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THEME ARTICLE

SIDEBAR: COMPELLING PRODUCTION OF ADVERSE INCIDENT REPORTS

May 2017 - Nicholas C. Johnson

Hospitals fight tooth and nail to avoid producing adverse incident reports. Learn how to craft a motion that will survive their opposition.

Almost all hospitals in the United States have an adverse incident reporting system in which risk managers accumulate documents about events that have injured or killed patients.[1] Congress enacted the Patient Safety Quality Improvement Act of 2005 (PSQIA) to encourage hospitals to maintain this reporting system and to simultaneously protect the confidentiality of the information, also known as "patient safety work product."[2]

Seizing on this privilege, defendant hospitals perennially cite the PSQIA as legal authority for withholding documents. But a careful reading of the act, along with recent U.S. Department of Health and Human Services (HHS) guidance, can help you overcome defense objections and obtain vital documents for your medical negligence case.

When requesting documents related to adverse incidents, the exact wording is less important than the substance. Incorporate language broad enough to encompass all relevant documents. For example, I have had success with the following language, notwithstanding the anticipated objection:

> Any and all records you made or received regarding the adverse medical incident in question, including but not limited to: records, reports, and investigations required by state or federal law to be reported to any governmental agency or body, and/or that are reported to or that were reported to or reviewed by the facility's peer review, risk management, quality assurance, credentials, patient safety disciplinary, or any other similar committee or any representative of such committees.

The hospital will likely object to this request, claiming the records are privileged under the PSQIA as patient safety work product. The objection may seem daunting, but before resigning yourself to defeat, file a motion to compel that outlines the PSQIA, the U.S. solicitor general's interpretation of the act, and the HHS guidance.

Use the statute's language. Include the statutory definition of patient safety work product: "Any 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."[3]

The act also specifically states what does not constitute patient safety work product: "information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product."[4] This language is critical because hospitals routinely claim that documents automatically become patient safety work product since they submit them to a patient safety organization—even though the statute clearly contradicts this argument.

Deposing the hospital's risk manager can help you determine whether documents exist separate from a patient safety evaluation system. The risk manager may generate notes from the final set of documents that is turned over to the patient safety evaluation system. According to a strict reading of the act, those notes are not patient safety work product.

In the motion, insist that the hospital prove its entitlement to the PSQIA's protection. The act is not self-executing—its privilege and confidentiality provisions apply only when a health care provider fully complies with the creation and operation of a patient safety organization.[5] This means the hospital must certify to HHS that it meets the requirements for a patient safety organization, and HHS must review and accept this certification. The HHS secretary maintains a list of qualifying patient safety organizations.[6] If the hospital does not meet these requirements, it likely will not prevail on its objection.

Even if the hospital satisfies these requirements, argue that the documents in question are not patient safety work product—either because the documents exist separately from the patient evaluation system, such as handwritten notes, or, if applicable, because the hospital has a duty to report adverse incidents to the state.

State reporting requirements. A couple of state supreme courts have considered whether state reporting requirements conflict with the PSQIA. In *Tibbs v. Bunnell*, for example, the Kentucky Supreme Court ruled that an adverse incident report was not privileged under the act because collecting the documents in question was required under state law "as part of . . . regulatory oversight of [the state's] healthcare facilities."[7] If your state has reporting requirements for adverse medical incidents, citing *Tibbs* along with those statutes will further support your arguments against privilege.

The *Tibbs* defendants' petition for certiorari to the U.S. Supreme Court was denied.8 In an amicus brief on the government's behalf, the U.S. solicitor general argued that the petition should be denied because the Kentucky Supreme Court correctly decided the issue.[9] Cite the solicitor general's amicus brief as persuasive guidance in your motions.

You may also want to cite the recent Florida Supreme Court decision in *Charles v. Southern Baptist Hospital of Florida, Inc*.[10] That case grappled with the interaction between the PSQIA and the Florida Constitution's Amendment 7, which grants patients the right to access adverse medical incident reports.[11] The Florida Supreme Court held, 5-2, that the PSQIA did not preempt Amendment 7, because "Congress did not intend to preempt state laws or Amendment 7 through the passage of the Federal Act. . . . The Federal Act was intended by Congress to improve the overall health care in its system, not to act as a shield to providers. . . . Moreover, health care providers should not be able to unilaterally decide which documents will be discoverable and which will not in medical malpractice cases."[12]

Refer to HHS guidance. Your motion to compel should also discuss HHS's May 24, 2016, guidance on interpreting the PSQIA. The department wrote that the statute was intended "to protect the additional information created through voluntary patient safety activities, not to protect records created through providers' mandatory information collection activities." It gave an example similar to *Tibbs*: "A provider may have an external obligation to maintain certain records about serious adverse events that result in patient harm. The document the provider prepares to meet its requirement about such adverse events is not [patient safety work product]."

Congress recognized that a fear of being sued had a chilling effect on providers, but HHS explained that the PSQIA "was not designed to prevent patients who believed they were harmed from obtaining the records about their care that they [previously] were able to obtain. . . . Nor was the Patient Safety Act intended to insulate providers from demonstrating accountability through fulfilling their external obligations."[13]

If you confront the PSQIA argument head-on in your motion to compel, you may succeed in obtaining adverse incident documents that hospitals would rather keep hidden.

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Notes

1. Donna O. Farley et al., *Adverse-Event-Reporting Practices by U.S. Hospitals: Results of a National Survey*, 17 Quality & Safety in Health Care 416–23 (2008).
2. Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (2005); *and see* U.S. Dep't of Health & Human Servs., *Patient Safety and Quality Improvement Act of 2005 Statute and Rule*, www.hhs.gov/hipaa/for-professionals/patient-safety/statute-and-rule/index.html.
3. 42 U.S.C. §299b-21(7)(A) (2005).
4. 42 U.S.C. §299b-21(7)(B)(ii) (2005).
5. 42 U.S.C. §299b-21(4) (2005).
6. 42 U.S.C. §299b-24(d) (2005).
7. *Tibbs v. Bunnell*, 448 S.W.3d 796, 809 (Ky. 2014).
8. *Tibbs v. Bunnell*, 136 S. Ct. 2504 (2016) (denying cert petition).
9. Brief for the United States as Amicus Curiae, *Tibbs v. Estate of Luvetta Goff*, 2016 WL 3014493, at *10 (2016).
10. *Charles v. S. Baptist Hosp. of Fla.*, 2017 WL 411333 (Fla. Jan. 31, 2017).
11. Fla. Const. art. 10, §25.
12. *Charles*, 2017 WL 411333, at *13.

13. Patient Safety and Quality Improvement Act of 2005—HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations, 81 Fed. Reg. 32655-01 (May 24, 2016).