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New Federal Law May Expand Legal Protections for QA Documents

On July 29, 2005, President Bush signed the Patient Safety and Quality Improvement Act of 2005 ("PSQIA"). From a global perspective, the new law creates a system of review organizations that encourages the sharing of information on patient safety and medical errors, free from concerns that such information could be used in litigation and disciplinary proceedings. From a practical perspective, the new law broadens confidentiality and legal privilege protections for peer review and quality assurance activities in ways that may overcome certain disincentives found in current law that discourage active provider participation in such activities. Particularly in states like New York, where records related to peer review activities are routinely available to licensing and disciplinary bodies, where any statements (written or oral) made by the physician-targets of peer review are given no protections against disclosure, and where certain legal protections are not available in settings such as ambulatory surgery centers and nursing homes, the new law is welcome news.

The PSQIA creates extensive legal privileges for, and prohibits disclosure of, "patient safety work products" developed by or for newly-created "patient safety organizations". Notably, the new law preempts state laws that are not as protective of the documentation created in the course of such activities while leaving intact state laws that afford greater legal protections.

Under the new law, anything meeting the definition of "patient safety work product" will not be subject to any subpoena or administrative order (state, federal, or local), nor will it be discoverable or admissible in any civil, criminal, administrative, and/or any professional disciplinary proceeding (except proceedings alleging lack of good faith by a patient safety organization itself). In addition to the legal privilege, the law requires that patient safety work products must be

kept confidential and must not be disclosed, unless one of a few exceptions applies.

There are several exceptions, but even if one applies, the legal privilege and/or the confidentiality requirement are retained for all purposes other than the specific use or disclosure permitted by the exception. In other words, the patient safety organization can voluntarily use information pursuant to an exception, without endangering the legal privilege or the prohibition on disclosure, for all other purposes.

The law provides that to be certified as a "patient safety organization", the primary activity of the applicant-entity must be to improve patient safety and the quality of health care and it must have appropriate staffing and policies to support the stated patient safety activities. There are other specific requirements and it is expected that the forthcoming regulations will expand upon those particulars.

The law envisions that component entities of larger organizations (such medical staffs of hospitals or other health care providers) could be certified as patient safety organizations. While much depends on the regulations it is conceivable that a medical staff, medical affairs department or other component of a health care provider, or a large physician practice, could qualify as a patient safety organization. If this were to occur, it is possible that a good portion of what is typically done in a quality improvement or peer review program could be conducted within the confines of the patient safety organization and thus be afforded the protections created by the new law. In New York, this approach might offer a potential method for closing the "gaps" in the current state peer review and quality assurance laws.

No timetable is yet available for development of the implementing regulations.

OPMC Finding Binding in Civil Action

Applying the legal doctrine of *collateral estoppel*, a New York Supreme Court judge recently held that a physician could not contest liability in a civil action following a finding by the Office of Professional Medical Conduct (OPMC) that the physician committed a battery on the plaintiff. *Richards v. Smith*, NY Slip Op. 25347 (Kings County, July 5, 2005). At its administrative hearing, OPMC unanimously concluded that the physician inappropriately touched the plaintiff during a physical examination. As a result, the physician's medical license was revoked. The patient subsequently brought a civil action for assault and battery against the physician. The judge in the civil action granted the patient's motion for summary judgment on the issue of the physician's liability for battery, noting that it was the same as that in the OPMC hearing, and that the physician had a full and fair opportunity to contest the battery allegation at the OPMC hearing, having been represented by counsel and afforded the right to testify and call witnesses on his behalf. The judge's ruling was in line with prior holdings that an administrative determination may preclude further litigation of the same claim or issue, and was made despite the physician's acquittal in the criminal action preceding the OPMC hearing.

Legislation Establishes New Hospital Reporting Requirements

Governor Pataki recently signed new legislation requiring hospitals to track, report and make public patient infection rates. The legislation, which was supported by both Healthcare Association of New York State and the Greater New York Hospital Association, requires hospitals to report infections that were not present at time of the patient's admission (so-called hospital-acquired infections). The New York State Department of Health is to establish a statewide database of all reported hospital-acquired infections, as well as a summary that will be easily understood by consumers. The Department will also make grants available to hospitals for implementing staff education and training in hospital-acquired infection prevention and control.

Under the Department of Health's Statewide Planning and Research Cooperative System (SPARCS), New York hospitals are required to report to certain information,

including hospital inpatient, ambulatory surgery and emergency department data (Public Health Law § 2816). A new provision of the law now requires hospitals to report data concerning patients who are transferred, admitted or treated by the hospital subsequent to a medical, surgical or diagnostic procedure performed by licensed health care professionals at office-based sites or in other non-hospital settings. The official justification of the law is to "provide the State with necessary data to identify deficiencies in the safety of non-hospital-based health facilities and procedures". To review the legislation go to: <http://www.assembly.state.ny.us/leg/?bn=A04122&sh=t>

Compliance Corner

New York Hospitals Pay Millions to Settle Medicaid Whistleblower Suits

Pursuant to settlement agreements with the federal government in whistleblower lawsuits, Mount Vernon Hospital and Catskill Regional Medical Center agreed to pay \$2.65 and \$1.5 million, respectively, to settle claims that they paid illegal kickbacks for the referral of Medicaid patients in need of chemical dependency treatment services. Neither hospital admitted any wrongdoing in the settlements. According to the whistleblower's attorneys, in the case of Catskill Hospital, the payments were made pursuant to "sham" administrative services agreements with a case management company for administrative services that were rarely provided, had no monetary value or were duplicative of services already provided by the Hospital. In the Mount Vernon case, the Hospital was not licensed to provide chemical dependency services and, therefore, could not bill for the services but paid "patient brokering fees" for patients and consulting fees under a sham agreement. For his efforts, the whistleblower, an employee of a company related to the case management company, will receive \$530,000 from Mount Vernon Hospital and \$300,000 from Catskill Hospital, plus payment by the Hospitals of all his attorney fees.



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