A Win For Fla. Hospitals On Patient Safety Data Confidentiality

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In a sweeping ruling on Sept. 5, the U.S. District Court for the Middle District of Florida enjoined the U.S. Department of Health and Human Services from enforcing the mandatory penalties for disclosure of patient safety work product against Florida Health Sciences Center Inc., and concluded that the Patient Safety Quality Improvement Act of 2005, or PSQIA, preempts Florida law and prevents valid patient safety work product from disclosure.

In Florida Health Sciences Center Inc. v. Azar, the plaintiff hospital, a defendant in a medical malpractice action before Florida's Circuit Court of the Thirteenth Judicial Circuit in and for Hillsborough County, had been ordered to produce 241 documents from the hospital's patient safety evaluation system that had been submitted to PSO of Florida, the patient safety organization of which the hospital is a member.[1]

The state court decision relied on Article X, Section 25 of the Florida Constitution (commonly known as Amendment 7), adopted in 2004, which provides patients a right of access to certain internal hospital review records. The state court had entered a civil contempt finding against the hospital, ordering it to pay $100 per day that it did not produce the records.[2]

The hospital appealed that decision, and also commenced a federal declaratory action, arguing that it was "between a rock and a hard place," because producing the 241 protected patient safety work product records in the state court action would subject it to a mandatory fine from the U.S. government.[3] The HHS largely agreed with most of the hospital's arguments, but asked the Middle District to dismiss the action, because the HHS had not stipulated that it would necessarily fine the hospital.[4]

The Middle District denied the HHS's argument that dismissal was appropriate, finding that the fine pursuant to the PSQIA for disclosure of patient safety work product is mandatory. In granting summary judgment for the hospital, the court enjoined the US government from fining the hospital.[5]

However, the court went much further, analyzing Amendment 7 and the recent Florida Supreme Court opinion in Charles v. Southern Baptist Hospital of Florida Inc., and finding that the PSQIA preempts Florida law, including Amendment 7.[6] Therefore, Amendment 7 does not provide a patient a right to have access to valid patient safety work product protected by the terms of the PSQIA.[7]

Amendment 7 was promoted on the 2004 Florida ballot as a consumer rights initiative, to

aid consumers and patients in making informed decisions in selecting a health care provider. In practice, it has often been used as a plaintiff's tool of discovery in litigation, to obtain otherwise confidential records of internal investigations and proceedings from the health care facilities and providers that conduct such investigations and proceedings.

Florida law requires that health care facilities and providers conduct internal risk management, credentialing, peer review and quality assurance investigations and proceedings in an effort to improve the quality of health care in Florida and reduce incidents of medical malpractice.[8] The same statutes that obligated health care facilities and providers to conduct these investigations and proceedings also expressly provide that records and information relating thereto would not be subject to discovery in any civil or administrative action.[9]

By its terms, Amendment 7 provides patients with a right to have access to certain of those statutorily protected records. At issue in the Florida Supreme Court's Charles decision were whether Amendment 7 could be used to compel certain incident reports, required to be created pursuant to Section 395.0197 of the Florida statutes, over which the defendant hospital claimed the separate federal patient safety work product privilege pursuant to the PSQIA.[10]

The Charles decision, in January 2017, held that the records at issue were not patient safety work product, and that they fell within an exception to the PSQIA, expressly because they were created pursuant to state statute.[11] This decision ignited a firestorm over patient safety work product, largely due to its expansive dicta unrelated to the records at issue.

This issue has been hotly debated in Florida state courts, predominantly in medical malpractice litigation, in which plaintiffs often invoke Amendment 7 in order to discover records protected by Florida statutes and federal privileges. The Middle District of Florida's new decision strictly interprets the opinion in Charles to hold that Baptist Hospital's records were only accessible under Amendment 7 because the records were not patient safety work product to begin with, and disregards the remaining dicta concerning preemption.

The Middle District found that the Charles opinion was limited to records that were not valid patient safety work product, the narrowest reading of Charles. And its preemption analysis directly opposes the broad findings in Charles, finding them to be unpersuasive dicta.

Specifically, the federal court found that the Charles decision was limited because Baptist Hospital's records at issue were not patient safety work product to begin with; they had been submitted to the hospital's patient safety evaluation system — but not to its patient safety evaluation system — as they were incident reports required to be created pursuant to statute, and therefore "collected, maintained, or developed separately" from a patient safety evaluation system.[12]

The Middle District's decision is a clear victory for hospitals invoking patient safety work product protections, and supports the argument that records properly submitted to patient safety organizations are protected patient safety work product, which should not be subject to production pursuant to Amendment 7.

Hospitals with patient safety evaluation systems who are members of patient safety organizations should take careful note of this decision, which supports the protections provided to records within those systems. As these types of records are consistently the subject of discovery requests in medical malpractice actions, the Middle District's decision directly impacts and supports arguments to protect them.

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[1] Fla. Health Sciences Ctr. Inc. v. Azar, Case No. 8:18-cv-00238-JSM-CPT (M.D. Fla. Sept. 5, 2019).

[2] Id.

[3] Id.

[4] Id.

[5] Id.

[6] Id.

[7] Id. (analyzing Charles v. S. Baptist Hosp. of Fla. Inc., 2019 So. 3d 1199 (Fla. 2017).

[8] See, e.g., §§ 395.0191, 395.0193, 395.0197, 766.101, Fla. Stat. (2019).

[9] Id.

[10] See Charles, 209 So. 3d at 1199.

[11] Id.

[12] Charles, 2019 So. 3d at 1199.