HCPro

Credentialing & Peer Review Legal Insider

Volume 12
Issue No. 12

DECEMBER 2015

Patient safety work product privilege at center of possible Supreme Court case

Hospitals and patient safety organizations (PSO) across the country are eagerly awaiting to see if the U.S. Supreme Court will hear a case that address the question of the scope of privilege and confidentiality protections afforded under the federal law to reports, analyses, and studies relating to a hospital's patient safety activities, which are collected within its patient safety evaluation system and reported to a PSO. The other question is whether this federal law, known as the Patient Safety and Quality Improvement Act of 2005 (PSQIA), preempts state law that otherwise would permit the discovery of this sensitive information.

In the case of *Tibbs v. Bunnell,* a patient's family filed a wrongful death and medical malpractice suit against three surgeons employed at University of Kentucky Hospital following the patient's death due to complications from an elective spine surgery.

During litigation the patient's estate sought to discover a post-incident event report generated by a surgical nurse through the University of Kentucky Hospital's Patient Safety Evaluation System (PSES), which was reported to its contracted federally-certified PSO. The hospital objected and asserted that it was protected under PSQIA and therefore not subject to discovery. The trial court ruled that the report was not protected under PSQIA and the hospital appealed to the Kentucky Court of Appeals.

The appellate court found that the privilege provided by the PSQIA did preempt the Kentucky state law, but only for documents that contained "self-examining analysis" that was created by the treating practitioner. The court then sent the matter back to the trial court to conduct an in-chambers inspection of the report to see if it did in fact contain self-examining analysis.

The hospital appealed the Court of Appeals order to the Supreme Court of Kentucky. The hospital argued that the appellate court had incorrectly narrowed the scope of privilege protections under PSQIA, which it maintained, were designed by Congress to be quite broad in the furtherance of improving patient care.

In August 2014, the Kentucky Supreme Court, in a 4-2 decision, reversed the Court of Appeals decision but ruled that the incident report was not protected under PSQIA because its collection, creation, maintenance, and utilization was required under Kentucky state law and therefore could not be collected within the hospital's PSES and thus treated as protected patient safety work product.

The hospital then petitioned the U.S. Supreme Court to reverse the decision. In October, after receiving the plaintiff's objection to the petition, the Supreme Court invited the U.S. solicitor general to file a brief on his views of the case and whether the petition should be granted or denied.

The solicitor general is expected to prepare a brief and present it to the Supreme Court in December, which will then make its decision whether or not to hear the case no later than January, says **Michael Callahan, Esq.,** partner at Katten Muchin Rosenman, LLP, in Chicago.

It should be noted that nothing the solicitor general says is binding on the Supreme Court, adds Callahan. "The Supreme Court is just trying to get a better sense from the government as to the importance of this case and the proper interpretation of PSQIA." He adds that both sides—the hospital and the plaintiff—will have an opportunity to meet with the solicitor general beforehand to make their respective arguments about the merits of the case.

Rory Jaffe, MD, MBA, executive director of CHPSO, a PSO serving providers in the western United States, is optimistic that the Supreme Court will hear the case. "The Supreme Court takes a very small percentage of the cases presented to it, but at least it's showing some interest in this case by requesting additional information. We're hopeful that it'll take it. It's a classic case of federal versus state interpretation."

The case does offer an opportunity to address a question that would otherwise play out in all 50 states, because most of the disputes to date have been in state medical malpractice cases, such as *Tibbs*, says Callahan. A decision by the Supreme Court would give guidance to all state and federal courts around the country as well as to all providers participating in PSOs as well as PSOs. The crux of the issue is whether or not the Kentucky Supreme Court interpretation of the scope afforded under the PSQIA is too narrow. In amicus briefs filed with the court, hospitals and other organizations, such as the American Medical Association (AMA) and the American Hospital Association, have said the interpretation was in fact too narrow.

Callahan, who prepared an amicus brief on behalf of

the University HealthSystem Safety Intelligence PSO that was supported by a dozen of hospitals, PSOs, and associations, including the AMA, adds, "I think the conflict between a state court's clear misinterpretation of a federal law designed by Congress to apply to all license providers around the country, has made it a more interesting case for the Supreme Court to consider."

Furthermore, if the Court agrees to hear the case it will attract more attention to PSQIA and its goal of improving patient care, says Callahan, as well as the required role of PSOs to receive protected adverse event information from its provider members to be analyzed to produce de-identified benchmark studies, safety reports, identify good and bad practices, and conduct similar evaluations to be shared with its members and the federal government.

If the Supreme Court chooses not to hear the case, the status of federal privilege will remain uncertain, says Jaffe. If it doesn't take the case up, many providers will likely not participate in PSOs if they are in states where the courts have not already made a decision regarding the privilege. With the status unknown in various states, there may end up being a patchwork version of the federal program. Jaffe believes this may be one reason the Supreme Court is somewhat interested in this case.

"It took this many years to get a case worthy of Supreme Court review so it'd be a shame for them to pass this up," says Jaffe.

PSQIA and PSOs

PSQIA was passed in 2005 in response to the Institute of Medicine's report "To Err Is Human: Building a Safer Health System," which was published in 1999. The report estimated that each year 44,000 to 98,000 patients die in hospitals as a result of preventable medical errors. The majority of these errors, the report states, were not due to individuals' lack of training or recklessness, but instead were caused by faulty systems and processes.

There were a number of implications and recommendations from the report, Jaffe says, but two were particularly important. The first was a recommendation to develop a mandatory nationwide public reporting to states of severe events for accountability. The second was to develop a voluntary private reporting system for reporting all safety issues, minor and severe, for educational purposes.

"That's what's been done with the patient safety act. It has provided a way for organizations to share their experiences, to learn from each other, and get help from each other," Jaffe says.

One difficulty with redesigning healthcare delivery, Jaffe says, is that it involves complex systems. Changes often create unintended consequences. Changes have to be done by doing smaller experiments and then rolling them up into bigger modifications. However, by doing it as a group, the process is accelerated by allowing providers to tap each other's experience and knowledge.

"This is how aviation really got better. If one airline had a near miss and there was something dangerous about that was found, you'd be incensed if they didn't tell the other airlines. And yet that's how the situation was in healthcare because hospitals would have been penalized for sharing information because they would have lost their ability to defend themselves in court by losing the privilege," Jaffe says.

The fear is that a plaintiff's attorney might come and get everything because the information reported to PSO is typically not protected under various state laws. If the federal law were stripped away, this information would pretty much be public, he adds.

Concerns about how state courts would review these types of cases has inhibited reporting to PSOs, says Jaffe. The types of things that would be reported to PSOs—events, near misses, unsafe conditions, etc.—have previously been held as confidential within individual organizations. "With PSOs we're trying to get these organizations to free up that information and report it to PSOs whilst sharing with each other and really become a learning system. But there are hospitals and other providers who are nervous about the privilege and are waiting to see what the courts do with it before they start reporting," Jaffe says.

Callahan says more guidance is needed. In his talks with organizations and providers, in-house counsels have expressed the most hesitancy. Although the laws may look great on paper, without court decisions there is little direction on how these laws will be interpreted. Whereas in other states, such as Illinois, New York, and Texas, the state statutes have been on the books for some time.

"Here in Illinois there's 50 to 60 appellate court cases that have interpreted our state statute, the Medical

Studies Act. So here we know how it will be interpreted and hospitals have designed their policies to maximize the protections. The statute isn't perfect, but hospitals have done their workarounds and are comfortable with how the protections are to be implemented. When challenged, hospitals usually win these state discovery disputes," says Callahan.

"This outcome is generally true around the country although the state's statutes vary greatly in terms of scope or protected activities and the kinds of healthcare entities which are covered under the law. Also, these state protections do not apply in federal court actions, such as antitrust and discrimination claims."

With the federal law, the question is how providers and PSOs should interpret the PSQIA, as well as the courts, Callahan says. There will be some hesitancy to commit to sharing information if, as occurred in *Tibbs*, courts view the confidentiality and privilege as very limited.

"Needless to say there is some reluctance out there to fully commit to a PSO until we get some clarification, which is why hopefully the Supreme Court will recognize that and take the case," he says.

PSOs and the ACA

Providers currently participating in PSOs aren't the only ones who should be watching for the outcome of *Tibbs v. Bunnell*. A condition of the Affordable Care Act (ACA) set to begin on January 1, 2017, requires hospitals with more than 50 beds to join PSOs if they are contracted to provide healthcare services to patients enrolled in a state insurance exchange.

"If the Supreme Court accepts the case, the decision will be coming out sometime during summer of 2016, which would be five to six months before this requirement goes into effect," Callahan says. "That date will come up quickly for people who aren't already in a PSO."

There will likely be a lot of movement in this area, not just from hospital but also physician groups, nursing homes, surgicenters, and all other licensed entities, especially those operating in multiple states because PSQIA applies nationwide and the protections are generally broader than those provided under state law, Callahan says.

The law was originally set to go in effect in January 2015 and even then there had been a spike in interest as providers were bumping up against the deadline, says Callahan. It was then that the federal government announced that it needed to take another look at the law and pushed it back to 2017 to make sure there would be enough PSOs to accommodate all the additional hospitals.

"There are still a lot of questions out there on how to operationalize PSOs in order to obtain the maximum benefit, especially when there's not a lot of case law out there to give direction, Callahan says.