IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

RICHARD RUMSEY, Plaintiff, v. GUTHRIE MEDICAL GROUP, P.C., by and through its officers, agents and/or employees, and ROBERT PACKER HOSPITAL, by and through its officers, agents and/or employees, Defendants.	No. 4:18-CV-01605 (Judge Brann)

MEMORANDUM OPINION

SEPTEMBER 26, 2019

Plaintiff Richard Rumsey brings this medical malpractice action against the defendant medical entities, whom I will collectively refer to as "Guthrie." Rumsey alleges that Guthrie was negligent in failing to test or treat him for a MRSA infection that escalated following an elective procedure.

In discovery, Rumsey has sought information pertaining to Guthrie's infection-prevention procedures. Guthrie in turn objects to three discovery requests and previously instructed a witness—Andrew Klee, an infection-prevention specialist for Guthrie—not to answer questions at his deposition pertaining to the same, asserting that these are protected by the patient safety work product privilege.

The patient safety work product privilege is intended to promote candor in patient safety evaluations from clinicians who may otherwise mince their words out of fear of malpractice litigation.[1] The hope is that enabling blunt criticism will help to stem the staggering number of deaths from preventable medical errors each year—which at least one study estimated was the third-leading cause of death in the United States.[2] All fifty states, the District of Columbia, and the federal government have enacted some form of this privilege.[3] Of those, Guthrie claims privilege under the federal Patient Safety and Quality Improvement Act[4] (PSQIA) and the Pennsylvania Medical Care Availability and Reduction of Error Act[5] (the "MCARE Act"), the latter applicable here through Federal Rule of Evidence 501.

The PSQIA creates a framework through which medical care providers may engage in privileged peer review of their patient safety practices. First, the provider develops a process for collecting, managing, and analyzing patient safety data; this process is called the "patient safety evaluation system." The provider then discloses that data to a certified third-party patient safety organization. Ultimately, privilege attaches to the underlying patient safety work product that is prepared for the purpose

[1] *See* S Rep No 108–196, at 2 (2003); HR Rep No 109–197, at 9 (2005).
[2] Martin A. Makary & Michael Daniel, *Medical Error—The Third Leading Cause of Death in the US*, 353 Brit Med J 1 (2016).
[3] Charles G. Kels, *Odd Man Out? The Medical Peer Review Privilege in Federal Litigation*, 60 Fed Law 52, 52 (Dec. 2013).
[4] 42 USC §§ 299b-21–26.
[5] 40 Pa CSA § 1303.311(b).

of disclosing to a patient safety organization as part of a patient safety evaluation system. The MCARE Act provides a similar structure.[6]

With that overview in mind, I first look to the language of the statutes.[7] The PSQIA defines "patient safety work product" as:[8]

> Any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—
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> (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.

The PSQIA goes on to clarify:[9]

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

[6] *See* 40 Pa CSA § 1303.311.
[7] *Doe v Hesketh*, 828 F3d 159, 167 (3d Cir 2016).
[8] 42 USC § 299b-21(7)(A).
[9] 42 USC § 299b-21(7)(B).

Essentially, documents generated by the evaluation process are protected, but such information does not become privileged merely by virtue of having been reported. "[T]he critical inquiry is the purpose of creating the information, and the information will only be considered patient safety work product if it is created 'for the purpose of reporting' to a patient safety organization."[10]

As noted above, the MCARE Act operates similarly. It provides:[11]

> **(a) Prepared Materials.—**Any documents, materials or information solely prepared or created for the purpose of compliance with section 310(b) or of reporting . . . 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.
>
> **(b) Meetings.—**No person who performs responsibilities for or participates in meetings of the patient safety committee or governing board of a medical facility pursuant to section 310(b) shall be allowed to testify as to any matters within the knowledge gained by the person's responsibilities or participation on the patient safety committee or governing board of a medical facility, provided, however, the person shall be allowed to testify as to any matters within the person's knowledge which was gained outside of the persons's [*sic*]

[10] *Crawford v Corizon Health, Inc*, 2018 WL 3361147, at *2 (WD Pa July 10, 2018), quoting Patient Safety Act Guidance, 81 Fed Reg 32655, 32656.
[11] 40 Pa CSA § 1303.311 (emphasis in original).

> responsibilities or participation on the patient safety committee or governing board of a medical facility pursuant to section 310(b).

The MCARE Act's protection is similar to the PSQIA's but narrower in that it must be "solely" prepared for that purpose. Privilege under the MCARE Act has been applied only where (1) the documents were solely prepared or created for the purpose of compliance with the MCARE Act's "serious events" reporting requirements; (2) they arise out of matters reviewed by the patient safety committee or the governing board; and (3) they are not otherwise available from original sources.[12]

I now turn to Guthrie's objections. Guthrie objected to three requests for discovery.

i) Request No. 6: "A copy of all infection prevention and infection control materials which Defendants received prior to May 1, 2017 from [Vizient] and/or any other company."

The MCARE Act privileges only documents "solely prepared or created for the purpose of *compliance with* section 310(b) or of *reporting* . . . ."[13] The patient safety organization neither "compl[ies] with" nor "report[s]"—the provider does. Therefore, documents generated by Vizient, a patient safety organization, are not privileged under the MCARE Act.

[12] *Haines v Cherian,* 2016 WL 831946, at *5 (MD Pa Feb 29, 2016), quoting *Venosh v Henzes,* 2013 WL 9593953, at *10 (Pa Ct Common Pleas July 17, 2013).
[13] 40 Pa CSA § 1303.311(a) (emphasis added).

However, the documents fall under the PSQIA's definition—documents that are produced by the patient safety organization for the purpose of conducting patient safety activities.[14] Vizient was a patient safety organization that Guthrie conducted patient safety activities with. The information arising out of this relationship is protected under the PSQIA.[15]

ii) Request No. 9: "A copy of Defendants' agendas, notes and any and all other written records of Defendants' monthly (or other than monthly) quality committee meetings from May 1, 2016 to May 1, 2017 insofar as they discuss infection prevention or infection control."

This is the quintessential example of patient safety work product privilege. Quality committee meetings are a core aspect of Guthrie's patient safety evaluation system. Agendas, notes, and other written records from these meetings are squarely work product and are "deliberations or analysis of" a patient safety evaluation system. These are protected under the PSQIA and the MCARE Act, as well as Pennsylvania's Peer Review Protection Act.[16]

iii) Request No. 20: "A copy of any and all correspondence and communication between Defendants and any federal, state, county or local governmental agency within the past 5 years on the subject of infection prevention, infection reporting, infection management and infection rates."

These are not "work product" within the relevant definition. Corresponding with governmental agencies is not a part of Guthrie's patient safety evaluation

[14] 42 U.S.C. § 299b-21(7)(A)(i)(II).
[15] I further find that the phrase "and/or any other company" is vague and overly broad.
[16] 63 Pa CSA § 425.4 ("[P]roceedings and records of a review committee shall be held in confidence and shall not be subject to discovery.").

program, nor is it a part of its process of disclosing peer-review information to its patient safety organizations. For that same reason, such correspondence would not have been generated for the purpose of reporting. Therefore, these documents are not privileged. However, the time frame requested is overly broad; I now limit it to communications from May 1, 2015 to May 1, 2017.

Guthrie also objected to a series of questions at the deposition of Andrew Klee. The patient safety work product privilege bars a witness from testifying to the proceedings of quality committee meetings or other knowledge he gained by virtue of participating in the patient safety evaluation system.[17] However, the privilege is not so broad as to cover Guthrie's infection-prevention policies generally, and information available outside of the evaluation system does not become privileged merely by virtue of its use in the evaluation process.

Here, Rumsey's counsel asked questions regarding subjects such as Guthrie's quality committee meetings, how the committee determined infection preparedness, the data used to reach preparedness conclusions, and why they collected certain data and not others. These questions seek information generated by the patient safety evaluation system, and I will not order the parties to reopen the deposition to have them answered.

* * *

[17] 42 USC § 299b-21(7)(A)(ii); 40 Pa CSA § 1303.311(b).

The patient safety work product privilege is a quiet corner of the room, not a private island. The statutes carve an exception to the presumption of free and open disclosure to facilitate a specific, carefully designed process of disclosure. If they are cautious to remain within the confines of the patient safety evaluation system, medical professionals may provide the brutally honest feedback hospitals need to keep their patients safe without fear of its use in litigation.

An appropriate Order follows.

BY THE COURT:

s/ Matthew W. Brann
Matthew W. Brann
United States District Judge