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PSO Monthly Brief

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Courts in Several Jurisdictions Test Legal Protections from Patient Safety and Quality Improvement Act of 2005

A question frequently asked by ECRI Institute PSO members and those considering participation with a federally-certified Patient Safety Organization (PSO) is whether any court decisions have yet tested the PSO legal protections. So far, three federal district courts in different judicial circuits have issued decisions related to the Patient Safety and Quality Improvement Act of 2005 and the PSO regulations.

A lesson that can be drawn from them is that providers must be able to demonstrate to a court that the information they seek to protect was assembled or developed for reporting to a PSO. The Act only protects patient safety information that is or will be reported to a PSO.

KD, a minor, et al., v. United States of America

A plaintiff in a lawsuit pending in the U.S. District Court in Delaware sought disclosure of documents related to ongoing peer review monitoring of a National Institutes of Health research protocol involving insertion of pacemakers in children, in which he had participated as a human research subject. The United States, a party defendant, resisted disclosure, asserting privilege under Maryland's medical peer review statute, the federal doctrine of "self-critical analysis," and federal common law privilege. To determine whether the documents should be privileged from discovery, the court engaged in a complex legal analysis.

The court noted that a federal privilege for medical peer review materials had not been recognized in the jurisdiction in which the case was brought and nor were the materials requested protected under the federal Health Care Quality Improvement Act of 1986. Nevertheless, the court concluded that the confidential evaluative materials produced by the National Institutes of Health review process should be protected from discovery based on the public policy evident in Maryland privilege law, the intent of Congress in passing the Patient Safety and Quality Improvement Act, and the circumstances of the case.

The court noted that, by enacting the Patient Safety Act, Congress had shifted its policy from disfavoring privilege toward granting broad confidentiality protections and privilege from disclosure to information collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety. In addition, the court noted that the Act protects all "patient safety work product," and in its remarks cited the definition of patient safety work product from the Patient Safety Act.

Finding a federal privilege applicable in this case, the court emphasized that the privilege would apply only to materials prepared with the expectation that they would be kept confidential and had not in fact been disclosed. (KD, a minor, et al., v. United States of America, No. 7-515-GMS-MPT [U.S. Dist. Ct., Dist. Del. May 25, 2010].)

Schlegal v. Kaiser Foundation

In another case, a health system sought to protect peer review information from discovery by invoking the privilege granted by the Patient Safety Act. The U.S. District Court in California rejected the health system's contention that a report generated by the health system's peer review committees, following investigations by state and federal agencies regarding its kidney transplant program, was protected from discovery by the Act. The court noted that the Act carves out a narrow peer review privilege for work product prepared by a PSO or prepared for and reported to a PSO. The court found no evidence that the investigations conducted by the health system and state and federal agencies were prepared for and reported to a PSO. Additionally, there was no indication that the "mission and primary activity" of any of the relevant entities concerned the goal of patient safety as defined by the statute. (Schlegal v. Kaiser Foundation, No. CIV 07-0520 MCE KJM [U.S. Dist. Ct., Eastern Dist. Cal. Oct. 10, 2008].)

Massi v. Walgreen Co.

A U.S. District Court for the eastern district of Tennessee concluded that the privilege provided under the Patient Safety Act did not apply to various documents relating to an investigation and interviews conducted by a pharmacy with regard to an improperly filled prescription, which allegedly resulted in a patient experiencing a stroke. The court declined to apply the privilege, finding that no adequate showing was made that the information sought was assembled or developed for the purpose of reporting it to a PSO, as that term is defined by the statute. (Massi v. Walgreen Co., No. 3:05-CV-425 [U.S. Dist. Ct., E. Dist. Tenn. Oct. 25, 2006].)

Source: ECRI Institute. Risk Management Reporter, December 2010. These abstracts are a summary of recent court decisions affecting healthcare facilities and their risk management and patient safety programs. When reviewing these abstracts, keep in mind that laws and court decisions vary among jurisdictions and that decisions of lower courts may be overturned on appeal. For specific legal guidance regarding the significance or applicability of this decision, contact legal counsel.

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How Can We Help You?

Whether you have questions about the final rule or want to learn more about ECRI Institute PSO and/or support for other PSOs, we would be happy to hear from you. Please contact ECRI Institute at pso@ecri.org or call (610) 825-6000, ext. 5558.