



In this issue:

Massachusetts Enacts Amendments to Hospital and Clinic Licensure Regulations.....1

OIG: On-Call Physicians May Be Compensated for Providing Services to Uninsured Patients...5

DPH Issues "Frequently Asked Questions" for Biopharma Gift-Giving Law..... 8

Enforcement of Red Flags Rule Delayed for Three Months..... 9

FDA Issues Draft Guidance on Presenting Risk Information in Prescription Drug and Medical Device Promotion..... 10

HHS Releases Guidance for Securing Health Information..... 11

HHS and DOJ Launch Healthcare Fraud Prevention and Enforcement Action Team.....12

The Rogers Law Firm

50 Braintree Hill Office Park
Suite 302
Braintree, MA 02184

Phone: 781.794.1600

Fax: 781.794.1610

www.therogerslawfirm.com

Wilson D. Rogers, Jr.
Peter Pommersheim
Michael J. Fazio, Jr.
Wilson D. Rogers, III
Francis J. O'Connor
Mark C. Rogers
Megan M. Grew
Robert E. Driscoll, Jr.
Lawrence P. Donnelly

**MASSACHUSETTS ENACTS
AMENDMENTS TO HOSPITAL
AND CLINIC LICENSURE
REGULATIONS**

The Public Health Council ("PHC") of the Massachusetts Department of Public Health ("DPH") recently enacted amendments to Massachusetts' regulations regarding hospital licensure¹ and licensure of clinics² ("final regulations"). The final regulations implement certain provisions of Chapter 305 of the Acts of 2008, An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care (the "Act"), which was signed into law by Governor Deval Patrick on August 10, 2008. The final regulations purport to increase safety and improve quality of care by:

- (1) bringing greater transparency to the health care system;
- (2) prohibiting hospitals and clinics from seeking payment for certain adverse events; and
- (3) requiring hospitals and clinics to form patient councils and to develop methods to respond to a deterioration in a patient's condition.

The proposed amendments were initially released for comment by DPH on February 11, 2009. Public comment hearings were held on March 23, 2009 in Boston and on March 30, 2009 in Springfield, and the public comment period closed on April 6, 2009. Testimony and written comments were received from approximately forty (40) organizations and individuals.

This article summarizes revisions to the proposed amendments included in the final regulations. For a detailed discussion of the proposed amendments, see the related article in The Rogers Law Firm's Health Care Practice Group April Newsletter, available at:

<http://therogerslawfirm.com/newsletters/Volume26.pdf>.

¹105 CMR 130.000 et seq.

²105 CMR 140.000 et seq.

HOSPITAL LICENSURE REGULATIONS

The Act added five (5) new requirements to the hospital licensing statutes enumerated at M.G.L. c. 111. The final regulations include technical and substantive changes to the proposed amendments. A summary of the revisions incorporated into the final regulations follows:

1. Reporting and Reimbursement for Serious Reportable Events ("SREs")

In 2007, DPH revised its reporting forms to require hospitals to identify and report those incidents that meet the National Quality Forum's ("NQF's") definition of Serious Reportable Event ("SRE"), in addition to the previous reporting requirements. Twenty-eight (28) events currently meet the definition of an SRE on the NQF's most recent list of NQF-endorsed events. The Act requires hospitals to report SREs to DPH and prohibits hospitals from charging or seeking reimbursement for services provided as the result of an SRE that meets criteria established in the statute and by DPH regulations.

The final regulations require hospitals to report all serious incidents or accidents, including SREs, to DPH. Section 130.331(A) describes incidents that must be reported to DPH "immediately," and section 130.331(C) describes those incidents that must be reported within seven days of occurrence. DPH revised the language about which deaths must be immediately reported to DPH to read: "Death that is unanticipated, not related to the natural course of the patient's illness or underlying condition, or that is the result of an error or other incident as specified in guidelines of [DPH]." In addition, the amendments were revised to require that accidents or incidents resulting in serious physical injury to a patient must be reported within seven days, rather than immediately.

Section 130.332 requires hospitals to file a written report with DPH within seven (7) days of the date of discovery of all SREs. In order to charge or seek reimbursement for services provided as a result of an SRE, the amendments require a hospital to make a preventability determination following a documented review process to determine whether the SRE was: (1) preventable; (2) within the hospital's control; and (3) unambiguously the result of a system failure based on the hospital's policies and procedures. No later than thirty days after the date the initial SRE report is filed with DPH a hospital must (1) make the required preventability determination, (2) update the initial SRE report to describe its preventability determination, and (3) provide copies of the updated report to DPH, any responsible third-party payers and the patient. The updated report must include at least the following information:

- (i) narrative description of the SRE;
- (ii) analysis and identification of the root cause of the SRE;
- (iii) analysis of the preventability criteria required by 105 CMR 130.332(C)(1);
- (iv) description of any corrective measures taken by the hospital following discovery of the SRE; and
- (v) whether the hospital intends to charge or seek reimbursement for services provided by the hospital as a result of the SRE.

Language was added to the final regulations requiring hospitals to suspend claims processing pending the outcome of the preventability determination: "A hospital shall immediately suspend or rescind any claims to any patient or responsible third-party payer pending the preventability determination and notification requirements of 105 CMR 130.332(C)." Lastly, section 130.332 has been revised to include four sections: (A) Definitions; (B) Reporting of SREs; (C) Preventability Determination; and (D) Reimbursement for SREs.

2. Reporting of Healthcare-Associated Infections ("HAIs")

In 2008, DPH promulgated an amendment to the hospital licensure regulations requiring hospitals to report HAI process and outcome measures to the National Healthcare Safety Network ("NHSN") and to grant access to HAI data to DPH and the Betsy Lehman Center. The definition of HAI at 105 CMR 130.1700 was revised in the final regulations to add the following: "Healthcare-Associated Infection means a localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that: (i) occurs in a patient in a hospital; (ii) was not present or incubating at the time of the admission during which the reaction occurs; and (iii) meets the criteria for a specific infection site as defined by the Federal Centers for Disease Control and Prevention and its NHSN."

3. Patient and Family Advisory Council ("PFAC")

The final regulations require hospitals to establish patient and family advisory councils to facilitate patient and family participation in hospital care and decision-making, information sharing, and policy and program development. The PFAC will advise the hospital on matters including but not limited to: patient and provider relationships, institutional review boards, quality improvement initiatives and patient education on safety and quality matters. The proposed amendment requires hospitals to adopt and implement policies and procedures that govern a PFAC's goals, membership, training, and roles and responsibilities. The proposed amendments were revised to extend the implementation deadline from September 1, 2009 to October 1, 2010, and to require hospitals to prepare a written report by September 30, 2009 outlining their plans to meet the October 1, 2010 timeline. The amendments were further revised to require hospitals to prepare an annual report beginning on October 1, 2010, documenting compliance with the PFAC requirement and describing the PFAC's accomplishments during the preceding year. The final regulations will also require hospitals to make the September 30, 2009 plan and October 1st annual reports "publicly available through electronic or other means, and to [DPH] upon request." Lastly, the final regulations require that the PFAC family and patient members should be "representative of the community served by the hospital."

4. Retention of Patient Records

The final regulation governing hospital patient records has been revised to comply with amendments to M.G.L. c. 111, § 70. The proposed amendments: (1) reduce the record retention period from 30 to 20 years; (2) clarify that the retention period runs from the date of discharge or the final treatment related to the episode of care contained in the record; (3) require hospitals to notify DPH before destroying records; (4) permit hospitals to convert existing paper records to electronic digital format before the expiration of the retention period and to create original records in electronic digital format; and (5) require hospitals to notify patients in writing of the hospital's record retention and destruction policies. Language was added to the final regulations to clarify that a hospital may - but is not required to - notify patients before destroying records.

5. Rapid Response Method ("RRM")

The final regulations require acute care hospitals to adopt an early recognition and response method for staff members, patients and families to request additional assistance directly from a specially-trained individual if a patient's condition appears to be deteriorating. The final regulations were revised to require written documentation for each instance of activation of the RRM, "including assessment of patient and family member satisfaction with the RRM," consistent with the Joint Commission's National Patient Safety Goals.

6. Additional Changes Incorporated in the Final Regulations:

a. *Maternal and Newborn Services*

The final regulations include several technical corrections to the existing maternal and newborn service sections. The final regulations were revised to read: "The hospital shall plan, develop and budget its nurse staffing pattern for the maternal and newborn service using data from a patient classification system acceptable to [DPH]. If a classification system is not used, the hospital shall apply nationally recognized staffing standards acceptable to [DPH] to the facility's case-mix and volume." The word "emergency" was added before "cesarean surgical birth" at sections 130.630(C)(17), 130.640(D)(3)(k) and 130.650(D)(2)(m) in response to comments received and as a technical correction.

The final regulations also adopt a standard requiring the capability to begin an emergency cesarean surgical birth within thirty (30) minutes of the decision to perform the procedure for all levels of care. Accordingly, a Level III Maternal Service will now be required to have the capability of beginning an emergency cesarean surgical birth within thirty minutes of the decision to perform the procedure, rather than 15 minutes. Thirty minutes is consistent with the American Academy of Pediatrics and American College of Obstetricians and Gynecologists ("ACOG") document titled, Guidelines for Perinatal Care, Sixth Edition, October 2007, as well as with the joint statement from ACOG and American Society of Anesthesiologists, Optimal Goals For Anesthesia Care in Obstetrics, last amended October 22, 2008.

b. *Operators of fluoroscopy equipment*

Extensive comment was received on the proposed amendment requiring individuals who operate the x-ray system in a hospital cardiac catheterization lab to comply with DPH's radiation control regulations. Those regulations restrict the operation of fluoroscopy equipment to physicians and radiologic technologists. Although hospitals must comply with the radiation control regulations whether they are specifically referenced at 105 CMR 130.940(H) or not, the reference has been deleted. DPH's radiation control program will evaluate its existing operator requirements. Meanwhile, hospitals must comply with the current staffing requirement unless and until the radiation control regulation is revised.

c. *Board certification for physician director of catheterization services that perform interventional cardiology*

Several commentators opined that board certification in interventional cardiology is not necessary for the physician director of a cardiac catheterization service that performs interventional cardiology procedures, as opposed to one that performs only diagnostic procedures. The proposed amendments were revised to provide the following: "The physician director of a cardiac catheterization service that performs therapeutic procedures who is not board certified in interventional cardiology may meet the requirement of this section by appointing a director of interventional cardiology who is board certified in interventional cardiology to assist with oversight."

d. *Five year post-fellowship experience requirement for director of electrophysiology services*

A grandfathering provision was added to the final regulations providing as follows: "Any physician director of electrophysiology services who was in the position on February 11, 2009 but who

does not meet the five year post-fellowship experience requirement shall be grandfathered regarding that five year requirement."

e. Peer review of service

Objections were raised to proposed amendments that require cardiac catheterization services to obtain a review by a "nationally recognized peer review organization approved by [DPH]," and the requirement that any physician conducting the peer review shall not have a practice based in Massachusetts. The final regulations were revised to require review by an "appropriately qualified peer review organization or individual(s)", but retained the requirement that the reviewer must be from outside the state.

LICENSURE OF CLINICS REGULATIONS

The Act adds four new requirements to the clinic licensing statutes, enumerated at M.G.L. c. 111. The revisions to the amendments to the clinic licensure regulationsPT essentially mirror those to the hospital licensure regulations in the areas of SREs, HAIs, and patient record retention. Additionally, the final regulations for clinic licensure include minor amendments to implement the new Determination of Need requirements. The final regulations also require notification to DPH of clinic closures and temporary interruption of service.

CONCLUSION

DPH has submitted the final regulations to the Secretary of the Commonwealth for publication in the Massachusetts Register. Based upon the Massachusetts Register's publication schedule, the final regulations will be published and therefore take effect on June 12, 2009. If you have any questions or concerns regarding the hospital licensure and/or licensure of clinics final regulations, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

OIG: ON-CALL PHYSICIANS MAY BE COMPENSATED FOR PROVIDING SERVICES TO UNINSURED PATIENTS

The Office of Inspector General ("OIG") of the United States Department of Health and Human Services recently issued an Advisory Opinion (Advisory Opinion 09-05) indicating that a hospital may compensate on-call physicians for services they provide to uninsured patients, without the threat of sanctions. This article provides an overview of the Advisory Opinion.

BACKGROUND

The Advisory Opinion pertains to a proposed arrangement of a non-profit 400-bed general hospital to amend the hospital's Bylaws to reflect a new on-call coverage policy: The hospital will allow participating physicians to submit claims to the hospital for payment for services rendered to certain indigent and uninsured patients presenting to the hospital's Emergency Department. The basis for the proposed arrangement is that the hospital currently has no arrangement to compensate its physicians for on-call services they render to Emergency Department patients who are indigent and uninsured. According to the hospital, most physicians dislike the duty of performing on-call coverage for its

Emergency Department because telephone calls requesting the physician to respond to the Emergency Department come at all hours, disrupting their professional and personal lives. The hospital also reports that one of its specialty practice groups has reduced its Emergency Department coverage to the minimum required under the hospital's current policy, citing no payment for on-call services. As a result of this, there are weeks each month when the hospital does not have needed specialists on-call and is forced to outsource emergency care pursuant to transfer agreements with other hospitals. The hospital believes that the proposed arrangement will address these issues and allow the hospital to better serve its patients.

The proposed arrangement would only apply to services rendered to "Eligible Patients." An Eligible Patient is one who does not have a sponsoring insurance plan and must eventually qualify for a state funded program as verified by the hospital's patient accounting department. In order for physicians to participate in the proposed arrangement, the physician must meet the following criteria: (i) must be an active member of the hospital's medical staff; (ii) must sign a Letter of Agreement with the hospital which provides, among other things, that the physician agrees to participate in the proposed arrangement and adhere to its policies; and (iii) must provide on-call coverage at the hospital's Emergency Department as part of the organized on-call schedule for the physician's medical staff department or specialty.

Under the proposed arrangement, a participating physician may submit a completed claim request to the hospital's Patient Financial Services Office after completing his/her provision of care to an Eligible Patient. The physicians receiving compensation under this proposed arrangement agree to waive all billing or collection rights, or claims against any third-party payer or the Eligible Patient for services rendered. The physicians will be compensated according to the following:

- Emergency consultations on an Eligible Patient: \$100.00 flat fee
- Care of Eligible Patients admitted as inpatients from the Emergency Department: \$300.00 per admission
- Surgical procedure or procedures performed on an Eligible Patient admitted from the Emergency Department: \$350.00 flat fee for the primary surgeon of record
- Endoscopy procedure or procedures performed on an Eligible Patient admitted from the Emergency Department: \$150.00 flat fee for the physician performing the endoscopic procedure

The compensation amounts set forth above were calculated by the hospital using an evaluation method that took into account the following factors: patient activity levels for Emergency Department patients; a blended fee incorporating fees across public, private and self-payers; an overall average length of stay based on average lengths of stay for public, private and self-payers; payer mix; and physicians' likely time commitment for the service. The hospital has certified that payments made under the proposed arrangement would be made solely on the services actually needed and provided and without regard for referrals or any other business generated between the hospital and the physicians. Furthermore, the hospital has certified that the payment amounts are within the range of fair market value for services rendered.

OIG ANALYSIS

In reviewing the proposed arrangement, the OIG noted that on-call coverage compensation potentially creates considerable risk that physicians may demand such compensation as a condition of doing business at a hospital. In particular, on-call compensation arrangements have the potential of violating the Anti-Kickback Statute. 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 or services reimbursable by a Federal health care program. According to the Advisory Opinion, the problematic on-call compensation structures that might disguise kickback payments could include: (i) "lost opportunity" or similarly designed payments that do not reflect bona fide lost income; (ii) payment structures that compensate physicians when no identifiable services are provided; (iii) aggregate on-call payments that are disproportionately high compared to the physician's regular medical practice income; or (iv) payment structures that compensate the on-call physician for professional services for which he or she receives separate reimbursement from insurers or patients, resulting in the physician essentially being paid twice for the same service.

The OIG noted that the Personal Services and Management Contracts Safe Harbor under the Anti-Kickback Statute is potentially applicable to the proposed arrangement. However, the OIG noted that the proposed arrangement does not fit squarely within the terms of the Safe Harbor as the Safe Harbor requires that the aggregate amount of compensation be set in advance. Under the proposed arrangement, the payments to physicians could vary month to month. Nevertheless, the OIG concluded that the proposed arrangement presents a low risk of fraud and abuse and stated that they would not subject the hospital to administrative sanctions under the Anti-Kickback Statute based on the following reasons:

- The hospital certified that the payment amounts are within the range of fair market value for services rendered, without regard to referrals or other business generated between the parties;
- The circumstances giving rise to the proposed arrangement suggest that the hospital has a legitimate rationale for revising its on-call coverage policy and reduce the risk that it will be used as a way to funnel unlawful remuneration to physicians for referrals;
- The proposed arrangement includes features that minimize the risk of fraud and abuse:
 - the proposed arrangement will be offered uniformly to all physicians;
 - the proposed arrangement will impose tangible responsibilities on all physicians;
 - the method of scheduling on-call coverage will be covered by the hospital's Medical Staff Bylaws;
 - the process for submitting physicians' claims for payment helps ensure that physicians are only paid for services rendered to Eligible Patients; and
- The proposed arrangement appears to be an equitable mechanism for the hospital to compensate physicians who actually provide care that the hospital must furnish to be eligible for state program funding.

The OIG found that the proposed arrangement appears to contain safeguards sufficient to reduce the risk that the remuneration is intended to generate referrals of federal health care program business.

CONCLUSION

Although the OIG concluded that the hospital would not be subject to sanctions under the proposed arrangement, it is important to note that the OIG's opinion in this regard pertains only to the particular hospital which requested the Advisory Opinion. Nevertheless, it is clear from this Advisory Opinion that a hospital can structure an on-call compensation policy to compensate physicians for providing services to uninsured patients, which will not subject the hospital to sanctions under the Anti-Kickback Statute. Any such arrangement, however, should be reviewed by legal counsel to ensure that it is appropriately structured to avoid any potential fraud and abuse liability exposure.

If you have any questions or concerns regarding the Advisory Opinion or how to structure an appropriate on-call compensation policy, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

DPH ISSUES "FREQUENTLY ASKED QUESTIONS" FOR BIOPHARMA GIFT-GIVING LAW

The Massachusetts Department of Public Health ("DPH") has issued a document entitled "Frequently Asked Questions for Pharmaceutical and Medical Device Manufacturer Conduct" (the "FAQ"). The FAQ pertains to final regulations promulgated by DPH implementing a new law governing gift giving and other sales and manufacturing practices of pharmaceutical and medical device manufacturers in Massachusetts. The final regulations require pharmaceutical and medical device manufacturers to:

- Adopt and comply with the most recent Marketing Code of Conduct as adopted by DPH;
- Adopt and submit to DPH the description of a training program designed to ensure that all representatives who are employed by or acting on behalf of a pharmaceutical or medical device manufacturer and who visit healthcare practitioners, have sufficient knowledge of the Marketing Code of Conduct, general science and product-specific information;
- Certify to DPH that they are in compliance with the Marketing Code of Conduct;
- Adopt and submit to DPH policies and procedures for investigating and taking corrective action in response to instances of non-compliance with the Marketing Code of Conduct; and
- Submit to DPH the name, title, address, telephone number, and electronic mail address of the compliance officer it has identified who is responsible for operating, monitoring and enforcing the Marketing Code of Conduct.

Pharmaceutical and medical device manufacturers must also certify to DPH that they have performed annual audits to ensure compliance with the Marketing Code of Conduct.

The FAQ is one of the means by which DPH is responding to questions by the healthcare industry regarding the new regulations. The following is just a few of the issues addressed by the FAQ:

- A representative of a pharmaceutical or medical device manufacturer may not take a physician out for a meal, outside of the hospital setting, unless the doctor is a bona fide employee or board member of the company;
- A manufacturer may provide educational items to a healthcare practitioner;
- The regulations prohibit payments from pharmaceutical and medical device manufacturers to healthcare practitioners except as compensation for bona fide services. Payment of expenses in conjunction with bona fide services, as defined in the regulations and in connection with product training pursuant to a contract to purchase a medical device, is permissible. A pharmaceutical or medical device manufacturer may provide meals to healthcare practitioners at restaurants located in the hospital; and
- If a pharmaceutical or medical device manufacturer has a contract with a healthcare practitioner that provides for entertainment or any other prohibited activity under the regulations beyond July 1, 2009, the contract must be voided or renegotiated to come into compliance with the new law.

The final regulations take effect on July 1, 2009, and submission of the first required disclosure report by pharmaceutical and medical device manufacturers will be due by July 1, 2010. The information reported by pharmaceutical or medical device manufacturers to DPH will be available to the public through the DPH website (www.mass.gov/dph) and will be searchable by pharmaceutical and medical device manufacturers and by healthcare practitioners.

If you have any questions regarding the FAQ or the final regulations, please don't hesitate to contact any of the attorneys at The Rogers Law Firm.

ENFORCEMENT OF RED FLAGS RULE DELAYED FOR THREE MONTHS

The United States Federal Trade Commission ("FTC") recently announced that it was again delaying enforcement of the new "Red Flags Rule" until August 1, 2009, "to give creditors and financial institutions more time to develop and implement written identity theft prevention programs." The Red Flags Rule was promulgated by the FTC in response to the Fair and Accurate Credit Transactions Act of 2003 ("FACTA"). FACTA directed financial regulatory agencies to promulgate rules requiring "creditors" and "financial institutions" to implement programs to identify, detect and respond to patterns, practices or specific activities that would indicate identity theft. A "creditor" is defined by FACTA as 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. Based upon this definition, the Red Flags Rule pertains to physician offices, clinics and hospitals. The American Medical Association had argued to the FTC that physicians should not be considered "creditors" under the law because they submit claims to health insurance carriers - which they believe should be considered the creditor.

Nevertheless, the FTC said physicians are creditors because they extend credit to patients when they bill them and do not require up-front payment.

If they have not already done so, healthcare providers must develop a written program that identifies and detects the relevant warning signs - or "Red Flags" - of identity theft. These warning signs include, for example, unusual account activity, fraud alerts on a consumer report, or attempted use of suspicious account application documents. The program must also 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 provider, include appropriate staff training and provide for oversight of any service providers.

The Red Flags Rule provides all financial institutions and creditors the opportunity to design and implement a program that is appropriate to their size and complexity, as well as the nature of their operations. The FTC has issued guidelines to assist covered entities in designing their programs. The guidelines can be found at www.ftc.gov/redflagsrule. A covered entity which fails to comply with the Red Flags Rule is subject to a civil penalty of not more than \$2,500 per knowing violation, which could amount to a \$2,500 fine for each covered account that a business maintains.

If you have any questions regarding the FTC Red Flags Rule and how to develop a written identity theft program, please don't hesitate to contact any of the attorneys at The Rogers Law Firm.

FDA ISSUES DRAFT GUIDANCE ON PRESENTING RISK INFORMATION IN PRESCRIPTION DRUG AND MEDICAL DEVICE PROMOTION

On May 27, 2009, the United States Food and Drug Administration ("FDA") issued draft Guidance entitled "Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion" (the "Guidance"). The Guidance is intended for pharmaceutical and medical device manufacturers and describes factors the FDA considers when evaluating advertisements and promotional labeling for prescription drugs, advertisements for restricted medical devices, and promotional labeling for all medical devices for their compliance with the Federal Food, Drug and Cosmetic Act (the "Act") and its related regulations.

According to the FDA, the Guidance was issued in response to requests by stakeholders in pharmaceutical and medical device manufacturers for a specific guidance on how the FDA evaluates prescription drug and medical device promotional pieces to determine whether they adequately present risk information. The Guidance is broken down into three categories of "Considerations": General Considerations (factors that relate to both the content and format of a promotional piece); Content Considerations (how the FDA evaluates the content of risk presentations in determining whether a promotional piece is accurate and non-misleading); and Format Considerations (how the FDA considers formatting factors when assessing whether a piece is false or misleading).

The FDA states that the Guidance "is intended to help regulated industry gain a better understanding of what they should consider as they develop the content and format of their promotional communications." The Guidance can be accessed on the FDA's website at www.fda.gov. The FDA is accepting public comments on the Guidance through August 25, 2009.

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

HHS RELEASES GUIDANCE FOR SECURING HEALTH INFORMATION

The United States Department of Health and Human Services ("HHS") recently published Guidance regarding technologies and methodologies to secure health information and prevent harm by rendering health information unusable, unreasonable, or indecipherable to unauthorized individuals (the "Guidance"). The Guidance was issued by HHS pursuant to the American Recovery and Reinvestment Act of 2009 (the "Act"). In particular, Title XIII of the Act - Health Information Technology for Economic and Clinical Health Act - sets forth substantial changes to the HIPAA Privacy and Security Rules. Prior to the Act, HIPAA did not require a covered entity or business associate to notify an individual about a privacy or security breach related to his/her Protected Health Information ("PHI"). The Act now requires a covered entity or business associate to notify individuals whose "Unsecured Protected Health Information" has been, or is reasonably believed to have been, accessed, acquired or disclosed as a result of a privacy or security breach. The Act defines "Unsecured Protected Health Information" to mean PHI that has not been secured through the use of a technology or methodology specified by the Guidance.

According to the Guidance, PHI is rendered unusable, unreadable, or indecipherable to unauthorized individuals only if it is:

- (a) encrypted by "the use of an algorithmic process to transfer data into a form in which there is a low probability of assigning meaning without use of a confidential process or key"; or
- (b) the media on which the PHI is stored or recorded has been destroyed in one of the following ways:
 - (i) paper, film or other high property media have been shredded such that PHI cannot be read or otherwise cannot be constructed; or
 - (ii) electronic media had been cleared, purged or destroyed such that PHI cannot be retrieved.

If you have any questions or concerns regarding the Guidance or the Act, please don't hesitate to contact any of the attorneys at The Rogers Law Firm.

HHS AND DOJ LAUNCH HEALTHCARE FRAUD PREVENTION AND ENFORCEMENT ACTION TEAM

On May 20, 2009, the United States Department of Health and Human Services ("HHS") and the United States Department of Justice ("DOJ") launched the Healthcare Fraud Prevention and Enforcement Action Team (the "Team"). The purpose of the Team is to prevent fraud in the Medicare and Medicaid programs. The Team will include HHS and DOJ staff members, law enforcement agents and prosecutors. The Team plans to expand existing enforcement teams in Miami and Los Angeles and establish new teams in Houston and Detroit. Furthermore, the Team will set up additional task forces in ten other major cities, which were not named. The Team intends to have enforcement teams increase site visits to durable medical equipment suppliers and expand training to help providers identify and prevent fraud or other mistakes. The Team will use electronic claims data to detect unusual billing problems.

According to the Miami Herald, healthcare fraud costs U.S. taxpayers at least \$60 billion annually. HHS and DOJ's creation of the Team is a clear signal to healthcare providers that the Federal Government is increasing its efforts to detect and prevent fraud and abuse in the healthcare industry.



50 Braintree Hill Office Park
Suite 302
Braintree, MA 02184

Phone: 781.794.1600
Fax: 781.794.1610

www.therogerslawfirm.com

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.

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 at The Rogers Law Firm at 781.794.1600.