Illinois Health and Hospital Association

PSQIA Case Law Alert:
Ungurian v. Wilkes-Barre Hospital Company d/b/a Wilkes-Barre General Hospital

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In April 2020, the Pennsylvania Superior Court issued its opinion in the case of Ungurian v. Wilkes-Barre Hospital Company d/b/a Wilkes-Barre General Hospital, 298 MDA 2019 (Pa. Super. Ct. Apr. 28, 2020).

Summary

Susan Ungurian ("Ungurian") sued the Wilkes-Barre General Hospital ("Hospital") and other defendants, alleging the defendants' negligence caused the total and permanent incapacity of her son, Jason Ungurian, who underwent cystoscopy at the Hospital.[1] During discovery, the Hospital objected to requests for an Event Report and a Root Cause Analysis Report, asserting the documents were patient safety work product ("PSWP")[2] privileged under the Patient Safety and Quality Improvement Act of 2006 ("PSQIA").[3] The Hospital supported its privilege claims with an affidavit from the Hospital's Director of Patient Safety Services.[4] The trial court found the Hospital failed to meet its burden of establishing that the documents were privileged and ordered the documents to be produced.[5] On appeal, the appellate court affirmed the trial court holding.[6] The appellate court's ruling on the inapplicability of the PSQIA privilege to the Event Report and Root Cause Analysis is detailed below.

Event Report

With regards to the Event Report, the Director of Patient Safety Services stated:

"1. Hospital has maintained a relationship with a patient safety organization ("PSO") . . . since 2012;

2. The purpose of the relationship with the PSO is to allow the confidential and protected exchange of patient safety and quality information in the conduct of patient safety activities;

3. Hospital has maintained a patient safety evaluation system ("PSES"), facilitated by the use of an event reporting system ("ERS"), as its internal process for collecting, managing, and analyzing information that may be reported to its PSO;

4. The PSES encompasses information assembled, developed, deliberated upon, or analyzed from patient safety and quality activities and includes information that may result in documents such as occurrence reports, cause analyses, and root cause analyses;

5. Hospital prepares the documents sought by Mrs. Unguarian for the express purpose of improving patient safety and care quality and are maintained within Hospital's PSES for reporting to the PSO;

[1] Ungurian v. Wilkes-Barre Hospital Company d/b/a Wilkes-Barre General Hospital, 298 MDA 2019, at *5–6 (Pa. Super. Ct. Apr. 28, 2020).
[2] 42 C.F.R. § 3.20.
[3] Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (codified as amended at 42 U.S.C. §§ 299b-21 to 299b-26). *Ungurian*, at *6 and *8.
[4] *Ungurian*, at *7.
[5] *Id.* at *9–13.
[6] *Id.* at *17–19.

6. Hospital did not collect, maintain, or develop the Burry Event Report separately from its PSES, did not disclose the Burry Event Report and the Burry Event report is not required to be publicly disclosed or report."[7]

Despite the Hospital's comprehensive affidavit with regards to its PSO relationship, the trial court found that the Hospital failed to allege that it developed the report for the purpose of reporting to its PSO and thus failed to establish that the Event Report was PSWP protected by the PSQIA privilege.[8]

The court pointed to number 3 above in the affidavit in which the Hospital alleged the ERS is used as part of its PSES process for collecting, managing, and analyzing information that *may* be reported to its PSO. The trial court explained that the Event Report "**must** be developed for the purpose of reporting to a PSO" and the affidavit only confirmed that the Event Report "**could have** been developed for a purpose other than reporting to a PSO and still be managed within the ERS."[9]

On appeal, the Hospital asserted in its appellate brief that it submitted the Event Report to its PSO.[10] The appellate court, however, refused to accept this assertion because it was neither included in the trial court record via the affidavit, nor did the Hospital support the assertion with a citation to the record.[11] Thus, the appellate court agreed with the trial court's analysis and affirmed the decision.[12]

Root Cause Analysis Report

With regards to the Root Cause Analysis Report, the Director of Patient Safety Services stated:

1. The Root Cause Analysis Report was produced by the Hospital's Root Cause Analysis Committee "'during the course of a peer review concerning [Jason] Ungurian's medical care' . . . to evaluate Jason Ungurian's care and to improve patient safety and quality of care."[13]

2. The Hospital maintains the Root Cause Analysis Report within its ERS, which is part of its PSES, for reporting to its PSO and that it submitted the Root Cause Analysis Report to the PSO.[14]

Despite the Hospital alleging it maintained the Root Cause Analysis Report in its PSES and submitted the report to its PSO, the trial court found that the Hospital failed to allege that it developed the report "for the purpose of reporting to the PSO" and consequently that the Hospital failed to establish that the report was PSWP protected by the PSQIA privilege.[15]

The trial court further found that Root Cause Analysis Report was not entitled to protection under the PSQIA because it was not contained solely in the Hospital's PSES.[16] The Hospital had "admitted that the information contained in the Root Cause Analysis Report 'is not contained solely in the PSES'" as there was

[7] *Id.* at *16.
[8] *Id.* at *16–17.
[9] *Id.* at *17.
[10] *Ungurian*, at *18 (fn. 11).
[11] *Id.*
[12] *Id.* at *17–18.
[13] *Id.* at *8.
[14] *Id.*
[15] *Id*.
[16] *Ungurian*, at *8.

an email that discussed and identified the report outside the PSES.[17] The trial court held that this defeated the Hospital's claim that the report was privileged under the PSQIA.[18] The appellate court agreed with this analysis and affirmed the trial court's decision.[19]

State Privileges

For purposes of this article, only the PSQIA privilege is discussed. However, it is important to note that the Hospital also asserted the Event Report and Root Cause Analysis Report, along with other documents at issue, were privileged under the Pennsylvania Peer Review Protection Act ("PRPA").[20] The trial court found, and the appellate court affirmed, that none of the documents were privileged under the PRPA.[21] Whether a certain privilege protection applies will depend upon the documents or information in question, how PSES policies and procedures are structured, and how patient safety activities are organized.

Key Takeaways

- This case is good reminder that the burden of establishing the PSQIA privilege and other relevant state law privileges applies falls on the defendant provider.

- This case highlights the necessity of having strong affidavits that allege all of the facts necessary to establish compliance with the PSQIA such that the documents or information at issue are protected by the PSQIA privilege. Particularly in Pennsylvania, the courts clearly require the affidavit allege the document or information was prepared for the purpose of reporting to the PSO.

- In this case, the affidavit from the Director of Patient Safety Services was the only evidence provided to support the Hospital's privilege claim. Providers should also consider providing additional support, including, but not limited to, additional affidavits, PSES policies and procedures, PSO contract, and any other documents to establish the provider followed its policies and complied with the PSQIA and Patient Safety Rule.

- As this is a Pennsylvania case, it is not controlling law in Illinois; however, plaintiffs may try to use this case as persuasive authority. For Illinois case law determining the applicability of PSQIA privilege, see the *Department of Financial and Professional Regulation v. Walgreen Co.* (2012) and *Daley v. Teruel* (2018). For persuasive case law favorable to PSOs and providers, see *Lewis v. Upadhya*y (2015), *Quimbey v. Community Health System Professional Services Corporation* (2016), *Taylor v. Hy-Vee, Inc*. (2016), *Wantou v. Wal-Mart Stores, Inc.* (2018), and *Rumsey v. Guthrie Medical Group, P.C.* (2019).

For information about how to join a patient safety organization, contact the Midwest Alliance for Patient Safety ("MAPS") at MAPSHelp@team-iha.org or 630-276-5657. MAPS is a federally certified patient safety organization and an IHA company.

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[17] *Id*.
[18] *Id.* at *8.
[19] *Id.* at *18–19.
[20] 63 Pa. CSA § 425.4.
[21] *Ungurian*, at *22–26 and *28.