



**PSQIA Case Law Alert:  
Hite v. Mary Immaculate Hospital, Inc.**

Kathryn E. Brown, Staff Counsel  
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In April 2020, the Circuit Court of Virginia issued its opinion in the case of *Hite v. Mary Immaculate Hospital, Inc.*, No. CL1903813P-11 (Va. Cir. Apr. 20, 2020) on a motion to quash a subpoena requesting Patient Safety Work Product (“PSWP”) protected by the Patient Safety and Quality Improvement Act of 2005 (“PSQIA”).<sup>1</sup>

**Background**

La-Rue Hite (“Hite”) instituted a lawsuit against Mary Immaculate Hospital (“MIH”) and MIH nurse Felicia Harris (“Harris”) asserting personal injury arising out of an in-patient fall. MIH produced, pursuant to a pre-suit records request and a subpoena, over 1,000 pages of medical records, audit trails, and radiology studies.<sup>2</sup> Of those documents produced, MIH redacted certain information in two (2) Quantros Incident Reports asserting such redacted information constituted PSWP.<sup>3</sup> Hite disputed the redactions. The Court conducted an evidentiary hearing on this dispute, with testimony from MIH’s Risk Manager, Harris, and MIH’s Director of Patient Safety. At the hearing, MIH submitted a binder of documents, including the unredacted Quantros Incident Reports, for an in camera review by the judge.<sup>4</sup>

**PSWP under the Deliberations and Analysis Pathway**

MIH argued that the redacted language in the Quantros Incident Reports constituted deliberative analysis and that the redacted information was submitted to MIH’s patient safety organization (“PSO”), and therefore, such information was protected as PSWP under the PSQIA.<sup>5</sup> In opposition to MIH, Hite contended that the redacted information was not privileged under the PSQIA because the “first-hand incident reports by the actual individual provider are patient medical records or other original patient provider records” and such patient medical records and other original records are exempted from the definition of what constitutes PSWP.<sup>6</sup>

The Court disagreed with Hite, explaining that the Quantros Incident Reports are not part of the patient medical record, nor do they constitute original patient and provider records merely because they were produced solely by Harris. Instead, the Court explained that to constitute PSWP, the information must “identify or constitute deliberation or analyses of, or identify the fact of reporting pursuant to, a patient safety evaluation system. Factual information giving rise to the deliberative analysis is not PSWP. Furthermore, it must be reported to the PSO.”<sup>7</sup> After reviewing and considering the redacted information,

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<sup>1</sup> 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).

<sup>2</sup> *Hite v. Mary Immaculate Hospital, Inc.*, No. CL1903813P-11, at \*2 (Va. Cir. Apr. 20, 2020).

<sup>3</sup> MIH also asserted that the redacted information was protected by Virginia Code Section 8.01-581.17 (*Id.* at \*3) but the Court disagreed. *Id.* at \*6.

<sup>4</sup> *Id.* at \*2, n. 3.

<sup>5</sup> *Id.* at \*3. The Court acknowledged in a footnote that Ms. Wood, the Director of Patient Safety for Bon Secours Health System (the health system in which MIH operates), testified that Quantros Incident Reports 1 and 2 were entered into the Quantros system and transmitted in batches to MIH’s PSO sometime before February 25, 2020. *Id.* at \*8, n. 4.

<sup>6</sup> *Id.* at \*8. Based on Harris’ testimony at the evidentiary hearing, the court had concluded that the information contained in the disputed Quantros Incident Reports was created solely by Harris. *Id.* at \*6.

<sup>7</sup> *Id.* at \*9. It is unclear whether the Court’s use of “it” refers to the factual material or the deliberations and analysis. MIH alleged that it submitted the factual information to its PSO. Meanwhile, deliberations or analysis do not need to

the Court concluded that some of the information was more factual than deliberative and thus did not constitute PSWP, while other information was deliberative and analytical and thus constituted PSWP.

Although the Court states that the factual information underlying the deliberation and analysis is not PSWP, the U.S. Department of Health and Human Services (“HHS”) has explained in commentary to the Patient Safety Rule:

“information that constitutes the deliberation or analysis within a patient safety evaluation system is protected. Information underlying the analysis may have been either reported to a PSO and protected or collected in a patient safety evaluation system. Information documented as collected within a patient safety evaluation system is protected based on the modification to the definition of patient safety work product. Thus, information underlying an analysis may be protected. . . .”<sup>8</sup>

Note also that under the Reporting Pathway, information that is “assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a patient safety evaluation system for reporting to a PSO . . .”<sup>9</sup> constitutes PSWP. MIH alleged that the Quantros Incident Reports were transmitted to MIH’s PSO; the Court, however, did not consider whether the factual information was protected as PSWP under the Reporting Pathway.

#### **PSQIA Preemption of State Law**

Additionally, the Court addressed whether the PSQIA preempted state law. MIH, as a healthcare provider doing business in Virginia, is subject to Virginia Code Section 8.01-581.17 (“Virginia Code”), which protects as privileged communications the proceedings, minutes, records, and reports of, and communications originating in or provided to a medical staff committee, utilization review committee, or certain other groups prescribed by the law. MIH also voluntarily availed itself of the requirements and protections of the PSQIA, which provides greater protections than those afforded under the Virginia law. In considering the issue of preemption, the Court noted that some jurisdictions have found that the language of the PSQIA denotes federal preemption, while others have found the opposite.<sup>10</sup> The Court, however, ultimately found that it “need not reach the issue of preemption” because the “PSQIA provides protections that overlay Section 8.01-581.17”<sup>11</sup> Though the Court states it does not need to decide the issue of preemption, it seems to impliedly do so by explaining that the PSQIA protects certain information that would otherwise not be protected under the Virginia law.<sup>12</sup>

#### **Protective Order**

During the evidentiary hearing, MIH sought a protective order for the (a) Policy/Procedure Manual of Bon Secours Health System, (b) PSO Membership Agreement, and (c) correspondence from the PSO to Bon Secours Mercy Health Data Manager, Risk Services.<sup>13</sup> Each page of the PSO Membership Agreement was

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be submitted to a PSO in order to be protected so long as it is collected in the provider’s PSES. See Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,743 (Nov. 21, 2008).

<sup>8</sup> 73 Fed. Reg. at 70,743 (emphasis added).

<sup>9</sup> 42 C.F.R. § 3.20 (Patient Safety Work Product, section (1)(i)(A)) (emphasis added). This is often referred to as the “Reporting Pathway.”

<sup>10</sup> *Hite*, No. CL1903813P-11, at \*9. See the following cases which have upheld PSQIA preemption of state law: Florida Health Sciences Centers, Inc. v. Azar, 420 F. Supp. 3d 1300, 1305 (M.D. Fla. 2019); Daley v. Teruel, 107 N.E.3d 1028, 1045–46 (Ill. App. Ct. 2018); and Univ. of Ky. v. Bunnell, 532 S.W.3d 658, 665 (2017).

<sup>11</sup> *Hite*, No. CL1903813P-11, at \*10.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.* at \*12.

labeled confidential and the correspondence from the PSO to Bon Secours was clearly marked “Privileged and Confidential.”<sup>14</sup> The Court found the labels dispositive because they indicated MIH’s and the PSO’s mutual desire and intent for the documents to remain confidential, and, therefore, held that MIH had shown good cause that they be subject to the protective order.<sup>15</sup> The Policy/Procedure Manual, on the other hand, did not bear any label indicating the document was confidential; accordingly, the Court held that it was not subject to the protective order.<sup>16</sup> Note that depending upon the content and purpose of the correspondence from the PSO, MIH may have been able to argue the correspondence was privileged under the PSQIA based on the definition of PSWP, which includes written statements that could improve patient safety, health care quality, or health care outcomes and are developed by a PSO for the conduct of patient safety activities.

### Key Takeaways

- To protect the facts underlying deliberations and analysis, providers should either submit the underlying facts to its PSO or document them as having been collected in the PSES, and assert such facts are accordingly protected under the Reporting Pathway.
- In camera reviews can be subjective and nuanced. Providers should consider providing additional support for their privilege claims, including, but not limited to, affidavits, Patient Safety Evaluation System 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 such that the facts and deliberations or analysis are protected as PSWP.
- Plaintiffs continue to argue that the PSQIA does not preempt state law; the Secretary of HHS, however, has stated otherwise.<sup>17</sup>
- Materials and correspondence (depending upon the content and purpose) received by a Provider from its PSO may constitute PSWP.
- In addition to the PSQIA, there may be state law privileges, like Illinois’ Medical Studies Act, and common law privileges, like the attorney client privilege, that protect information from discovery.

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

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<sup>14</sup> *Id.* at \*13.

<sup>15</sup> *Id.* MIH had the burden of establishing good cause for the protective order and argued that the proprietary information contained in the Policy/Procedure and the PSO Membership Agreement should be protected from further improper disclosure. *Id.* at \*12. The Court’s order does not specify whether this same argument was utilized by MIH for the protection of the correspondence.

<sup>16</sup> *Id.* at \*13.

<sup>17</sup> Florida Health Sciences Centers, Inc. d/b/a Tampa General Hospital v. Azar, 420 F. Supp. 3d 1300, 1305 (M.D. Fla. 2019) (stating “the Secretary ‘agrees that Amendment 7 is preempted by the Patient Safety Act.’”).