

Client Newsletter

In This Issue:

President Bush Signs Patient Safety and Quality Improvement Act of 2005.1

U.S. District Court Upholds Peer Review Privilege2

Charity Care Litigation Update.3

Supreme Judicial Court Upholds Revocation of Physician’s Medical License . 4

IRS Issues Proposed Regulations on Intermediate Sanctions5

OIG Issues Favorable Advisory Opinion on Proposed Donation to Medical School. . 6

Medical Liability Reform Bill Passes U.S. House.7

President Bush Signs Patient Safety and Quality Improvement Act of 2005

On July 29, 2005, President Bush signed into law the “Patient Safety and Quality Improvement Act of 2005” (“Act”). The Act creates a voluntary system for health care providers to confidentially report medical errors and other patient safety information to patient safety organizations (“PSOs”). The legislation comes in response to a recent Institute of Medicine Report which indicates that medical errors are the eighth leading cause of death in the United States.

The legislation provides that the U. S. Department of Health and Human Services (“HHS”) will certify both public and private entities as PSOs whose primary activity will be to improve patient safety and the quality of health care. Any entity or individual that is licensed or certified under state law to provide health care services, including but not limited to, hospitals, long-term care facilities, pharmacies, clinical laboratories, physicians, physician assistants and nurse practitioners, may voluntarily report medical errors and other patient safety information to PSOs. The PSOs will analyze the information which is submitted in order to develop strategies for improving patient safety.

The information submitted by health care providers to PSOs will be referred to as “Patient Safety Work Product” (“PSWP”). The Act defines PSWP as data, reports, records, memorandum, analyses and written or oral statements that : (1) are assembled or developed by a provider, are reported to a PSO, and could result in improved patient safety or health care quality; (2) are developed by a PSO to conduct patient safety activities and could result in improved patient safety or health care quality; or (3) identify or constitute the deliberations or analysis of a patient safety evaluation system or identify the fact of reporting pursuant to a patient safety evaluation system.

PSWP is confidential and privileged under the Act. The legislation provides that PSWP: (1) is not subject to subpoena or discovery in a federal, state or local, criminal, civil or administrative proceeding; (2) is not subject to disclosure under the federal Freedom of Information Act; and (3) may not be admitted in a professional disciplinary proceeding of a professional disciplinary body. The Act does, however, set forth circumstances under which PSWP can be disclosed. PSWP can be

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disclosed: (1) in a criminal proceeding, if a court makes an in camera determination that the PSWP contains material evidence of a criminal act; (2) in a civil action brought by an individual to enjoin adverse employment action against him/her based on his/her good faith report of PSWP; or (3) if the disclosure is authorized by each provider identified in the PSWP. The Act does not pre-empt state confidentiality and/or privilege protections which provide more stringent confidentiality for PSWP type material. Also, the Act provides for a civil monetary penalty of up to \$10,000.00 for the knowing or reckless disclosure of identifiable PSWP in violation of the Act.

In addition to the confidentiality provisions pertaining to PSWP, the Act also provides that an adverse employment action cannot be taken against an individual for a good faith report of PSWP to a PSO. Furthermore, an accrediting body may not take action against a provider based on the provider's good-faith participation in reporting of PSWP.

It is important to note that the reporting of PSWP to PSOs by health care providers is voluntary and there is no action taken against a provider for not reporting this information. HHS will be publishing implementing regulations pertaining to the Act. The Rogers Law Firm will monitor these regulations and will provide updates accordingly.

U.S. District Court Upholds Peer Review Privilege

The U.S. District Court of Massachusetts recently refused to order Blue Cross Blue Shield of Massachusetts, Inc. ("Blue Cross") to turn over confidential peer review materials sought by the U.S. Government as part of a healthcare fraud investigation. The case, In re: Administrative Subpoena Blue Cross Blue Shield of Massachusetts, Inc., 2005 WL 1801694 (D. Mass.), concerns an investigation by the U.S. Department of Health and Human Services ("HHS") of a physician who had been diagnosing patients with a rare disease, who either did not have the disease or who have not been subjected to enough tests to determine whether or not they had the disease. HHS alleges that the physician then billed Medicaid and/or Medicare fraudulently for expensive specialized treatment which is used to treat patients with the disease. The Government has been investigating the physician to determine whether or not this conduct amounts to healthcare fraud.

As part of its investigation, the Government subpoenaed several documents from Blue Cross. Although Blue Cross complied with the subpoena, it declined to produce documents from its Medical Peer Review Committee. Blue Cross indicated that the Medical Peer Review Committee was in the process of conducting an internal investigation of the physician. Pursuant to Blue Cross' refusal to produce the materials from its Medical Peer Review Committee, the Government brought a motion in Federal Court to compel Blue Cross to produce the peer review documents. Although there is no Federal medical peer review privilege, the U.S. District Court of Massachusetts is bound by the law of the U.S. First Circuit Court of Appeals. In the First Circuit's decision of In re: Hampers, 651 F. 2nd 19, 22-3 (First Cir., 1981), the Court held that a State privilege should be recognized in a Federal case if (a) the forum state recognizes the privilege, and (b) the privilege is "intrinsically meritorious." The Government acknowledged that Massachusetts recognizes a medical peer review privilege. However, the Government argued that the privilege is not intrinsically meritorious to the case. Whether or not a privilege is "intrinsically meritorious" is determined by a four-part analysis: (i) whether the communications "originate in confidence that they will not be disclosed"; (ii) whether this element of confidentiality is essential to the full and satisfactory maintenance of the relations between the parties; (iii) whether the relationship is a vital one which ought to be "sedulously fostered"; or (iv) whether "the injury that

would inure to the relation by the disclosure of the communications would be greater than the benefit thereby gained for the correct disposal of litigation.”

The Court found that the first three factors of the four-part analysis were met in this case. As to the fourth factor regarding whether or not the injury that would inure to the relation by the disclosure of the communication would be greater than the benefit thereby gained for the correct disposal of litigation, the Court looked to the Affidavit submitted by the Medical Director of Blue Cross. In his Affidavit, the Medical Director stated that “Blue Cross believes that the ability to conduct peer review of providers in its networks will be hampered if it is ordered to produce materials it deems protected by the medical peer review privilege. While it was difficult at times to retain outside consultants to perform the reviews necessary for the process, it would be almost impossible to retain the experts if the process were subject to public disclosure. Moreover, other institutions might be unwilling to share information with Blue Cross if Blue Cross is unable to maintain the confidentiality of this information.” In response to this Affidavit, the Government submitted an Affidavit from a special agent involved in the investigation. The investigator’s Affidavit stated that the underlying purpose of the investigation is to “combat fraud against the Federal Government.” In its decision, the Court ruled that the Government must give a more “particular answer” to indicate why the peer review records are particularly needed. Based on the Government’s failure to provide a more particular answer as to why the peer review documents were needed, the Court held that Blue Cross had demonstrated that injury would inure to the peer review process if disclosure of materials were ordered and refused to order Blue Cross to produce the documents.

Charity Care Litigation Update

Beginning in the summer of 2004, several class action lawsuits were filed in U.S. District Courts against non-profit hospitals and health care systems in regard to their alleged failure to provide free or discounted care to uninsured patients. These lawsuits alleged that tax exemptions conferred upon these non-profit hospitals and health care systems under state and federal law, create a contract between these organizations and the government. The uninsured plaintiffs claim that they are third-party beneficiaries of these contracts. Pursuant to these purported contracts, the plaintiffs allege that the hospitals are obligated to provide free or reduced cost care to uninsured patients. The Plaintiffs have further alleged that non-profit hospitals have been unjustly enriched through deceptive and unfair billing and collection activities.

Since the first lawsuits were filed in the summer of 2004, there have now been more than seventy-five (75) lawsuits filed in federal courts. These lawsuits implicate over 500 hospitals and health care systems in twenty-nine states. The American Hospital Association (AHA) has been named in many of these lawsuits. The lawsuits allege that AHA has been involved in a conspiracy with these non-profit hospitals by advising its members to charge their uninsured and underinsured patients more than patients who are covered by Medicare, Medicaid or private insurance.

Attorneys for the Plaintiffs in these charity care litigation cases, led by Richard Scruggs, a well-known tobacco trial lawyer from Mississippi, have banded together in an effort to gain leverage in the litigation. However, a request to consolidate all of these cases was denied by the Judicial Panel on Multidistrict Litigation. The Court held that the Plaintiffs failed to show that the “actions share sufficient common questions of fact” to warrant the consolidation of the cases in one federal court.

The hospital defendants have responded to these lawsuits by filing motions to dismiss. To date, twenty-seven of these federal cases have been dismissed in part or altogether. The basis for these dismissals have ranged from lack of standing to failure to state a claim upon which relief can be granted. Furthermore, no court has supported the plaintiffs' claims that federal and state tax exemption creates a third-party beneficiary contract to provide free or discounted care to uninsured patients. In Harrington, et al. v. Baystate Medical Center, et al., the only charity care litigation to be filed in the U.S. District Court of Massachusetts, the Court dismissed (with no published opinion) all of the Plaintiffs' claims. The Plaintiffs have appealed the court's decision to the U.S. First Circuit Court of Appeals. The lead Plaintiff in the case, Diane Harrington, was treated at Baystate Medical Center after falling down a set of stairs. Ms. Harrington, who does not have health insurance, could not afford to pay Baystate's bill of \$2,983.04. According to the Complaint, Baystate Medical Center charged a 12% annual interest to Ms. Harrington's bill and threatened to seize her personal property.

As a result of the numerous dismissals of these cases from federal courts, Plaintiffs' attorneys have appeared to change strategy and are now voluntarily dismissing the remaining cases which have been filed in federal courts, and have been re-filing them in state courts. They have also changed the focus of their allegations. Whereas previously in Federal Court the Plaintiffs focused on the theory that federal and state tax exemption creates a third-party beneficiary contract to provide free or discounted care to uninsured patients, the Plaintiffs have now changed their theory to allege that charging the uninsured full, undiscounted rates for hospital services is discriminatory and unlawful. This theory is based on the fact that hospitals discount services to insured patients based on the rate negotiated by the patient's insurer (e.g. Tufts, Blue Cross/Blue Shield). However, these hospitals are still charging uninsured patients the full, undiscounted rate for these same services. This switch in theory by the Plaintiffs has only occurred recently, and therefore, it is unclear as to whether or not the courts will be receptive to this argument. Nevertheless, many legal analysts agree that this new theory has a much greater likelihood of success than the third party beneficiary theory proposed by the Plaintiffs in Federal Court.

It is interesting to note that early on in this litigation, one of the Defendants, North Mississippi Health Services, announced a memorandum of understanding for a settlement agreement with the Plaintiffs in their case. The memorandum provided for \$150 million in future discounts and free care to uninsured patients, and \$200,000 in refunds to uninsured patients who had actually paid for services. Despite this memorandum of understanding, North Mississippi Health Services withdrew from the settlement, citing "the devastating economic impact" it would have on the system. Counsel for the Plaintiffs in that case have now filed a motion with the court requesting that the memorandum of understanding be enforced.

Supreme Judicial Court Upholds Revocation of Physician's Medical License

On August 11, 2005, the Massachusetts Supreme Judicial Court ("SJC") held that the Massachusetts Board of Registration in Medicine ("Board") did not violate a physician's due process rights when it revoked his license to practice medicine following his two convictions for Medicaid fraud. The case, Kobrin v. Board of Registration in Medicine, 444 Mass. 837 (2005), concerns the medical license of Dr. Kennard Kobrin, a board certified psychiatrist. In December of 2002, a jury convicted Dr. Kobrin of Medicaid fraud for referring patients to a psychologist who conducted tests that were medically unnecessary. In November of 2004, the Board revoked Dr. Kobrin's license to practice medicine. The Board found that it had the authority to discipline a physician whose conduct undermines public confidence in the integrity of the profession. Dr. Kobrin appealed the Board's decision to the SJC.

Pursuant to Massachusetts General Laws, Chapter 112, Section 5(g), the Board has authority to take action against a physician who has been convicted of a crime. Furthermore, pursuant to the SJC's ruling in Levy v. Board of Registration, 378 Mass. 519 (1999), the Board also has the authority to discipline a physician whose conduct undermines the public confidence in the integrity of the medical profession or who lacks good moral character. In his appeal, Dr. Kobrin argued that the legal principle of res judicata, precluded the Board's revocation of his license. Res judicata refers to both claim preclusion and issue preclusion. Claim preclusion makes a valid final judgment conclusive on the parties and prevents re-litigation of matters that were or could have been adjudicated in the action. Similarly, issue preclusion prevents re-litigation of an issue determined in an earlier action where the same issue arises in a later action, based on a different claim, between the same parties. Dr. Kobrin claimed that because the Board had dismissed a matter brought against him in 2000 involving allegations that he had illegally prescribed drugs to patients and otherwise provided sub-standard psychiatric care, the Board should be precluded from now revoking his license. The SJC held that the issue of res judicata did not preclude the Board from revoking his license. The Court stated that Dr. Kobrin's conviction in December of 2002, was more than two years after the Board issued its decision concerning the illegal prescription of drugs and sub-standard care of patients. Therefore, it was clear that the Board could not have previously litigated his Medicaid fraud convictions as those convictions had not yet occurred.

Dr. Kobrin also argued that he was entitled to an adjudicatory hearing before the Board where he could present evidence concerning the wrongfulness of his convictions. The SJC acknowledged that due process requires that Dr. Kobrin be given a hearing. However, the Court held that Dr. Kobrin was only entitled to a hearing to present mitigating factors, an explanation of his actions and to address the issue of the appropriateness of the sanction. Neither the pertinent statute, M.G.L., c. 112, §5, nor due process, require the Board to hold a hearing to take evidence concerning undisputed facts. The Court stated that such a hearing would be a "meaningless exercise." Dr. Kobrin had responded to the Board's allegation by admitting that he had been convicted and sentenced. The Court held that the Magistrate properly could rely on Dr. Kobrin's convictions as proof that he engaged in conduct that called into question his ability to practice medicine, and therefore, there was no issue of material fact for which a hearing was required. Furthermore, Dr. Kobrin had been permitted an opportunity to present mitigating factors in regard to his revocation through his memorandum on disposition to the Board. In conclusion, the Court found that Dr. Kobrin had not demonstrated any "extraordinary circumstances" that would justify the Court's interference in the Board's revocation of his license.

IRS Issues Proposed Regulations on Intermediate Sanctions

On September 9, 2005, the Internal Revenue Service ("IRS") issued a notice of proposed rule making in the Federal Register (70 Fed. Reg. 53599) clarifying the relationship between the requirements for tax exemption under Section 501(c)(3) of the Internal Revenue Code ("Code") and the imposition of excise taxes under Section 4958 of the Code. The proposed regulations provide guidance with respect to what factors the IRS will consider in determining whether a 501(c)(3) organization that engages in one or more excess benefit transactions could lose its tax exemption under Section 501(c)(3).

Pursuant to Section 4958 of the Code, any 501(c)(3) organization which engages in an excess benefit transaction may be subject to intermediate tax sanctions by the IRS. An excess benefit transaction is a transaction in which any economic benefit is provided by an applicable tax-exempt organization to a disqualified person (board member, senior manager, or other individuals who have substantial influence over

the affairs of the organization) if the value of the economic benefit provided exceeds the value of the consideration derived for providing the benefit. The sanctions are considered intermediate, because they are between the IRS not taking any action and a complete revocation of exemption. If a 501(c)(3) organization engages in an excess benefit transaction, the disqualified person who benefited must correct the transaction or repay the amount by which the benefit exceeded fair market value. Furthermore, the disqualified person and organization managers who knowingly participate in the transaction are subject to excise taxes. The proposed regulations issued by the IRS, set forth examples in which the IRS appears to take the position that organizational managers who are aware that an excess benefit has been conferred, but do not act to terminate and correct that transaction, are equally as culpable as managers who actively participated in approval of the transaction.

The proposed regulations indicate that the IRS will apply a “facts and circumstances” test in order to determine whether to revoke the tax-exempt status of a 501(c)(3) organization which engages in an excess benefit transaction. The facts and circumstances which will be considered include: (1) the size and scope of the organization’s exempt activities before and after the excess benefit transaction; (2) the size and scope of the excess benefit transaction in relation to the size and scope of the organization’s exempt activities; and (3) whether the organization has been involved in multi-excess benefit transactions. The proposed regulations also set forth the following facts and circumstances which might mitigate against the revocation of exempt status: (1) the organization’s implementation of safeguards that are reasonably calculated to prevent future violations; and (2) correction of the excess benefit transaction.

The IRS is accepting comments on the proposed regulations until December 8, 2005.

OIG Issues Favorable Advisory Opinion on **Proposed Donation to Medical School**

The Office of Inspector General (“OIG”) of the United States Department of Health and Human Services, issued a favorable Advisory Opinion on August 16, 2005, regarding a proposed donation of a medical office building by a for-profit hospital corporation to a state-affiliated medical school. The Advisory Opinion, which does not identify by name any of the parties involved, concerns a three-story medical office building located on the campus of one of the corporation’s for-profit hospitals. The building will be used by the medical school to operate a Family Medicine Outpatient Clinic.

The parties involved requested an Advisory Opinion from the OIG as to whether or not the donation of the building would violate the Anti-Kickback Statute. The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. In its analysis, the OIG commented that under the Anti-Kickback Statute the proposed donation is “problematic”, as it involves a substantial one-time donation by a hospital to a referral source. The medical school employs, and is affiliated with, physicians who make referrals to the hospital. Therefore, the medical school is a referral source for the hospital.

Despite its concerns regarding the involvement of a referral source, the OIG concluded that it would not impose sanctions on the proposed donation for the following reasons: (i) the proposed donation will confer a community benefit on the clinic’s patients, most of whom are either Medicaid beneficiaries or uninsured; (ii)

the proposed donation continues a common mission that the medical school and the hospital have shared for thirty years – training physicians and providing quality medical care; (iii) the medical school has certified that it will take a number of steps to insulate physician judgment and income from pressure to refer patients to the hospital; and (iv) the medical school will own, operate and maintain the building for use by the medical school.

The Advisory Opinion affirms the OIG’s position that charitable donations play an essential role in sustaining and strengthening health care.

Medical Liability Reform Bill Passes U.S. House

On July 27, 2005, the United States House of Representatives passed the “Help Efficient, Accessible, Low Cost, Timely Healthcare (HEALTH) Act of 2005” (the “bill”). The bill, which was introduced by Representative Phil Gingrey (R-Georgia), passed by a margin of 230-194. The bill places a \$250,000.00 cap on non-economic damages in medical malpractice actions and limits punitive damages to the greater of twice the amount of economic damages or \$250,000.00. The Bill was filed in an effort to control rising malpractice insurance premiums and to ensure affordable, high quality health care.

A similar piece of legislation, the “Patients First Act”, recently failed in the United States Senate by a vote of 49 to 48. The Senate bill also contains a cap of \$250,000.00 on non-economic damages. Senate Majority Leader Bill Frist has indicated his intention to schedule a second vote on the bill in October. There is already some preliminary discussion of a potential compromise between the Senate and the House regarding the \$250,000.00 cap.

In accordance with M.G.L., c. 231, §60H, in a Massachusetts medical malpractice action, the jury is instructed that if it finds the defendant liable, it is not to award the plaintiff more than \$500,000.00 for pain and suffering, loss of consortium, embarrassment, and other items of general damages, unless it determines that there is substantial or permanent loss or impairment of a bodily function or substantial disfigurement, or other special circumstances in the case that warrant a finding that the imposition of such a limitation would deprive the plaintiff of just compensation for injuries sustained. Most analysts agree that the Massachusetts cap has been largely ineffective in diminishing pain and suffering jury awards against Massachusetts physicians.

The Rogers Law Firm will continue to monitor the Medical Liability Reform Bill and will provide updates accordingly.

This Newsletter is published by The Rogers Law Firm to keep its clients informed of developments in health law. The Newsletter should not be construed or relied upon as legal advice or legal opinion on any specific facts or circumstances. If you have any questions or concerns regarding the articles contained in the Newsletter or would like legal advice or legal opinion concerning a specific matter, please do not hesitate to contact any of the attorneys at The Rogers Law Firm, at (617) 723-1100.