An Uncertain Privilege Is No Privilege At All: How Courts And Litigants Misunderstand The Federal Patient Safety Work Product Privilege Under The Patient Safety And Quality Improvement Act (PSQIA)

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ABSTRACT

Passed in 2005 by the United States Congress, the Patient Safety and Quality Improvement Act (the "PSQIA" or the "Act") was designed to give healthcare providers a safe arena in which to honestly assess patient care without fear of those evaluations being used in civil litigation. The PSQIA has received less attention in the Pennsylvania courts than its more well-known state law counterparts: the Peer Review Protection Act and the patient safety provisions of the Medical Care Availability and Reduction of Error Act. When the PSQIA has come before the courts, the application of its confidentiality and privilege provisions has been uneven, resulting in an "uncertain privilege" that is "little better than no privilege at all."[4] The purpose of this article is to familiarize readers with the PSQIA, analyze case law applying the Act, and provide tips on implementing patient safety evaluation systems consistent with the statute to best employ the Act's protections.

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4. *See* Upjohn Co. v. United States, 449 U.S. 383, 393 (1981).

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I. BACKGROUND: THE PATIENT SAFETY AND QUALITY IMPROVEMENT ACT

A. Legislative History

Pennsylvania courts have failed to properly apply the confidentiality and privilege provisions of the federal Patient Safety and Quality Improvement Act (PSQIA).

The Patient Safety and Quality Improvement Act (the "PSQIA" or the "Act") was passed by Congress in 2005 to establish a "confidential and nonpunitive system for reporting health care errors so that . . . errors can be identified and analyzed to improve patient safety by preventing future errors."[5] The purpose of the PSQIA was "to assure that health care workers can safely create candid and beneficial recommendations to save patients' lives without concern for disclosure in adverse litigation."[6]

The legislation was brought about, in part, as a result of a 1999 report from the Institute of Medicine ("IOM"), *To Err Is Human: Building a Safer Health System*, which found "that preventable medical errors were responsible for tens of thousands of deaths each year, costing the country tens of billions of dollars annually," and proposed a national agenda for reducing errors in health care.[7] In response to the IOM's findings, Congress passed the PSQIA, establishing a "voluntary program through which health care providers can share information relating to patient safety events . . . with the aim of improving patient safety and the quality of care nationwide."[8] The Act was designed to foster a culture of safety in medicine to allow "organizations and practitioners to systematically identify, analyze, and take appropriate action against preventable risks," and change the historical practice in which "serious adverse events or risks . . . were not routinely reported or shared among providers for fear of reprisal, shame, or litigation."[9]

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5. S. Rep. 108-196, at 3 (2003).

6. Tallahassee Mem'l Healthcare, Inc. v. Wiles, 351 So.3d 141, 153 (Fla. Dist. Ct. App. 2022), *reh'g denied* (Dec. 27, 2022), *review granted sub nom*. Wiles v. Tallahassee Mem'l, SC2023-0118, 2023 WL 3816758 (Fla. June 5, 2023) (Thomas, J., concurring).

7. KD ex rel. Dieffenbach v. United States, 715 F. Supp. 2d 587, 595 (D. Del. 2010) (citing Patient Safety and Quality Improvement; Notice of Proposed Rulemaking, 73 Fed. Reg. 8112, 8112–13 (Feb. 12, 2008)). The IOM report "cited studies that found that at least 44,000 people and potentially as many as 98,000 people die in U.S. hospitals each year as a result of preventable medical errors. Based on these studies and others, the Report estimated that the total national costs of preventable adverse events . . . to be between $17 billion and $29 billion, of which health care costs represent one half. One of the main conclusions was that the majority of medical errors do not result from individual recklessness or the actions of a particular group; rather, most errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent adverse events." *Id*. For a critique of the IOM report and a more nuanced discussion about medical errors generally *see* Danielle Ofri, M.D., WHEN WE DO HARM: A DOCTOR CONFRONTS MEDICAL ERROR (2020).

8. *Tallahassee Mem'l Healthcare, Inc*., 351 So. 3d at 153 (citing Patient Safety & Quality Improvement, 73 Fed. Reg. 70,732, 70,732 (Nov. 21, 2008)) (Thomas, J., concurring).

9. Amicus Brief of the Joint Commission, p. 8, Charles v. Southern Baptist Hosp. of Fla., 209 So.3d 119 (Fla. 2017).

B. The Text of the PSQIA

The central function of the PSQIA was the creation of a new federally recognized entity known as a patient safety organization, or PSO. The PSQIA provides detailed guidelines for creating and certifying a PSO in §299b-24 of the Act. The mission and primary activity of the PSO must be "activities that are to improve patient safety and the quality of health care delivery."[10] The PSO must be staffed by "appropriately qualified" individuals, including licensed or certified medical professionals, and collect patient safety work product "for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk."[11] While a PSO cannot be a component of a health insurance company,[12] a healthcare organization can create its own PSO provided that the PSO certifies that patient safety work product will be maintained separately from the parent organization and that the PSO will not make unauthorized disclosures to the parent organization.[13]

To become certified as a PSO, the entity must submit an initial certification to the Secretary of the U.S. Department of Health and Human Services (the "Department" or "HHS") verifying that the PSO will comply with the criteria set forth in §299b-24(b) of the Act and that it has policies and procedures in place to perform each of the eight patient safety activities delineated by the PSQIA.[14] Such patient safety activities include the collection and analysis of patient safety work product, and the development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.[15] Unless revoked earlier by HHS, a PSO's certification lasts for three years and can be renewed upon filing a subsequent certification request.[16] A list of PSOs currently or previously certified by HHS is maintained through the Agency for Healthcare Research and Quality, a division of HHS, and is available online.[17]

To ensure that the PSOs would be utilized by healthcare providers effectively, Congress included in the PSQIA robust confidentiality and privilege provisions. These protections "enable all health care providers, including multi-facility health care systems, to share data within a protected legal environment, both within and across states, without the threat that the information will be used against the subject providers."[18] The PSQIA protections are "the foundation to furthering the overall goal of the statute to develop a national system for analyzing and learning from patient safety events."[19] To effectuate its purpose, the privilege afforded to the medical community under the PSQIA is "broad" so as to encourage "blunt criticism."[20]

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10. 42 U.S.C.A. §299b-24(b)(1)(A).
11. *Id*. at §299b-24(b)(1)(B), (B)(1)(G).
12. *Id*. at §299b-24(b)(1)(D)
13. *Id*. at §299b-24(b)(2)(A)-(C).
14. *Id*. at §299b-24(a)(1).
15. *Id*. at §299b-21(5).
16. *Id*. at §299b-24(a)(2), (e).
17. *See* https://pso.ahrq.gov/pso/listed.
18. *Tallahassee Mem'l Healthcare, Inc*., 351 So. 3d at 153 (Thomas, J., concurring) (citing 73 Fed. Reg. 70732—01, (Nov. 21, 2008)).
19. Fla. Health Scis. Ctr., Inc. v. Azar, 420 F. Supp. 3d 1300, 1304 (M.D. Fla. 2019), *vacated on other grounds and remanded sub nom*. Fla. Health Scis. Ctr., Inc. v. Sec'y, U.S. Dep't of Health & Hum. Servs., 844 F. App'x 217 (11th Cir. 2021) (citing 73 Fed. Reg. at 70,741).
20. *Tallahassee Mem'l Healthcare, Inc*., 351 So. 3d at 154 (Thomas, J., concurring) (citing S. Rep. 108-196, at 3 (2003)); *see also* Statement of Interest of the United States, at p. 3 (May 3, 2019), Brawley v. Smith, 2019 WL 13030278 (Fla. Cir. Ct. Feb 1, 2019) ("The providers receive *broad privilege* and confidentiality protections for [patient safety work product], which alleviates concerns about [patient safety work product] being used against providers, such as in litigation. These broad protections are 'intended to encourage the reporting and analysis of medical errors,' H.R. Rep. No. 109-197 at 9, and are 'required to encourage

Key to understanding the scope of the PSQIA's privilege and confidentiality provisions is an appreciation of the term "patient safety work product" ("PSWP"), which is defined in the Act. Patient safety work product is "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" that fits within one of three categories:

> 1 – It was assembled or developed by a provider for **reporting to a PSO** and was reported to a PSO;[21]
>
> 2 – It was **developed by a PSO** for the conduct of patient safety activities and could result in improved patient safety, health care quality, or health care outcomes;[22] or
>
> 3 – It identifies or constitutes the **deliberations or analysis** of, or identifies the fact of reporting pursuant to, a patient safety evaluation system.[23]

The Act defines "patient safety evaluation system" (or "PSES") as a system that collects, manages, or analyzes information for reporting to or by a patient safety organization.[24]

The PSQIA provides two "clarifications" to the definition of patient safety work product. First, a "patient's medical record, billing and discharge information, or any other original patient or provider record" does not fall within the definition of patient safety work product.[25] Second, documents and information collected, developed, or maintained outside of a healthcare provider's patient safety evaluation system do not fall within the definition of PSWP, even if such documents are subsequently provided to a PSO.[26]

Having defined the universe of documents that qualify as patient safety work product, the PSQIA then provides two broad and important protections for those documents. First, the Act provides that PSWP "shall be privileged" and not subject to discovery in any state, federal, or administrative proceeding, nor disclosed pursuant to any subpoena or order.[27] PSWP also cannot be admitted into evidence in any matter and is not subject to FOIA requests.[28] Second, the PSQIA provides that patient safety work product must be kept confidential and "shall not be disclosed."[29]

The PSQIA privilege and confidentiality provisions are subject to a limited number of exceptions. First, if patient safety work product "contains evidence of a criminal act" and is not reasonably available from any other source, a court can order disclosure of the documents.[30] Second, the providers identified within the patient safety work product can voluntarily disclose the materials, provided all providers involved agree with the disclosure.[31]

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the reporting of errors and to create an environment in which errors became opportunities for learning and improvement,' S. Rep. 108-196 at 3.") (emphasis added); Rumsey v. Guthrie Med. Grp., P.C., No. 4:18-CV-01605, 2019 WL 4687560, *1 (M.D. Pa. Sept. 26, 2019) ("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.") (citing S Rep No 108–196, at 2 (2003); HR Rep No 109–197, at 9 (2005)).

21. 42 U.S.C.A. §299b-21(7)(A)(i)(I).
22. *Id*. at §299b-21(7)(A)(i)(II).
23. *Id*. at §299b-21(7)(A)(ii).
24. *Id*. at §299b-21(6).
25. *Id*. at §299b-21(7)(B)(i).
26. *Id*. at §299b-21(7)(B)(ii).
27. *Id*. at §299b-22(a).
28. *Id*.
29. *Id*. at §299b-22(b).
30. *Id*. at §299b-22(c)(1)(A).
31. *Id*. at §299b-22(c)(1)(C).

The PSQIA separately provides a larger number of exceptions to the confidentiality provision.[32] The Act provides that patient safety work product may be disclosed for the purpose of, among other things, carrying out patient safety activities, law enforcement purposes, and reporting to the FDA.[33]

Importantly, the confidentiality and privilege provisions of the PSQIA remain in effect even after a disclosure except in limited circumstances.[34] Thus, mere disclosure of PSWP does not necessarily waive privilege or confidentiality provisions applicable under the PSQIA.

C. HHS Regulations and Commentary

In February 2008, HHS published a Notice of Proposed Rulemaking pursuant to the PSQIA and sought public comment on the proposed rules.[35] A finalized set of rules was adopted in November of that year.[36] The Notice of Proposed Rulemaking and the final rules included extensive commentary from HHS about the PSQIA and the regulations.

In many instances the final rules simply restate the language of the statute.[37] One notable exception is the definition of patient safety work product, which includes the additional requirement that documents "assembled or developed by a provider for reporting to a PSO and [that] are reported to a PSO" must include the "date the information entered the patient safety evaluation system."[38] There is no similar requirement for documents that are protected under either of the other two prongs of the PSWP definition (i.e., information developed by PSOs or deliberations or analysis of a PSES).[39]

The final rules also fleshed out portions of the confidentiality and privilege provisions. For example, the regulations permit disclosure of PSWP to affiliated providers, as well as "a contractor of a provider or a PSO" that has been engaged to "undertake patient safety activities."[40] Healthcare providers and PSOs can also disclose PSWP to "attorneys, accountants, and other professionals" for "business operations."[41] The regulations also state that patient safety work product that is disclosed "in accordance with this subpart, *or disclosed impermissibly*, shall continue to be privileged and confidential."[42]

The Department stated that the final rules intentionally kept the definition of patient safety evaluation system general to allow the term to "be flexible and scalable to meet the needs of specific providers and PSOs."[43] The Department also eschewed any express requirement that the creation and operation of a patient safety evaluation system be reduced to a written policy, stating that such a system exists "whenever a provider engages in patient safety activities for the purpose of reporting to a PSO."[44] Rather than instituting a specific requirement for documentation, HHS con-

32. *Id*. at §299b-22(c)(2).
33. *Id*. at §299b-22(c)(2).
34. *Id*. at §299b-22(D)(1), (2).
35. *See* Patient Safety and Quality Improvement, N.P.R.M., 73 Fed. Reg. 8,112-01 (Feb. 12, 2008), 2008 WL 355358 (F.R.).
36. *See* Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732-01 (Nov. 21, 2008), 2008 WL 4948973 (F.R.), codified at 42 C.F.R. Part 3.
37. *See generally* 42 C.F.R. §3.10, *et seq*.
38. 42 C.F.R. §3.20.
39. *Id*.
40. *Id*. at §3.206(b)(4).
41. *Id*. at §3.206(b)(9).
42. *Id*. at §3.208 (emphasis added).
43. 73 Fed. Reg. at 70,739.
44. *Id*. at 70,738.

sidered documentation to be a "best practice" and "encourage[d] providers to document their patient safety evaluation systems."[45] Finally, HHS rejected concerns that the broad definition of patient safety evaluation system would lead to the "stashing away of harmful documents and information."[46] The Department noted that the PSQIA and the final rules promulgated pursuant to the Act were carefully drafted to ensure that "information generally available today remains available, such as medical records, original provider documents, and business records."[47]

In a lengthy discussion about the definition of patient safety work product, the Department stated that the final rules permit "functional reporting" of information to PSOs by "authorizing [a] PSO access . . . to specific information in a patient safety evaluation system and authority to process and analyze that information."[48] This allows entities with established relationships with PSOs to avoid formally submitting documents to a PSO as a prerequisite for that information to be deemed "reported" under the Act.[49] HHS further clarified that information obtained for the purpose of reporting to a PSO becomes privileged "upon collection," which obviates the need to rush the reporting to trigger the PSQIA's privilege protections.[50]

The Department also addressed how the protections of the PSQIA operate when providers are simultaneously subject to state-mandated reporting. The final rules were crafted to protect information entered into a patient safety evaluation system upon collection. If a provider determines that information collected in the PSES needs to be provided to the state under a separate reporting statute, the provider can voluntarily remove that information from the PSES so that it can be reported. There is no need for providers to "maintain duplicate systems to separate information to be reported to a PSO from information that may be required to fulfill state reporting obligations."[51] Rather, the rules give providers the "flexibility to protect . . . . information as patient safety work product within their patient safety evaluation system while they consider whether the information is needed to meet external reporting requirements."[52]

Finally, the Department reaffirmed that "information that constitutes the deliberation or analysis within a patient safety evaluation system is protected."[53] Thus, for example, a "provider can fully protect internal deliberations in its patient safety evaluation system over whether to report information to a PSO."[54] Such "deliberations and analysis are protected, whether the provider chooses to report the underlying information to the PSO or not."[55] Information underlying such analysis is also protected if "documented as collected within a patient safety evaluation system."[56]

II. CASE LAW CONSTRUING THE PSQIA

Despite the broad protections afforded to patient safety work product under the express terms of the PSQIA and associated regulations, courts have been reticent to

45. *Id*.
46. *Id*. at 70,739.
47. *Id*.
48. *Id*. at 70,741.
49. *Id*.
50. *Id*.
51. *Id*. at 70,742.
52. *Id*.
53. *Id*. at 70,743.
54. *Id*. at 8,122
55. *Id*.
56. *Id*. at 70,743.

apply these protections as drafted, which has undermined the purpose of the Act by causing providers trepidation in utilizing patient safety systems. In this section, the case law in Pennsylvania and elsewhere on the PSQIA will be analyzed.

A. Pennsylvania Case Law

One of the first cases in Pennsylvania to address the PSQIA in detail was *Venosh v. Henzes*, a 2013 decision from the Lackawanna County Court of Common Pleas.[57] The suit involved allegations of arterial and nerve injury during the course of a total knee replacement surgery, which necessitated a second vascular surgery.[58] At issue were two documents drafted pursuant to one of the defendant-hospital's policies, referred to as the "Event Reporting policy" in the opinion.[59] These documents discussed the original orthopedic surgery and the subsequent vascular procedure, and were completed by nurses and co-signed by a department head.[60] The defendant-hospital objected to production of the documents on the grounds that they were protected under the PSQIA, which the court aptly described as a statute designed to encourage "a culture of safety and quality" in health care by providing confidentiality and legal protections to information that is "collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety."[61]

The court opened its analysis of the PSQIA by quoting in full the definition of patient safety work product in 42 U.S.C. §299b-21(7).[62] As set forth in the discussion above, this definition provides that documents that are reported to the PSO, as well as documents that constitute the deliberations or analysis of a patient safety evaluation system, fall within the definition of patient safety work product under the PSQIA.[63] In the court's further analysis of the PSQIA, however, the court limited the scope of the definition of PSWP to *only* those documents actually reported to the PSO.[64] Citing state and federal case law from Illinois and Tennessee, the *Venosh* court concluded that the PSQIA privilege is *only* applicable "if the patient safety work product materials are . . . actually furnished to a PSO."[65]

This reading of the PSQIA is not supported by the plain language of the Act, and the case law cited in *Venosh* provides minimal support for this interpretation which fails to give effect to the full definition of patient safety work product under 42 U.S.C. §299b-21(7).[66] While it is true that actually reporting to a PSO *is* required

57. Venosh v. Henzes, 31 Pa.D.&C. 5th 411 (Lackawanna C.P. July 17, 2013).
58. *Id*. at *1.
59. *Id*.
60. *Id*. at *8-9.
61. *Id*. at *8-9, 11-12 (internal citations omitted) (citing Dep't of Fin. and Prof. Regulation v. Walgreen Co., 970 N.E.2d 552, 557 (Ill. App. Ct. 2d Dist. 2012)). Note that the defendants in *Venosh*, as well as most of the parties in the cases discussed herein, invoked various protections under state law in addition to the PSQIA in an effort to keep documents privileged. A discussion of the protections afforded under state laws is outside the scope of this review and will not be addressed.
62. *Venosh*, 31 Pa.D.&C. 5th 411 at *11-12.
63. *Id*. (citing 42 U.S.C. §299b-21(7)(A)(i)-(ii)).
64. *Id*. at *12.
65. *Id*. at *12.
66. The court relied on Sevilla v. U.S. and Department of Financial and Professional Regulation v. Walgreen Company, both of which provide only a brief overview of the PSQIA and do not discuss the statute in detail or the various prongs of the definition of patient safety work product. *See* Sevilla v. U.S., 852 F. Supp. 2d 1057, 1068 (N.D. Ill. April 4, 2012); Dep't of Fin. and Prof. Regulation v. Walgreen Co., 970 N.E.2d 552, 557 (Ill. App. Ct. 2d Dist. 2012). The decision in *Walgreen* had no cause to analyze the definition of PSWP in detail because the documents had in fact been reported to the PSO. *Walgreen*, 970 N.E.2d at 557-558. The discussion in *Sevilla* appears to be mere dicta. *Sevilla*, 852 F. Supp. 2d at 1068. The Tennessee Supreme Court decision, Lee Medical, Inc. v Beecher, makes clear that its discussion of the PSQIA is only dicta, stating that the parties did not analyze the PSQIA in their briefs or at argument, so the Act was given no further consideration in the case. *See* Lee Med., Inc. v Beecher, 312 S.W.3d 515, 535 (Tenn. 2010).

to meet the statutory definition of patient safety work product under §299b-21(7)(A)(i)(I), no such similar requirement exists in §299b-21(7)(A)(ii), which protects documents that constitute the deliberations or analysis of a patient safety evaluation system.[67] There is no discussion in *Venosh* regarding this prong of the definition of PSWP.

Ultimately the court found the record to be devoid of evidence that the defendant-hospital was participating in a PSO or that the documents at issue had been provided to a PSO, which the court deemed fatal to the defendant's invocation of the PSQIA.[68] This decision was upheld on appeal to the Superior Court, which adopted the trial court's opinion in full in an unpublished memorandum and order.[69]

Following the Superior Court's affirmance of *Venosh* in 2014, the PSQIA did not reach the appellate court again until 2020 with the decision in *Ungurian v. Beyzman*.[70] The plaintiff there brought a medical malpractice action alleging injuries to her son that left him incapacitated after a procedure to treat kidney stones.[71] The defendant-hospital in the case asserted that two documents were protected from disclosure by the PSQIA: an event report created by a nurse anesthetist and a root cause analysis report generated by the hospital's root cause analysis committee.[72] In support of its contention, and in contrast to the defendant in *Venosh*, the hospital produced an affidavit that stated that the hospital was a member of a PSO and maintained a patient safety evaluation system, which "collected, managed, and analyzed information that may be reported to its PSO."[73] The affidavit further asserted that the documents at issue were "for the express purpose of improving patient safety and care quality and are maintained within Hospital's PSES for reporting to the PSO."[74]

The Superior Court opened its analysis with a summary of the PSQIA that replicated the error in *Venosh*, citing only §299b-21(7)(A)(i)(I) for the proposition that the PSQIA solely protects documents that are "assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization."[75] As noted above, characterizing the PSQIA's protections in this way fails to give effect to the full text of the statute, which also protects the deliberations and analysis that occur within the patient safety evaluation system as set forth in §299b-21(7)(A)(ii).

Having thus artificially limited the scope of the protections provided by PSQIA, the Superior Court proceeded to hold that neither document qualified as privileged under the Act.[76] With respect to the event report, the court held the defendant-hospital failed to meet its burden of showing it was prepared for *and* actually reported to the PSO.[77] Regarding the root cause analysis report, the court held that it did not qualify as patient safety work product because the hospital did not proffer evidence that it was prepared for the purpose of reporting to the PSO.[78] The court further noted that the hospital "admitted that the information contained in the Root Cause

67. *Compare* 42 U.S.C. §299b-21(7)(A)(i)(I) *with* §299b-21(7)(A)(ii).
68. *Venosh*, 2013 WL 9593953, at *12.
69. *See* Venosh v. Henzes, 2014 WL 10896822 (Pa. Super. July 11, 2014).
70. 232 A.3d 786 (Pa. Super. 2020).
71. *Id*. at 790.
72. *Id*. at 794-96.
73. *Id*. at 795.
74. *Id*.
75. *Id*. at 794-95.
76. *Id*. at 795-96.
77. *Id*. at 796. Notably the court refused to consider the defendant's claim in its briefing that the event report had been submitted to the PSO because such information had not been included in the submitted affidavit. *Id*. at 796, n.11.
78. *Id*. at 796.

Analysis 'is not contained solely in the PSES'" because an email about the root cause analysis was sent from the hospital's chief quality officer to a physician at an outside institution.[79]

Although the court correctly noted at the outset of its discussion that the discoverability of the documents required that it "analyze the language of [the] PSQIA," using "general principles of statutory construction," the court's analysis failed to give effect to all terms of the PSQIA, which is required when interpreting a statute.[80] This analysis wholly ignored §299b-21(7)(A)(ii) of the PSQIA, which protects the deliberations and analysis that occur within the patient safety evaluation system.[81] As in *Venosh*, whether the documents would have been protected had the PSQIA been applied as drafted remains unknown because the court's factual analysis was limited solely to the elements relevant to §299b-21(7)(A)(i)(I) of the PSQIA.

The other aspect of the analysis in *Ungurian* worth comment is the court's determination that the root cause analysis was not privileged because it had sent to a third party. As already discussed, the PSQIA authorizes patient safety work product to be disclosed without waiver of the privilege for various reasons, including "to carry out patient safety activities" and for "business operations."[82] Moreover, disclosure of patient safety work product "shall not be treated as a waiver of privilege or confidentiality" under the Act whether the disclosure was permitted or not.[83] The fact that a document was shared by the hospital's chief quality officer with a physician at an outside institution is not, therefore, a basis upon which to order production of the document to an opposing party in litigation.[84] It is unclear why the *Ungurian* court did not consider or give effect to these provisions of the PSQIA.

To date, the PSQIA has not been the subject of any Pennsylvania Superior Court opinions since *Ungurian*.

B. PSQIA Case Law from Other Jurisdictions

In contrast to the decisions arising within the Pennsylvania state courts, other jurisdictions have not struggled to effectuate all of the relevant terms of the PSQIA.[85]

In *Rumsey v. Guthrie Medical Group, P.C.*, a decision from the Middle District of Pennsylvania, the plaintiffs sought agendas, notes, and any other written records from the defendant-hospital's quality committee.[86] After reviewing the legislative history and text of the PSQIA, including all three prongs of the definition of patient safety work product, the court concluded that the requested documents were privileged and not subject to discovery.[87] In the court's view, the records were "squarely work product" within the meaning of the PSQIA and privileged as "deliberations or

79. *Id*.

80. *Ungurian*, 232 A.3d at 794; *see* Unionville-Chadds Ford Sch. Dist. v. Chester Cnty. Bd. of Assessment Appeals, 692 A.2d 1136, 1143 (Pa. Cmwlth. 1997), *aff'd*, 714 A.2d 397 (Pa. 1998) ("Because the legislature is presumed to have intended to avoid mere surplusage, every word, sentence, and provision of a statute must be given effect.").

81. *See Ungurian*, 232 A.3d at 794-95.

82. 42 U.S.C. §299(b)-22(c)(2)(A); 42 C.F.R. §3.206(b)(9).

83. *Id*. at §299(b)-22(d)(1); 42 C.F.R. §3.208.

84. *Ungurian*, 232 A.3d at 793, 796.

85. A full survey of all PSQIA case law is beyond the scope of this article, but there are a number of other cases that involve a more straightforward application of the PSQIA that will be helpful to practitioners dealing with the PSQIA, including: Daley v. Teruel, 107 N.E.3d 1028 (Ill. Ct. App. 1st Dist. 2018); Nelms v. Wellpath, LLC, 21-10917, 2023 WL 2733379 (E.D. Mich. Mar. 31, 2023); and Franco v. Yale New Haven Hosp., Inc., CV-20-6103795-S, 2023 WL 2769929 (Conn. Super. Ct. Mar. 31, 2023).

86. Rumsey v. Guthrie Medical Group, P.C., 2019 WL 4687560, *3-4 (M.D. Pa. Sept. 26, 2019).

87. *Id*. at *1, 3.

analysis of a patient safety evaluation system."[88] The court further held that deposition questions directed to a hospital employee about quality committee meetings and the committee's deliberations sought "information generated by the patient safety evaluation system" and did not need to be answered.[89] A broad application of the terms of the PSQIA was necessary in the court's view to provide the space for healthcare providers to give "brutally honest feedback . . . to keep their patients safe without fear of its use in litigation."[90]

The Southern District of Florida likewise protected patient safety work product under the deliberations and analysis prong of the PSQIA in *Hacking v. U.S.*[91] In that case, the defendant sought to obtain three documents from a third-party medical center: two patient safety analyses and a serious event analysis.[92] The medical center asserted that the two patient safety analyses were privileged under the PSQIA because they were developed within the patient safety evaluation system and reported to a PSO.[93] Following an *in camera* review and analysis of a sworn affidavit, the court agreed and ordered that they not be produced.[94]

As to the serious event analysis, the court noted that there was no evidence the document was produced to a PSO, but found this was "not fatal to [the] claim of privilege."[95] The court held that documents evidencing the deliberations and analysis of a patient safety evaluation system are also protected as patient safety work product under the PSQIA whether produced to a PSO or not.[96] The court determined that the serious event analysis provided a detailed review of the event and identified causal factors in an effort to prevent a recurrence.[97] As such, the court concluded the document fell within the definition of patient safety work product and was, therefore, privileged.[98]

The court rejected the argument that the documents were not privileged because employees of the medical center were not familiar with the term "patient safety evaluation system," stating that familiarity with particular terminology is not essential to invoking the PSQIA's protections.[99] Rather, the fact that the medical center had a contract with a certified PSO and had a system in place to report to that PSO was sufficient evidence that a patient safety evaluation system existed.[100]

Finally, in *Hyams v. CVS Health Corporation*, the Northern District of California permitted the defendant corporation to withhold portions of documents that constituted the deliberations and analysis of the patient safety evaluation system.[101] The defendant asserted privilege over 71 documents containing information obtained during an audit under the deliberations and analysis definition of patient safety work product in the PSQIA.[102] The court reviewed the documents and analyzed

88. *Id*. at *3.
89. *Id*. at *3-4.
90. *Id*. at *4.
91. Hacking v. U.S., 2:19-cv-14449-AMC (S.D. Fla. April 28, 2021).
92. *Id*. at 1.
93. *Id*. at 2.
94. *Id*.
95. *Id*.
96. *Id*. at 2.
97. *Id*.
98. *Id*.
99. *Id*. at 3.
100. *Id*. at 3; *see also* 73 FR Department stating that such a system exists "whenever a provider engages in patient safety activities for the purpose of reporting to a PSO."
101. Hyams v. CVS Health Corporation, 18-cv-06271-PJH, 2019 WL 6727536, at *6 (N.D.Cal. Dec. 11, 2019).
102. *Id*. at *2.

the language of the PSQIA, issuing an order that allowed the defendant to redact portions of documents that were "comprised of deliberations."[103] The court held, however, that the facts upon which such deliberations or analysis were based would not be privileged under the PSQIA unless reported to a PSO and, therefore, separately protected under the definition of patient safety work product in §299b-21(7)(A)(i)(I).[104]

III. PRACTICAL TOOLS FOR HEALTHCARE PROVIDERS AND LITIGANTS

Given the varying outcomes when the PSQIA has come before the courts, it is incumbent upon healthcare providers and their counsel to make the application of the PSQIA's protections easier for the courts by carefully constructing their patient safety evaluation systems and formulating their litigation strategies. Doing so helps to reduce the risk that courts will compel the production of patient safety work product that should otherwise remain protected under the Act. The following is a non-exhaustive list of things to consider when implementing patient safety evaluation systems and seeking to defend patient safety work product in litigation.

A. Creating Robust Patient Safety Systems

Contract with a certified PSO. Healthcare providers should contract with a certified PSO. A list of current PSOs certified by the Agency for Healthcare Research and Quality is available at the organization's website.[105]

Develop and Implement Written Policies to Outline the Patient Safety Evaluation System. Although such policies are not expressly required by the PSQIA or the implementing regulations, documentation of a patient safety evaluation system is recognized as a "best practice" and can provide a roadmap to help courts seeking to understand the basis for privilege objections. Policies should identify how and what information is entered into the patient safety evaluation system, who is responsible for analyzing that information, and what and how any information is passed along to the PSO. Providers should also include in their policies descriptions for how patient safety work product will be evaluated internally and utilized to improve patient safety.

Consider Developing a "Functional Reporting" Agreement with PSOs. Given the more robust protections that courts seem to give to information actually reported to a PSO, healthcare providers should consider arranging a "functional reporting" process with PSOs, particularly with respect to the facts collected within a patient safety evaluation system. As recognized in the guidance from HHS, functional reporting systems allow PSOs access to information in a patient safety evaluation system as that information is entered, which reduces administrative burdens associated with a more formal reporting process.

Ensure Employees Are Educated About the PSES. Healthcare providers and organizations need to be sure that any physicians, nurses, and other healthcare providers who might enter information into a PSES or analyze such information are educated and regularly reminded about the system to ensure that system integrity is maintained.

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103. *Id*. at *2, 6.
104. *Id*. at *2-3.
105. *See* https://pso.ahrq.gov/pso/listed.

Carefully Structure the PSES to Allow Compliance with State Reporting. One complication with the PSQIA unique to Pennsylvania healthcare providers is the language of the state's mandatory patient safety reporting statute and confidentiality provisions found in the Medical Care Availability and Reduction of Error (MCARE) Act, 40 P.S. §1303.301, *et seq*. Of note, the MCARE Act's confidentiality provisions will apply only to documents "solely prepared or created for the purpose of compliance" with the MCARE Act's reporting obligations.[106] Healthcare providers in Pennsylvania should consider carefully how to structure their PSES and state reporting systems such that any documents created for reporting to the state can take advantage of the MCARE Act's confidentiality provisions.

B. Defending the Privileges in Litigation

Get Information and Supporting Documentation to Counsel Early in the Discovery Process. Even if a healthcare system has the most well thought-out and expertly crafted PSES policies, such policies will be useless if not conveyed to counsel so that proper objections can be raised at the outset of discovery. Counsel need to be aware about how a healthcare provider's PSES operates and how any documents withheld from production fit in that system to make the proper objections to discovery and the best arguments at the trial court level.

Pay Close Attention to Language in Supporting Affidavits. The case law summarized above shows just how closely courts may scrutinize supporting affidavits for any suggestion that the PSQIA does not apply.[107] Counsel should be familiar with the case law in Pennsylvania about the PSQIA to ensure that any affidavits preemptively address any concerns that courts have previously expressed in *Ungurian*, *Venosh*, and elsewhere.

IV. CONCLUSION

With courts issuing highly variable opinions that sometimes apply the protections of the PSQIA in incomplete ways, the promise of a system through which healthcare providers can provide frank and "brutally honest" discussion to improve patient safety remains elusive. Some would likely cheer this outcome as a defeat of yet another "secretive" statutory scheme that does little to improve patient safety, but such handwringing is unwarranted. As the Illinois Appellate Court recognized in *Daley v. Teruel*, concerns that the PSQIA will stymie litigants pursuing proper claims against healthcare providers are without any factual basis: "nothing about these documents being privileged renders the facts that underlie the patient safety work product as also privileged. Plaintiffs can still obtain medical records . . . have their experts analyze and make opinions about those records, and depose doctors and nurses regarding an incident."[108] The U.S. Congress and Department of Health and Human Services took pains when crafting the PSQIA and associated regulations to create a system that improves patient safety while balancing the interests of healthcare providers and patients. Failing to apply the terms of the legislation and regulations as they are drafted undermines those efforts. Providers and their counsel can help to realize the PSQIA's promise of a strong privilege that will advance the goal of improved patient safety by planning and implementing clear patient safety evaluation systems and zealously defending those systems with well-developed arguments.

106. 40 P.S. §1303.311(a) (2014).
107. *See, e.g.*, *Ungurian*, 232 A.3d at 795.
108. Daley v. Teruel, 107 N.E.3d 1028, 1044 (Ill. Ct. App. 1st Dist. 2018).