Katten

HEALTH CARE ADVISORY

11th Circuit Rejects 'Sole Purpose' Argument as Basis for Denying Privilege Protections Under Patient Safety Act

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Background

At long last, the "sole purpose" argument used by trial courts and plaintiffs' attorneys was soundly rejected in a recent decision issued by the 11th Circuit Court of Appeals, *In Re: BayCare Medical Group*, No. 23-12571, May 14, 2024. In that case, a surgeon filed an employment discrimination lawsuit after she was terminated by BayCare Medical Group and St. Joseph's Hospital in Tampa, Florida. The termination was based on her alleged commission of several surgical errors. During discovery, she sought to require that BayCare disclose "internal documents about the performance of other doctors who were not fired despite also committing errors." She also demanded the production of "referral logs," which identified complaints brought against physicians. In response, BayCare argued that these documents (collectively the "quality files") were privileged under the Patient Safety and Quality Improvement Act (PSQIA) and, therefore, not subject to discovery.

Although BayCare introduced evidence to establish that the quality files were collected within its Patient Safety Evaluation System (PSES) and, therefore, were privileged, the district court ruled that the PSQIA does not privilege documents if they had a "dual purpose" as approved to the sole purpose of reporting to a Patient Safety Organization (PSO). The trial court also stated that because the information in dispute was not used for the "sole purpose" of reporting to a PSO, they were not privileged because they also were used for internal safety analysis and peer review. BayCare subsequently filed a writ of mandamus requesting that the 11th Circuit direct the district court to vacate its order compelling disclosure of the privileged documents because of the court's erroneous ruling.

Rejection of 'Sole Purpose' and 'Dual Purpose' Arguments

In response to BayCare's argument that there is no "sole purpose" requirement in the PSQIA, the Court of Appeals stated as follows:

> We agree with BayCare. Under the plain text of this statute, it does not matter whether BayCare created, used, or maintained the disputed documents for multiple purposes. Contrary to the district court's order, nowhere does the statute require that privileged information be "kept solely for provision to a Patient Safety Organization. Instead, the Act privileges work product so long as it "identif[ies] or constitute[s] the deliberations or analysis of, or identifies the fact of reporting pursuant to a "patient safety evaluation system." [42 USC] Section 299b-21(7)(A), regardless of whether it is reported to a patient safety organization. The relevant administrative rule confirms as much. BayCare "may use patient safety work product for any purpose within [its]

> legal entity." Patient Safety and Quality Improvement, 72 Fed. Reg. 70732-01 at 70779 (Nov. 21, 2008). Nothing prohibit[s] the disclosure of patient safety work product among physicians and other health care professionals, particularly for educational purposes or for preventing or ameliorating harm." *Id.* at 70778.

The Court of Appeals further stated that:

> As far as we are aware, the only basis for imposing a "sole purpose" test is a brief reference in HHS's supplemental guidance from 2016. *See* HHS Guidance Regarding Patient Safety Work Product and Provider's External Obligations, 81 Fed. Reg. 32655-01 (May 24, 2016). It includes a small chart of information that "[c]ould be" patient safety work product if it is "prepared solely for reporting to" a patient safety organization. *Id*. at 32656. But that supplemental guidance by definition isn't law (*See* Kisor v. Wilkie, 588 US 558, 139 S.Ct. 2400, 2420, 204 L.Ed.2d 841 (2019). And that portion of the 2016 guidance contradicts HHS's final rule – which does have legal effect. *See id*. The regulation is clear – [U]ses of a patient safety work product within a legal entity are not regulated and thus, patient safety work product may be used within an entity for any purpose, including "credentialing, disciplinary, peer related purposes." Patient Safety and Quality Improvement, 73 Fed. Reg. 70732-01 at 70779.

The Court concluded:

> The upshot is that the district court abused its discretion when it applied a wrong legal standard to assess BayCare's assertion of privilege. Because the district court applied a "sole purpose" exception to the plain text of the act, we direct the district court to vacate its order and reconsider BayCare's assertion of privilege.

Although BayCare's typical practice is to report the quality files to a PSO, it is unclear, based on the Court's decision, whether these materials were indeed reported. Instead, the district court was directed to "ask whether each document reflects 'identificat[ion],' 'deliberations,' or 'analysis' about 'the collection, management or analysis of information for reporting to or by a patient safety organization.'"

Takeaways

Rejection of 'Sole Purpose' and 'Dual Purpose' Arguments

A number of trial and appellate courts have relied on one or both of these arguments to reject the assertion that the discovery documents in dispute were PSWP. These courts have looked to the supporting affidavit, legal arguments or policies for language which stated whether the disputed documents in question were prepared for the "sole purpose" of reporting to a PSO. Aside from the fact that no such language exists in the PSQIA, the clear and stated purpose of passing the PSQIA by Congress to provide privilege protections for a provider's purpose of creating PSQIA is for internal use and review in a hospital's continuing efforts to improve patient safety and reduce risk. For a court to conclude that the PSWP could only be reported to a PSO and not also be used for any patient safety activity, such as internal safety analyses and peer review, was clearly contrary to and would have defeated the clear purposes of the PSQIA.

Court's Decision Clarifies That Use of PSWP Outside of the Provider's PSES Is Permitted

Another argument used by courts to reject the privilege was to determine if the PSWP was used for a purpose not explicitly identified in the PSES policy. If so, then the information could not be PSWP.

The *BayCare* decision cites the Patient Safety Act, the Preamble, as well as the HHS guidance that, to the contrary, such information "may be used within an entity for <u>any</u> purpose, including 'credentialing, disciplinary, peer related purposes.'" (Emphasis added.)

Recommendations

1. While most trial court judges who preside over medical malpractice cases are familiar with the state peer review statutes, they are less knowledgeable about the Patient Safety Act. Consequently, it is extremely critical that the provider and their legal counsel take every opportunity to educate the judge as to the Act itself as well as the scope of privilege protections afforded under this federal law. In addition, the courts are not likely to understand how the provider conducts its patient safety, quality improvement, peer review and related activities and operations.
2. The best method for educating the court is a combination of a strong legal brief that cites supporting case law and includes detailed affidavits, the provider's PSES policy, its event reporting policy and other relevant policies, such as their QAPI plan, all of which should be considered as part of the overall PSES policies for the provider.
3. The affidavit should be prepared by an individual who is specifically knowledgeable about or directly involved with the PSWP at issue.
4. The affidavit should specifically cite the relevant and attached policies and provide details as to how the PSWP in question is generated, collected, maintained, shared and used within the organization to improve patient care and whether it was either reported to the PSO or treated as privileged deliberations or analysis.
5. Additionally, when preparing the affidavit, consideration should be given to adding screenshots of the forms, reports or other non-privileged information utilized by the hospital, particularly if the provider is using the reporting pathway.
6. Most jurisdictions require that the defendant party also must submit a privilege log that specifically identifies what information is claimed to be privileged as well as the basis of the privilege such as the Patient Safety Act. It is important that the privilege log not be the only support for the privilege claim. At some point in time, if not at the outset, the affidavits, legal argument and materials noted above should also be included.
7. Remember that the state peer review protections and the protections under the Patient Safety Act are not mutually exclusive. Both can apply depending on the requirements for claiming the privilege under both statutes.
8. Keep in mind that information that is privileged PSWP cannot also be considered attorney-client work product or vice versa. The courts already have ruled that information prepared in anticipation of litigation and would be privileged under attorney-client work product is not also information used to improve patient care. Defendant parties are always better off claiming the Patient Safety Act and state protections, if applicable.
9. Most of the adverse court decisions that have been published are due to the lack of specific knowledge of and experience in maximizing the privilege protections under the PSQIA when responding to a discovery demand or court order to disclose PSWP. If the defense counsel does not have this background and experience, consider seeking the assistance of outside counsel who has successfully represented clients in these discovery disputes before trial and appellate courts around the country and has worked collaboratively with defense counsel in these matters.

Next Steps

After reviewing this advisory, as well as the linked *BayCare* decision, feel free to let us know if you have any questions. Katten's Health Care team can help with any of the following:

1. A review of and revisions to PSES and related policies in order to maximize the privilege protections under the PSQIA and applicable state laws.
2. Preparing for and presenting in-service/webinar educational programs for risk managers, quality personnel, senior management, in-house and outside legal counsel and others regarding any or all aspects of the PSQIA, including policy development and defending against discovery demands for PSWP.
3. Litigation assistance, working collaboratively with defense counsel in preparing legal arguments, drafting supporting affidavits and oral arguments in response to a motion to compel or court order, as well as the preparation of trial, appellate and amicus briefs.

CONTACTS

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