

2025 PA Super 148

ERIN AND STEPHEN BOYLE, : IN THE SUPERIOR COURT OF
PARENTS AND NATURAL GUARDIANS : PENNSYLVANIA
OF BB, A MINOR, AND IN THEIR :
OWN RIGHT :

v. :

MAIN LINE HEALTH, INC., MAIN LINE :
HOSPITALS, INC., MAIN LINE :
HEALTHCARE, AND SCOTT BAILEY, :
M.D. :

No. 2454 EDA 2023

Appellants

Appeal from the Order Entered August 21, 2023
In the Court of Common Pleas of Montgomery County Civil Division at
No(s): 2019-15082

BEFORE: LAZARUS, P.J., KING, J., and LANE, J.

OPINION BY KING, J.:

FILED JULY 17, 2025

Appellants, Main Line Health, Inc., Main Line Hospitals, Inc., Main Line HealthCare, and Scott Bailey, M.D. (collectively, "Main Line Defendants"), appeal from the order entered in the Montgomery County Court of Common Pleas, which granted the discovery motion of Erin and Stephen Boyle, parents and natural guardians of B.B., a minor (collectively, "the Boyles").¹ We affirm in part and reverse in part.

¹ "Pennsylvania courts have held that discovery orders involving potentially confidential and privileged materials are immediately appealable as collateral to the principal action." **Berkeyheiser v. A-Plus Investigations, Inc.**, 936 A.2d 1117, 1123-24 (Pa.Super. 2007). **See also Farrell v. Regola**, 150 A.3d 87, 95 (Pa.Super. 2016), *appeal denied*, 641 Pa. 464, 168 A.3d 1259 (2017) (*Footnote Continued Next Page*)

The relevant facts and procedural history of this case are as follows. On June 6, 2019, the Boyles initiated this action by filing a complaint against the Main Line Defendants seeking damages for injuries suffered by B.B. during his birth at Lankenau Hospital (“Hospital”).² After the Main Line Defendants filed preliminary objections, the Boyles filed an amended complaint on September 3, 2019, which asserted claims for professional negligence against both the Hospital and Dr. Bailey, negligent infliction of emotional distress with regard to Erin Boyle, and loss of consortium with regard to Erin and Stephen Boyle. (Boyles’ First Amended Complaint, filed 9/3/19).

The matter proceeded to discovery.³ Relevant to this appeal, the Boyles sought to obtain documents from the Main Line Defendants relating to the review and investigation of issues relating to Erin Boyle’s delivery of B.B (“the Boyle Event”). On January 31, 2023, in response to the Boyles’ request for production of documents, the Main Line Defendants provided a privilege log identifying four documents that the Boyles had sought that the Main Line

(holding that collateral order doctrine, as provided by Pa.R.A.P. 313 applies if appellant asserts that trial court has ordered it to produce materials that are privileged).

² Lankenau Hospital is a part of Main Line Health, Inc.

³ The parties have litigated several other issues during discovery which are not relevant to the instant appeal. ***See Boyle v. Main Line Health, Inc.***, 272 A.3d 466 (Pa.Super. filed Jan. 10, 2022) (unpublished memorandum) (reversing trial court order striking subpoenas of Stephen Boyle’s mental health records).

Defendants claimed were privileged: (1) the Patient Safety Occurrence Worksheet (“PSOW”); (2) the Situation Background Assessment/Recommendations (“SBAR”); (3) the Patient Safety Reporting System (“PSRS”); and (4) the Potentially Compensable Event (“PCE”) report to Claims Management.⁴ The Main Line Defendants asserted that the documents were privileged pursuant to the Medical Care Availability and Reduction of Error (“MCARE”) Act⁵ and the Patient Safety and Healthcare Quality Improvement Act (“PSQIA”).⁶

On March 2, 2023, the Boyles filed a motion to compel the production of these documents. The court appointed a discovery master who conducted a hearing on March 23, 2023. On May 4, 2023, the trial court entered an order directing the Main Line Defendants to supplement the privilege logs with the requisite factual basis to demonstrate proper invocation of the Pennsylvania Peer Review Protection Act (“PRPA”),⁷ MCARE Act, and PSQIA. The Main Line Defendants complied, serving an amended privilege log on May 18, 2023. The Main Line Defendants specified that the PSRS report was protected from disclosure under the MCARE Act, and the PSOW and SBAR

⁴ The PCE Report has since been produced and is not at issue in this appeal. (Trial Court Opinion, filed 2/6/24, at 2).

⁵ 40 P.S. §§ 1303.101-1303.910.

⁶ 42 U.S.C. §§ 299b-21-26.

⁷ 63 P.S. 425.4.

were protected as confidential patient safety work product under the PSQIA. The Main Line Defendants admitted that no peer review was conducted and they did not assert any privilege under the PRPA. On June 20, 2023, the Boyles filed a second motion to compel production of these documents.

On August 21, 2023, the trial court entered an order directing the Main Line Defendants to produce the contested documents. On September 15, 2023, the Main Line Defendants filed a motion for reconsideration.⁸ While the motion for reconsideration was pending, the Main Line Defendants filed a timely notice of appeal on September 20, 2023. The court entered an order directing the Main Line Defendants to file a concise statement of errors per Pa.R.A.P. 1925(b) on October 23, 2023. The Main Line Defendants filed their Rule 1925(b) statement on November 9, 2023.

The Main Line Defendants raise the following issues for our review:

A. Did the [trial] court err in ordering the production of a [PSRS] report submitted to the Pennsylvania Patient Safety Authority under MCARE's mandate and pursuant to its privilege protection?

B. Did the [trial] court err in ordering the production of patient safety work product that is strictly and preemptively privileged under the Federal [PSQIA]?

(Main Line Defendants' Brief at 5) (unnecessary capitalization omitted).

Our standard of review of a trial court's order rejecting claims of

⁸ Although the trial court did not enter an order ruling on the Main Line Defendants' motion for reconsideration, the court stated in its 1925(a) opinion that the motion was denied. (**See** Trial Court Opinion, 2/6/24, at 2).

statutory privilege is well settled.

[I]n reviewing the propriety of a discovery order, our standard of review is whether the trial court committed an abuse of discretion. Abuse of discretion occurs if the trial court renders a judgment that is manifestly unreasonable, arbitrary or capricious; that fails to apply the law; or that is motivated by partiality, prejudice, bias or ill-will.

Carlino E. Brandywine, L.P. v. Brandywine Village Associates, 260 A.3d 179, 195-96 (Pa.Super. 2021) (citations and quotation marks omitted). However, to the extent that we are faced with questions of law, our scope of review is plenary. **Berkeyheiser, supra** at 1125. Furthermore:

The party asserting a privilege bears the burden of producing facts establishing proper invocation of the privilege. **Custom Designs & Mfg. Co. v. Sherwin-Williams Co.**, 39 A.3d 372, 376 (Pa.Super. 2012)[, *appeal denied*, 618 Pa. 688, 57 A.3d 71 (2012)]. “[T]hen the burden shifts to the party seeking disclosure to set forth facts showing that disclosure will not violate the ... privilege.” **Id.** (citation omitted). “Absent a sufficient showing of facts to support [a] privilege ... the communications are not protected.” **Ford-Bey v. Professional Anesthesia Services of North America, LLC**, 229 A.3d 984, 991 (Pa.Super. 2020)[, *appeal denied*, 663 Pa. 444, 242 A.3d 1251 (2020)].

Ungurian v. Beyzman, 232 A.3d 786, 795 (Pa.Super. 2020).

In their first issue, the Main Line Defendants assert that the trial court erred when it ordered production of the PSRS report. The Main Line Defendants argue that the court erred when it applied additional requirements that are not included in the MCARE statute, *inter alia*, requiring the Hospital to prove that the investigation of the Boyle Event was initiated at the request of a patient safety board, that the PSRS document itself be reviewed by the

patient safety committee, and in requiring the Hospital to show that there was a peer review meeting regarding the Boyle event. The Main Line Defendants insist that based on the statutory language of MCARE, the PSRS is a protected submission under MCARE sections 311(a) and 311(d). First, the Main Line Defendants contend that the PSRS report was prepared solely for reporting under MCARE section 313, and second that the report arose out of a matter, the Boyle Event, that was submitted to and reviewed by the Hospital's patient safety committee as required by section 311(a). The Main Line Defendants claim that the PSRS met all requirements to be privileged under MCARE, and the trial court's imposition of additional requirements was an error of law that must be reversed. Based on the facts of this case as set forth in the certified record, we disagree.

Chapter 3 of the MCARE Act relates to patient safety and was enacted to reduce medical errors for the purpose of ensuring patient safety. 40 P.S. § 1303.301. Chapter 3 requires medical facilities to develop, implement, and comply with a patient safety plan and establish internal reporting systems for healthcare workers to report incidents and serious events. 40 P.S. §§ 1303.307(b)(3), 1303.308(a). The patient safety plan must also designate a patient safety officer and establish a patient safety committee. 40 P.S. at § 1303.307(b)(1)-(2).

Section 310(b) of the MCARE Act requires the patient safety committee to:

- (1) receive reports from the patient safety officer.
- (2) evaluate the patient safety officer's investigations and actions on all reports.
- (3) review and evaluate the quality of patient safety measures utilized by the medical facility, which must include 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) give quarterly reports to the administrative officer and governing body of the medical facility about the number of serious events and incidents and the committee's recommendations to eliminate future serious events and incidents.

40 P.S. § 1303.310(b). The Hospital must also report all incidents to the Pennsylvania Patient Safety Authority ("PPSA"). 40 P.S. § 1303.313(b).

In addition to the requirements for reporting, the General Assembly created a corresponding confidentiality section in the MCARE Act which provides as follows:

§ 1303.311. Confidentiality and compliance

(a) Prepared materials.--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 3131 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 [person]'s responsibilities or participation on the patient safety committee or governing board of a medical facility pursuant to section 310(b).

(c) Applicability.--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).

(d) Received materials.--Except as set forth in subsection (f), any documents, materials or information received by the authority or department from the medical facility, health care worker, patient safety committee or governing board of a medical facility 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 shall not be discoverable or admissible as evidence in any civil or administrative action or proceeding. Any records received by the authority or department from the medical facility, health care worker, patient safety committee or governing board of a medical facility pursuant to the requirements of this act shall not be discoverable from the department or the authority in any civil or administrative action or proceeding. Documents, materials, records or information may be used by the authority or department to comply with the reporting requirements under subsection (f) and section 304(a)(7) or (c) or 306(b).

40 P.S. § 1303.311(a)-(d).

This Court discussed the MCARE Act privilege in ***Ford-Bey***, where the plaintiff's estate sued the hospital for medical malpractice after Ms. Ford-Bey suffered cardiac and respiratory failures following wrist surgery and remained in a vegetative state after the surgery until she died about a month later. ***Ford-Bey, supra*** at 792. A hospital administrator, Ms. Gill, conducted a root cause analysis to determine the cause of Ms. Ford-Bey's decline, and in doing so interviewed hospital staff members involved in the surgery and aftercare of Ms. Ford-Bey. The administrator took notes on a form of standard questions and authored at least one report that she sent to the PPSA. During discovery, Ms. Ford-Bey requested all data and documents from the root cause analysis. The hospital asserted that section 311(a) of the MCARE Act protected such materials from disclosure. The trial court ordered the hospital to produce the notes that Ms. Gill took while conducting the root cause analysis.

On appeal, this Court considered whether the trial court erred in its interpretation and application of the MCARE Act. This Court emphasized that MCARE confidentiality extends to "documents, materials or information **solely** prepared or created for the purpose of compliance with section 310(b)." ***Ford-Bey, supra*** at 797 (emphasis added) (quoting 40 P.S. § 1303.311(a)). This Court explained that "aside from Gill's filing with the PPSA a report, which the trial court held remained confidential, [the h]ospital failed to produce evidence demonstrating Gill **solely** prepared or created her notes for the purpose of complying with MCARE." ***Id.*** (emphasis added). Therefore, this

Court concluded that the hospital did not meet its burden of invoking the privilege set forth in section 311 of MCARE, and affirmed the trial court's ruling that the MCARE privilege did not apply. ***Id.*** at 798.

This Court again considered the applicability of the MCARE Act's section 311(a) statutory privilege in a recent unpublished decision, ***Lahr v. Lehigh Valley Hosp., Inc.***, 311 A.3d 587, 2023 WL 8665017 (Pa.Super. 2023) (unpublished memorandum).⁹ In that case, Ms. Lahr sued Lehigh Valley Hospital, Lehigh Valley Physicians Group, and the attending physicians for medical malpractice and other claims after her newborn baby died of complications related to infections. During discovery, Ms. Lahr moved to compel the hospital to produce patient safety reports regarding herself and/or her newborn. The hospital asserted that the patient safety reports were immune from discovery under MCARE and PRPA. The trial court conducted a hearing during which it heard testimony concerning the hospital's patient safety reporting policy.

The testimony at the hearing showed that the patient safety officer investigated three reports submitted involving Ms. Lahr and/or her newborn, and classified two of the three reports as "incidents" and reported them to the PPSA. The officer classified the third report as a non-event. The director of OB-GYN quality assurance and performance improvement testified that she

⁹ **See** Pa.R.A.P. 126(b) (stating we may rely on unpublished decisions of this Court filed after May 1, 2019 for their persuasive value).

typically uploads summaries of patient safety reports into the electronic peer review file; however, she could not confirm whether she had done so in this case. The Obstetrics Peer Review Committee engaged in peer review of all documents in the files. Following the hearing, the trial court granted Ms. Lahr's motion to compel. **Lahr, supra** at *1-3.

On appeal, this Court considered "section 311(a)'s protections of 'documents, materials or information solely prepared or created for the purpose of ... reporting under [section 308(a)] 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)....'" **Id.** at *7 (quoting 40 P.S. § 1303.311(a)) (brackets in original). Concluding that the three contested patient safety reports were solely prepared for reporting under MCARE section 308(a), this Court turned to whether the documents "ar[o]se out of matters reviewed by the patient safety committee." **Id.** at *8.

This Court explained:

Reading section 311(a) and (c)'s requirements together, it is clear the General Assembly intended that a party seeking section 311(a)'s protection demonstrate a document was prepared or created pursuant to a patient safety committee's or governing board's responsibility, **see** [40 P.S. § 1303.311], and the document arose from matters reviewed by the patient safety committee, such as receiving the patient safety officer's report, evaluating the patient safety officer's investigation and actions on all reports, or reviewing and evaluating the quality of a hospital's patient safety measures. **See** [40 P.S.] §§ 1303.310(b), 1303.311(a).

Id. Therefore, this Court held that section 311(a) does not apply simply

because the patient safety reports are the types of documents typically reviewed by a patient safety committee. Rather, the General Assembly's choice of the language "matters reviewed" rather than "matters typically reviewed" indicates that a party asserting the privilege is required to demonstrate more than the fact that a patient safety committee would typically review the patient safety reports. This Court explained "that a party claiming a document is protected under section 311(a) need not demonstrate a patient safety committee or governing board actually reviewed the contested document." *Id.* at *9. However, at a minimum "section 311(a) requires proof that the document, materials or information or reporting requirement arose out of 'matters reviewed' by a patient safety committee or a governing board pursuant to their section 311(b) responsibilities." *Id.*

Instantly, the Main Line Defendants offered the affidavit of Nanci Gallagher, RN, who was working as the MCARE patient safety officer at the Hospital, and who was charged with investigating the Boyle Event. She averred that, in accordance with the MCARE Act, the Hospital had a patient safety plan and patient safety officer. (Affidavit of Nanci Gallagher, RN, dated 3/31/23, at ¶¶ 2, 4). The Hospital's patient safety plan also established a patient safety committee pursuant to MCARE and set forth requirements for both internal and external reporting. (*Id.* at ¶¶ 5, 6).

Ms. Gallagher further stated that while she was investigating the Boyle Event in accordance with the patient safety plan, she completed both the SBAR

and PSOW, which were submitted to the Hospital's federal patient safety organization. (*Id.* at ¶¶ 8, 9, 10). In addition, Ms. Gallagher stated that the event was a "serious event" under the Hospital's policy; accordingly, to comply with the MCARE Act, she created the PSRS report and submitted it to the Pennsylvania Patient Safety Reporting System. (*Id.* at ¶ 14). Because the event was designated a serious event, Ms. Gallagher stated that the Hospital sent a standard written disclosure confirmation to Erin Boyle regarding the event. (*Id.* at ¶ 16).

The Main Line Defendants also submitted an affidavit from Patricia Walsh, RN, MSN, who was working as the system manager for risk and safety at the time of the Boyle Event. Ms. Walsh explained that in order to comply with the PSQIA, the Hospital contracted for services with a federally approved patient safety organization and developed and implemented a formal patient safety evaluation system. (Affidavit of Patricia Walsh, RN, MSN, dated 3/29/23).¹⁰

¹⁰ After the trial court issued its ruling in favor of the Boyles, the Main Line Defendants submitted a supplemental affidavit of Nurse Walsh as an attachment to their motion for reconsideration of the court's order. In this supplemental affidavit, Nurse Walsh averred that the patient safety committee of the Hospital reviewed the Boyle Event. (Affidavit of Patricia Walsh, RN, MSN, dated 9/13/23, at ¶ 8).

We recognize that evidence that the Boyle Event was reviewed by the patient safety committee could have provided the foundation required to establish that the documents created as a result of the Boyle Event were privileged under section 311(a). However, as an appellate court, we are confined to a
(Footnote Continued Next Page)

Thus, the record reflects that the Hospital had both a patient safety plan and a patient safety officer. The Hospital's patient safety plan also established a patient safety committee pursuant to MCARE and set forth requirements for both internal and external reporting as required by sections 307(b) and 308(a). **See** 40 P.S. §§ 1303.307(b), 1303.308(a). The Hospital determined that the Boyle Event was a serious event and, in accordance with MCARE, sent written notification to Erin Boyle. **See** 40 P.S. § 1303.308(b). Furthermore, the patient safety officer, Ms. Gallagher, created the PSRS report and submitted it to the Pennsylvania Patient Safety Reporting System. 40 P.S. § 1303.313(b). Based on our review, we conclude that the PSRS was solely prepared for the purpose of reporting under MCARE. **See Ford-Bey, supra.**

We next must discern whether the PSRS report arose out of a matter reviewed by a patient safety committee or a governing board pursuant to their section 311(b) responsibilities. **See Lahr, supra.** In the record before the trial court, neither Ms. Gallagher nor Ms. Walsh stated that the Hospital's patient safety committee or governing board had reviewed the Boyle Event. As this Court made clear in **Lahr**, MCARE's privilege applies to documents

determination of whether the facts of record supported the trial court's decision. **Chryszanavicz v. Chryszanavicz** 796 A.2d 366, 369 (Pa.Super. 2002) (explaining that document attached to party's motion for reconsideration in trial court did not constitute entry of that document into evidence; hence document was not before this Court in evidence). Therefore, we cannot consider the supplemental affidavit of Nurse Walsh or the Main Line Defendants' arguments relying thereon when deciding this appeal. **See id.**

solely created for compliance with MCARE, only when the documents arose out of matters reviewed by a patient safety committee or governing board. **Lahr, supra** at *8. Here, without evidence of record that the Boyle Event was reviewed by a patient safety committee or governing board, we cannot conclude that the PSRS report met the criteria for privilege under section 311(a). **See id.** Based on the record before the court in this case, we agree with the trial court that the Main Line Defendants did not meet their burden of establishing that the PSRS report arose out of a matter reviewed by a patient safety committee or a governing board pursuant to their section 311(b) responsibilities. As such, we affirm the trial court's order requiring the Main Line Defendants to disclose the PSRS report.¹¹

In their second issue on appeal, the Main Line Defendants argue that the trial court erred when it granted the Boyles' motion to compel, finding that

¹¹ We note that the trial court found that the section 311(a) privilege under the MCARE Act did not apply because the Main Line Defendants did not provide evidence that any of the documents at issue were presented to the patient safety committee. This interpretation misreads the requirements set forth in **Lahr** and imposes an additional burden. The **Lahr** Court did not require an actual review of the patient safety reports by the patient safety committee. Rather, this Court held in **Lahr** that the party asserting a statutory privilege under section 311(a) of the MCARE Act must only prove that the reports arose out of a matter reviewed by the committee, not that the documents themselves were specifically reviewed. **See Lahr, supra** at *9. However, the trial court's misapplication of **Lahr** does not affect our disposition because, as previously stated, the Main Line Defendants did not establish that the Boyle Event was reviewed by a patient safety committee or a governing board pursuant to the responsibilities imposed by section 311(b). **See Plasticert, Inc. v. Westfield Ins. Co.**, 923 A.2d 489 (Pa.Super. 2007) (explaining that we may affirm trial court's order on any valid legal basis).

the PSOW and SBAR did not fall within the statutory privilege set forth in the PSQIA. The Main Line Defendants claim that in accordance with the PSQIA, the Hospital developed a patient safety evaluation system which was responsible for collecting, analyzing, and managing patient safety work product and distributing it to a patient safety organization. The Main Line Defendants contend that the Hospital participated with a federally approved patient safety organization, ECRI PSO, and that it conducted internal patient safety analysis. The Main Line Defendants further assert that as part of the Hospital's investigation of the Boyle Event and its analysis thereof, Ms. Gallagher created the SBAR and PSOW on September 8, 2017, for the purpose of reporting to a patient safety organization and that the SBAR was reported to the ECRI PSO as part of the Hospital's reporting system. The Main Line Defendants insist that these documents, "are quintessential examples of ... documents that qualify for PSQIA privilege protection" under subsection (ii) of the PSQIA. (Main Line Defendant's Brief at 45). Therefore, the Main Line Defendants insist that they have met their burden of establishing that the documents constituted privileged "patient safety work product" as defined by the PSQIA at Section 299b-21(7)(A). We agree.

Preliminarily, we must discern whether the Main Line Defendants preserved this issue for our review. Pennsylvania Rule of Appellate Procedure 302(a) provides that issues not raised in the trial court are waived and cannot be raised for first time on appeal. Pa.R.A.P. 302(a). ***See also Gustine***

Uniontown Assocs., Ltd. v. Anthony Crane Rental, Inc., 892 A.2d 830, 835 (Pa.Super. 2006) (holding that purpose of Rule 302(a) is “to provide th[e] [trial] court with the opportunity to consider the issue, rule upon it correctly, and obviate the need for appeal”).

In their privilege log, the Main Line Defendants did not limit the privilege asserted under the PSQIA to any specific subsection.¹² Rather, the Main Line Defendants asserted in their privilege log that the PSOW and SBAR were privileged and protected pursuant to “the Patient Safety and Healthcare Quality Improvement Act 42 U.S.C. 299b-21, *et seq.*, 42 C.F.R. Part III, §§ 3.10, *et seq.*” (Privilege/Non-Disclosure Log on Behalf Main Line Defendants Regarding the Boyles’ Third Request for Production of Documents, dated 1/31/23).¹³ Section 299b-21(7)(A) of the PSQIA defines privileged patient safety work product as “data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements” which “are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization;” “are developed by a patient safety organization for the conduct of patient safety activities; and which could

¹² In their brief, the Boyles argue that the Main Line Defendants waived their claim that the PSOW and SBAR were privileged because they did not specifically focus their argument in the trial court on the “deliberations or analysis” component of PSQIA’s definition of “patient safety work product.”

¹³ As this Court has explained, “[a] privilege log provides an acceptable format to identify documents, the applicable privilege, and the basis upon which privilege is claimed.” ***Carlino E. Brandywine, L.P., supra*** at 197.

result in imposed patient safety, health care quality, or health care outcomes” or “**which identify or constitute the deliberations or analysis of ... a patient safety evaluation system.**” 42 U.S.C. § 299b-21(7)(A)(i)-(ii) (emphasis added).

Here, the Main Line Defendants asserted in their privilege log that the relevant documents were privileged as patient safety work product under the PSQIA generally. Notably, this is not a situation where the Main Line Defendants are asserting an entirely new theory in support of the claim that the PSOW and SBAR are privileged. Rather, the Main Line Defendants had already asserted privilege under the PSQIA generally. Hence, the Main Line Defendants provided the trial court an opportunity to consider or address whether the PSQIA privilege was applicable to the PSOW and SBAR documents under each subsection, including the “deliberations and analysis” component set forth in subsection (ii). Therefore, we conclude that this assertion was sufficient to present the trial court with the opportunity to consider the issue of whether the documents constituted patient safety work product under any of the three subsections of the PSQIA, and we decline to find waiver under these circumstances. **See** Pa.R.A.P. 302(a); **Gustine Uniontown Assocs., Ltd., supra**.¹⁴

¹⁴ We further conclude that the Main Line Defendants’ motion for reconsideration did not raise a new theory of privilege, or a new ground upon which privilege was asserted. Rather, the motion for reconsideration aptly (Footnote Continued Next Page)

Accordingly, we turn to the merits of the Main Line Defendants' argument that the SBAR and PSOW fell within the statutory privilege set forth in the PSQIA. By way of background, the PSQIA was enacted to establish a nationally uniform set of protections for healthcare providers, and to encourage hospitals and other healthcare providers to analyze and discuss patient safety and healthcare quality, including medical errors, without fear of those evaluations being used in civil litigation. **See** S. Rep. No. 108-196 (2003); H.R. Rep. No. 109-197 (2005).

Relevant to the instant case, the PSQIA contains privilege provisions which state that "patient safety work product" shall be privileged and shall not be subject to a state subpoena, subject to discovery, or admitted as evidence. 42 U.S.C. § 299b-22(a). We reiterate that the PSQIA defines "patient safety work product" as follows:

Except as provided in subparagraph (B), the term 'patient safety work product' means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—

(i) which

(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

(II) are developed by a patient safety organization for the conduct of patient safety activities; and which

pointed out to the trial court that it had failed to address one of the subsections under which the PSQIA privilege applies.

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). The PSQIA provides that “patient safety work product” shall be privileged and shall not be subject to a state subpoena, subject to discovery, or admitted as evidence. 42 U.S.C. § 299b-22(a).

Information that constitutes “patient safety work product” under the “deliberations or analysis” option set forth in section 299b-21(7)(A)(ii), is protected when it is done within the patient safety evaluation system. Notably, “‘patient safety work product’ excludes ‘information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.’” ***Ungurian, supra*** at 795 (quoting 42 U.S.C. § 299b-21(7)(B)(ii)).

Here, the Main Line Defendants introduced an affidavit from Ms. Walsh, the system manager for risk and safety at the time of the Boyle Event, who explained that the Hospital contracted with a federally approved patient safety organization and developed and implemented a formal patient safety evaluation system. (Affidavit of Patricia Walsh, RN, MSN, dated 3/29/23). In accordance with the patient safety evaluation system, Ms. Gallagher, the patient safety officer for the Hospital, created the PSOW and the SBAR. (Affidavit of Nanci Gallagher, dated 3/31/23, at ¶ 9). The SBAR was drafted to inform key members of the Hospital’s patient safety committee of the facts

and recommendations as a result of the investigations and sent to the patient safety organization; the PSOW tracked the patient safety evaluation system investigation and noted the results of the investigation. (***Id.*** at ¶¶ 5, 9). Both documents were uploaded to the Hospital's federal patient safety organization, ECRI PSO. (***See id.*** at ¶ 12); (Affidavit of Patricia Walsh at ¶ 4).

Upon review, we agree with the Main Line Defendants that these documents, produced solely in accordance with the patient safety evaluation system and reported to the patient safety organization, are a quintessential example of "patient safety work product" privileged documents as the "deliberations or analysis of" a patient safety evaluation system. ***See*** 42 U.S.C. § 299b-21(7)(A)(ii). Furthermore, there is no requirement in the PQSIA that such "deliberations and analysis," as set forth in subsection (ii), be reported to a patient safety organization to qualify as protected "patient safety work product."¹⁵

¹⁵ The trial court correctly stated that in order for a document to constitute "privileged patient safety work product," "the documents and information must be assembled or developed by a provider for reporting to a patient safety organization and must have been reported to the patient safety organization." (Trial Court Opinion at 6). However, the trial court then appears to impose an additional burden on the Main Line Defendants, requiring them to also prove that an official patient safety investigation or review was conducted. (***Id.*** at 7) (stating: "Defendants have stated...that no official patient safety investigation or review was conducted concerning [the Boyle Event;] Defendants have failed to meet their burden of showing that the documents plaintiffs seek meet the definition of "patient safety work product." There is no evidence that the documents at issue were reviewed by ECRI..."). This additional burden is not supported either by the PSQIA itself or by any binding authority.

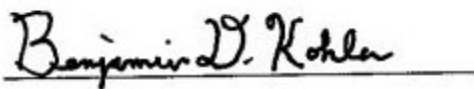
Based upon the foregoing, we conclude that the trial court erred when it found that the SBAR and PSOW, which were created in accordance with the patient safety evaluation system, and which contained the analysis of the patient safety officer, did not constitute “patient safety work product.” Therefore, we reverse the trial court’s order finding that the PSQIA privilege did not apply. We further conclude that the Main Line Defendants met their burden of proof that the PSQIA privilege applies, and hold that the burden now shifts to the Boyles “to set forth facts showing that disclosure will not violate the ... privilege.” ***Ungurian, supra*** at 795.

Accordingly, we affirm in part, reverse in part, and remand to the trial court for further proceedings. Jurisdiction is relinquished.

President Judge Lazarus joins the opinion.

Judge Lane files a concurring/dissenting opinion.

Judgment Entered.

A handwritten signature in black ink, reading "Benjamin D. Kohler", is written over a horizontal line.

Benjamin D. Kohler, Esq.
Prothonotary

Date: 7/17/2025