

**Client Newsletter**

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**Proposed Legislation Alters Reporting Requirements for Massachusetts Public Charities**

Several Massachusetts State Senators recently filed a Bill with the Massachusetts State Legislature which would alter the reporting requirements for certain public charities. The intent of the proposed legislation is to require religious organizations to disclose financial information in filings with the Public Charities Division of the Massachusetts Attorney General’s Office. The proposed legislation, however, also expands upon the scope of information to be disclosed by all public charities, including hospitals, as part of their filings with the Attorney General’s Office.

The proposed legislation amends M.G.L. c. 12, § 8F, to require that public charities disclose to the Attorney General’s Office the address of each parcel of real property owned by the charity and “any related organization”. It is likely that such disclosure will be made through amendments to the current Form PC. The proposed legislation defines a “related organization” as follows:

- (a) Any entity, whether for-profit or non-profit, which the public charity directly or indirectly owns, or which directly or indirectly owns the public charity. “Owns,” means directly or indirectly holding more than fifty (50%) percent of voting membership rights or voting stock;
- (b) Any entity, whether for-profit or non-profit, under common control with a public charity. “Control” means over fifty (50%) percent of an entity’s, director’s, trustee’s, or other members of the governing body are representative of, or are directly or indirectly controlled by a second entity;
- (c) Any entity, whether for-profit or non-profit, (i) a purpose of which is to benefit or further the purposes of the reporting organization, or which the reporting organization was established to benefit or further in its purposes and (ii) which engaged in business transactions or business arrangements, including pledges or assignments of collateral or loan guarantees or other contracts of suretyship with the reporting organization, or paid compensation to, an officer, director, trustee or employee of the reporting organization.

The proposed legislation's broad definition of a "related organization" would arguably require Caritas Christi and the Caritas Christi Member Hospitals to list in its annual Form PC, the address of each parcel of real property of the Caritas Christi Health Care System, as well as all real property owned by the Roman Catholic Archbishop of Boston, a Corporation Sole.

The Rogers Law Firm will monitor this proposed legislation and will provide updates on its course through the Massachusetts Legislature.

## **Implementation of the HIPAA Security Rule**

### **Introduction**

On April 21, 2005, the Health Insurance Portability and Accountability Act ("HIPAA") Security Rule, promulgated by the United States Department of Health and Human Services ("HHS"), will become effective for all health care providers who transmit any health information that is electronically maintained or used in an electronic transmission. The purpose of the Security Rule is to adopt national standards for safeguards to protect the confidentiality, integrity and accessibility of electronic protected health information. It is important that hospitals take all actions necessary to ensure compliance with the Security Rule prior to the effective date of April 21, 2005.

### **HIPAA Security Rule**

The Health Insurance Portability and Accountability Act was enacted on August 21, 1996. The purpose of the legislation is to protect the health insurance of employees as they change employment or leave the workforce. As part of the legislation, Congress included an administrative simplification provision which is designed to improve efficiency in healthcare delivery by standardizing electronic data interchange and protecting the confidentiality and security of health data. The administrative simplification provision is comprised of four distinct categories: 1) Standards for Electronic Transactions; 2) Unique Identities Standards; 3) Security and Electronic Signature Standards; and 4) Privacy and Confidentiality Standards. HHS has promulgated rules with respect to each of these categories. The HIPAA Privacy Rule, which pertains to the confidentiality of individually identifiable health information in any form (i.e. written, electronic, or verbal), has been the focus of health care entities over the last few years as they sought to meet the compliance deadline of April 14, 2003. Although the HIPAA Security Rule has not received the same amount of attention as the HIPAA Privacy Rule, its impact upon the healthcare industry will nevertheless be significant.

The HIPAA Security Rule is intended to protect the confidentiality, integrity and availability of "electronic protected health information" ("E PHI"). The term "electronic protected health information" is defined by the Security Rule as individually identifiable health information which is maintained in any electronic medium. The Security Rule applies to health plans, health care clearing houses, and health care providers who transmit any health information in electronic form. HHS, however, created an exception for information that was not in electronic format prior to being transmitted. Therefore, the Security Rule does not apply to information transmitted via facsimile because such information was not in electronic form before its transmission.

The HIPAA Security Rule mandates that covered entities, including hospitals, comply with four general requirements:

- (1) Ensure the confidentiality, integrity and availability of all electronic protected health information the covered entity creates, receives, maintains or transmits.
- (2) Protect against any reasonably anticipated threats or hazards to the security or integrity of such information.
- (3) Protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required by the Privacy Rule.
- (4) Ensure compliance by its workforce.

Beyond these general requirements, the Security Rule is divided into three distinct categories: administrative safeguards, physical safeguards and technical safeguards. These categories represent a total of eighteen standards to be met by each covered entity. Many of the standards include “implementation specifications” which serve as instructions for implementing the standards. The implementation specifications are either “required” or “addressable”. If an implementation specification is required, the covered entity must adopt the implementation specification. If, however, an implementation specification is “addressable”, a covered entity may choose to implement the specification as set forth in the Rule, or may choose an alternative approach. A covered entity which does not incorporate an addressable implementation specification in accordance with the Rule, must document its decision and set forth the reasoning as to why the implementation specification is not reasonable and appropriate for that covered entity.

(A) Administrative Safeguards

The Administrative Safeguards of the HIPAA Security Rule are administrative actions, policies and procedures designed to manage the selection, development, implementation and maintenance of security measures to protect EPHI. There are nine standards associated with the administrative safeguards of the HIPAA Security Rule. These standards are as follows:

Security Management Process: This standard requires covered entities to develop and maintain policies and procedures to prevent, detect and correct security violations.

Assigned Security Responsibility: A covered entity must identify the security official who is responsible for the development and implementation of policies and procedures required by the HIPAA Security Rule.

Workforce Security: This standard requires a covered entity to implement policies and procedures to ensure that all members of its workforce have appropriate access to EPHI. This standard also requires a covered entity to ensure that those workforce members who do not need access to EPHI are prevented from obtaining access.

Information Access Management: A covered entity must have policies and procedures in place for establishing how individuals will be authorized to access EPHI.

Security Awareness and Training: A covered entity must implement a security awareness and training program for all members of its workforce.

Security Incident Procedures: This standard requires a covered entity to implement policies and procedures to address security incidents. A “security incident” is defined by the Security Rule as “the attempted or successful unauthorized access, use, disclosure, modification or destruction of information or interference with system operations in an information system.”

Contingency Plan: A covered entity must establish policies and procedures for responding to an emergency or other occurrence that damages systems which contain EPHI.

Evaluation: This standard requires a covered entity to perform periodic technical and non-technical evaluations that determine the extent to which a covered entity’s security policies, procedures and processes are in compliance with the Security Rule.

Business Associate Contracts and Other Arrangements: A covered entity must obtain satisfactory assurances from business associates that they will appropriately safeguard any EPHI that is created, received, maintained or transmitted on behalf of the covered entity.

(B) Physical Safeguards

The Physical Safeguards of the HIPAA Security Rule are the physical measures, policies and procedures to protect a covered entity’s electronic information systems and EPHI from natural and environmental hazards, and unauthorized physical access. The standards for the Physical Safeguards are as follows:

Facility Access Controls: A covered entity must implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are located, while ensuring that properly authorized access is allowed.

Workstation Use: This standard requires a covered entity to implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access EPHI.

Workstation Security: A covered entity must implement physical safeguards for all workstations that can access EPHI in order to limit access to only authorized users.

Device and Media Controls: This standard requires the implementation of policies and procedures for the receipt and removal of hardware and electronic media that contain EPHI into and out of a covered entity, and the movement of these items within a facility.

(C) Technical Safeguards:

The Technical Safeguards are standards for a covered entity’s use of technology to protect EPHI and the control of access to it. There are five standards associated with the Technical Safeguards:

Access Control: A covered entity must implement technical policies and procedures for electronic information systems that contain EPHI to allow access to only those persons or software programs that have appropriate access rights.

Audit Controls: This standard requires a covered entity to implement hardware, software and/or procedural mechanisms that record and examine activity in information systems that contain or use EPHI.

Integrity: A covered entity must implement policies and procedures to protect EPHI from improper alteration or destruction.

Person or Entity Authentication: A covered entity must implement policies and procedures to verify the identity of the person or entity seeking access to EPHI.

Transmission Security: This standard requires a covered entity to implement technical security measures to guard against unauthorized access to EPHI that is being transmitted over an electronic communications network.

### Conclusion

Compliance with the HIPAA Security Rule requires a significant amount of time and effort on the part of covered entities. There are several policies and procedures which need to be drafted and implemented, exclusive of the technological aspects associated with the Rules. (Covered entities are required to maintain these policies and procedures for a period of six years and must review them periodically in order to address environmental or operational changes affecting the security of EPHI.) By classifying many of the implementation specifications associated with the Security Rule standards as “addressable” as opposed to “required”, HHS provided an element of flexibility to ensure compliance with the Security Rule is specifically tailored to each covered entity.

A covered entity which does not comply with the Security Rule is subject to both civil and criminal penalties. A covered entity which violates the Security Rule is subject to civil penalties of \$100.00 per violation, up to \$25,000 per year for each requirement violated. The criminal penalties range from \$50,000 in fines and one year in prison up to \$250,000 in fines and 10 years in prison.

Hospitals must ensure that they are compliant with the HIPAA Security Rule prior to April 21, 2005.

## **Massachusetts Changes Civil Commitment Time Limits**

On December 1, 2004, Governor Mitt Romney signed into law a Bill which changes the time limits associated with the Massachusetts statutory process for the commitment of individuals with a mental illness. Specifically, the Bill increases the time within which a court must schedule a hearing for a Petition of the Commitment of a Dangerous Person under M.G.L. c. 123, § 7, from four to **five** days. The Bill also amends M.G.L. c. 123, § 12, “Emergency Restraint of a Dangerous Person”, by decreasing the length of an involuntary hospitalization from four to **three** days.

These changes in the Massachusetts statutory process for commitment of individuals with a mental illness become effective on March 1, 2005. Therefore, a facility which seeks an involuntary commitment under M.G.L. c. 123, § 12, must now file a petition within three days.

## Class Action Charity Care Litigation Update

The non-profit hospitals and health care systems which are defendants in forty-eight class action lawsuits filed in United States District Courts across the country have received several recent favorable rulings in these cases. The lawsuits, brought by uninsured patients, allege that various non-profit hospitals and health care systems render insufficient amounts of charity care to justify their federal, state and local tax exemptions. Plaintiffs' attorneys representing these uninsured patients recently attempted to consolidate these cases into one Federal District Court. The consolidation would allow the Plaintiffs' attorneys to combine their resources and efforts into one forum. However, the U.S. Judicial Panel on Multi-District Litigation denied this request. The Panel found that consolidation "would neither serve the convenience of the parties and witnesses, nor further the just and efficient conduct of this litigation." The Panel's ruling is considered a victory for the Defendant non-profit hospitals and health care systems, as the cases will now proceed in the individual Federal District Courts in which the cases were filed.

In addition to the Panel's ruling against consolidation of these cases, the Defendant non-profit hospitals and health care systems have been bolstered by recent decisions of U. S. District Court judges in three of these cases. Judge Virginia Emerson Hopkins, of the U. S. District in Birmingham, Alabama, recently dismissed a lawsuit by uninsured patients against Baptist Health Systems and the American Health Association. Kizzire v. Baptist Health System, Inc., N.D. Ala. No. 04-1247. Judge Hopkins ruled that the Plaintiffs' claims had been previously litigated in State Court, and therefore, the Plaintiffs were barred from re-litigating the claims in Federal Court. Also, in the matter of Amato v. University of Pittsburgh Medical Center, W.D. Pa. No. 04-1025, Magistrate Robert C. Mitchell of the U. S. District Court for the Western District of Pennsylvania found that Federal claims against the University of Pittsburgh Medical Center lacked merit. The Plaintiffs alleged that they were third-party beneficiaries of the hospital's tax-exempt recognition by the Federal Government under Section 501(c)(3) of the Internal Revenue Code. The Court, however, found that there was no basis for the Plaintiffs to file suit as alleged third-party beneficiaries of an implied contract between the exempt hospital and the Federal Government.

In the matter of Darr v. Sutter Health, N.D. Cal. No. 04-2624, the U.S. District Court for the Northern District of California dismissed all federal claims which had been filed by the Plaintiffs against Sutter Health. (The Court refused to take jurisdiction over the Plaintiffs' state law claims and dismissed them without prejudice to refiling in state court.) The Court ruled that there was no authority to allow the Plaintiffs to assert that they had an "implied right of action" to bring claims to enforce the hospital's alleged obligations under 26 U.S.C. § 501 (c)(3).

In the only class-action charity case to be filed in Massachusetts to date, the Defendants, Bay State Medical Center and Bay State Health Systems, Inc., have filed a Motion to Dismiss the case. Harrington, et al. v. Bay State Medical Center, et al., D. Mass. No. 04-11663. As in Amato, the Plaintiffs in Harrington argued that they are third-party beneficiaries of a contract between the Defendants and the Federal Government as a result of the Defendants' tax-exempt status. In the Motion to Dismiss, the Defendants argue that they do not have a contract with the Federal Government arising from their tax-exempt status. Rather, they argue that their tax-exempt status is an operation of law under § 501(c)(3). The Court has not yet ruled on the Defendants' Motion to Dismiss.

## Massachusetts Court Orders New Trial After Finding Medical Expert Lied Under Oath

Massachusetts Superior Court Judge Diane Kottmyer recently ordered a new trial in the wrongful death action of Wojcicki v. Caragher, M.D. (Suffolk Superior Court, Civil Action No. 00-0124), after determining that an expert who testified on behalf of the physician Defendant gave false and misleading testimony under oath. Judge Kottmyer also ordered the expert to pay Plaintiff's attorneys' fees and expenses in the amount of \$17,355.00 and pay the Commonwealth expenses in the amount of \$2,585.00 to cover the costs associated with seating a second jury.

The Plaintiff filed a wrongful death action against Dr. Joan E. Caragher alleging negligence in the care she rendered to Sherry Wojcicki on July 2, 1999, when Ms. Wojcicki was brought to the Emergency Room of Addison Gilbert Hospital after suffering a severe stroke. Ms. Wojcicki had a recurrence of breast cancer in 1999, for which she received two courses of chemotherapy. The final dose of chemotherapy was administered on July 1, 1999, the day before she was brought to the Emergency Room. The Plaintiff alleges that Dr. Caragher had departed from the applicable standard of care for physicians practicing the specialty of Emergency Medicine when she failed either to offer thrombolytic therapy ("t-PA") to Ms. Wojcicki or promptly transfer her to another hospital where she could receive such therapy.

At trial, the Plaintiff relied heavily upon an article entitled "Tissue Plasminogen Activator for Acute Ischemic Stroke", published in the *New England Journal of Medicine* on December 14, 1994. The article reported the results of a study consisting of two trials conducted at various medical centers through the country by the National Institute of Neurological Disorders and Strokes ("NINDS Study"). The results of the NINDS Study had a significant impact on the treatment of stroke patients in Emergency Rooms, in that it was believed by many neurologists to show that administration of t-PA to victims of severe stroke within three hours of the onset of stroke decreased the impairment caused by the stroke. The administration of t-PA, however, carries a significant risk of death due to intracranial hemorrhage, and therefore, it is essential to carefully screen patients before administering t-PA.

Counsel for Dr. Caragher called Dr. Fred Hochberg as an expert witness at trial. Dr. Hochberg is a neuro-oncologist at Massachusetts General Hospital. Dr. Hochberg repeatedly testified that none of the patients involved in the NINDS Study had cancer. Such testimony supports Dr. Caragher's decision to refrain from treating Ms. Wojcicki with t-PA. However, the Plaintiff's expert, Dr. Guy Rordorf, a neurologist and stroke specialist at Massachusetts General Hospital, testified at trial that there was no published or unpublished data to support Dr. Hochberg's testimony that no cancer patients were included in the NINDS Study. Despite this testimony from Dr. Rordorf, the jury returned a verdict in favor of Dr. Caragher.

Counsel for the Plaintiff filed a Motion for a new trial in which he alleged that Dr. Hochberg had presented false and perjurious testimony in regard to the NINDS Study. Specifically, the Motion alleged that Dr. Hochberg falsely testified that no cancer patients had participated in the NINDS Study. In support of the Motion, the Plaintiff submitted Affidavits of Dr. John R. Marler, the NIH Coordinator for the Study and Dr. Barbara C. Tilley, the Lead Biostatistician for the Study. Both Dr. Marler and Dr. Tilley confirmed that fifty-nine patients included in the Study had responded positively to a Study questionnaire regarding whether or not they had been diagnosed as having a malignancy.

After a hearing regarding the Plaintiff's Motion for a New Trial, Judge Kottmyer ordered that Dr. Hochberg appear for a deposition and testify as to the basis for his trial testimony. At his deposition,

Dr. Hochberg defended his trial testimony and stated that to the best of his knowledge no active cancer patients had been included in the NINDS Study. Dr. Hochberg stated that his testimony in this regard was based upon a telephone conversation he had with Dr. Tilley, the NINDS Biostatistician, which occurred approximately two weeks before the trial. Counsel for the Plaintiff subsequently requested that Dr. Hochberg produce telephone records in support of his testimony regarding his telephone conversation with Dr. Tilley. The telephone records which were produced by Dr. Hochberg, however, reflect only a thirty second phone call to Dr. Tilley's office in Charleston, South Carolina on the first day of the trial. Counsel for the Plaintiff subsequently produced an Affidavit of Dr. Tilley in which she stated that she had never before spoken with Dr. Hochberg. Furthermore, Dr. Tilley stated that on November 17, 2003, she was in San Francisco attending a meeting of the American Public Health Association and was not in her office.

After reviewing all of the evidence regarding Dr. Hochberg's testimony, Judge Kottmyer ordered a new trial and sanctioned both the Defendant and Dr. Hochberg. Judge Kottmyer stated that she found "clear and convincing evidence" that Dr. Fred Hochberg, an expert witness called by the Defendant: (1) intentionally testified at the trial of this case as to the existence of a fact when he did not know whether the fact was true; (2) deliberately mislead the Court and the jury as to whether he had reviewed the Study data; and (3) testified falsely at his deposition that he had a telephone conversation with Dr. Tilley and that she provided the information on which his trial testimony was based." The Court ordered Dr. Hochberg to pay Plaintiff's attorneys' fees in the amount of \$17,355.00, and pay an additional \$2,585.00 to the Commonwealth to cover the costs associated with seating a second jury. Judge Kottmyer also sanctioned the Defendant, Dr. Caragher, and ordered her to pay attorneys' fees and expenses of the Plaintiff in the amount of \$68,000.00 for the baseless and misleading testimony which was presented to the jury on her behalf.

It is unclear at this time as to whether or not either Dr. Caragher or Dr. Hochberg will appeal the Court's sanctions.

## **Department of Public Health Expands Flu Vaccine Distribution Guidelines**

The Massachusetts Department of Public Health ("DPH") recently revised its Flu Vaccine Distribution Guidelines to include individuals sixty-five years of age and older and others who are considered high risk. In accordance with the revised Guidelines, which were issued by DPH on December 1, 2004, health care providers should now administer flu vaccine to individuals in the following high risk categories:

- All children aged 6 to 23 months;
- Adults aged 65 years or older;
- Persons 2 to 64 years with underlying chronic medical conditions;
- All women who will be pregnant during the influenza season;
- Residents of nursing homes and long-term care facilities;
- Children 6 months to 18 years on chronic aspirin therapy;

- Health care workers involved in direct patient care and emergency first responders;
- Out-of home caregivers and household contacts of children 6 months and younger.

The DPH Commissioner has also issued a “Revised Order to Establish Rules and Priorities the Distribution and Use of Influenza Vaccine” (“Order”) to all health care providers in Massachusetts. The Order, which was issued in accordance with M.G.L. c. 111, § 5A, supersedes the prior Order issued by DPH regarding distribution and use of the influenza vaccine, which was issued on October 13, 2004. The Order states that the health care provider shall make every reasonable effort to administer influenza vaccine in accordance with the most recent Guidelines issued by DPH. For purposes of the Order, “health care provider” means any person or entity authorized under the laws of Massachusetts to purchase, store, distribute, possess, prescribe, dispense or administer influenza vaccinations.

In accordance with M.G.L. c. 111, § 5A, any health care provider who violates any provision of this Order shall be punished by a fine of not less than \$50.00 nor more than \$200.00 or by imprisonment for not more than six months, or both. Furthermore, health care providers who violate this Order will be referred to the appropriate professional Board of Registration.

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