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Possible Relief for Hospitals in the Protection of PSO Information?

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Last Thursday, September 5, 2019, Judge James Moody, Jr. of the United States District Court for the Middle District of Florida issued a positive ruling for hospitals dealing with patient safety organization (PSO) data. The opinion can be reviewed here. Note, while this decision is not binding on state courts, it is persuasive authority. It may be used to argue against the production of adverse incident materials.

Federal Judge Moody commented regarding some specific issues:

Subject Matter Jurisdiction

The Plaintiff, Tampa General Hospital (TGH), was facing daily monetary sanctions pursuant to federal law in a state court action if it knowingly disclosed patient safety data. The federal statutory penalty is expressed in mandatory terms in both the Patient Safety Act and the Administrative Rules. Since the U.S. Department of Health and Human Services (HHS) had refused to assure TGH it would not be penalized if TGH produced the Patient Safety Work Product (PSWP), the court had to act.

Pre-Emption

Both TGH and HHS agreed that the Patient Safety Act expressly preempts Florida Amendment 7. Judge Moody states that the language in the Patient Safety

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Act clearly is an express preemption clause. The key point, in this particular case, is that the documents that TGH maintained, were *made for and submitted to*, a PSO. They were therefore not subject to forced disclosure in the state court medical malpractice action.

The federal court addressed the Florida Supreme Court's opinion in *Charles v. S. Baptist Hosp. of Fla.*, Inc., 209 So. 3d 1199 (Fla. 2017). The distinct difference is that the documents in *Charles* had not been submitted to a PSO. Preemption therefore was not directly at issue.

Amendment 7, adopted in Florida in 2004 provides "a right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident." However federally, the Patient Safety Act, "established a system under which health care providers can voluntarily collect and report medical errors in an attempt to educate themselves on preventable medical errors." Thereunder, each participating provider establishes a patient safety evaluation system (PSES) in which relevant information would be collected, managed, and analyzed. Importantly, the provider would then forward this information to the PSO. The PSO collects, analyzes and provides feedback and recommendations regarding ways to improve patient safety and quality of care. Finally, information provided to PSO's would also be shared with a central clearing house which aggregates the data and allows it to be used as an evidence-based management resource.

To encourage participation, a protected legal environment was created, meaning information shared with a PSO per the federal law is shielded from production in a state proceeding. These legal protections are the foundation to furthering the overall goal of the federal statute to develop a national system for analyzing and learning from patient safety events. The Act also provides that if a

facility discloses this patient safety work product in violation of the confidentiality provisions it shall be subject to a civil monetary penalty of not more than $10,000.00 for each act constituting such a violation.

Consequently, there are a number of preconditions that must be met to garner the protections under the Patient Safety Act. Systems must be in place and followed, including forwarding the information to the PSO as part of the process. This new opinion, however, is the first Florida decision, albeit in federal court, that distinguishes the Florida Supreme Court's opinion. It offers some hope for achieving the overall goal of having a national system to improve quality patient care.
