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In This Issue:

HHS Publishes Final HIPAA Enforcement Rule 1

Legislation Amends Massachusetts Medical Record Retention Requirements 2

OIG Excludes Hospital From Participation in Federal Health Care Programs. 2

MedPAC Proposes Changes to Medicare Program 3

FDA Issues Guidance on Hospital Bed Designs……… .3

Legislation Proposed to Protect Financial Privacy of Non-Profit Employees. 4

Amendments Proposed to Public Charities Legislation. 5

SJC Outlines Basis for Invading Peer Review Privilege……………………..6

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HHS Publishes Final HIPAA Enforcement Rule

On February 16, 2006, the United States Department of Health and Human Services ("HHS") published the Final HIPAA Enforcement Rule ("Enforcement Rule"). The Enforcement Rule replaces the interim rules which were issued by HHS in 2003. The Enforcement Rule details the bases and procedures for imposing civil monetary penalties on covered entities that violate any of the administrative simplification rules of the Health Insurance Portability and Accountability Act ("HIPAA"). The administrative simplification provisions include standards for transactions, code sets and the security and privacy of individually identifiable health information. The Centers for Medicare and Medicaid Services ("CMS") states that the Enforcement Rule "covers the enforcement process from its beginning, which would usually be a complaint or compliance review, through its conclusion. A complaint or compliance review may result in an informal resolution, a finding of no violation, or finding of a violation. If a finding of violation is made, a civil monetary penalty will be sought for a violation, which can be challenged by the covered entity through a formal hearing and appellate review process."

The Enforcement Rule provides that HHS must impose a civil monetary penalty against a covered entity if it determines that a HIPAA violation has occurred. The Secretary for HHS cannot impose a civil monetary penalty in the amount of more than $100.00 for each violation or in excess of $25,000 for identical violations during the calendar year. In determining the amount of any civil monetary penalty, HHS may consider the following factors: (a) the nature of violation, in light of the purpose of the rule violated; (b) the circumstances, including the consequences, of the violation, including but not limited to (1) the time period during which the violation(s) occurred, (2) whether the violation caused physical harm, (3) whether the violation hindered or facilitated an individual's ability to obtain health care and (4) whether the violation resulted in financial harm; (c) the degree of culpability of a covered entity (i.e. whether the violation was intentional or beyond the direct control of the covered entity); (d) the history of prior compliance with the administrative simplification provisions; (e) the financial condition of the covered entity; and (f) such other matters as justice may require.

The Enforcement Rule is effective as of March 16, 2006.

Legislation Amends Massachusetts Medical Record Retention Requirements

State Senator Richard Moore has filed legislation with the Massachusetts Legislature, which seeks to amend the medical record retention requirements of hospitals and clinics in Massachusetts. The legislation, entitled "An Act Regarding Medical Record Retention Requirements" ("Act") amends Section 70 of Chapter 111 of the Massachusetts General Laws, to reduce the time period for which a hospital or clinic must maintain a patient's medical record after the discharge or final treatment of the patient from thirty to fifteen years. The Act also requires hospitals and clinics to notify patients of the revised medical record retention period and that records will be terminated after the retention period has elapsed.

The Act also amends M.G.L., c. 111, § 70 to require that medical records maintained by a hospital, in any form, be kept for the applicable retention period. In its current form, M.G.L., c. 111, § 70 provides that when medical records have been "photographed or micro-photographed", the hospital, upon notifying in writing the Supervisor of Public Records, may destroy the original records so photographed and micro-photographed and such photographs and micro-photographs shall have the same force and effect as the original records from which they were made. The Act, however, amends M.G.L. c. 111, § 70 to provide that medical records, in any form, must be kept for the applicable retention period and can only be destroyed upon notifying the Department of Public Health that the applicable retention period has lapsed and the records will be destroyed. Therefore, those hospitals which seek to save storage space by transforming medical records onto microfilm and then destroying the original medical records will, if the Act is passed, be required to maintain both the hard copy and the microfilm copy of the patient's medical record.

The Joint Committee on Public Health has recommended favorable action on the Act. The Rogers Law Firm will continue to monitor the legislation and will provide updates accordingly.

OIG Excludes Hospital From Participation in Federal Health Care Programs

On March 10, 2006, the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") announced that it was excluding Miami's South Beach Community Hospital from participating in Medicare, Medicaid and all other federal health care programs. The announcement marks only the second time in HHS' thirty-year history that a hospital has been excluded from federal health care programs.

South Beach Community Hospital is a private, for-profit hospital which was formerly a not-for-profit entity known as South Shore Hospital and Medical Center. In 2002, the hospital entered into a Corporate Integrity Agreement ("CIA") with the OIG, as part of the resolution of a False Claims Act case brought against the hospital. As part of the CIA, the hospital agreed to take certain actions to ensure the appropriate submission of future claims for payment to federal health care programs. In December of 2005, the OIG notified the hospital that it had violated the CIA by failing to meet multiple reporting requirements, and failing to retain an Independent Review Organization to perform required audits. The OIG notified the hospital that it considered these failures as material breaches of the hospital's obligations under the CIA. The OIG provided the hospital with thirty days to demonstrate that it had cured the breaches or that it was timely pursuing cure of the breaches

with due diligence. Shortly thereafter, the OIG performed a site visit of the facility to determine if the material breaches had been cured. Based upon its review, the OIG concluded that the hospital had failed to take timely corrective actions necessary to cure the breaches. As a result, OIG exercised its contractual right under the CIA to exclude the hospital from participation in all federal health care programs for a period of five years. The hospital has a right to request a hearing before an HHS Administrative Law Judge, with a right under the CIA to further appeal to the HHS Department Appeals Board. It is unlikely, however, that the hospital will appeal the decision. The hospital filed for bankruptcy in February and closed its doors at the beginning of March after transferring the last of its patients. Furthermore, Florida's Agency for Health Care Administration ordered the hospital not to reopen.

MedPAC Proposes Changes to Medicare Program

The Medicare Payment Advisory Commission ("MedPAC") recently issued a report to Congress proposing several changes to the Medicare Program ("Medicare"). MedPAC is an independent federal body which was established by the Balanced Budget Act of 1997 to advise the U.S. Congress on issues affecting the Medicare Program. The March 2006 MedPAC Report recommends that Medicare begin differentiating among providers in order to increase the efficiency of the Medicare Program. Specifically, the report recommends that Medicare implement a "quality incentive payment policy" by paying more to hospitals that have higher quality performance. The report states that due to the trend of higher health care spending, along with the retirement of baby boomers and the Medicare's new prescription drug benefit, policymakers need to take steps now in order to slow growth in Medicare spending and encourage greater efficiency from health care providers. The report also recommends increases in the base payment for hospital inpatient and outpatient prospective payment systems.

In regard to physicians, MedPAC recommends an increase in the physician fee schedule. MedPAC also reiterates its position that it does not support the impending fee cuts for physicians which are set to go into effect between 2007 and 2011. MedPAC believes these fee cuts could threaten beneficiary access to physician services.

The MedPAC report is available at: http://www.medpac.gov.

FDA Issues Guidance on Hospital Bed Designs

On March 9, 2006, the U.S. Food and Drug Administration ("FDA") published final guidance designed to reduce the occurrence of hospital bed entrapments. The guidance, which is entitled "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment" ("Guidance") identifies special issues associated with hospital bed systems and provides design recommendations for manufacturers of new hospital beds and suggestions for health care facilities on ways to assess existing beds. According to the FDA, an entrapment can occur when part of a patient's body becomes caught between parts of the bed, such as in the space between the mattress and the side rail. This can result in strangulation and death. The FDA announced that it has received approximately 691 entrapments reports over a period of twenty-one years, from January 1,

1985, to January 1, 2006. In these reports, 413 people died, 120 were injured and 158 were near miss events, with no serious injury as a result of intervention. The FDA indicated that elderly patients in hospitals and nursing homes, especially those who are frail, confused, restless or who have uncontrollable body movement, are most vulnerable to entrapment.

The Guidance characterizes the body parts at risk for entrapment, identifies the locations of hospital bed openings that are potential entrapment areas, recommends the dimensional criteria for new hospital bed systems, provides information about reporting entrapment adverse events, and includes a description of recommended test methods for assessing gaps in hospital bed systems.

The Guidance is available on the FDA's website at: http://www.fda.gov/cdrh/beds/.

Legislation Proposed to Protect Financial Privacy of Non-Profit Employees

Representative Rachel Kaprielian of Watertown has filed legislation with the Massachusetts House of Representatives which seeks to protect the financial privacy of employees of non-profit organizations. The legislation, entitled "An Act to Protect the Financial Privacy of all Employees of Non-Profit or Charitable Corporations" ("Act") seeks to amend Chapter 12, Section 8F of the Massachusetts General Laws pertaining to the Annual Reports of public charities. The statute provides that each year, a public charity must file an Annual Report (Form PC) with the Division of Public Charities of the Massachusetts Attorney General's Office. Furthermore, a public charity which receives more than $100,000 in gross support and revenue during the fiscal year covered by its Annual Report, must also submit a complete audited financial statement along with its Annual Report. The Act amends the statute to provide that "the Director of the Division of Public Charities shall not require the submission or filing of the names, address, or other personal identifying information of a public charity's employees and if such personal information has already, at the time of adoption of this Act, been filed or submitted to the Division or is at any time inadvertently filed or submitted to the Division, the Director and all Division personnel shall refrain from publishing such personal identifying information." The Act also provides that any personal identifying information filed with the Division shall not be deemed a public record.

The Division of Public Charities has acknowledged that it is closely monitoring the Act as it could have a substantial impact upon its operations. In the ordinary course, Annual Reports and audited financial statements of public charities are made available to the public by the Division of Public Charities. If the Act is passed, the Division will no longer be able to publish this information if it includes personal identifying information of a public charity's employees. Furthermore, the Division will be required to refrain from making any previous Annual Reports and audited financial statements available to the public until such time as all personal identifying information has been redacted.

The Rogers Law Firm will continue to monitor this legislation and will provide updates accordingly.

Amendments Proposed to Public Charities Legislation

At a recent non-profit law conference, Assistant Attorney General Jamie Katz, Chief of the Public Charities Division of the Massachusetts Attorney General's Office, stated that the public charities legislation which was introduced by Attorney General Tom Reilly in May of 2005, has undergone four significant changes within the Legislative Committees. The legislation, which is entitled "An Act to Promote the Financial Integrity of Public Charities" ("Act") amends Chapter 12 of the Massachusetts General Laws pertaining to public charities. The Act clarifies the standards applicable to charities with respect to financial integrity and imposes certain mechanisms to aid the boards and senior managers of charities in equipping their organizations with appropriate financial controls and disciplines. According to Mr. Katz, the following changes have been made to the Act:

1. **Board Certification**

   The proposed legislation required a Board's review and acceptance of a public charity's Annual Report to the Public Charities Division. The Act now provides that Boards will not be required to review and accept the Annual Report. Nevertheless, individuals who sign the Annual Report will have to certify that they themselves have reviewed the filings.

2. **Whistleblower Protection**

   The proposed legislation required that charities have policies in place to prohibit whistleblower retaliation. The Act now includes a provision which strictly prohibits a public charity's retaliation against a whistleblower.

3. **Audit Committees**

   The proposed legislation provided that there could be no non-board members on the Audit Committee. The legislation also provided that there could be no members on the Audit Committee who could be considered a related party (i.e. any member who has a material financial interest in any entity doing significant business with a public charity or who has engaged in a related party transaction within three years preceding his/her appointment to the Audit Committee). The Act now provides that non-board members and related party members will be allowed to serve on a public charity's Audit Committee, but with some restrictions. Mr. Katz did not elaborate on what these restrictions will include.

4. **Related Party Transactions**

   The legislation initially proposed incorporating some of the standards set forth by the United States Internal Revenue Service for Intermediate Tax Sanctions resulting from a related party transaction. According to Mr. Katz, the IRS Intermediate Sanctions have now been fully incorporated into the Act.

According to Mr. Katz, the Act is still in Legislative Committees in the Massachusetts Legislature. The Rogers Law Firm will continue to monitor the Act and will provide updates accordingly.

SJC Outlines Basis for Invading Peer Review Privilege

The Massachusetts Supreme Judicial Court ("SJC") recently held that a physician-employee who was terminated by his hospital-employer was not entitled to privileged medical peer review documents as part of the discovery process in his discrimination lawsuit against the hospital. In the matter of Pardo v. The General Hospital Corporation, et al., 446 Mass. 1 (2006), the Court held that the medical peer review privilege "can only be invaded on some threshold showing that a member of the medical peer review committee did not act in good faith in connection with his activities as a member of the committee." The decision is significant in that it provides guidance with respect to the discovery of privileged medical peer review materials in civil litigation.

The Plaintiff, Dr. Francisco S. Pardo, was employed by Massachusetts General Hospital ("Hospital") as a Radiation Oncologist. In the spring of 1993, Dr. Pardo learned that his long-time partner was ill with AIDS. In October of 1993, Dr. Pardo informed his supervisor, Dr. Herman V. Suit, Chief of Radiation Oncology at the Hospital, that his partner had AIDS and that he might need to take some time off to care for him. The evidence at trial demonstrated that after this discussion, Dr. Suit continued to support Dr. Pardo in the advancement of his career. In the summer of 1994, Dr. Suit recommended Dr. Pardo for promotions at the Hospital and at Harvard Medical School. Dr. Suit also recommended Dr. Pardo for further grant funding for research.

In January of 1995, Dr. Suit reprimanded Dr. Pardo for removing certain laboratory research data books from Dr. Suit's laboratory. He subsequently ordered Dr. Pardo not to enter the laboratory without his permission. In March of 1995, Dr. Suit informed Dr. Pardo that he was placing his academic probation on hold. Shortly thereafter, Dr. Suit became concerned about Dr. Pardo's clinical teaching and patient care activities. This concern was based upon a five-page memorandum which was submitted to Dr. Suit by Dr. Alan Hartford, a medical resident in the Radiation Oncology Department. The memorandum detailed numerous instances over the course of the preceding three months demonstrating that Dr. Pardo had not provided adequate supervision and training of residents. After reviewing the memorandum, Dr. Suit spoke with Dr. Allan Thornton, who took care of Dr. Pardo's patients in his absence. Dr. Thornton informed Dr. Suit that he also had numerous areas of concern regarding Dr. Pardo. In particular, he noted that Dr. Pardo was often difficult to reach, either by page or telephone; he was repeatedly unavailable at the Radiation Oncology Clinic; he repeatedly failed to comply with certain protocols; he had poor recordkeeping, including failure to make notations in the charts of patients; and he had a history of obtaining "inadequate and spurious" consent by patients. Dr. Thornton also noted that Dr. Pardo's care for patients was often left to a resident and that he was rarely in attendance at departmental conferences.

In May of 1995, Dr. Suit informed Dr. Pardo that he was removing him from teaching and supervising residents, and would cease assigning residents to him effective July 1, 1995. Dr. Suit met with the Executive Committee of the Radiation Oncology Department in late June of 1995. The Committee concluded it would no longer commit to funding Dr. Pardo's salary for his research beyond the next two years. In August of 1995, Dr. Suit removed Dr. Pardo from participating in an experimental radiation project because Dr. Pardo had failed to follow certain procedures concerning the use of an experimental machine to irradiate brain tumors.

On August 17, 1995, Dr. Pardo filed a Complaint with the Massachusetts Commission Against Discrimination ("MCAD") in regard to the Hospital's treatment of him following the disclosure of his sexual orientation. Following the filing of this Complaint, disputes continued to arise between Dr. Pardo and Dr. Suit. Specifically, according to Dr. Suit there was concern at the Hospital regarding Dr. Pardo's "truthfulness, clinical judgment and interpersonal interactions." In December of 1995, Dr. Suit recommended that the Plaintiff's reappointment to the medical staff be limited to six months, and that his clinical work be supervised.

The Hospital's General Executive Committee considered Dr. Suit's recommendation in January of 1996, and voted unanimously to recommend that the Plaintiff be reappointed for a six month period without clinical privileges. The Hospital's Board of Trustees subsequently adopted the recommendation of the General Executive Committee. Dr. Suit appealed the Board's decision to a Staff Review Committee. In the interim, when Dr. Pardo's temporary reappointment to the medical staff expired, his employment at the Hospital was terminated. Thereafter, a peer review hearing was held before the Staff Review Committee. The Staff Review Committee recommended that the Board reverse its decision with respect to the Plaintiff's clinical privileges, but upheld the Board's decision denying the Plaintiff's application for reappointment in July of 1996. The Board restored the Plaintiff's clinical privileges nunc pro tunc for the period January to June, 1996.

Dr. Pardo filed suit against the Hospital and the Partners HealthCare System. He alleged that he was discriminated against on the basis of his sexual orientation and that the Hospital retaliated against him when he complained about the discrimination. At trial, the jury returned a verdict in favor of the Hospital and Partners HealthCare System. Dr. Pardo appealed the trial court's decision, claiming, among other things, that a pre-trial order denying his request for discovery of certain documents that the Hospital claimed were privileged under the Medical Peer Review Statute, was in error. Specifically, he asserted that his allegations of "bad faith" on the part of Dr. Suit and others at the Hospital, triggered the statutory exception to the privilege. The Medical Peer Review Statute (M.G.L., c. 111, § 204) provides that "proceedings, reports and records of a Medical Peer Review Committee shall be confidential and shall not be subject to subpoena or discovery." There is, however, an exception under M.G.L., c. 111, § 204(b), which permits discovery of medical peer review materials where a committee member did not act "in good faith" in connection with his activities as a member of the committee. The SJC ruled that this exception is not "a blanket exception to the medical peer review privilege where there is a claim that a physician's actions are motivated by discriminatory animus." The SJC noted that in each case the judge must determine whether a medical peer review privilege exists. The judge must then, and only then, examine whether the privilege applies to a particular document. Once a judge has made the determination that the peer review privilege does apply to a particular document, the burden shifts to the Plaintiff to make a showing that the proceedings themselves, rather than the reasons for initiating the proceedings, were not conducted "in good faith." The SJC held that the trial court judge did indeed follow this process when addressing Dr. Pardo's Motion to obtain the peer review materials. There was no evidence put forth by Dr. Pardo which demonstrated that the medical peer review proceedings were not conducted in good faith. Therefore, the SJC stated that the judge correctly denied Dr. Pardo's motion to obtain the peer review documents as he did not meet his burden that the proceedings themselves were not conducted "in good faith."

As previously stated, the SJC's decision in this case is important in that it confirms that in order to obtain privileged medical peer review documents in a civil litigation context, a judge must determine whether the peer review privilege exists and whether or not it is applicable to a particular document. The Plaintiff must then demonstrate to the Court that the Medical Peer Review Committee proceedings, rather than the reasons for initiating the proceedings, were not conducted "in good faith."

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.