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HEALTHCARE LITIGATION NEWS

Essential Legal Updates for the Healthcare Industry Fall 2006

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MICHIGAN SUPREME COURT DECISION SIGNIFICANTLY IMPACTS HOSPITAL PEER REVIEW OF PHYSICIAN PRACTICES

Under a long line of cases decided by the Michigan Court of Appeals over a period of almost twenty-five years, the medical staff decisions of private hospitals have not been subject to judicial review. As a result, hospital governing boards have been generally free to make these decisions without fear of interference by state courts. The Michigan Supreme Court's recent decision in *Feyz v Mercy Memorial Hospital* has changed this legal landscape.

This case arose when Dr. Bruce Feyz issued standing orders to nurses regarding medications that were at variance with the hospital's approved standing orders. The hospital instructed the nursing staff to disregard the doctor's orders, and when Dr. Feyz disputed this action, the hospital placed him on indefinite probation. The doctor responded by filing suit in state court.

The trial court dismissed the doctor's case, relying in part on the judicial non-reviewability doctrine and upon Michigan's peer review immunity statute which insulates defendants who participate in peer review from liability for their conduct unless they act with malice. The doctor appealed and the Michigan Court of Appeals reversed the trial court's dismissal of the case. In its opinion reinstating the doctor's case, the Michigan Court of Appeals largely abandoned the established non-reviewability doctrine. The hospital decided to appeal the decision of the Court of Appeals to the Michigan Supreme Court.

One of the issues presented to the Michigan Supreme Court was the applicability of the non-reviewability doctrine to hospital peer review decisions. The Supreme Court acknowledged that lower courts had traditionally not reviewed medical staff decisions by private hospitals, but also stated that this non-reviewability doctrine had never been approved by Michigan's highest court.

After discussing the history and background of the doctrine, the Michigan Supreme Court specifically declined to adopt the doctrine as Michigan law. Instead, the Court stated that cases involving challenges to peer review actions must be decided by applying the Michigan peer review immunity statute. The Court found that this statute grants immunity to persons or organizations that provide information to peer review groups or that perform protected peer review communicative functions. Under this statute, these persons or organizations are protected from suit so long as they act without "malice." The Court defined "malice" as "supplying information or data with knowledge of its falsity or with reckless disregard of its truth or falsity." Thus, persons or committees supplying information or recommendations as part of the hospital peer review process are insulated from liability for their actions so long as they do not know that the information they provide is false, or provide it in reckless disregard of its truth or falsity.

Significantly, however, the Court also found that this immunity did not extend to the hospital itself in making medical staff decisions. Instead, the immunity applied only to the persons and others who participated in the peer review process.

As a result of the Supreme Court's repudiation of the non-reviewability doctrine and its construction of the immunity statute, private hospitals are no longer free, as a matter of state law, to make medical staff decisions without being subject to judicial scrutiny. Hospitals can no longer rely on the non-reviewability doctrine to avoid potential liability for these decisions. Physicians may now be more inclined to legally challenge hospital medical staff decisions.

Physicians and hospitals should be aware, however, that the Michigan Supreme Court's decision in *Feyz* dealt entirely with state law. Hospitals and peer review participants may also be entitled to legal immunity for peer review activities under federal law, specifically the Health Care Quality Improvement Act and/or the Patient Safety and Quality Improvement Act of 2005 (see discussion infra, page 2). The *Feyz* decision did not address the applicability of federal law to peer review decisions. Any challenge to peer review decisions will also require analysis of the applicable provisions of these two Acts.

The *Feyz* decision has altered the legal standards for both physicians and hospitals involved in the peer review process. Legal considerations will have to be carefully analyzed by hospitals and physicians to meet the potential legal challenges that may occur during and after peer review. Competent legal counsel should be consulted by both physicians and hospitals to assist in this process.

PATIENT SAFETY and QUALITY IMPROVEMENT ACT OF 2005 COULD OFFER PROVIDERS BROAD PROTECTION FROM LITIGATION

In response to an Institute of Medicine report finding that medical errors cause approximately 98,000 deaths per year, Congress and the White House enacted the Patient Safety and Quality Improvement Act, which is designed to encourage healthcare professionals to report their errors without fear of being sued or subject to administrative discipline. The Act, however, is effectively in abeyance until the Department of Health and Human Services issues final regulations implementing the Act, which are not legislatively required at any particular time but were expected to be announced as early as September 2006.

Signed into law on July 29, 2005, the Act permits healthcare providers – including hospitals, nursing homes, pharmacies, physicians, nurses, psychologists, social workers, physical therapists and others – to voluntarily and confidentially report medical errors to patient safety organizations. Specifically, providers are entitled to treat as confidential any information that (1) is assembled or developed by a provider for reporting to a patient safety organization and is reported to the organization, (2) is developed by a patient safety organization for the conduct of patient safety activities and could result in improved patient safety, health care quality or health care outcomes or (3) identifies or constitutes the deliberations or analysis of a patient safety evaluation system (i.e., the means by which information is reported to a patient safety organization). Patient safety activities are broadly defined under the Act to include, among other things, efforts to improve patient safety and the quality of healthcare delivery. Such an all encompassing definition could very well protect any activity(even if it does not relate to a medical error) so long as it arguably relates to patient safety and better health care delivery.

The above-listed information, whether it is records, data, memoranda, reports, analyzes (such as root cause analyzes) or oral or written statements, is considered patient safety work product under the Act. Thus, providers, patient safety organizations and others possessing patient safety information cannot disclose the information because it is confidential. The information may not be disclosed pursuant to a federal, state or local civil, criminal or administrative subpoena or order, including those issued in connection with a disciplinary action against a provider. Nor may patient safety work product be subject to discovery in a federal, Michigan or local civil, criminal or administrative proceeding, including any disciplinary proceeding against a provider, or admitted as evidence in any such proceeding. The information is also exempt from discovery under the Freedom of Information Act (or any similar federal, Michigan or local law) and from use in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under Michigan law.

The Act confers providers with enormous protection in litigation if they voluntarily communicate medical error information to a patient safety organization. The key, of course, is that the information be connected to a patient safety organization. The Act is clear that patient safety work product does not include information that is collected, maintained or developed separately from a patient safety evaluation system. If, for example, the information is separately collected by the provider and then reported to a patient safety organization, it is not automatically considered confidential patient safety work product. Original records, such as medical records, billing and discharge information or any other original patient or provider record, are also not patient safety work product, either. It is therefore very important that a provider wishing to invoke the Act's protection for peer review information, root cause analyzes, patient safety information or quality assurance reports contract with and rely on a patient safety organization.

Although the Act does insulate certain information from use in litigation, providers should still be aware that there are a number of exceptions to the Act's confidentiality and privilege provisions. For example, the following information and disclosures are not confidential or protected under the Act:

- Patient safety work product containing material evidence of a criminal act if the evidence cannot reasonably be obtained elsewhere
- Disclosures that allow a reporter of medical errors to seek equitable relief for adverse employment action
- Disclosures needed to carry out patient safety activities

- Patient safety work product sent to grantees, contractors or other entities conducting research to the extent that disclosure of any protected health information contained in the work product would be allowed under HIPAA

Patient Safety and Quality Improvement Act of 2005

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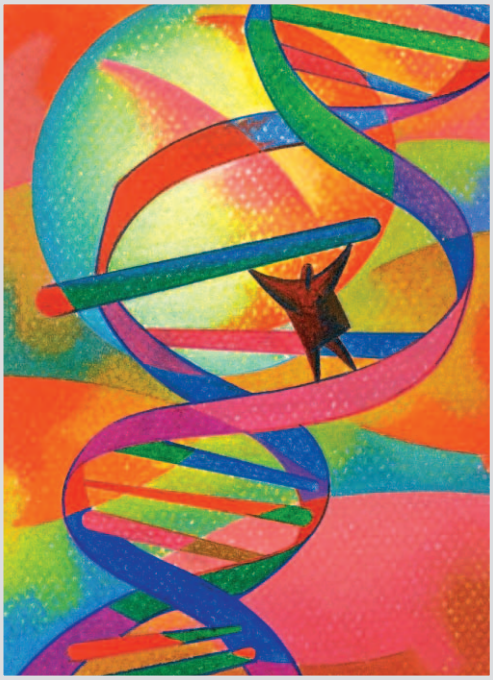
- Disclosures to the FDA with respect to a product or activity regulated by the FDA
- Disclosures deemed by the Department of Health and Human Services as necessary and consistent with the goals of the Act
- Disclosures to law enforcement authorities relating to the commission of a crime
- Voluntary disclosures to an accrediting body
- Disclosures (by any person other than a patient safety organization) that does not include materials that assess the quality of care or describe or relate to one or more actions or inactions by an identifiable provider
- Disclosures of non-identifiable patient safety work product (information that may be disclosed under HIPAA and does not allow for the identification of any particular provider)

Providers who wish to keep information concerning medical errors privileged and confidential should take care not to engage in any disclosures that would be deemed an exception to the protective provisions of the Act. Providers should also take steps to ensure that any medical error information is created, gathered and maintained by a patient safety organization. Any public or private entity can serve as a patient safety organization provided that (1) its mission is to conduct activities that are to improve patient safety and the quality of health care delivery, (2) it has qualified staff, including licensed or certified medical professionals, (3) it has contracts with more than one provider for the purpose of receiving and reviewing patient safety work product, and (4) it is not a component of a health insurance issuer. A patient safety organization may also be a component of an existing organization if the entity maintains patient safety work product separately from the rest of the organization, establishes appropriate security measures to maintain the confidentiality of the patient safety work product, does not make unauthorized disclosures of patient safety work product to the rest of the organization in breach of confidentiality and maintains a mission that does not pose a conflict of interest with the rest of the organization.

As stated earlier, the Agency for Healthcare Research and Quality (a research arm of the Department of Health and Human Services) expected to issue regulations governing patient safety organizations and the certification process as early as September 2006, however no regulations have been published yet. It is possible that these regulations will curtail some of the sweeping protections provided by the Act. In the meantime, providers should think about whether they wish to afford themselves of the protections conferred by the Act since reporting under the Act is voluntary. Once the federal regulations are issued, it maybe that the process of reporting medical errors to a patient safety organization is so burdensome and the risk of litigation from such information so small that an entity determines it is not cost-effective to participate in voluntary reporting. For those providers who are interested in reporting medical error information, they should begin by first identifying potential patient safety organizations with whom to contract. Then, these providers should work on ways to create a patient safety evaluation system that is separate and distinct from other internal peer review and quality assurance processes that may be protected by state law, but not necessarily by the Act. And, although the Act itself penalizes persons who violate the Act, providers should also adopt internal policies that discipline employees for violating the Act, unlawfully disclosing patient safety work product or punishing other employees who report medical errors to the patient safety organization. Finally, any provider engaging in voluntary reporting should consult with competent and qualified legal counsel in order to ensure that the entity's medical error information will be treated as patient safety work product under the Act.



RECENT SEVENTH CIRCUIT CASE REAFFIRMS BURDEN ON PLAINTIFF TO PROVE DEFENDANT ACTUALLY FILED A FALSE CLAIM WITH THE GOVERNMENT

On August 17, 2006, the United States Court of Appeals for the Seventh Circuit held that under the federal False Claims Act, it is not the defendant's burden to show that every claim for payment filed with the federal government was lawful.

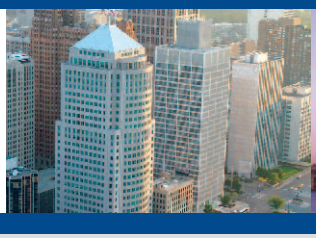
In *United States v. NCS Healthcare of Illinois, Inc. & NCS Healthcare, Inc.*, the plaintiff, a former employee of the pharmacy-defendant, alleged that the pharmacy submitted false claims for payment for medications that had been recycled, repackaged and previously paid for by Illinois Medicaid (funded in part by the federal government) for other patients. The plaintiff, however, could not show one particular recycled medication that had actually been submitted to Illinois Medicaid for payment. Specifically, the plaintiff failed to show that the pharmacy had first submitted a claim for payment for a medication for one patient, recycled the medication for use by another patient and then submitted another claim for the same medication to Illinois Medicaid.

To overcome this problem, the plaintiff asserted that she did not need to make this showing. Instead, she claimed that the pharmacy failed to keep records of the submissions and thus, had contaminated the evidence needed to prove her case under the False Claims Act. Because of this "contamination," the plaintiff argued that it was impossible for her to tie a particular recycled medication to a particular submitted claim.

The Seventh Circuit disagreed. Following the lead of the three other federal circuits that have addressed this issue, the Court of Appeals stated that the plaintiff had the burden to establish that at least once, Illinois Medicaid had paid for a medication that had been returned to the pharmacy, re-dispensed by the pharmacy and then rebilled to Medicaid. The plaintiff could not shift this burden of identifying a false claim from herself to the defendant. Such a finding would defy the plain language of the False Claims Act. The Court recognized that no relevant False Claims Act case establishes that the defendant has the obligation to prove that every claim it ever filed was lawful and it acknowledged that the mere fact that the pharmacy kept horrible records would not make this so.

The Court of Appeals for the Sixth Circuit (reviewing federal district court cases from Michigan) may follow the Seventh Circuit's ruling, which appears to reaffirm the principle that in order to state a False Claims Act claim against healthcare providers, plaintiffs must show that an identifiable and false claim was submitted to a government entity for payment. Absent such a showing, Michigan providers should be entitled to dismiss these actions against them.

For further information about this legislation or other healthcare matters contact the authors David French (734.668.7783) or Sonal Mithani (734.668.7786).



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