Medical Law Perspectives
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Three Important Hospital Actions Concerning Incident Report Discovery

In one of the few cases to discuss hospital incident report privilege protections in medical malpractice actions, the administrator of a deceased patient's estate brought this action against a hospital for the failure to adequately monitor and treat the blood glucose levels of the patient. During the litigation, the administrator filed a motion seeking production of reports prepared in connection with the incident alleged to have contributed to the patient's death. The hospital opposed the motion claiming the reports were privileged patient work product under the Patient Safety and Quality Improvement Act.

In one of the plaintiff's written interrogatories, the plaintiff asked the hospital to state whether the incident identified in the complaint was reported to, or investigated by, any hospital or governmental committee, agency, or body. The hospital objected on the basis that the interrogatory sought privileged information, and directed the plaintiff to an attached privilege log, in which it claimed privilege on six documents including incident reports.

The trial court ordered the hospital to produce three documents it had collected within its patient safety evaluation system (PSES), and reported to Clarity PSO, a federally certified patient safety organization.

The Appellate Court of Illinois noted that a party may meet its burden of proving the applicability of a privilege by submitting the allegedly privileged materials for an in camera review or by submitting affidavits setting forth facts sufficient to establish the applicability of the privilege to the particular documents being withheld.

The court determined the reports prepared by the hospital in connection with the incident that allegedly contributed to the patient's death satisfied the requirements for privileged patient work product under the Patient Safety and Quality Improvement Act (Act). The court determined the hospital had demonstrated through its policies, documents, and unrebutted affidavits that the reports qualified as privileged patient safety work product (PSWP) under the Patient Safety and Quality Improvement Act of 2005 (PSQIA) and, therefore, were not discoverable. The court found the reports contained data, discussions, and reflections, which was the sort of information the Act protected, they were prepared by the hospital solely for submission to a federally certified patient safety organization, and the information they contained had the ability to improve patient safety and the quality of health care.

Also, the reports did not lose their status as privileged patient work product under the Act based on the Act's medical records exception merely because the information required to be in the patient's medical record was also contained in the reports and did not mean that the reports were no longer patient work product, and nothing in the record demonstrated that the reports contained information that should have been, but was not, included in patient's original medical records. The reports did not lose their status as privileged patient work product under Act based on the Act's exception for information collected and prepared for purposes other than reporting to a patient safety evaluation system, where an affidavit of the hospital's associate general counsel averred that the reports were assembled solely for submission to a federally certified patient safety organization, and nothing in the record demonstrated otherwise. The reports did not lose their status as privileged patient work product under the Act based on the reporting requirements of the Illinois Adverse Events Law, where, as of the date of the medical malpractice action, the Illinois Department of Public Health had not yet established an adverse health events reporting system, so that the hospital had no reporting obligation.

The court also determined the Federal Patient Safety and Quality Improvement Act preempted the trial court's production order concerning the reports because the Act contained an express preemption clause precluding discovery of patient safety work product in federal, state, or local civil, criminal, or administrative proceedings, the clause demonstrated Congress's intent to supersede any court order requiring production of

documents that met the definition of patient safety work product, and the Act specified that it did not preempt laws requiring the reporting of information that was not patient safety work product.

The court reasoned that the plaintiff has failed to demonstrate that these documents fall under an exception to the definition of patient safety work product, nothing about these documents being privileged renders the facts that underlie the patient safety work product as also privileged, and the plaintiffs can still obtain medical records, as plaintiff did in this case, have their experts analyze and make opinions about those records, and depose doctors and nurses regarding the incident. The court held the incident reports were protected from discovery.

See: Daley v. Teruel, 2018 IL App (1st) 170891 (Ill.App. 1 Dist., 2018).

Medical Law Perspectives: Liability for Electronic and Other Medical Record Information Disclosure

Attorney Michael R. Callahan, a prominent healthcare law practitioner, provides the following lessons from this and other cases to assist risk managers and health providers in making the strongest case against attempts to discover and access incident reports. Michael.callahan@kattenlaw.com

DEVELOP A SPECIFIC AND BROADLY WORDED PATIENT SAFETY EVALUATION SYSTEM (PSES) POLICY

One of the fundamental documents to be introduced to a court in demonstrating that the materials in dispute are indeed patient safety work product (PSWP) under the Patient Safety and Quality Improvement Act is a provider's patient safety evaluation system (PSES) policy. Courts are not going to simply accept the word of a hospital or other provider that information qualifies as PSWP. The provider should conduct an inventory of all its performance improvement, quality assurance, peer review, and other related patient safety activities, as well as the various committees, reports and other analyses being conducted within the organization. This is the starting point when determining the scope of activities risk managers and providers want to include within the PSES and therefore claim is privileged PSWP. The details of these activities and the information to be protected should be reflected within the PSES. When seeking to claim privilege protections over an incident report, committee minutes or other internal analysis, a provider can then cite the specific reference within the PSES as evidence of the hospital's intent to treat this information as privileged. The provider also should include a "catch all" paragraph to account for other privileged patient safety activities that are not included in the PSES policy.

USE SUPPORTING DETAILED AFFIDAVITS

Judges generally are very bright and well-educated individuals but have little practical or substantive knowledge about the inner workings of a hospital or the scope of the ongoing patient safety activities which take place.

The role of the provider and its legal counsel is to effectively educate the court so that judges have a better understanding as to the context of why the disputed materials are indeed PSWP. As was true in the Walgreens and Daley decisions, the Appellate Court in each case relied heavily on the affidavits that were submitted to demonstrate compliance with the PSQIA requirements in order to determine whether the information qualified as PSWP. In the Daley decision, the Appellate Court accepted all of the representations as true, as it is required to do, especially when these representations were not rebutted by the plaintiff.

The types of representations and documents to include with the affidavit include the following:

· The PSO AHRQ certification and recertification letters.

· The provider's PSO membership agreement.

· The PSES policy.

· Screen shots of the redacted forms, reports, etc., for which the privilege is being asserted.

· Documentation as to when the information was reported, either electronically or functionally, or when the information qualified as "deliberations or analysis" under this separate pathway.

· A description of how information is collected within the PSES, and how it qualifies as PSWP, if not otherwise set forth in the PSES.

· A representation as to how the PSWP is used for internal patient safety activities.

· A representation that the information has not been collected for unrelated purposes, such as satisfying a state or federal mandated reporting requirement.

· If possible, a representation that the provider is not required by state or federal law to make the information available to a governmental agency or other third party.

· An affidavit from the PSO acknowledging the provider's membership and that the information, if reported, was received and is being used to further the provider's and the PSO's privileged patient safety activities.

CAREFULLY DESCRIBE YOUR PSWP PATHWAY
As noted by the Appellate Court in Daley, a provider can create PSWP via actual reporting, functional reporting, or through deliberations or analysis.

The PSES policy should specifically identify the materials or information that fall into which pathway. Keep in mind that privileged information via the deliberations or analysis pathway automatically becomes PSWP and cannot be dropped out for another purpose.

Many hospitals, which are members in a PSO, electronically report their incident reports. Incident reports obviously take many different forms. But the reality is a hospital generates hundreds, if not thousands, of incident reports and more likely than not, does not send every single one of them to the PSO. If your PSES policy states all such incident reports are to be reported, but are not in fact sent to the PSO, a plaintiff attorney could argue that the report should not be considered PSWP. If the hospital does want to treat them as PSWP, then these unreported incident and other reports should either be functionally reported or treated as deliberations or analysis.

Michael R. Callahan is a Partner at Katten Muchin Rosenman LLP. He assists hospital, health system and medical staff clients on a variety of health care legal issues related to accountable care organizations (ACOs), patient safety organizations (PSOs), health care antitrust issues, Health Insurance Portability and Accountability Act (HIPAA) and regulatory compliance, accreditation matters, general corporate transactions, medical staff credentialing and hospital/medical staff relations. Mr. Callahan recently served as chair of the Medical Staff Credentialing and Peer Review Practice Group of the American Health Lawyers Association, was appointed as the public member representative on the board of directors of the National Association Medical Staff Services, and was an adjunct professor in DePaul University's Master of Laws in Health Law Program.

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Alice Leiter, J.D: Policy Counsel, Health Privacy Project, Center for Democracy & Technology

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Amanda Parsons, M.D.: Deputy Commissioner of Health Care Access and Improvement, New York City Department of Health and Mental Hygiene

What Policy Steps Should Be Taken to Protect the Privacy of Electronic Patient Health Records?
Nicolas P. Terry, J.D.: Indiana University Robert H. McKinney School of Law

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