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Florida Supreme Court Rules That Hospital "Adverse Medical Incidents" Reported to a PSO Are Not Privileged From Discovery: Impact on Participating Providers and PSOs

Background

Southern Baptist Hospital of Florida (Hospital) was sued in a medical malpractice action in which the plaintiff sought to discover records relating to "adverse medical incidents" that occurred at the Hospital and involved any physicians who worked for the Hospital or with respect to any persons who were involved in the care of the plaintiff during the three years previous to her treatment through the date of the discovery request.

The Hospital, which participated in PSOFlorida (PSO) provided reports to the State as required under Florida's mandated reporting statutes. It also produced two occurrence reports specific to the plaintiff that had been collected in the Hospital's PSES but had not yet been reported to the PSO. Other documents which were "primarily occurrence reports" were not produced because the Hospital stated they were reported to the PSO and, therefore, were PSWP under the Patient's Safety Act and Quality Improvement Act of 2015 (Patient Safety Act) and not subject to discovery.

The Supreme Court of Florida's decision in *Charles v. Southern Baptist Hospital of Florida, Inc.* is available here.

The Trial Court Decision

The Plaintiff moved to compel production of the documents based on the following arguments:

- the Act only protects documents created solely for the purpose of reporting to a PSO;
- such information is not privileged and confidential if it was collected and maintained for another purpose or for dual purposes;
- Article 10, Section 25 of the Florida Constitution (Amendment 7) provides patients the rights to access to "any records made or received . . . relating to an adverse medical incident," and therefore the Hospital was obligated to turn over the disputed records; and
- information cannot be protected if relating to the Hospital's obligation to comply with federal, state or local laws or accrediting or licensing requirements.

The trial court agreed with the plaintiff's arguments and held:

> "All reports of adverse medical incidents, as defined by Amendment No. 7, which are created, or maintained pursuant to any statutory, regulatory, licensing, or accreditation requirements are not protected from discovery under [the Patient Safety Act]."

- Based on this ruling, the Hospital was ordered to produce "all records in its possession relating to the adverse medical incidents" that occurred during the requested timeframes.

First District Court of Appeals

The First District Court of Appeals granted the Hospital's petition for writ of certiorari and reversed the decision of the trial court. In doing so, the Court made the following conclusions:

- the documents at issue clearly met the definition of PSWP because they were placed into the Hospital's PSES where they remained pending submission to a PSO;
- the documents at issue were not original patient records and were not collected, maintained or developed separately from the PSES;
- information qualifies as PSWP if it is placed in a PSES for reporting to a PSO and does not existing outside of the PSES. For these reasons, the Court determined that the documents were PSWP and, therefore, not discoverable; and
- the Court further held that the Patient Safety Act pre-empted the otherwise broad discovery permitted under Amendment 7 under the circumstances of this case.

Florida Supreme Court Decision

- The plaintiff's appealed to the Florida Supreme Court, and even though the parties entered into a Stipulation of Dismissal a day before oral arguments were scheduled, the Court accepted the appeal under its mandatory jurisdiction because the Court of Appeals declared "invalid a state statute or a provision of the state constitution" when it determined that the Patient Safety Act pre-empted Amendment 7 and because it involved "an issue of statewide importance."
- This appeal attracted national attention because it was only the second state supreme court to review a challenge under the Patient Safety Act. Parties which filed amicus briefs in support of the Hospital, included multiple PSOs, the AMA, The Joint Commission, the Florida Medical Association and AQIPs.
- The Court went into great length in describing various provisions of the Patient Safety Act, including the definitions of PSWP, the scope of the privilege protections, as well as information that did not qualify as PSWP. It cited to a provision of the Patient Safety Act regarding information which did not qualify as PSWP and specifically a provision of the Act which states that PSWP: "does not include information that is collected, maintained or developed separately, or exists separately, from a patient safety evaluation system." Further that the Patient Safety Act should not be interpreted in order to "limit, alter, or effect the requirements of Federal, State or local law pertaining to information that is not privileged or confidential under [the Act]."
- Upon laying this foundation, the Court then focused on provisions of state law requiring hospitals to establish an internal risk management program, which "shall include the use of incident reports to be filed with an individual of responsibility who is competent in risk management techniques." (§395.0197(4)-(7) Fla. Stat. (2015))
- The statute also defines the term "adverse incident," which is an event "over which healthcare personnel could exercise control relating to medical intervention and which results in a number of listed injuries and other events." These adverse events are to be submitted as part of an annual report by the hospital. Amendment 7, but not the statute, defines the term "adverse medical incident" but does not create any reporting obligation.
- Another statutory provision requires that hospitals establish an internal reporting system, which includes information requirements such as a "clear and concise description of the incident and the names of individuals involved directly or indirectly with the incident," which then must be analyzed to identify trends or patterns, recommendations for corrective actions and risk management prevention, and that, at least, a quarterly report be made to the Board of Directors. The last section of the Administrative Code states that the "evidence of recommended and accomplished corrective actions shall be made available for review to any authorized representative of the Agency upon request during normal working hours." (Fla. Admin. Code 59A-10.0055)
- After identifying these state provisions, the Court then went on to cite to Amendment 7, which gives individuals the right to access any records made or received in the course of business by health care facility or provider relating to any adverse medical incident. Taken together, the Court concluded that hospitals are required to keep adverse medical incident reports, and that such reports must be made available to patients upon their request.

The Court then states:

> "Simply put, adverse medical incident reports are not patient safety work product because Florida statutes and administrative rules require providers to create and maintain these records and Amendment 7 provides patients with a constitutional right to access these records. Thus, they fall within the exception of information 'collected, maintained, or developed separately, or exists separately, from a patient safety evaluations system' (citation). In addition, their disclosure fits squarely within the provider's recordkeeping obligations under state law. (citation)."

- To support this interpretation, the Court cites to both the recent Kentucky Supreme Court decision in *Baptist Health Richmond, Inc. v. Clouse*, which reached a similar conclusion involving a Kentucky statute, as well as to the HHS PSO Guidance Regarding Patient Safety Work Product and Providers' External Obligations (Guidance), which was published on May 24, 2016.
- Essentially, the Florida Supreme Court determined that information collected within a PSES and reported to a PSO does not automatically become PSWP and, in fact, cannot qualify as PSWP if state law requires that the documents be created and maintained.

Pre-Emption

- Although the Supreme Court could have stopped there, it decided to address the Appellate Court's holding that the Patient Safety Act pre-empted Amendment 7. It rejected the Appellate Court's analysis and ruled that because Amendment 7 was constitutionally adopted after overwhelming support by Florida voters, that the Patient Safety Act is voluntary and not required, and, furthermore, because, in its opinion, Congress recognized the importance of preserving patient rights and compensation for negligence committed against them, records which were available to patients prior to passage of the Act should remain available.

Comments

- The decision in *Charles* was fully expected given the current Supreme Court's view that the "primary purpose of medical malpractice actions is not to punish the health care provider, but to compensate the victim of medical malpractice who is many times severely injured." Anyone who saw a videotape of the oral argument in *Charles* witnessed the hostility of the judges toward the oral arguments made by the Hospital's attorney in support of the Court of Appeals decision which, therefore, made the outcome very predictable.
- The decision can be criticized at a number of levels, not the least of which is its failure to distinguish adverse incident reports referenced in Florida statutes, which the Hospital did report, from other documents, such as RCAs, which need not be reported. Although the Court's pre-emption analysis is faulty, no doubt plaintiff's attorneys are likely to argue that Amendment 7 effectively pre-empts the Patient Safety Act, which, if this position is adopted by lower courts, could render the Act somewhat meaningless in Florida.
- *Charles* is now the second state Supreme Court decision, after *Clouse*, to cite to the HHS PSO Guidance in support of its interpretation that records which must be collected and maintained pursuant to state, federal, local law or accreditation standards do not qualify as PSWP.
- Because the Court did not mention other records in dispute, such as RCAs, hospital attorneys are likely to argue that the *Charles* decision only applies to adverse medical incident reports and no other information that qualifies as PSWP.

Recommendations

- Although the decisions in *Charles*, *Clouse* and *Tibbs v. Bunnell* are binding only on the courts in Florida and Kentucky, respectively, providers and PSOs should expect, in light of the Guidance, these decisions that plaintiff's attorneys and government agencies will attempt to broadly define what types of information must be "collected and maintained" under applicable laws and, therefore, do not qualify as PSWP.
- It is therefore important for providers to review applicable state and federal laws and to make a good faith assessment as to whether documents are intended to be treated as PSWP fall into Bucket 1 (mandated reports); Bucket 2 (records which a provider is required to collect and maintain); or Bucket 3 (information that qualifies as PSWP and does not fall into Bucket 1 or 2 and are collected for reporting to a PSO and are reported or constitute deliberations or analysis).

- A question to ask is whether state, federal or other authorities specify the form or content of these so-called Bucket 2 documents. As with Bucket 1 documents, a licensed provider should only include the minimal amount of information that is required, nothing more and nothing less. In other words, if no form or specific content is set forth in the statute, then create a Bucket 2 document with minimal information, mostly factual, which can then be produced to a plaintiff or an enforcement agency if requested.
- Where a provider has Bucket 1 and/or Bucket 2 obligations, it should consider creating a third set of documents which do not reference or include the actual name of the records identified under state or federal law (i.e., "adverse incident report") but which are identified within the PSES and are being collected for the purpose of reporting and are reported or are being treated as deliberations or analysis.
- Although this creates a degree of redundancy and additional administrative burden, which the Act supposedly was seeking to avoid, providers and PSOs must adapt to the changing legal landscape. The alternative is to be prepared to face similar challenges in light of existing court decisions and the Guidance as well as your local courts, many of which tend to support plaintiffs in malpractice actions.
- The other method of creating PSWP is to determine whether it constitutes "deliberations or analysis". This is an alternative pathway which does not require a report to the PSO. Although D or A is not specifically defined, most PSWP arguably falls into this category if collected within the provider's PSES. Such information automatically becomes PSWP if it does not fall into Bucket 1 or Bucket 2 and does not have to be actually or functionally reported to a PSO.

For questions or assistance with policies, compliance with the Patient Safety Act, or with any pending or anticipated discovery disputes, please contact Michael Callahan and Laura Keidan Martin or any member of the **Health Care** or **Health Care Litigation** teams.

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