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The Patient Safety Act goes [back] to Washington

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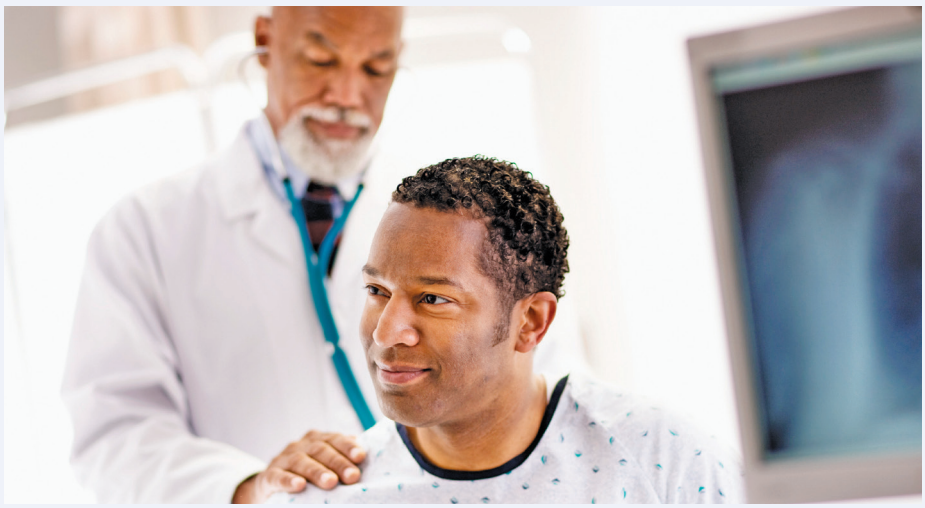

The scope of a little-known but nonetheless significant federal healthcare law, the Patient Safety and Quality Improvement Act ("Patient Safety Act), may soon be considered by the United States Supreme Court. In a petition filed on March 18, 2015, three physicians associated with the University of Kentucky Hospital asked the Supreme Court to hear an appeal of a decision by the Kentucky Supreme Court in *Tibbs v. Bunnell*. At issue in this appeal is whether the fact that certain state laws require the collection and maintenance of information related to patient safety incidents nullifies the federal patient safety privilege and confidentiality provisions that apply to that information when it is collected pursuant to the Patient Safety Act.

The Patient Safety Act was passed by Congress in 2005 in response to a 1999 Institute of Medicine report in which the IOM concluded that a significant number of patients die in hospitals each year as a result of preventable systemic and/or process-based medical errors. The IOM recommended, among other things, that providers be encouraged to share information about patient safety events to facilitate development of best practices and quality improvement. The IOM cautioned, however, that providers would be unwilling to communicate within and among healthcare facilities without confidentiality protections to ensure that such communications would not be discoverable in litigation. Implemented in 2009, the PSQIA calls for the creation of Patient Safety Organizations. PSOs are certified public or private entities that are approved by the Agency for Healthcare Research and Quality and will work with providers to collect and analyze patient safety information to foster improvements in the quality and safety of patient care by applying expert analysis to data collected from a wide array of medical providers.

To facilitate open and effective communications between and among PSOs and providers, the Patient Safety Act contains both privilege and confidentiality provisions that broadly protect information compiled and/or collected for these patient safety and quality improvement purposes. The information collected and/or developed for this purpose is known as Patient Safety Work Product, and it is both confidential and privileged from discovery/admissibility in civil, criminal or administrative proceeding except in certain very limited circumstances. To allow traditional reporting activities to continue, however, the Patient Safety Act

provides that original hospital records and information collected for reporting to state and/or federal regulatory entities are not PSWP; the privilege and confidentiality provisions only apply to information created and/or collected for the purpose of reporting to a PSO. The guidance from the Department of Health and Human Services that accompanied the Final Rule implementing the Patient Safety Act made clear that a state could not compel disclosure of PSWP, and there is a $10,000 penalty for wrongful disclosure of identifiable patient safety work product.

A plain reading of the Patient Safety Act, and the guidance from HHS that accompanied it, makes clear that the privilege and confidentiality provisions are intended to be read broadly to accomplish the goal of creating a "culture of safety" in which patient events can be discussed without blame and the risk of discovery in litigation. This would be a significant change for providers in Virginia, where many courts have applied a narrow interpretation to Virginia statutes protecting post-event analysis. The Patient Safety Act is a whole new animal and it cannot be interpreted by applying existing precedents under Virginia or other state law. The Kentucky Supreme Court, however, didn't see it that way.

The patient whose care was at issue in *Tibbs* allegedly died as a result of complications from an elective spine surgery performed by three physicians at the University of Kentucky Hospital. On the same day as the surgery, a surgical nurse created an incident report through the UK Patient Safety Evaluation System, which is the system used to collect information for reporting to a PSO. Peer review documents and other incident reports are not otherwise privileged from discovery in malpractice litigation under Kentucky law, but the physicians argued that the Patient Safety Act applied to this report.

The estate sought to obtain this particular report through discovery; the physicians sought a protective order barring discovery on the grounds that the report was PSWP. The trial court denied the request for a protective order on relatively narrow grounds, opining that, if the report was prepared by someone involved in the surgery and with first-hand knowledge, it was not PSWP – it was an original medical record. The physicians requested a writ of prohibition against discovery from the Kentucky Court of Appeals, which granted the writ and ordered that the report would be protected from discovery if a review of the report by the trial court revealed that it contained the "self-examining analysis" that the Patient Safety Act was designed to foster. The estate appealed to the Kentucky Supreme Court.

Before deciding that the report in question was not privileged, pursuant to the Patient Safety Act, the Kentucky Supreme Court first considered the purpose articulated by Congress in adopting the Act. The Kentucky Supreme Court, citing the 1999 IOM report, observed that, although malpractice actions had traditionally been the cornerstone of efforts to regulate the quality of patient care, roughly 98,000 people reportedly died each year in the United States from potentially preventable medical errors, many of which were unaddressed through the litigation process and/or through efforts by the joint commission and other bodies to encourage peer review and sentinel-event analysis and reporting.

The Kentucky Supreme Court found the scope of the Patient Safety Act to be even broader than the "self-examining analysis" standard applied by the Court of Appeals, saying that it also extended to data, documents and communications that supported that "self-examining analysis." The court nonetheless found that the report in question was not and could not be patient safety work product because its collection, maintenance and use were required by certain regulatory oversight laws of the Commonwealth of Kentucky. Specifically, the court found that Kentucky Administrative regulations relating to Kentucky hospitals required that administrative reports, including incident and other reports made in the ordinary course of business, shall be established, maintained and used, as necessary, to guide the operation of Kentucky hospitals. "Thus," the court opined, "information normally contained in an incident report is not privileged under the Act and may be discovered…." And, thus, the appeal.

There have been only a handful of cases where trial courts in Virginia have interpreted the scope of the privileges articulated in the Patient Safety Act. Many attorneys arguing for patients have used the same rationale as the Kentucky Supreme Court, arguing that the information must be collected to satisfy other reporting requirements and could not, therefore, be PSWP. The Joint Commission on Accreditation of Healthcare Organizations (joint commission) is one of the entities frequently cited by attorneys for patients as requiring such analysis. Patients argue that, because

this information must be collected and maintained to satisfy the joint commission's requirements, it cannot be PSWP. The joint commission, however, filed an amicus brief on behalf of the three physicians and argued that the Kentucky Supreme Court got it wrong.

The joint commission, which was actively involved in the development of the Patient Safety Act, observed that "the broad patient safety work product privilege Congress adopted in the Patient Safety Act was necessitated by a gap in privilege protection that critically undermined the development and sharing of information in the name of improving patient safety." The joint commission further observed that Congress adopted the patient safety work product privilege, including the express preemption provisions, "to create a nationwide 'culture of safety' where patient risk is minimized through recordation, collaboration, and evaluation free from the fear that such efforts will later be Exhibit A in a civil jury trial." The joint commission reported that Congress's efforts have been successful in that PSOs are improving patient care and safety; the commission also observed that the patient safety work product privilege has played an important part in that success.

The evaluation of "sentinel events" through "root cause analysis" is a prime example. PSOs encourage hospitals to conduct a root cause analysis following any unexpected occurrence involving death or serious physical or psychological injury, or any procedural aberration that, if repeated, would create a significant risk of harm to patients. As the name "root cause analysis" suggests, that mode of analysis requires evaluation of systems and procedures above and beyond what may appear to be an individual mistake. This sort of analysis pays substantial dividends in terms of improving patient care and is made possible, at least in part, by the protection that the patient safety work product privilege provides.

The decision below puts the life-saving progress enabled by methods such as root cause analysis at risk. At worst, a carve-out for medical "information normally contained in" documents subject to a state reporting or record keeping obligations threatens to create an exception that swallows the rule…. As the petition explains, there will nearly always be a colorable argument that patient safety work product is information of the sort "normally contained in" documents subject to a state reporting or record keeping requirement…. As a result, the "normally contained in" exception could render Congress' patient safety work product privilege a nullity and eliminate the critical health care benefits that flow directly from that privilege. The vast majority of states have reporting and recordation requirements resembling the one at issue here….

In addition to the Joint Commission, the American Medical Association, American Hospital Association, Federation of American Hospitals; a number of national PSOs; and a number of hospitals and health systems also joined in briefs in support of the three physicians. In arguing that the United States Supreme Court should take up this issue, the petitioners and their supporters observed that, if the decision by the Kentucky Supreme Court is embraced by other jurisdictions, it will adversely affect efforts by providers to achieve quality outcomes that are part of healthcare reform efforts to Medicare and Medicaid and are intended to help control runaway healthcare costs and reduce patient deaths. In fact, Section 1311(h)(1) of the Patient Protection and Affordable Care Act of 2009 mandates, at some future date, participation with a PSO for any hospital with more than 50 beds before any qualified health plan functioning on the state/federal health care may contract with that hospital. Additionally, the PPACA directs the Secretary of Health and Human Services to develop a program made available to hospitals with high readmission rates to work with PSOs to reduce and/or eliminate preventable readmissions. The Center for Medicare/Medicaid Services is tasked with developing the list of hospitals with high readmission rates. Thus, smaller hospitals and/or facilities that do not intend to participate with the exchanges but which received Medicaid/Medicare funding will also be working with PSOs.

Whether this case will be heard by the Supreme Court has not yet been decided. Health care has certainly been a popular topic of appeals in the last few years, however, and there is no doubt that much clarity could be brought to this issue if the Supreme Court were to provide some guidance. In the interim, healthcare entities should ensure they have the right policies and procedures in place in the event they need to demonstrate that the Patient Safety Act applies to any patient safety activities undertaken by their providers.

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