
CLIENT NEWSLETTER

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CMS Revises Hospital Conditions of Participation

On November 27, 2006, the Centers for Medicare and Medicaid Services ("CMS") issued a final rule in the *Federal Register* implementing certain revisions to the hospital Conditions of Participation ("CoPs"). The final rule revises and updates the CoP requirements for the following areas: completion of a history and physical examination; authentication of orders; securing medication; and completion of the post-anesthesia evaluation. CMS stated that the revisions to the CoPs was initiated in response to broad criticism from the medical community that the requirements governing these particular areas do not reflect current practice.

The revisions to the CoP for history and physical examination provide that a hospital's medical staff bylaws must be amended to include a requirement that a medical history and physical examination be completed no more than thirty days before or twenty-four hours after admission for each patient by a physician, an oromaxillofacial surgeon or other qualified individual in accordance with state law and hospital policy. If the history and physician examination is completed within thirty days before admission, the hospital must ensure that an updated history and physical examination is performed and documented within twenty-four hours of admission or prior to surgery.

The revised CoP for authentication of verbal orders provides that with the exception of influenza and pneumococcal polysaccharide vaccines, orders for drugs and biologics must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with state law, and who is responsible for the care of the patient. The revised CoP further provides that if verbal orders are used, they are to be used infrequently. Also, when verbal orders are used, they must only be accepted by persons who are authorized to do so in accordance with hospital policy and procedures consistent with federal and state law.

The Massachusetts Department of Public Health ("DPH") recently voted on emergency amendments to DPH regulations to require the reporting of the name of any patient who tests positive for HIV. At the time of publication of this edition of the Client Newsletter, DPH has yet to issue emergency amendments to the regulations. The Rogers Law Firm will issue a Client Advisory once the emergency amendments are promulgated.

CMS revised the CoP for pharmaceutical services to provide that all drugs and biologicals must be kept in a secure area and locked when appropriate. The drugs listed in Schedules II, III, IV and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970, must be kept locked within a secure area. Only authorized personnel may have access to locked areas.

The revised CoP for post-anesthesia services states that with respect to in-patients, a post-anesthesia evaluation must be completed and documented by an individual qualified to administer anesthesia within forty-eight hours after surgery.

The revised CoPs will become effective January 26, 2007. The Rogers Law Firm is available to assist in revising medical staff bylaws and hospital policies in order to ensure compliance with revised CoPs before January 26, 2007.

HHS Health Information Technology Regulations Now in Effect

On August 8, 2006, the United States Department of Health and Human Services (“HHS”) issued two separate final regulations to support physician adoption of electronic prescribing (“e-prescribing”) and electronic health records technology. One set of final regulations was issued by the Centers for Medicare and Medicaid Services (“CMS”) and the other set of final regulations was issued by the Office of Inspector General (“OIG”). The CMS regulations create two new exceptions to the Stark Law (42 C.F.R. 411.357(v) and (w)). Similarly, the OIG regulations create two new safe harbors under the Anti-Kickback Statute (42 C.F.R. 1001.952(x) and (y)). These exceptions and safe harbors allow hospitals and certain other health care organizations to provide physicians with the following: (i) interoperable electronic health record software, information technology and training services; and (ii) hardware, software or information technology and training services necessary for e-prescribing. The regulations became effective as of October 10, 2006.

The final HHS regulations allow hospitals and other health care organizations to enter into arrangements with physicians for the provision of e-prescribing technology, without violating the Stark Law or Anti-Kickback Statute. Specifically, hospitals and other health care organizations are permitted to provide physicians with non-monetary remuneration consisting of items and services in the form of hardware, software, or information technology and training services, provided certain conditions are met.

As with the final HHS regulations pertaining to e-prescribing, the final regulations for electronic health records permit hospitals and other health care organizations to provide physicians with a non-monetary remuneration consisting of items and services in the form of software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records, provided certain provisions are met.

When the regulations were announced this past August, our firm issued a Client Advisory (“*HHS Issues Final Health Information Technology Regulations*”¹) detailing the regulations. In the Client Advisory, we cautioned that the “Health Information and Technology Promotion Act of 2006” could preempt the final HHS regulations by issuing new safe harbors and exceptions to provide even greater flexibility for hospitals and other health care organizations to provide e-prescribing and electronic health records technology to physicians. The U.S House of Representatives passed the legislation this past July. However, the 109th Congress has now

¹ This Client Advisory can found at www.therogerslawfirm.com/Client%20Advisories/client_advisory.pdf

concluded with no action on the legislation by the U.S. Senate. Therefore, the final HHS regulations have not been preempted. It is unclear if the Senate intends to take up the legislation when the new session convenes next month.

It is the recommendation of The Rogers Law Firm that any consideration to provide physicians with e-prescribing or electronic health records technology be first discussed with our office, in order that we may appropriately structure an arrangement that meets the requirements of the final regulations from HHS. It is important to note that there are differences between the safe harbors and exceptions for e-prescribing and those of electronic health records. For example, the electronic health records exceptions and safe harbors have a recipient cost-sharing requirement, while the safe harbors and exceptions associated with e-prescribing do not. Furthermore, any proposed arrangement to provide physicians with e-prescribing or electronic health records technology needs to be analyzed under applicable IRS regulations pertaining to tax-exempt organizations.

OIG Issues Advisory Opinion on Hospital Gainsharing Arrangement

The Office of the Inspector General (“OIG”) of the U.S. Department of Health and Human Services, recently issued an advisory opinion regarding a proposed gainsharing arrangement between a hospital and a group of cardiac surgeons. Although the OIG concluded that the proposed arrangement would result in an improper payment under both the civil monetary penalty section of the Social Security Act and the Anti-Kickback Statute, it stated that it would not impose sanctions on the hospital because of the safeguards in place to protect patients from an inappropriate reduction of services.

The proposed arrangement provides that the hospital would pay the surgeon group a share of the first-year cost savings directly attributable to specific changes in the surgeon group’s operating room practices. The hospital had hired a program administrator, who conducted a study identifying twenty-four specific cost-saving opportunities related to the cardiac surgery department. Specifically, the program administrator identified three specific categories of recommendations to curb the inappropriate use or waste of medical supplies. The first category consists of five recommendations that involve limiting the use of certain surgical supplies. The second category consists of the substitution, in whole or in part, of less costly items for the items currently being used by the surgeons. The substitutions involve items and services for which a product substitution will have no appreciable clinical significance. The final category consists of product standardization of certain cardiac devices where medically appropriate. The program administrator concluded that the recommendations presented substantial cost-saving opportunities for the hospital without adversely impacting the quality of patient care.

The proposed arrangement by the hospital would pay the surgeon group fifty percent of the cost savings achieved by implementing the program administrator’s recommendations for a period of one year. At the end of that year, cost savings would be calculated separately for each of the recommendations in order to preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, would not be credited to the surgeon group. In regard to calculating the payment to the surgeon group, the cost savings will be calculated by subtracting the annual costs incurred for the items specified in the twenty-four recommendations when used by the surgeons and the surgeon group during the specified surgical procedures from the historic costs for the same items when used during comparable surgical procedures in the base year.

The hospital and the surgeon group will document the activities and the payment methodology under the proposed arrangement and will make the documentation available upon request to the Secretary of the United

States Department of Health and Human Services. Furthermore, the hospital and the surgeon group will disclose the proposed arrangement to patients, including the fact that the surgeon group's compensation is based on a percentage of the hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the hospital for a procedure covered by the proposed arrangement. If pre-admission disclosure is impractical, disclosure will be made before the patient consents to the surgery. The proposed arrangement provides that disclosures will be made in writing to patients, and patients will have an opportunity, if desired, to review the details of the proposed arrangement, including the specific cost-saving measures applicable to the patient's surgery.

In its advisory opinion, the OIG notes that the proposed arrangement implicates both the civil monetary penalty section of the Social Security Act and the Anti-Kickback Statute. (The advisory opinion also noted that the Stark Law was also implicated, however, the Stark Law falls outside of the scope of the OIG's advisory opinion authority.) The civil monetary penalty section of the Social Security Act establishes a civil monetary penalty against any hospital, or critical access hospital, that knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make such payments are liable for civil monetary penalties of up to \$2,000 per patient covered by the payment. The OIG concluded that the proposed arrangement implicated the civil monetary penalty. Nevertheless, the OIG noted that the proposed arrangement includes several safeguards to protect patients from an inappropriate reduction of services. These safeguards include the following: transparency of the proposed arrangement; credible medical support for the physician that implementation of the recommendations would not adversely affect patient care; the proposed arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the surgeon group; individual physicians will still have available the same selection of cardiac devices after implementation of the proposed arrangement, as they did before; the hospital and surgeon group will provide written disclosures of the proposed arrangement to patients whose care may be affected by the proposed arrangement; the financial incentives are reasonably limited in duration and amount; and because the surgeon group's profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate this proportion of cost savings is mitigated.

The OIG also noted that the proposed arrangement implicates the Anti-Kickback Statute. The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration in order to induce or reward referrals of items or services reimbursable by a Federal health care program. The OIG stated that the proposed arrangement could encourage the surgeons to admit Federal health care program patients to the hospital, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the hospital's payment, depending on cost savings. The OIG stated that although the proposed arrangement could result in illegal remuneration under the Anti-Kickback Statute, it would not impose sanctions under these particular circumstances based on three significant factors. First, the circumstances and safeguards of the proposed arrangement reduces the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Second, the structure of the proposed arrangement eliminates the risk that the proposed arrangement will be used to reward cardiologists or other physicians who refer patients to the surgeon group or its surgeons. Third, the proposed arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. In light of these circumstances and safeguards, the OIG concluded that the proposed arrangement poses a low risk of fraud or abuse under the Anti-Kickback Statute.

Despite the OIG's opinion that it would not impose sanctions regarding the proposed arrangement between the hospital and the cardiac surgeons, it reiterated its concerns regarding arrangements between hospitals and physicians to share cost savings. The OIG noted that the proposed arrangement in these circumstances is markedly different from many gainsharing plans. In particular, the proposed arrangements sets

out the specific actions to be taken and ties the remuneration to the actual, verifiable costs savings attributable to those actions. Such transparency allows an assessment of the effect of the proposed arrangement on quality of care and assures that the identified actions will be the cause of the savings.

January 1st Deadline Approaching for Compliance with Deficit Reduction Act and Amendment to the Stark Law

Health care providers have until January 1, 2007, to comply with section 6032 of the Deficit Reduction Act and the Centers for Medicare and Medicaid Services (“CMS”) imposed amendment to the Stark Law. The Deficit Reduction Act requires health care entities to establish written policies regarding false claims recovery. The Stark Law will be amended to preclude physicians from referring patients for nuclear medicine services to an entity with which the physician, or a member of his or her immediate family, has a financial relationship.

Section 6032 of the Deficit Reduction Act

Section 6032 of the Deficit Reduction Act is entitled “Employee Education About False Claim Recovery.” The provision amends the Social Security Act to provide that before January 1, 2007, any entity that receives or makes annual payments under Medicaid of at least \$5 million dollars, shall:

- (A) Establish written policies for all employees of the entity (including management), and of any contractor or agent of the entity, that provide detailed information about false claims and statements, and whistleblower protections under such laws, with respect to the role of such laws in preventing and detecting fraud, waste and abuse in federal health care programs;
- (B) Include as part of such written policies, detailed provisions regarding the entity’s policies and procedures for detecting and preventing fraud, waste and abuse; and
- (C) Include in any employee handbook for the entity, a specific discussion of the laws described in sub-paragraph (A), the rights of employees to be protected as whistleblowers, and the entity’s policies and procedures for detecting and preventing fraud, waste and abuse.

There are two relevant false claims laws for health care entities in Massachusetts which receive or make annual payments under Medicaid of at least \$5 million dollars: the Federal False Claims Act and the Massachusetts False Claims Act. The Federal False Claims Act (“FCA”), 31 U.S.C. §§ 3729-3733, prohibits a person from “knowingly” submitting a false claim to obtain federal funds, including reimbursement under the Medicare or Medicaid programs. Under the FCA, a person “knowingly” submits a false claim if he/she: had actual knowledge of the information; acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information. The FCA provides for damages of up to three times the loss sustained by the government, and a penalty of \$5,000 to \$10,000 per violation.

The FCA has a “qui tam” provision, which allows private individuals to file a lawsuit in the name of the U.S. Government, charging fraud by government contractors and others who receive or use government funds.

The FCA also contains whistleblower protection provisions, which provide that any employee who is discharged, demoted, harassed or otherwise discriminated against because of lawful acts by the employee in furtherance of an action under the FCA is entitled to all relief necessary to make the employee whole.

The Massachusetts False Claims Act (“MFCA”), M.G.L., c. 12, §§ 5B to 5O, provides that any person who knowingly presents a false or fraudulent record to obtain payment or approval of a claim by the Commonwealth (or political subdivision thereof), or is the beneficiary of an inadvertent submission of a false claim, will be liable to the Commonwealth for a civil penalty of not less than \$5,000.00 and not more than \$10,000.00 per violation. In addition, the person will be liable to the Commonwealth for three times the amount of damages that the Commonwealth sustained because of the act of that person. Under the MFCA, a person “knowingly” presents a false or fraudulent record if he/she: possesses actual knowledge of relevant information; acts with deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information.

The MFCA has a “qui tam” provision, which allows private individuals to bring an action in civil court if he/she has independent knowledge of a violation of the MFCA. The MFCA also has a whistleblower protection provision which prohibits an employer from discharging, demoting, suspending, threatening, harassing, denying a promotion or in any other manner discriminating against an employee in the terms or conditions of employment because of the lawful acts done by the employee in furtherance of a false claims action. The MFCA also prohibits an employer from making, adopting or enforcing a rule, regulation or policy that prevents an employee from disclosing information to the government or that limits an employee’s right to file a false claims action.

Amendment to the Stark Law

The Stark Law (42 U.S.C. §1395nn) or Physician Self-Referral Law, precludes a provider from referring Medicare-Medicaid beneficiaries for designated health services to entities which they, or members of their immediate family, have a financial relationship. The designated health services include: clinical laboratory services; physician therapy services; occupational therapy services; radiology services (including MRI, CAT Scans and ultrasound services); radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices and supplies; home health services; out-patient prescription drugs; and in-patient and out-patient hospitalization services. The Stark Law defines a “financial relationship” as an ownership/investment interest in an entity or a direct or indirect compensation arrangement with an entity. A compensation arrangement includes any arrangement involving any remuneration (direct or indirect, overt or covert, in cash or in kind) between a physician and an entity. The possible penalties under the Stark Law include: (1) denial of payment and an obligation to refund payments made as a result of a tainted referral; (2) civil monetary penalties of up to \$15,000.00 for each referral that a person “knows or should know” violates the Stark Law; (3) civil monetary penalties of up to \$100,000.00 for schemes to circumvent the Stark Law; (4) possible exclusion from the Medicare and Medicaid programs; and/or (5) liability under the False Claims Act.

On November 21, 2005, CMS announced that as of January 1, 2007, the “designated health services” under the Stark Law will be expanded to include nuclear medicine. Therefore, physicians will be precluded from referring patients for nuclear medicine services to entities with which they, or members of their immediate family, have a financial relationship. Therefore, a physician who has invested in either nuclear medicine equipment or a facility that provides nuclear medicine services, is now faced with three options: (1) divest their ownership interest in the nuclear medicine equipment or the facility which provides nuclear medicine; (2) restructure the financial relationship so it complies with existing Stark Law exception (i.e. in-office ancillary

service exception, space and equipment lease exception, personal services arrangement exception, fair market value compensation exception, etc.); or (3) maintain the ownership interest and refer patients for nuclear medicine services to another entity.

CMS decided not to grandfather existing financial relationships between physicians and nuclear medicine facilities.

The Rogers Law Firm is available to assist in meeting the January 1, 2007 deadline for compliance with section 6032 of the Deficit Reduction Act and the amendment to the Stark Law.

AHA Submits Community Benefit Report to IRS

The American Hospital Association (“AHA”) recently submitted a report (the “Report”) to the United States Internal Revenue Service (“IRS”) regarding last year’s IRS Compliance Check Questionnaire to non-profit hospitals. The Report, which is entitled “Community Benefit Information from Non-Profit Hospitals: Lessons Learned from the 2006 IRS Compliance Check Questionnaire”, was prepared by Ernst & Young at the request of the AHA in order that AHA could have an independent analysis of hospitals’ responses to the Compliance Check Questionnaire. The Report is based upon a review of 133 responses by non-profit hospitals (representing almost thirty percent of the total hospitals responding to the IRS Compliance Check Questionnaire).

The Report has several key findings, including the following: 100% of the general/medical hospitals operated an Emergency Room that was open twenty-four hours a day, 365 days a year and provided services to all members of the community regardless of a patient’s ability to pay; 100% of the hospitals indicated all patients were charged the same prices for the same services, regardless of insurance or ability to pay; 100% of the hospitals have a written policy stating the circumstances under which the hospital would provide uncompensated care to patients; and 100% of the hospitals indicated that they provided community programs in addition to uncompensated care and charity programs, including community medical treatment programs, immunization programs and health education.

The Report states that the key conclusion from the findings is that all of the hospitals included in the Report are meeting the community benefits standard as articulated by the IRS in Revenue Ruling 69-545. The community benefits standard provides that in order for non-profit hospitals to maintain 501(c)(3) tax-exempt status, they shall have the following: independent community board; open medical staff; an emergency room which accepts patients regardless of the ability to pay; acceptance of Medicare/Medicaid patients; and excess funds are used for charitable purposes.

It is widely believed that the IRS is seeking to revise the basis for a tax exemption for a hospital. The Rogers Law Firm will continue to monitor any developments in this regard and will provide updates accordingly. The Report can be found at www.aha.org/aha/content/2006/pdf/061127-ErnstYcombenreport.pdf.

Reminder on Reporting of Diseases Dangerous to the Public Health

Children's Hospital of Boston was recently cited for failure to timely report an outbreak of whooping cough to the Boston Public Health Commission. Pursuant to Chapter 111, § 111A of the Massachusetts General Laws, if a physician knows or has cause to believe that a person with whom he or she visits is infected with a disease dangerous to the public health, he or she shall immediately give written notice to the Board of Health of the town where the patient is being attended.

The applicable regulations provide broad discretion to the Massachusetts Department of Public Health in regard to the classification of those diseases which are dangerous to the public health. For a current list of diseases which are reportable to the local boards of health, please visit:

www.mass.gov/dph/cdc/surveillance/rptbldiseases.hcp.pdf.

New Hospital Discharge Requirements Released by CMS

The Centers for Medicare and Medicaid Services ("CMS") issued a final rule in the November 27, 2006, issue of the *Federal Register* (71 *Fed. Reg.* 68708) implementing new requirements for hospital discharge notices. The final rule, which applies to the discharge notices for both the Medicare and Medicare Advantage Programs, will become effective on July 1, 2007. The final rule makes significant changes to the proposed rule for discharge procedures which was detailed in our June 2006 Client Newsletter. The proposed rule provided for a two-step process when discharging patients. Hospitals would have been required to deliver to a patient on the day prior to discharge, a standardized, largely generic notice of the non-coverage to each Medicare beneficiary whose physician concurs with the discharge. If a patient exercises his or her right to an appeal, the hospital would be required to give to the patient a more detailed notice. The proposed rule drew a considerable amount of criticism from hospitals as being overly burdensome. As a result, in the final rule CMS revised the discharge process.

The final rule requires the discharge notification process for Medicare and Medicare Advantage Programs such that hospitals will be required to comply with the following process: (1) deliver a revised "Important Message from Medicare" notice to a patient within two days after admission and obtain the signature of the patient or patients representative; (2) deliver a copy of the signed notice as a reminder if the original notification is not delivered within two days of discharge; and (3) deliver a more detailed discharge notice to patients who request an appeal of their discharge. The final rule simplifies the discharge process by not requiring delivery of an entirely new separate notice of rights to the patient on the day prior to discharge.

This Newsletter is published by The Rogers Law Firm to keep its clients 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 (617) 723-1100.