
HEALTH CARE PRACTICE GROUP NEWSLETTER

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OCR Issues FAQs on Disclosures of Family Medical History

The Office for Civil Rights (“OCR”) of the United States Department of Health and Human Services recently issued a new series of frequently asked questions (“FAQs”) regarding the HIPAA Privacy Rule’s application to family medical history. The FAQs support the roll-out of the Surgeon General’s family health history portal, “My Family Health Portrait”, a new version of the web-based tool that enables individuals to electronically record, save and email family medical information in formats that are compatible with electronic health records.

The FAQs provide that the HIPAA Privacy Rule permits a health care provider to disclose protected health information about a patient to another health care provider for the purpose of treating another patient (e.g. to assist the other health care provider with treating a family member of the doctor’s patient). As an example, the FAQs state that an individual’s doctor can provide information to the doctor of the individual’s family member about the individual’s adverse reactions to anesthetics prior to the family member undergoing surgery.

Massachusetts health care providers need to be aware that the FAQs only state that the HIPAA Privacy Rule “permits” a health care provider to disclose protected health information about a patient to another health care provider for the purpose of treating another patient. Pursuant to Massachusetts law regarding the confidentiality of patient health information, however, a provider is precluded from disclosing information about a patient to another provider for the purpose of treating another patient without a written authorization from the patient or an appropriately issued subpoena or court order. The HIPAA Privacy Rule preempts any contrary state law unless the state law is more stringent than the related provision of HIPAA or unless a specific exception

applies. In this particular instance, Massachusetts law is more stringent than the HIPAA Privacy Rule, and therefore controls.

The FAQs also state that when a health care provider, in the course of treating an individual, collects or otherwise obtains an individual's family medical history, this information becomes part of the individual's medical record and is treated as protected health information about the individual. This FAQ is consistent with Massachusetts law.

The FAQs are available at <http://www.hhs.gov/ocr/privacy/familyhealthhistoryfaq.pdf>. If you have any questions regarding the FAQs or the issue of HIPAA preemption and Massachusetts law, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

Physician Payments Sunshine Act Filed in Congress

Senators Charles Grassley (R-IA) and Herb Kohl (D-WI) recently introduced into Congress the Physician Payments Sunshine Act of 2009 (the "Act"). The Act would require manufacturers of pharmaceuticals, medical devices, and biologics to publicly report the money they give to physicians over \$100 every year. The manufacturers would report the payments to the United States Department of Health and Human Services. The information would then be posted online and available for public inspection. Under the Act, a manufacturer's failure to report the information could result in penalties as high as \$1 million.

Senators Grassley and Kohl filed a similar piece of legislation in 2007 which was never considered by Congress. The Senators have indicated that they are confident the Act will be passed during this session of Congress. Senator Grassley stated that "The goal of our legislation is to lay it all out, make the information available for everyone to see, and let people make their own judgments about what relationships mean or don't mean. If something's wrong, then exposure will help to correct it."

The Act is similar to Massachusetts legislation which was recently signed into law by Governor Deval Patrick.¹ The Massachusetts law requires pharmaceutical and medical device manufacturers to report on an annual basis to the Massachusetts Department of Public Health ("DPH") any economic benefit provided to a health care practitioner with a value of at least \$50. The Massachusetts law requires DPH to publish regulations pertaining to this annual disclosure requirement. The regulations are currently in proposed form and will not be finalized until the spring.

The Rogers Law Firm will continue to monitor the Physician Payments Sunshine Act and the related Massachusetts regulations and will provide updates accordingly. In the meantime, if you have any questions or concerns regarding financial relationships between health care providers and pharmaceutical and medical device manufacturers, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

¹ Chapter 305 of the Acts of 2008, "An Act to Promote Cost Containment, Transparency, and Efficiency in the Delivery of Quality Healthcare".

First Circuit Upholds Decision to Report Physician to National Practitioner Data Bank

On January 14, 2009, the United States Court of Appeals for the First Circuit upheld the trial court decision on an administrative agency ruling made by Secretary Leavitt (“Secretary”) of the United States Department of Health and Human Services (“HHS”). The Secretary’s ruling determined that a provider is “under investigation”, as defined by the Health Care Quality Improvement Act (“HCQIA”) until the health care entity’s decision-making authority has taken a final action or formally closes the investigation. The Secretary issued a written decision citing this interpretation of the HCQIA to affirm that the reporting hospital appropriately submitted to the National Practitioner Data Bank (“NPDB”) the resignation of one of its physicians, Dr. Doe, who was “under investigation”.

The underlying issue in this dispute began in July 2005 when an operating room nurse filed a written report against Dr. Doe for threatening her. The hospital then temporarily suspended Dr. Doe’s privileges and used an ad hoc investigative committee (“AHC”) to assess the allegation. On August 2, 2005, the AHC reported to the hospital’s medical staff executive committee confirming the allegations and that the nurse reasonably perceived Dr. Doe’s actions as threatening. The executive committee determined it would allow Dr. Doe to return to work if he complied with amendments to his contract to include regular proctoring and psychological evaluations. However, on August 11, 2005, Dr. Doe rejected the proposal and voluntarily resigned. The hospital accepted the resignation on August 19 and subsequently reported the resignation to the NPDB pursuant to the HCQIA, which requires hospitals to report to the NPDB certain events relating to professional competence and conduct.

In September 2005, Dr. Doe requested an administrative review of the hospital’s filing to the NPDB and claimed that the investigation ended when the AHC presented its report to the executive committee and that his resignation therefore did not occur while “under investigation”. Upon administrative review, the Secretary issued a written decision on May 25, 2007, indicating that “[a]n investigation is ...considered ongoing until the health care entity’s decision making authority takes a final action or formally closes the investigation.”¹ Therefore, because the hospital had not closed the investigation or taken final action, the Secretary concluded that Dr. Doe resigned while under investigation and the hospital had a duty to report him to the NPDB. Dr. Doe then brought an action against the Secretary in federal district court. The district court found in favor of the Secretary.

On appeal, the Court found that the Secretary is well-qualified in the appropriate area of expertise to interpret the HCQIA and did so with a methodical process making use of interpretative resources and citing the 2001 HHS Guidebook which is consistent with this interpretation. In addition, the Court held that one purpose of the NPDB and the HCQIA is to protect patients from incompetent practitioners. Allowing providers who are under investigation to resign without being reported to the NPDB would permit questionable conduct to go without proper investigation or discipline and not be reported. The Court found this contrary to the legislative intent and would perhaps allow incompetent providers to continue practicing without public exposure.

If you have any questions or concerns regarding reporting obligations to the NPDB, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

¹ 2009 WL 81655 (C.A.1 (Me.)).

Record-Breaking \$46.7 Million Recovered by Attorney General's Medicaid Fraud Division

The Massachusetts Medicaid Fraud Division ("Division") of the Office of the Attorney General announced the recovery of over \$46.7 million from investigations and prosecutions for Medicaid fraud in 2008. The Division is responsible for protecting the Massachusetts Medicaid program, MassHealth, from fraud and abuse. In 2008, the Division primarily collected from thirteen (13) civil settlements, including: \$7 million from Teva Pharmaceuticals USA, Inc. and \$1.8 million from Boehringer Ingelheim Roxane, Inc. In addition, the Division led a seven year investigation of CVS/Caremark, resulting in a settlement reached by the National Association of Medicaid Fraud Control Units, returning \$3.7 million of the \$36.7 million recovery to Massachusetts.

The U.S. Attorney's Office for the District of Massachusetts also participated in a joint investigation with the U.S. Department of Justice and a five-person national Medicaid fraud team which included an Assistant Attorney General from the Division. This ended with a multi-state settlement in which Massachusetts recovered \$9.2 million from Bristol-Myers Squibb Company. Finally, an Assistant Attorney General from the Division participated in a four-person national Medicaid fraud team investigation of Merck & Co., Inc., culminating with the largest healthcare fraud settlement to date. Negotiating on behalf of 49 participating states, the team recovered \$10.5 million for Massachusetts as part of two global settlements totaling \$649 million.

IRS Issues 2009 Annual Report and Work Plan Including New Exempt Organization Compliance Initiatives

The United States Internal Revenue Service ("IRS") Exempt Organizations program ("EO") recently released its 2009 Annual Report and Work Plan. The document describes the EO's accomplishments and the initiatives and projects to be undertaken in the coming year. The 2009 Work Plan contains several items relevant to tax-exempt healthcare organizations.

Form 990

The Work Plan notes the accomplishment of the revised Form 990 and states that the EO will work with the members of the nonprofit sector to prepare them for their new filing requirements. The EO explains that as it receives new Form 990 filings, it will "begin to evaluate the information reported; interact with the regulated community to obtain feedback of any challenges encountered; and assess whether the form is serving its intended purpose." The Work Plan also indicates that regulations implementing the Form 990 revisions (which were published in September 2008) will be finalized in 2009.

Charitable Spending Initiative

The Work Plan announces a new 2009 initiative regarding charitable spending. The EO will begin a long-range study to learn more about sources and uses of funds in the charitable sector and their impact

on the accomplishment of charitable purposes. The EO intends to look at fundraising, public contributions, grants, and revenues from related or unrelated trades or businesses, types and amounts of direct and indirect unrelated business income expenses, officer compensation, fundraising expenses, program service activities and the effect each has on funds available for charitable spending. The EO states that the first stage of this initiative will focus on organizations with unusual fundraising levels and organizations that report unrelated trade or business activity and relatively low levels of program service expenditures.

Nonprofit Governance Initiative

Another new 2009 initiative regarding nonprofit governance is announced in the Work Plan. The EO states that this initiative will focus on three areas of nonprofit governance. First, the EO will develop a checklist to be used by IRS agents in examinations of exempt organizations to determine whether the organization's governance practices impacted the tax compliance issues identified in the examination and to educate organizations about possible governance considerations. Second, the EO will commence a training program to educate its employees about nonprofit governance implications in the determinations, rulings and agreements, and education and outreach areas. Third, the EO will begin identifying Form 990 governance questions that could be used in conjunction with other Form 990 information in possible compliance initiatives, such as those involving executive compensation, transactions with interested persons, solicitations of non-cash contributions, or diversion or misuse of exempt assets.

Gifts In-Kind

In FY 2009, the EO will review valuation issues surrounding non-cash gifts, such as pharmaceuticals, used clothing, or excess inventory of discontinued products, provided to 501(c)(3) organizations, that then turn around and contribute them to other domestic or international charities. The EO has stated that it will focus on how non-cash gifts are valued, the expenditures involved in the transactions, and the accuracy of the reporting on the Form 990.

Hospital Compliance Initiative

The Hospital Compliance initiative is on-going. In FY 2007, the EO released an interim report on its nonprofit hospital project that discussed the initial results of a compliance check questionnaire regarding the community benefit issue. The Work Plan notes that the FY 2007 report recommended that the EO further evaluate the results by obtaining additional research and analyzing the differences in community benefit expenditure amounts and types to take into account varying demographics, such as rural and urban communities and hospitals. The Work Plan announces that in FY 2009, the EO will issue a follow-up report discussing the results of its analysis on the community benefit issue, as well as the results of the executive compensation examinations conducted in this project.

If you have any questions or concerns regarding the EO 2009 Work Plan and Compliance Initiatives, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

Massachusetts Court Holds Physician Who Negligently Harvests Cancerous Body Parts from a Donor May Be Liable to Unknown Recipients

On December 11, 2008, in *Basore et al. v. Ayvazian et al.*, the Massachusetts Superior Court (Tucker, Richard T., J.) issued a decision holding that a physician who negligently harvests cancerous body parts from a donor may be liable to unknown recipients of the body parts, even though there is no physician-patient relationship between the harvesting physician and the other recipients. In *Basore*, the plaintiff, Danny Basore, Administrator of the Estate of Leslie T. Skirvin, is seeking damages for the wrongful death of Leslie T. Skirvin (the “patient”). The named defendants include the physicians and institutions that allegedly performed roles in the harvesting of organs from a donor at UMass Medical Center, including a kidney that was transplanted into the patient, and the transplantation of those organs. Following his transplantation surgery on February 4, 2002, the patient died from complications allegedly resulting from the cancerous kidneys received from the donor. The plaintiff claimed that the defendants were negligent in their failure to discover the cancerous nature of the organs harvested from the donor. The defendants filed a Motion to Dismiss for failure to state a claim upon which relief may be granted.

The alleged pertinent facts are as follows:

- One of the defendant physicians came to Massachusetts from Baltimore and participated in the harvesting of organs from the donor, recovering the donor’s lungs at that time for transplantation to a waiting patient in Baltimore.
- At the time of the removal of the lungs from the donor, that physician was made aware of several large lymph nodes in the mediastinum portion of the donor's chest cavity and inquiries were made of the physician whether a biopsy should be performed to determine if cancer was present in the lymph nodes.
- The physician responded in the negative and a biopsy of the lymph nodes was not performed until after the transplantation of the lungs, liver, heart and kidneys harvested from the donor.
- Metastasized Glioblastoma multiforme brain tumor cells were found during biopsy of the lymph nodes following the organs’ transplantations.

The defendants argued that the plaintiff had no claim against them because no physician-patient relationship existed and the defendants did not owe a duty of care to the patient, and that the decision of *Coombes v. Florio*, 450 Mass. 182 (2007)¹ cannot be given retroactive affect. The SJC held in *Coombes* that a defendant owes a duty of care to all persons who are foreseeably endangered by his conduct, with respect to all risks which make the conduct unreasonably dangerous. The *Coombes* court went on to analyze the foreseeability of the risk that an impaired driver might cause an automobile accident and compared that to other areas in which the law has extended a duty of reasonable care to third persons.

The Court rejected the defendants’ arguments, noting that liability is not based on medical malpractice, but rather on common-law negligence for conduct foreseeably endangering third persons.

¹ For a detailed discussion of the SJC’s decision in *Coombes v. Florio*, please see “SJC Expands Physician Liability”, *The Rogers Law Firm Health Care Practice Group Newsletter*, December 2007, Volume 18 (available online at: <http://therogerslawfirm.com/newsletters/Volume18.pdf>).

The Court held that it is reasonable to conclude that it was foreseeable that the negligent harvesting of organs, despite signs of metastasized cancer, presented a risk to patients who might receive organs from the donor. The Court held that in this regard a legal duty does exist, not within medical malpractice liability terms, but under general negligence principles that required the physician to exercise due care in the harvesting of the organs so as not to unreasonably endanger patient recipients of the transplanted organs. The Court added that because the *Coombes* decision did not state new law, but rather applied existing law to unique facts, there is no reason why the *Coombes* principles of negligence law should not be applied for the actions involved in *Basore*. The Court therefore denied the defendants' Motion to Dismiss.

The Rogers Law Firm will continue to monitor the progress of *Basore et al. v. Ayvazian et al.* and provide updates as appropriate. Meanwhile, if you have questions or concerns regarding the decision in *Basore*, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

IRS CIRCULAR 230 DISCLOSURE: To ensure compliance with requirements imposed by the Internal Revenue Service, we inform you that any U.S. federal tax advice contained within this communication (including any attachments) was not intended or written to be used, and cannot be used, by any person for the purpose of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein.

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