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PHYSICIAN SUPERVISION REQUIREMENTS AMENDED UNDER CMS 2010 OPPTS FINAL RULE

The Centers for Medicare and Medicaid Services (“CMS”) recently issued its final calendar year 2010 Hospital Outpatient Prospective Payment System Rule (the “Rule”). The Rule, which becomes effective January 1, 2010, amends and clarifies the CMS requirements for supervision of hospital outpatient services. These changes to the supervision requirements will present a significant challenge for many hospitals.

The following is an overview of the more notable modifications to the Rule’s physician supervision requirements for hospital outpatient services:

- Clinical psychologists, physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives (“Non-Physician Practitioners” or “NPPs”) may directly supervise most hospital outpatient services they may perform themselves within their state’s scope of practice and hospital-granted privileges and provided they meet collaboration and supervision requirements;
- Either physicians or NPPs must provide actual “direct supervision” of outpatient therapeutic services provided “incident to” the services of a physician;

Four TRLF Attorneys Named to 2009 Massachusetts Super Lawyers and Rising Stars

Wilson D. Rogers, Jr. has been selected for inclusion in 2009 Massachusetts *Super Lawyers* in the area of business/corporate law. Additionally, Mark C. Rogers and Robert E. Driscoll, Jr. have been named to 2009 Massachusetts *Rising Stars* in the area of health law, and Megan M. Grew has been named to 2009 Massachusetts *Rising Stars* in the area of medical malpractice defense. The lists were recently published in *Super Lawyers Magazine*, as well as the November issue of *Boston Magazine*.

- “Direct Supervision” for on-campus services can be from anywhere on the hospital’s campus, but supervising professionals must be “immediately available”;
- Supervising professionals for off-campus services must be present in the off-campus provider-based department and “immediately available” to furnish assistance and direction throughout the performance of the procedure; and
- NPPs may not supervise the provision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation. Only physicians may supervise these services.

One benefit of CMS’ clarification to the Rule is that for on-campus services, the supervising physician or NPP may be anywhere on the hospital campus as long as he/she is immediately available to furnish assistance and direction throughout the performance of the procedure being supervised. It is interesting to note that CMS did not define “immediately available” in the Rule. However, in the proposed Rule, CMS stated that “immediate” means “without interval of time”.

Certainly, with the issuance of the Rule, hospitals need to review their existing policies and procedures for supervision of outpatient services. Many hospitals will need to revise their policies to comply with the Rule.

If you have any questions or concerns regarding the Rule, or changes to your policies and procedures, please do not hesitate to contact any attorneys in the Health Care Practice Group of The Rogers Law Firm.

RED FLAGS RULE DELAYED UNTIL JUNE 1, 2010

The Federal Trade Commission (“FTC”) recently announced that it was delaying enforcement of the “Red Flags Rule” until June 1, 2010. The Red Flags Rule, which was mandated by the Fair and Accurate Credit Transactions Act of 2003 (“FACTA”) is an anti-debt fraud regulation requiring creditors (which term includes most health care providers) and financial institutions with covered accounts to implement programs to identify, detect, and respond to the warning signs, or red flags, that could indicate identity theft. FACTA’s definition of creditor includes any entity that regularly extends or renews credit, or arranges for others to do so, and includes all entities that regularly permit deferred payments for goods or services, such as finance companies, automobile dealers, mortgage brokers, utility companies, telecommunication companies, physician offices, clinics, hospitals and many other types of businesses. The Red Flags Rule requires these entities to develop a written identity theft prevention program that identifies and detects the relevant warning signs of identity theft. The written program must describe appropriate responses that would prevent and mitigate the crime and detail a plan to update the program. The Red Flags Rule requires that the written program be managed by the board of directors or senior employees of the entity, include appropriate staff training and provide for oversight of any service provider. A covered entity which fails to comply with the Red Flags Rule is subject to a civil penalty of more than \$2,500 for knowing violation, which could amount to a \$2,500 fine for each covered account that the business maintains.

The recent announcement by the FTC marks the fourth time the enforcement of the Red Flags Rule has been delayed. Furthermore, there is an effort within Congress to exclude certain small business, including healthcare practices with twenty or fewer employees, from complying with the Red Flags Rule. In addition, the American Medical Association is lobbying the FTC and Congress to republish the rule so there is sufficient opportunity to formally comment and state the AMA's objection to physician inclusion in the program.

It is important to note that in addition to the Red Flags Rule, most Massachusetts businesses must also comply with Massachusetts' new Data Security Regulations (the "Regulations"), which go into effect on March 1, 2010. The Regulations apply to all persons and businesses that own or license personal information about a Massachusetts resident. The Regulations set forth minimum requirements for safeguarding personal information (name plus social security number, driver's license number or financial account number) of Massachusetts residents that is stored either electronically or in hard-copy form. Similar to the Red Flags Rule, the Regulations require each entity to develop and adopt a written comprehensive information security program detailing your business or entity's policies and procedures for securing and protecting personal information.

The Rogers Law Firm has developed a comprehensive Data Security Compliance Program which assists entities in complying with both the Red Flags Rule and the Regulations.

If you have any further questions regarding the Red Flags Rule or the Regulations or are interested in learning more about The Rogers Law Firm's Data Security Compliance Program, please do not hesitate to contact Peter Pommersheim, Esq. at The Rogers Law Firm at 781-794-1600 or ppommersheim@therogerslawfirm.com.

MEDICARE PHYSICIAN FEE SCHEDULE ISSUED FOR 2010

The Centers for Medicare and Medicaid Services recently issued its Calendar Year 2010 Medicare Physician Fee Schedule Final Rule (the "Final Rule"). The Final Rule includes a 21.2% cut in Medicare payments to physicians in accordance with the Sustainable Growth Rate ("SGR"), which was a formula that was adopted in the Balanced Budget Act of 1997 to adjust annual payment rates to physicians. The formula has yielded negative updates every year since 2002, leading Congress to take action each year to avoid cutting physician payment rates. Although the U.S. House of Representatives recently passed legislation to delay the 21.2% rate decrease through February 28, 2010. The hope is that by delaying the rate cut until March 1, Congress will have time to pass a bill by then which will permanently repeal the SGR Formula. The U.S. Senate is expected to vote this Friday (December 18, 2009) on proposed legislation delaying the rate cut through February. The failure of Congress to take action to avoid a rate cut could lead to a significant number of physicians refusing to treat Medicare patients beginning January 1, 2010.

The Final Rule also implements a number of provisions from the Medicare Improvements for Patients and Providers Act of 2008, including:

- Increasing the Medicare share of payments for outpatient mental health services to 55% (from 50%) in order to begin a gradual transition to bring payment parity for mental health and medical services furnished to Medicare beneficiaries;
- Adding new Medicare benefit categories for cardiac and pulmonary rehabilitation services and for chronic kidney disease; and
- Implementing the requirement that suppliers of the technical component of Advanced Imaging Services be accredited beginning January 1, 2012. The accreditation requirement will apply to mobile units, physician's offices, and independent diagnostic testing facilities that create the images, but will not apply to the physicians who interpret them.

The Final Rule also includes changes for the Physician Quality Reporting Initiative and the E-Prescribing Incentive Program. The Physician Quality Reporting Initiative is a voluntary reporting program that provides an incentive payment to eligible professionals, including physicians, who satisfactorily report data on quality measures for covered professional services. Beginning January 1, 2010, group practices, defined as those with a minimum of 200 eligible professionals, as well as individuals, will be able to report on quality measures and receive the incentive payment.

The E-Prescribing Program promotes the use of electronic prescribing by authorizing incentive payments of 2% of total Medicare Part B allowed charges to eligible professionals or group practices who are successful electronic prescribers. The Final Rule simplifies the reporting requirements, provides broader eligibility for the E-Prescribing Incentive, and enables group practices to qualify for an incentive payment based on a determination at the group practice level, rather than at the individual eligible professional level, that the group practice is a successful electronic prescriber. The Final Rule also provides that beginning in 2012, eligible professionals who are not successful e-prescribers will be assessed a penalty.

If you have any questions regarding CMS's Final Rule for the Calendar Year 2010 MPFS, please do not hesitate to contact any attorneys in the Health Care Practice Group at The Rogers Law Firm.

IRS ISSUES GOVERNANCE CHECK SHEET FOR TAX-EXEMPT ORGANIZATIONS

On December 9, 2009, the United States Internal Revenue Service issued a "Governance Check Sheet" (the "Check Sheet") and a related "Governance Project Guide Sheet for Completing the Project Check Sheet" (the "Guide Sheet") to be used by IRS agents to capture data about governance practices and the related internal controls of tax-exempt organizations being examined. The data from the study will be utilized by the IRS to get a better understanding of the intersection between the governance practices and tax compliance of tax-exempt organizations. More importantly, the Check Sheet and the Guide Sheet can to be utilized by tax-exempt organizations to assess their governance practices. The IRS continues to emphasize the importance of good governance practices to increase the likelihood that tax-exempt organizations will comply with applicable tax regulations, protect their charitable assets

and serve their charitable beneficiaries.

The Check Sheet is broken down into the following categories: Governing Body and Management; Compensation; Organizational Control; Conflict of Interest; Financial Oversight; and Document Retention. Some of the more notable questions on the Check Sheet include:

- Does the organization have a written mission statement that articulates its current I.R.C. § 501(c)(3) purpose(s)?
- Does the organization's bylaws set forth the composition, duties, qualifications and voting rights of the members of the governing body and the organization's officers?
- Have copies of the most recent version of the entity's Articles of Organization and bylaws been provided to the board members?
- Are compensation arrangements for all officers, directors, trustees and key employees approved in advance by an authorized body of the organization composed of individuals with no conflict of interest with respect to their compensation arrangement?
- Does the authorized body rely upon comparability data in making compensation determinations?
- Do any of the organization's voting board members have a family relationship and/or outside business relationship with any other voting or non-voting board member, officer, director, trustee or key employee?
- Does the organization have a written Conflict of Interest Policy?
- How often does the organization provide board members with a written report regarding the organization's financial activities?
- How often did the board discuss/consider reports of the organization's financial activities?
- Prior to filing, was the Form 990 reviewed by the full board and/or a designated committee?
- Does the organization have a written policy for document retention and destruction?
- Does the board contemporaneously document its meetings and retain such documentation?

The Check Sheet can be a very useful tool for tax-exempt organizations, including non-profit hospitals in Massachusetts, to review their existing governance practices.

If you have any questions regarding the Check List or would like to know more about the best practices for governance of tax-exempt organizations, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

FDA RELEASES GUIDANCE FOR CLINICAL INVESTIGATOR RESPONSIBILITIES

The United States Food and Drug Administration (“FDA”) recently issued *Guidance for Industry, Investigator Responsibilities-Protecting the Rights, Safety and Welfare of Study Subjects* (the “Guidance”). The Guidance provides an overview of the responsibilities of a person who conducts a clinical investigation of a drug, biological product or medical device. The purpose of the Guidance is to help investigators better meet their responsibilities with respect to protecting human subjects and ensuring the integrity of the data from clinical investigations. Although the Guidance does not establish legally enforceable responsibilities for investigators, it does provide insight into the FDA’s current thinking on the interpretation and enforcement of specific federal regulations pertaining to the protection of study subjects.

The Guidance is intended to clarify for investigators and sponsors the FDA’s expectations concerning the investigator’s responsibility (1) to supervise the clinical study in which study tasks are delegated to employees or colleagues of the investigator or other third parties; and (2) to protect the rights, safety and welfare of study subjects. In regard to the supervision of a clinical study, the FDA focuses on four major areas: (1) whether delegates were qualified to perform the delegated task; (2) whether study staff received adequate training on how to conduct the delegated task and were provided with an adequate understanding of the studies; (3) whether there was adequate supervision and involvement in the ongoing conduct of the study; and (4) whether there was adequate supervision or oversight of any third parties involved in the study, to the extent such supervision or oversight was reasonably possible.

In regard to an investigator’s obligation to protect the rights, safety and welfare of study subjects, the Guidance states that such obligations include (1) providing reasonable medical care for the study subjects for medical problems arising during participation of the trial that are, or could be, related to the study intervention; (2) providing reasonable access to medical care when specialized care is needed; and (3) adhering to the protocol so that study subjects are not exposed to unreasonable risks.

The Guidance can be found at:

[fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm187772.pdf](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm187772.pdf).

If you have any questions or concerns regarding the Guidance and its implications for investigators and clinical research sites, please do not hesitate to contact any of the attorneys in the Health Care Practice Group at The Rogers Law Firm.

FORMER HOSPITAL FACILITIES ADMINISTRATOR CHARGED WITH STEALING MILLIONS OF DOLLARS

The Massachusetts Attorney General's Office recently announced the arraignment of a former project manager at a local hospital in connection with allegedly stealing millions of dollars from the institution in fraudulent construction contracts. The former project manager, John Lawler, was arrested after a two-year investigation by the Attorney General's Office into his alleged activities after receiving information from an investigator at a bank where Mr. Lawler kept a bank account. The investigator discovered that while working as a project manager for the hospital, Mr. Lawler oversaw the contracts and the accounts for construction projects done at the hospital. The Attorney General's Office alleges that Mr. Lawler set up fake bank accounts in the name of one of the construction companies and allegedly stole the hospital's payment checks to the construction company and deposited these funds in the fraudulent bank account for his personal use.

The Attorney General's Office stated that during its investigation it discovered that Mr. Lawler allegedly hired numerous smaller size contractors and provided these contractors with large amounts of construction work. The authorities allege that many of these contractors were the defendant's personal friends and many of the invoices submitted to the hospital by these contractors were also fraudulent. Investigators believe that Mr. Lawler helped these contractors submit fraudulent invoices from which the contractors received hundreds of thousands of dollars in payments, in return for which Mr. Lawler received either personal services or cash in return from these contractors. Mr. Lawler pled not guilty and is being held on \$350,000 cash bail.

The arraignment of Mr. Lawler should serve as a reminder to hospitals and other healthcare organizations to take the necessary steps to ensure that appropriate controls are in place within their organization to detect and prevent fraudulent and illegal acts. Specifically, healthcare facilities should ensure that there is appropriate coordination between corporate compliance, internal audit, senior management and the board to detect and prevent fraud and abuse.

This Newsletter is published by The Rogers Law Firm to keep health care providers and administrators 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 in The Rogers Law Firm's Health Care Practice Group at 781.794.1600.

LATEST NEWS:

TRLF Article on Proper Non-Profit Board Orientation

December 13, 2009 --- Mark C. Rogers, Esq., of The Rogers Law Firm, recently wrote an article for thenon-profittoolbox.com. The article, entitled "Orienting the Non-Profit Board", discusses how important it is for a non-profit organization to provide an appropriate orientation to new members of their board of directors (trustees). The article can be found at www.thenon-profittoolbox.com/2009/12/orienting-the-non-profit-board-mark-c-rogers-esq/.

TRLF Provides Webinar on Informed Consent in Clinical Trials

November 17, 2009 --- Mark C. Rogers, Esq., of The Rogers Law Firm, gave a webinar for FDAnews on informed consent in clinical trials. The webinar, entitled "Avoid Clinical Trial Liability: Improving Your Informed Consent Practices", was presented to over 100 people across the country involved with clinical research trials.

TRLF Successfully Defends Medical Malpractice Action

November 6, 2009 --- Wilson D. Rogers, III, Esq., of The Rogers Law Firm successfully defended a medical malpractice trial in the Essex Superior Court on behalf of a nurse. The Plaintiff had alleged that he had sustained injuries as a result of the attempted placement of a Foley catheter, first by the Nurse Defendant and subsequently by a Physician Co-Defendant. Specifically, the Plaintiff sustained injuries to his urethra and rectum, allegedly as a result of the placement of the catheter.

TRLF Secures Defense Verdict in Wrongful Death Action

October 30, 2009 --- Wilson D. Rogers, III, Esq., of The Rogers Law Firm, secured a defense verdict in a wrongful death action in Suffolk Superior Court on behalf of a nurse practitioner and two registered nurses. The case alleged that the nurse practitioner and the registered nurses were negligent with respect to their assessment and evaluation of a premature newborn who developed necrotizing enterocolitis. After a two-week trial, the jury returned a verdict finding that the nurse practitioner and the registered nurses were not negligent.



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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, home care organizations, 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.