dep. at 80.)

The Sentinel Event Policy was attached as Exhibit J to the Motion to Compel.[5] As a document critical to determination of the Hospital's claim of confidentiality under the MCARE Act, the Policy is worth quoting at length:

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[3] Argument was initially delayed by administrative confusion over whether the Motion should be preliminarily determined by a Special Discovery Master. Further delay was caused by the judicial emergency resulting from the Covid-19 pandemic.

[4] "Doyle Dep." refers to the deposition of Christopher Doyle, the Hospital's corporate designee, taken on October 1, 2019. Excerpts from the deposition were attached as Exhibit A to the Plaintiff's Supplemental Memorandum in support of its Motion to Compel (Seq. 281).

[5] To be precise, although Exhibits A through I were attached to the Motion to Compel, Exhibit J was attached to the separately filed Memorandum in support of the Motion (Seq. 272).

POLICY:

Unexpected events or occurrences involving death or serious physical or psychological injury, or the risk thereof (i.e. sentinel events), are to be reported to the Performance Improvement Department immediately upon identification. Any sentinel event requires immediate action to examine, indepth [sic], the event to determine why the incident occurred and how to reduce the likelihood of recurrence.

DEFINITIONS:

. . . .

B. Sentinel Event: Unexpected adverse occurrence involving death or serious injury or psychological injury or the risk thereof. Serious injury specifically includes the loss of limb or function. A sentinel event is an adverse event of a severe and urgent nature that can result in an unexpected and undesirable patient outcome. (Example: Surgery on the wrong patient or removal of the incorrect limb)

1. A sentinel event:

a. Potentially involves a continuing threat to patient care or safety;

b. Has significant potential for being reflective of serious underlying systems problems within an organization;

c. Potentially undermines public confidence in the organization.

PROCEDURE:

A. Upon notification of sentinel event occurrence, the . . . Hospital will immediately conduct an analysis of all factors involved with the event, in an effort to determine why the incident occurred. This analysis is defined as a "Root Cause Analysis", because the objective of the analysis is to determine the basic, causative factor(s) that led to the event.

1. Sentinel events will be reviewed by the administrative team and the Director of Performance Improvement within 24 hours of incident identification. The administrative team will determine if the incident requires an intensive assessment resulting in a root cause analysis, pursuant to preestablished criteria (indicators) which define actual or near occurrence of sentinel events.

2. While not always required, a root cause analysis is generally conducted by a collaborative organizational team, whose members have specific knowledge and authority to determine and correct the identified causative factors of the sentinel event. The CQI [Committee on Quality Initiatives] Coordinator Management will formulate recommendations for team membership and forward this to the administrative team for their approval. The administrative team will direct commencement of the root cause analysis by the designated team, within the next business day of their notification. In no instance will commencement of the analysis team begin over 72 hours from the date of the sentinel event.

3. If the root cause analysis finds the sentinel event to be caused by the performance and/or competence of a practitioner holding clinical privileges, the corrective action will be managed through the outlined medical staff committee process, under the supervision and direction of the board of the . . . Hospital.

4. If the root cause analysis finds the sentinel event to be caused by the performance and/or competence of a clinical staff member not holding clinical privileges, or of a non-clinical staff member, then the corrective action shall be managed by the department manager, in conjunction with the administrative team.

5. If the root cause analysis determines that the sentinel event is related to an organizational systems or process problem, the team will utilize the organization performance improvement model to design, implement and evaluate an improvement plan to correct the system issue and/or problem.

6. The analysis team will focus on the root causes of the event or occurrence . . . .

    a. Action plans will be developed with objectives that are formulated in an effort to prevent recurrence or the potential thereof, of the sentinel event.

    b. All analysis teams will include a member of the administrative team, or their specifically appointed designee. The analysis team will report any and all activities to the administrative team, as they occur.

    c. The analysis team will be afforded the time and resources by the administrative team to implement the approved action plan.

d. The analysis team will not, in any circumstance, delay implementation of the action plan or, as appropriate, elements of its components, over seven days from the date of the sentinel event.

7. The improvement plan determined by the analysis team, and the plan results, will be reported to the organizational administrative team, Performance Improvement Committee, appropriate committees of the medical staff, Governing Body, and at the direction of the administrative team, any other committees, teams, workgroups or individuals within the organization, as appropriate to the defined issue.

8. The sentinel event and/or the corrective plan will be communicated to other organizations or individuals at the sole discretion of the Administrator/CEO or his/her specific designee.

As stated above, the incident report submitted by Nurse Wheeler was referred to Lisa Gill for investigation. The evidence is inconsistent on Ms. Gill's official title. Christopher Doyle, the Hospital's CEO and corporate designee, referred to her variously as the Director of Quality, Director of Quality Care, and Director of Quality and Accreditation. (Doyle Dep. at 42, 80, 81.) She also was apparently the only member of the Performance Improvement Department. (Doyle Dep. at 81.) As such, it appears that she served as the Director of Performance Improvement referred to in Procedure section A(1) of the Sentinel Event Policy. It also appears that she functioned as the Hospital's "patient safety officer" pursuant to section 309 of the MCARE Act, 40 P.S. § 1303.309, *quoted infra*, note 11.

Whatever her title or titles, it is clear that Ms. Gill, upon reviewing the incident report, proceeded with a "Root Cause Analysis" ("RCA") as required by the Policy. (Doyle Dep. at 80.) In the course of the RCA, Ms. Gill conducted interviews and took notes on a guide or template. (Doyle Dep. at 105, 115, 120.) Mr. Doyle confirmed that he and Ms. McAnany, of Nueterra, received a copy of Ms. Gill's form. (Doyle Dep. at 117.) But in lengthy deposition testimony,

he could *not* confirm that Ms. Gill submitted a report, notes, or other materials to the Hospital's Patient Safety Committee or to the Board of the Hospital:

> Q. So . . . after the RCA was performed, what — I assume the next step would have been Lisa Gill prepared a report, correct?
>
> A. Correct.
>
> . . . .
>
> Q. What would she do with that report?
>
> A. I don't recall.
>
> The report that she used would have been a guide simply on how to conduct a root cause analysis, so it wouldn't have been anything that brought to a conclusion. It would have just been kind of a guidebook. It would have been two pages of, you know, this is Step 1, do this, Step 2, do that.
>
> Q. But the answer in the discovery that I read earlier, it says that she authored a report.
>
> A. Yeah, so she made notes on that form.
>
> Q. Did she submit a formal report to the CQI [Committee on Quality Initiatives]?
>
> A. I don't recall if she did or not. Or I know there was discussion, but I don't know if she submitted the actual report to CQI.
>
> Q. So she would have been writing notes about what people were saying at the RCA?
>
> A. Yes.
>
> Q. Okay. And so she didn't draft a formal report about the root cause analysis?
>
> A. I have no report for that.
>
> Q. So were there committee meetings — was there a CQI meeting about [Plaintiff]?
>
> A. Yes.

Q. And what was presented at that?

A. Discussion of — it was very limited. At the time we didn't know the outcome, and then we elevated it to the board, and at that point we had an attorney present to guide the board on what would be good next steps.

Q. So whatever report Lisa drafted, she did not submit it to the CQI?

A. Again, I don't recall. I'd have to look in the minutes.

Q. So I'm just — I'm sorry if I'm dense; what was the purpose of her report then?

A. It was a guide basically for how to run a root cause analysis.

Q. Okay. So it wasn't —

A. A template.

Q. The purpose of it wasn't to summarize what happened in the root cause analysis and provide that analysis to the CQI?

A. That's how — yeah, I would agree with that statement.

Q. That is was not for that purpose?

A. I would agree with that.

Q. Okay. And nor was it for the purpose of bringing the board up to speed on what occurred during the root cause analysis, correct?

A. I would agree with that.

Q. Okay. Do you know if she even submitted it to the board?

A. She did not submit it to the board.

Q. Okay.

A. She would not have. I would have, if anybody did —

Q. Do you believe you did?

A. — and I did not. [Doyle Dep. at 118-21.[6]]

C. The Court's Ruling

On December 7, 2021, the Court issued its Order disposing of the Motion. To the extent that the Hospital was withholding documents on a claim of attorney-client privilege, the Court denied the Motion.[7] The Court rejected, however, the Hospital's withholding of documents in reliance on section 311 of the MCARE Act. The Order provided:

> The Motion is **GRANTED** to the extent that it seeks production of any notes of Lisa Gill pertaining to the root cause analysis she conducted on June 17, 2015, and the subsequent report authored and submitted by Lisa Gill to the Pennsylvania Patient Safety Authority. The Hospital shall produce such documents within twenty (20) days of the date of this Order.

In an explanatory footnote, the Court stated its basis for this ruling:

> Section 311(a) [of] the Medical Care Availability and Reduction of Error (MCARE) Act, 40 P.S. § 1303.311(a), protects only documents "which arise out of matters reviewed by the patient safety . . . committee pursuant to section 310(b) [40 P.S. § 1303.310(b)] or the governing board of a medical facility pursuant to section 310(b)." In the present case, it appears that the root cause analysis was prepared by Ms. Gill, Director of Quality, in accordance with the Hospital's Sentinel Event Policy, as a result of an incident report submitted to her by Nurse Rebecca Wheeler. The evidence of record does not reflect that the report arose out of matters reviewed by the patient safety committee or the governing board. Even if the Hospital's patient safety committee had been involved, the Hospital has failed to show that its committee is constituted in compliance with section 310(a), which requires that the committee consist of at least three healthcare workers. 40 P.S. § 1303.310(a).

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[6] Other testimony established that after completing the RCA, Ms. Gill submitted a report on the incident to the Pennsylvania Patient Safety Authority through the Pennsylvania Patient Safety Reporting System Portal. (Doyle Dep. at 95). Although the Court initially required production of that report, it later struck that requirement on the Hospital's subsequent Motion for Partial Reconsideration. *See infra*, p.10.

[7] Specifically, the Court held that confidential communications between the Hospital's counsel and Nueterra, as the Hospital's agent, were protected by the attorney-client privilege.

On December 9, 2021, the Hospital filed the Motion of Defendant, Physician's Care Surgical Hospital, for Partial Reconsideration of the Court's Order of December 7, 2021 (Seq. 316). The Motion sought to strike the portion of the Order that required the Hospital to produce the Patient Safety Report submitted to the Pennsylvania Patient Safety Authority. In addition, the Motion sought reconsideration of the ruling that Ms. Gill's notes from the RCA were not confidential under the MCARE Act. In the alternative, Defendant asked this Court to certify its Order for interlocutory appeal.

Plaintiff filed its Answer to the Motion for Partial Reconsideration (Seq. 320) on December 20, 2021. Plaintiff agreed that he was not seeking production of the Patient Safety Report and therefore acknowledged that the portion of the Order relating to that report should be stricken. In all other respects, Plaintiff opposed the Motion. On December 27, 2021, the Court entered an Order essentially agreeing with Plaintiff's position (Seq. 321). It struck the portion of its prior Order that required production of the Patient Safety Report but otherwise denied the Hospital's Motion.[8]

On January 4, 2022, the Hospital filed a timely Notice of Appeal from the Court's Order of December 7, 2021 (Seq. 323).[9] On January 14, 2022, the Hospital filed a timely "Concise Statement of Errors Complained of on Appeal" ("Statement of Errors").[10]

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[8] Approximately two hours after the Court's December 27 Order was docketed, Defendant filed a Praecipe to Attach (Seq. 322), which included a new Exhibit C to the Motion for Partial Reconsideration — apparently a redacted copy of the "template" prepared by Ms. Gill. On January 19, 2022, Plaintiff filed a Motion (Seq. 328) to strike the exhibit, on the ground that it was filed after the underlying Motion had already been decided. On February 24, 2022, the Court entered an Order (Seq. 337) striking the Praecipe to Attach, on grounds set forth in a footnote to the Order.

[9] In addition, on January 26, 2022, the Hospital filed with the Superior Court a Petition for Permission to Appeal from this Court's December 27 Order, docketed at No. 13 EDM 2022.

[10] The Statement of Errors begins with a "Preface" that the Hospital "cannot readily discern the basis for this Court's order of December 7, 2021." Although such a statement is authorized by Rule 1925(b)(4)(vi)

II. DISCUSSION

The Hospital's claim of confidentiality of Ms. Gill's notes is based on section 311 of the MCARE Act, 40 P.S. § 1303.311. Specifically, section 311(a) provides:

> 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. Any documents, materials, records or information that would otherwise be available from original sources shall not be construed as immune from discovery or use in any civil or administrative action or proceeding merely because they were presented to the patient safety committee or governing board of a medical facility.

40 P.S. § 1303.311(a). An additional condition for confidentiality is set forth in section 311(c): "The confidentiality protections set forth in subsections (a) and (b) shall only apply to the documents, materials or information 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)." *Id.* § 311(c). Thus, by the express terms of the statute, documents are confidential under section 311 only if they meet three requirements: (1) they must have been "solely prepared or created for the purpose of compliance . . . or of reporting" under other designated sections of the MCARE Act; (2) they must "arise out of matters reviewed by the patient safety committee . . . or the governing board"; and (3) they must have been "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

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of the Pennsylvania Rules of Appellate Procedure, the rule does not appear to be applicable here. The Court's Order of December 7, 2021, included a footnote that concisely but clearly set forth the reasons for the Order. The Hospital may disagree with those reasons, but it can hardly assert that it is unable to "discern" them.

P.S. § 1303.310(b)]." (In addition, they must not "otherwise be available from original sources," but that requirement is not at issue in the present case.)

Section 310, in turn, sets forth the composition and responsibilities of a hospital's patient safety committee. 40 P.S. § 1303.310. Under section 310(a)(1), a hospital's patient safety committee must be

> composed of the medical facility's patient safety officer and at least three health care workers of the medical facility and two residents of the community served by the medical facility who are not agents, employees or contractors of the medical facility. . . . The committee shall include members of the medical facility's medical and nursing staff.

Id. § 1303.310(a)(1). Under section 310(b), the responsibilities of the patient safety committee include the review and evaluation of reports and investigations by the patient safety officer.[11]

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[11] Specifically, section 310(b) provides:

> A patient safety committee of a medical facility shall do all of the following:
>
> (1) Receive reports from the patient safety officer pursuant to section 309.
>
> (2) Evaluate investigations and actions of the patient safety officer on all reports.
>
> (3) Review and evaluate the quality of patient safety measures utilized by the medical facility. A review shall include the consideration of reports made under sections 304(a)(5) and (b), 307(b)(3) and 308(a).
>
> (4) Make recommendations to eliminate future serious events and incidents.
>
> (5) 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.

Id. § 1303.310(b). The duties of the "patient safety officer" are defined in section 309:

> A patient safety officer of a medical facility shall do all of the following:
>
> (1) Serve on the patient safety committee.
>
> (2) Ensure the investigation of all reports of serious events and incidents.

There is no published appellate case construing or applying the confidentiality protection of section 311. In the absence of governing appellate case law, the Common Pleas decision in *Venosh v. Henzes*, 31 Pa. D. & C.5th 411 (C.C.P. Lackawanna 2013) (Nealon, J.), *aff'd*, 105 A.3d 788 (Pa. Super. 2014) (unpublished memorandum), has emerged as the preeminent authority under section 311.[12] In *Venosh*, a patient brought suit for medical negligence against her surgeon, the surgeon's practice group, and the hospital where the surgery was performed. At the time of the patient's surgery, the hospital had an "Event Reporting" policy setting forth "the standard procedure for the reporting of any unusual occurrence or event which takes place at [the] Hospital." *Id.* at 415. In relevant part, the policy required that the "initial investigation" of an event be conducted by the "Department Head/Supervisor/Manager as soon as possible." *Id.* Any investigation thereafter would be conducted by an "investigative analyst," who would then report back to "the Department Head/Supervisor/Manager as to the cause of the event and measures taken to prevent recurrence when indicated." *Id.* The event reports were also "reviewed and analyzed by the Investigative Analyst for any developing trends," and those results were "reviewed by the [patient safety committee]." *Id.* at 416. Finally, under the "Event

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> (3) Take such action as is immediately necessary to ensure patient safety as a result of any investigation.
>
> (4) Report to the patient safety committee regarding any action taken to promote patient safety as a result of investigations commenced pursuant to this section.

Id. § 1303.309.

[12] *See, e.g.*, *Rumsey v. Guthrie Med. Grp., P.C.*, No. 4:18-CV-01605, 2019 WL 4687560, at *2 (M.D. Pa. Sept. 26, 2019); *Haines v. Cherian*, No. 1:15-CV-00513, 2016 WL 831946, at *5 (M.D. Pa. Feb. 29, 2016) (Mag. J.); *Lesterick ex rel. Lesterick v. Singh*, No. GD-13-016483, 2015 WL 13779478, at *4 (C.C.P. Allegheny, May 4, 2015) (all following *Venosh* or citing it with approval).

Reporting" policy, if the investigative analyst "determine[d] that a particular event require[d] more specific documented follow-up, the Department Head/Manager/Supervisor [was] asked to complete an 'Event Report Investigation and Follow-up' within five (5) days," which would be forwarded to the department's Vice-President or President and the Vice President of Corporate Development for final review. *Id.*

The plaintiff sought production of two "event reports" relating to her treatment, and the defendant hospital objected that the reports were confidential under section 311.[13] In a comprehensive opinion analyzing section 311, the court rejected the hospital's position. Initially, the court held that the hospital had the burden of proving that the reports fell within the scope of section 311: "Any limitations or restrictions upon discovery should be construed narrowly. . . . [T]he party opposing discovery bears the burden of establishing that the requested material is privileged and shielded from discovery. All doubts regarding the discoverability of information should be resolved in favor of permitting discovery." *Id.* at 420 (citations omitted).

Turning to section 311, the court explained:

> 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. Similarly, absent proof "that the . . . 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.

[13] The hospital also objected under section 4 of the Peer Review Protection Act, 73 P.S. § 425.4. The Hospital in the present case has not invoked that Act.

Id. at 432 (quoting *Forrest v. St. Luke's Hosp.*, 73 Pa. D. & C.4th 353, 355 n.1 (C.C.P. Lehigh 2005); *Treible v. Lehigh Valley Hosp. Inc.*, 75 Pa. D. & C.4th 22, 28 (C.C.P. Lehigh 2005)).

Applying these principles, the *Venosh* court found that the event reports were not "generated solely for the purpose of complying with the patient safety reporting requirements" contained in other provisions of the MCARE Act. *Id.* at 433. Rather, they were created pursuant to the hospital's policy "to make a record of the incident for litigation purposes and compile data to evaluate event trends." *Id.* at 434. Further, there was no evidence of record that the plaintiff's care "was ever reviewed by the patient safety committee or the board of trustees in compliance with [section 310(b)] of the MCARE Act." *Id.* Therefore, the court concluded that the event reports were not protected from discovery under section 311, and it ordered the production of the reports.[14] On appeal, the Superior Court affirmed this ruling in an unpublished memorandum that expressly adopted the trial court's opinion. *Venosh v. Henzes*, 105 A.3d 788 (Pa. Super. 2014).[15]

The analysis of *Venosh* applies to the present case in at least two respects. First, the Hospital's investigation was not made "solely for the purpose of complying with the patient safety reporting requirements" of the MCARE Act. *Venosh*, 31 Pa. D. & C.5th at 433; *see*

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[14] The *Venosh* court contrasted the hospital's "Event Reporting" policy with a new "Commonwealth Health Policy" adopted after a change in ownership of the hospital following the event in question. The stated purpose of the new policy was to prescribe "the standard procedure for reporting to the Patient Safety Improvement and Management Committee any unusual occurrence or event." *Id.* at 417. It stated 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.* Unlike the "Event Reporting" policy, the "Commonwealth Health Policy" made express reference to the MCARE Act and confirmed 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.*

[15] The text of the Superior Court's unpublished memorandum appears at No. 1498 MDA 2013, 2014 WL 10896822 (July 11, 2014).

MCARE Act § 311(a), 40 P.S. § 1303.311(a). It is undisputed that Ms. Gill's investigation was undertaken pursuant to the Hospital's Sentinel Event Policy. That Policy, like the "Event Reporting" policy in *Venosh*, is clearly not an implementation of the investigation or reporting requirements of the MCARE Act. The Policy makes no reference to the MCARE Act or its requirements. Further, the procedure prescribed by the Policy does not bear any meaningful resemblance to the procedure mandated by the MCARE Act. Most significantly, the Policy does not provide for any reporting of the investigation to the Hospital's patient safety committee, in accordance with section 310(b). It provides for the involvement of the Hospital's Board only "[i]f the root cause analysis finds the sentinel event to be caused by the performance and/or competence of a practitioner holding clinical privileges." (Policy, Procedure sec. A(3).) In short, the procedure required by the MCARE Act and the process prescribed by the Sentinel Event Policy occupy completely separate spheres.[16]

Second, wholly aside from the procedures in the Hospital's written Policy, there is no evidence that Ms. Gill's investigation was *in fact* "ever reviewed by the patient safety committee or the board of trustees in compliance with [section 310(b)]." *Venosh*, 31 Pa. D. & C.5th at 434. As noted *supra*, pp. 7-9, the Hospital's corporate designee could confirm only that he and Ms. McAnany, of Nueterra, had received a copy of Ms. Gill's form. To the extent that Ms. Gill did submit any material to the Committee on Quality Initiatives, it was not for the purpose of "summariz[ing] what happened in the root cause analysis and provid[ing] that analysis to" the Committee. (Doyle Dep. at 120.) Her form was not provided to the Hospital's Board, and in any

[16] It is true that in *Venosh*, the "Event Reporting" policy stated that one of its purposes was to "provide a record of the occurrence for legal purposes," *Venosh*, 31 Pa. D. & C.5th at 415, and no equivalent language appears in the Sentinel Event Policy in the present case. That difference, however, is not sufficient to distinguish this case from *Venosh*, since the Sentinel Event Policy, like the "Event Reporting" Policy in *Venosh*, simply does not implement the requirements of the MCARE Act.

event it was not prepared for the purpose of "bringing the board up to speed on what occurred during the root cause analysis." (Doyle Dep. at 120-21.) "[A]bsent proof that the 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." *Id.* at 432 (quotation marks omitted).

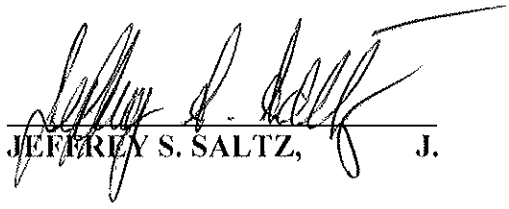
A final consideration is that even if the matter had been "reviewed by the patient safety committee," 40 P.S. § 1303.311(a), the Hospital failed to show that that committee had been established in compliance with the MCARE Act. As discussed *supra*, p. 12, section 310(a) of the Act requires that the patient safety committee be composed of the patient safety officer, at least three of hospital's health care workers (including members of the medical and nursing staff), and two independent members of the community. 40 P.S. § 1303.310(a). Plaintiff's counsel stressed this point during oral argument on the Motion to Compel, and counsel for the Hospital subsequently provided to Chambers a copy of an informal discovery letter that he had sent to Plaintiff's counsel, identifying the names of the members of the CQI committee and the patient safety committee. But while the *names* of the committee members were thus made of record, there is no evidence that these individuals filled the required categories specified by section 310(a). This specific issue was not addressed in *Venosh*, but the case does confirm that a party claiming that information is privileged or otherwise exempt from discovery has the burden of showing the facts necessary to establish that claim. *Venosh*, 31 Pa. D. & C.5th at 420. The Hospital failed to sustain that burden to establish that makeup of the patient safety committee conformed to the requirements of section 310(a). [17]

[17] Indeed, there is some doubt whether the Hospital even had a functioning patient safety committee. Section 7(1) of the Hospital's Medical Staff Bylaws (Pl.'s Supp. Mem., Ex. C) sets forth a list of the Hospital's committees that does not include a patient safety committee, although it recognizes that other

III. CONCLUSION

Because the Hospital could not establish that Ms. Gill's notes qualified for protection under the specific requirements of section 311 of the MCARE Act and the other statutory provisions referred to in section 311, the Court granted Plaintiff's Motion to Compel production of the notes.

BY THE COURT:



JEFFREY S. SALTZ, J.

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committees could be formed. The list of committees does include a "Committee on Quality Initiatives." Mr. Doyle testified that the CQI acts as the Hospital's "Safety Committee," and that the "Patient Safety Committee" is a subcommittee of the CQI. (Doyle Dep. at 40.) In any event, it is immaterial whether a patient safety committee existed, as the record is clear that any such committee was not involved in Ms. Gill's root cause analysis.