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RECENT UPDATES TO HIPAA PRIVACY RULE

Health care providers and payors should review their existing HIPAA policies and procedures to address two recent developments pertaining to the HIPAA Privacy Rule. The developments include the following: (1) the notification to individuals when their health information is breached; and (2) the classification of genetic information as health information.

In the first development, the breach of notification regulations provided for under the Medical Recovery and Reinvestment Act of 2009, became effective on September 23, 2009. Thus, covered entities must now notify an individual if the covered entity discovers a breach of the individual’s unsecured Protected Health Information (“PHI”). If a breach involves more than 500 residents of a state or jurisdiction, a covered entity will also have to notify the media about the breach. Furthermore, a business associate will need to notify a covered entity of any breach of unsecured PHI. Although the breach of notification regulations became effective on September 23rd, HHS has stated that it will not impose sanctions for noncompliance with the new requirements until February of 2010.

In the second development, the Office of Civil Rights (“OCR”) of the United States Department of Health and Human Services recently issued a proposed rule which modifies the HIPAA Privacy Rule to clarify that genetic information is health information. Furthermore, OCR’s proposed rule prohibits the use and disclosure of genetic information by covered health plans for eligibility determinations, premium computations, application of any pre-existing condition exclusions, and any other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits. The use of or disclosure of genetic information in violation of the HIPAA Privacy Rule could result in a fine of \$100 to \$50,000 per violation. The proposed rule has a 60-day public comment period.

If you have any questions regarding these recent developments effecting the HIPAA Privacy Rule, please do not hesitate to contact any of the attorneys in TRLF’s Health Care Practice Group.

H1N1 CAUSES CMS TO ISSUE EMTALA GUIDANCE FOR HOSPITALS

The anticipated H1N1 influenza resurgence this fall has led the Centers for Medicare and Medicaid Services (“CMS”) to issue a Guidance regarding the Emergency Medical Treatment and Labor Act (“EMTALA”). The purpose of the Guidance is to clarify options that are permissible under EMTALA in the event of a pandemic.

EMTALA is the Federal law that requires all Medicare participating hospitals with dedicated Emergency Departments to provide the following to all individuals who come to their Emergency Departments, regardless of their ability to pay: (i) an appropriate medical screening examination to determine if the individual has an emergency medical condition; and (ii) if there is an emergency medical condition, the hospital must treat and stabilize the emergency medical condition within its capability **or** transfer the individual to a hospital that has the capability and capacity to stabilize the emergency medical condition. The Guidance sets forth the following:

I. Hospitals May Set Up Alternative Screening Sites on Campus

The medical screening examination under EMTALA does not have to take place in the Emergency Department. A hospital may set up alternative sites on its campus to perform medical screening examinations. Individuals may be redirected to these sites after being logged in. Furthermore, the redirection and logging can even take place outside the entrance to the Emergency Department. The Guidance points out that the person who directs individuals to these alternative sites in the hospital should be able to recognize individuals who are obviously in need of immediate treatment in the Emergency Department. All other provisions of EMTALA apply to these alternative sites.

II. Hospitals may set up screenings at off-campus, hospital-controlled sites

The Guidance states that hospitals and community officials may encourage the public to go to off-campus hospital-controlled sites instead of the hospital for screening of influenza-like illness. However, a hospital is not permitted to tell individuals who have already come to its Emergency Department to go to the off-site location for the medical screening examination. Unless the off-campus site is already a dedicated Emergency Department of the hospital, EMTALA requirements do not apply. Hospitals can hold out these off-campus sites as influenza-like illness screening centers, however, they should not hold these sites out to the public as places that provide care for emergency medical conditions in general on an urgent, unscheduled basis.

III. Communities may set up screening clinics at sites not under the control of a hospital

Hospitals and community officials may encourage the public to go to screening clinics at sites not under the control of a hospital for screening of influenza-like illness. There is no EMTALA obligation at these sites. However, a hospital may not tell individuals who have already come to its Emergency Department to go to the off-site location for a medical screening examination.

IV. EMTALA Waivers

An EMTALA waiver allows hospitals to direct or relocate individuals who come to the Emergency Department to an alternative off-campus site in accordance with a state emergency or a pandemic preparedness plan for the required medical screening examination. Furthermore, an EMTALA waiver allows hospitals to effect transfers normally prohibited under EMTALA of individuals with unstable

emergency medical conditions, so long as the transfer is necessitated by the circumstances of the declared emergency. The EMTALA medical screening examination and the stabilization requirements can be waived for a hospital only if: the President has declared an emergency or disaster; the Secretary of the U.S. Department of Health and Human Services has declared a public health emergency; the Secretary invokes his/her waiver authority (which may be retroactive), including notifying Congress at least forty-eight hours in advance; and the waiver includes waiver of EMTALA requirements and the hospital is covered by the waiver.

In the event of an H1N1 pandemic, hospitals will need to pay special attention to the Guidance and any additional notices from CMS with respect to compliance with EMTALA. Hospitals should review and revise their EMTALA policies and procedures to address the Guidance.

If you have any questions regarding EMTALA or revising your hospital's EMTALA policies or procedures, please don't hesitate to contact any of the attorneys in the Health Care Practice Group at The Rogers Law Firm.

PhRMA REVISES CLINICAL TRIAL GUIDELINES

The Pharmaceutical Research and Manufacturers of America ("PhRMA") recently released revised principles on the Conduct of Clinical Trials and Communication of Clinical Trial Results (the "Guidelines"). The Guidelines are part of an ongoing effort by PhRMA to help ensure objectivity in research and enhance transparency in clinical research. According to PhRMA, the Guidelines "fortify our commitment to patients and health care professionals by increasing transparency in clinical trials, enhancing standards for medical research authorship and improving disclosure to manage potential conflicts of interest in medical research."

The Guidelines, which were unanimously approved by PhRMA's Board of Directors, include the following revised principles:

- Only individuals who make substantial contributions to medical manuscripts will be recognized as authors;
- Expand the universe of publicly available data about clinical trials with patients by committing to provide result summaries of all interventional clinical trials involving patients – regardless of whether the medicines are approved or the particular research programs have been discontinued;
- Enhance disclosure standards for published research that companies sponsor by requiring disclosure in medical journal manuscripts of all financial or personal relationships that might present a conflict of interest - whether in an article or a letter; and
- Increase transparency by committing companies to the timely registration of all interventional clinical trials involving patients on a public website to help patients who need medical care enroll in relevant studies.

The Guidelines became effective on October 1, 2009. If you have any questions regarding the Guidelines, please don't hesitate to contact any of the attorneys in the Health Care Practice Group at The Rogers Law Firm.

OIG: REFERRAL SERVICE ARRANGEMENT NOT SUBJECT TO ADMINISTRATIVE SANCTIONS

The Office of Inspector General (“OIG”) of the United States Department of Health and Human Services recently issued an Advisory Opinion regarding a proposed arrangement between a professional chiropractor association and a referral service. In Advisory Opinion 09-16, the OIG concluded that the proposed referral arrangement between the organizations did not constitute grounds for the imposition of civil monetary penalties for a violation of the Anti-Kickback Statute.

The association which requested the Advisory Opinion is a not-for-profit corporation open to membership for any chiropractor of good character, licensed to practice in the state where the association is incorporated (the “Association”). The referral service is a for-profit corporation that intends to advertise chiropractor services in the metropolitan area where the Association is located (the “Network”). The Network intends to provide referrals for chiropractic services through internet, print, radio or television advertising. A prospective patient who contacts the Network for a chiropractor referral will be asked to provide a zip code. The Network will then provide the patient with contact information for a participating chiropractor who practices in that zip code or, if no participating chiropractor practices in that zip code, in a nearby zip code. If more than one participating chiropractor is in the particular zip code, a name will be provided in sequence from a rotating list. The referral service will be open to participation by any chiropractor licensed to practice in the state for a standard flat fee of \$200 per month.

Pursuant to the proposed arrangement, the Association and the Network would enter into an agreement by which the Association’s members would have access to the Network’s referral service for a reduced fee of \$60 per month (the “Proposed Arrangement”). Except for this discount, the Association’s members would not be treated any differently than any other chiropractors who participate in the referral service. Also under the Proposed Arrangement, the Association would form a for-profit subsidiary. The Network would pay the subsidiary a flat fee of \$10 per month for each of the Association’s members who participate in the Network’s referral service. In return for this compensation, the Association would advertise and promote the Network’s referral service through e-mails and faxes to its members and to non-members through its quarterly publication, and at state-wide conventions, conference calls, webinars and other meetings.

In reviewing the Proposed Arrangement, the OIG undertook an analysis as to whether it violated the Anti-Kickback Statute or would be subject to civil monetary penalties under Section 1128A(a)(7) of the Social Security Act. 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 of services reimbursable by a Federal health care program. Pursuant to Section 1128A(a)(7), when a party commits an act described in the Anti-Kickback Statute, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party. It may also initiate administrative proceedings to exclude such party from Federal health care programs.

The OIG concluded that the Proposed Arrangement poses a minimal risk of fraud and abuse, and therefore, would not impose administrative sanctions under Section 1128A(a)(7) of the Social Security Act. The OIG’s conclusion in this regard was based upon the following factors:

- Although there would be a variation in the fees charged by the Network to participating chiropractors, the participation fee would not vary on the basis of referrals of Federally payable business. Furthermore, the referral of potential patients to participating chiropractors would be on a rotating basis, by geographic area, and would not be influenced by the variation and fees paid by participants.

- Although the Network’s proposed payment to the Association’s for-profit subsidiary of \$10 per month for each Association member who participates in the Network would vary with the amount of business generated for the Network, it would not vary with referrals of items or services payable by Federal health care programs. The OIG pointed out that unlike some sponsors of referral services, such as hospitals, the Network does not provide items or services payable by Federal health care services.
- The Network’s referral service would be open to participation by any chiropractor licensed to practice in the state, and participating chiropractors would receive referrals on an equal basis. Furthermore, the Network would impose no requirements on the manner in which participating chiropractors provide services to referred persons.

The OIG points out in the Advisory Opinion that the Proposed Arrangement does not qualify for protection under the Anti-Kickback Statute’s Safe Harbor for referral services as it does not meet the requirement that referral fees be assessed uniformly against all participants.

It is important to note that the OIG’s opinion in this regard pertains only to the Association which requested the Advisory Opinion. Nevertheless, it is clear from this Advisory Opinion that a professional association can structure an arrangement with a referral service that does not violate the Anti-Kickback Statute.

If you have any questions or concerns regarding this Advisory Opinion, please don’t hesitate to contact any of the attorneys in the Health Care Practice Group at The Rogers Law Firm.

PFIZER AGREES TO \$2.3 BILLION SETTLEMENT

Pfizer, Inc. and its subsidiary, Pharmacea and Upjohn Company, Inc., recently agreed to pay a \$2.3 billion settlement to the United States Government to resolve charges that the company illegally promoted several of its drugs, including the pain-killer, Bextra. The settlement represents the largest health care fraud settlement in the history of the United States Department of Justice (the “DOJ”).

According to the DOJ, Pfizer encouraged doctors to prescribe Bextra for off-label uses, such as acute pain. The settlement also includes \$1.0 billion dollars to resolve whistleblower complaints that Pfizer illegally promoted Bextra, Geodon (anti-psychotic medication), Zoivox (antibiotic) and Lyrica (epilepsy drug). The DOJ stated that Pfizer treated doctors to meals, paid them for speaking engagements and subsidized their travel to induce them to prescribe off-label uses for these four drugs and nine others.

Pursuant to the Settlement Agreement, Pfizer will enter into a Corporate Integrity Agreement (“CIA”) with the United States Department of Health and Human Services, which will require them to engage an independent review organization to help the company assess and evaluate its promotional and product-related business functions. Furthermore, Pfizer will have to create a mechanism for doctors to report questionable conduct by Pfizer sales representatives. In announcing the settlement, Pfizer expressly denied “all of these civil allegations, with the exception that Pfizer acknowledges certain improper actions related to the promotion of Zoivox.”

FIRST CIRCUIT ISSUES

EMTALA STABILIZATION DECISION

The United States First Circuit Court of Appeals recently issued a decision affirming summary judgment in favor of a hospital which was being sued for violations of the Emergency Medical Treatment and Labor Act (“EMTALA”). The Court ruled that a hospital cannot violate its duty to stabilize under EMTALA unless it actually transfers the patient.

In the case of *Alvarez-Tores v. Ryder Memorial Hospital, Inc.* (No. 08-2351, September 4, 2009), Adalberto Martinez Lopez came to Ryder Memorial Hospital’s Emergency Room complaining of chest pain and bleeding from a femoral dialysis catheter site. Mr. Martinez was examined by physicians and eventually admitted to the hospital. Physicians, however, were unable to stop the bleeding and the next day a blood transfusion was ordered. Furthermore, it was determined that Mr. Martinez required surgery and the recommendation was made by the physicians that he be transferred to another hospital for a specific procedure. Mr. Martinez died before he was transferred to the other hospital. His wife and children filed a civil action against the hospital and several physicians for medical malpractice and violations of EMTALA.

EMTALA is the Federal law that requires all Medicare participating hospitals with dedicated Emergency Departments to perform the following for all individuals who come to the Emergency Department regardless of their ability to pay: (i) appropriate medical screening examination to determine if the individual has an emergency medical condition; and (ii) if there is an emergency medical condition, the hospital must treat and stabilize the emergency medical condition within its capability or transfer the individual to a hospital that has the capability and capacity to stabilize the emergency medical condition.

In *Tores*, the District Court dismissed the EMTALA claims against the hospital for failure to screen or stabilize Mr. Martinez. The Plaintiffs appealed the stabilization ruling arguing that the hospital violated its duty to stabilize Mr. Martinez by failing to dispense a meaningful treatment until it became apparent that he was about to die. In the alternative, the Plaintiffs argued that even if the duty to stabilize applies only when a patient is transferred, “transfer” does not require a patient to physically leave the hospital, but only for a physician to enter an order of transfer. The First Circuit affirmed the District Court’s ruling stating that the duty to stabilize under EMTALA “does not impose the standard of care prescribing how physicians must treat a critical patient’s condition while he remains in the hospital, but merely prescribes a precondition the hospital must satisfy before it may undertake the transfer the patient.” The Court held that the hospital did not violate the stabilization provision because Mr. Martinez was never transferred. The Court stated that the duty to stabilize attaches when a hospital transfers a patient. EMTALA clearly defines “to stabilize” as “to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility.”

If you have any questions regarding the Court’s decision in *Tores*, please don’t hesitate to contact any of the attorneys in the Health Care Practice Group at The Rogers Law Firm.

OIG ISSUES 2010 WORK PLAN

The Office of Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”), recently issued its Work Plan for Fiscal Year 2010 (the “Work Plan”). The Work Plan describes activities that the OIG plans to initiate or continue with respect to the programs and operations of Federal health care programs during fiscal year 2010. The purpose of the OIG is to protect the integrity and well-being of Federal health care programs and hold accountable those who do not meet Federal health care program requirements or who violate Federal laws. The following sets forth some of the areas and issues the OIG intends to audit, evaluate and inspect during fiscal year 2010 for hospitals, physicians and other Medicare Part A/B providers:

Hospitals

- **Part A Capital Payments** – The OIG will review Medicare inpatient capital payments and determine whether capital payments are appropriate and analyze the appropriateness of the payment level.
- **Provider-Based Status of Inpatient and Outpatient Facilities** – The OIG intends to review cost reports of hospitals claiming provider-based status for inpatient and outpatient facilities. The OIG will determine the appropriateness of the provider-based designation and the potential impact on Medicare and its beneficiaries for hospitals improperly claiming such provider-based status.
- **Hospital-Based Status for Physician Outpatient Services under IPPS** – The OIG intends to review the appropriateness of payments for non-physician outpatient services that were provided shortly before or during Medicare Part A covered stays at acute care hospitals.
- **Hospital Readmissions** – The OIG will review Medicare claims to determine trends in the number of hospital re-admission cases.
- **Adverse Events** – The OIG will review adverse health care events to estimate the national incidents among Medicare beneficiaries, the methods of identifying adverse health care events, the implementation of Medicare’s Policy for Hospital-Acquired Conditions, the responses by Medicare oversight entities (i.e., State Surveyors and Certification agencies), and the policies and procedures of CMS and selected patient safety organizations for disclosing information about adverse health care events and the associated protections intended to ensure patient privacy.
- **Hospital Compliance with EMTALA** – The OIG intends to review CMS’ oversight of hospitals’ compliance with the Emergency Medical Treatment and Labor Act.
- **Payments for Diagnostic X-Rays in Hospital Emergency Departments** – The OIG intends to review a sample of Medicare Part B paid claims and medical records for diagnostic x-rays performed in hospital Emergency Departments to determine the appropriateness of payments.

Physicians and Other Medicare Part A/B Providers

- **Physician Billing for Medicare Hospital’s Beneficiaries** – The OIG will review the extent of Part B billing for physician services provided to Medicare hospital beneficiaries.
- **Medicare Payments for E-Prescribing** – The OIG will review Medicare incentive payments

made in 2010 to eligible health care professions for their 2009 e-prescribing activities.

- **ASC Payment System** – The OIG will review the appropriateness of the methodology for setting ambulatory surgical center payments rates under the revised ambulatory surgical center payment system.
- **Outpatient Physical Therapy Services Provided by Independent Therapists** – The OIG intends to review outpatient physical therapy services provided by independent therapists to determine whether they are in compliance with Medicare regulations.
- **Ambulance Services Used to Transport ESRD Beneficiaries** – The OIG will review the extent to which ambulance services are used to transfer end-stage renal disease beneficiaries to and from dialysis facilities. The OIG will examine factors such as the percentage of the population using ambulance services, the feasibility of contracting by free-standing facilities with ambulance suppliers and the coverage policies of other health insurance programs.

If you have any questions regarding the Work Plan, please do not hesitate to contact any of the attorneys in the Health Care Practice Group at The Rogers Law Firm.

The Rogers Law Firm has been representing health care providers in Massachusetts for over 30 years, including integrated health care delivery systems, hospitals, physician groups, ambulance services, nursing homes, hospices and individual providers. In addition to having a specialty group dedicated to health care law, we recognize that managers in the health care industry, now more than ever, need to be able to project and control costs, which is why we have introduced **Fixed Fee Assurance** for health care providers and organizations. This means we can provide a fixed fee cost for most legal projects in advance as opposed to open-ended billable hours, allowing you to better budget and plan for your legal bill from the outset.



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