
CLIENT NEWSLETTER

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CMS Issues Stark Law Phase III Regulations

The Centers for Medicare and Medicaid Services (“CMS”) recently published Phase III of the final Stark Law Regulations (“Phase III”). Phase III responds to comments CMS received from the Phase II Interim Final Rule, which was released by CMS on March 26, 2006. Phase III does not create any new exceptions to the Stark Law, but does make extensive revisions to the existing Stark Law regulations. This article provides an overview of the Stark Law, as well as the highlights of Phase III.

Stark Law

The Stark Law (42 U.S.C.A. § 1395nn), or Physician Self-Referral Law, precludes a provider from referring Medicare/Medicaid beneficiaries for designated health services to entities with which they, or members of their immediate family, have a direct or indirect financial relationship. Designated health services include: clinical laboratory services; physical 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 or orthotics and prosthetic devices and supplies; home health services; out-patient prescription drugs; and inpatient and outpatient 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. “Compensation arrangement” is defined as including any arrangement involving any remuneration between a physician and an entity. Remuneration includes any remuneration, direct or indirect, overt or covert, in cash or in kind. A physician who violates the Stark Law is subject to the following penalties: (1) repayment of all amounts billed to the Medicare and Medicaid Program that violate the Stark Law; (2) civil monetary penalties of up to \$15,000.00 for each claim submitted for which

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the person (including a hospital) knows, or should know, is for a service for which payment may not be made under the Stark Law; or (3) exclusion from the Medicare and Medicaid Programs. Furthermore, the U.S. Department of Justice has asserted that filing a Medicare or Medicaid claim in violation of the Stark Law constitutes a “false claim”, which could trigger liability under the federal False Claims Act. There is also a \$100,000.00 civil monetary penalty for entering into a scheme or arrangement which the physician or entity knows, or should know, has a principle purpose of assuring referrals by the physician to a particular entity, which if the physician directly made a referral to such entity, would violate the Stark Law. The Stark Law became effective on January 1, 1995. Since that time, CMS has issued a series of regulations interpreting the Stark Law. The Phase III Regulations represent the fourth set of final regulations issued by CMS since the Stark Law became effective.

Phase III Regulations

As mentioned previously, although Phase III does not create any new exceptions to the Stark Law, it does substantially revise the existing definitions and exceptions of the Stark Law. The following is an overview of the more notable revisions:

1. Rental of Office Space and Equipment

Phase III does not make any significant changes to the space and equipment lease exceptions. Nevertheless, the Preamble to Phase III states that in order to meet the requirement that the rental charges be set in advance, the “parties may not change the rental charges at **any time** during the term of the agreement.” (emphasis added) Therefore, if the parties agree to change the rental charges, they must terminate the lease and enter into a new lease. It must be noted, however, that in order to meet the rental of office space and equipment exception, the lease must have a term of at least one (1) year. Therefore, if the parties desire to terminate the lease and enter into a new lease in order to amend the rental charges, this may occur only after the first year of the original lease term. The parties may amend a lease during the first year as long as the rental charges are not changed.

2. Indirect Compensation Arrangements

Phase III revises the definition of “Indirect Compensation Arrangements” to provide that a physician will now be characterized as to “stand in the shoes” of a group practice of which he or she is a member and have a direct compensation arrangement with an entity providing designated health services that contracts with his or her group. The result of this amendment is that certain compensation arrangements will need to be analyzed for compliance with the exception for direct compensation arrangements, rather than the exception for indirect compensation arrangements.

3. Physician in the Group Practice

In many instances, a group practice will establish independent contractor relationships with other physicians for certain services billed by the group. Phase III points out that these relationships are typically structured so as to comply with the physician services and in-office ancillary services exceptions. These exceptions require, among other things, that the contracting physician qualify as a “physician in the group practice.” Phase III clarifies that for an independent contractor to qualify as a “physician in the group practice”, the group’s contract

must be with the individual physician, not a separate legal entity (i.e., a staffing company or other physician group).

4. Personal Services Arrangements

A personal service contract can be amended in the first year of the contract so long as the compensation is not amended. The compensation for a personal service contract cannot be amended at any time during the term of the agreement. Nevertheless, the parties can terminate a personal services arrangement and enter into a new one with different compensation terms after the completion of the first year of the contract.

5. Record-Keeping

Phase III emphasizes the importance of proper record-keeping with respect to physician financial relationships. CMS points out that record-keeping is necessary to enable designated health service entities to comply with a significant number of the Stark Law exceptions. It should be noted that beginning this month, CMS will send a notice to five hundred (500) hospitals across the country seeking information on the financial relationships between these hospitals and their physicians. It is possible that hospitals may be given as little as thirty (30) days notice to provide the required information. According to CMS, late responses are subject to civil monetary penalties of up to \$10,000.00 per day. The purpose of the disclosure is to allow CMS to ascertain whether arrangements between physicians and hospitals comply with the Stark Law.

6. Charitable Donations by a Physician

Phase III clarifies that a physician may not “offer” a charitable donation to a designated health service entity in any manner that takes into account the volume or value of referrals.

7. Profit Sharing and Productivity Bonuses

The previous Stark Law regulations provided that a physician in a group practice could receive a profit share from his/her group practice based directly on services that he or she personally performs and services that are “incident to” his or her personally performed services. Phase III states that a physician may be paid a share of overall profits from his/her group practice, provided such payment is not based on the volume or value of “incident to” services performed by the physician.

As to productivity bonuses, Phase III states that such compensation may be directly related to the volume or value of either services personally performed by the referring physician, his or her referrals for services that are “incident to” those personally performed services, or both. “Incident to” services are to be attributed to the ordering physician.

Phase III also clarifies what is meant by “incident to” in regard to physician services. Specifically, Phase III states that “incident to” services and supplies excludes services or supplies, such as x-rays or diagnostic imaging procedures, that have a separate Medicare benefit category, except as otherwise expressly permitted by statute (i.e., outpatient prescription drugs). The import of this clarification of “incident to” services is that when a group practice attempts to calculate personal productivity bonuses, it will no longer be permitted to directly attribute

diagnostic tests billed on an “incident to” basis to the ordering physician. Instead, the group practice will need to require that the income from the “incident to” services is distributed as a share of the overall profits of the group.

Phase III revises many other aspects of the Stark Law Regulations, including physician recruitment arrangements and expansion of the non-monetary compensation exception to allow a designated health service entity with a full medical staff to provide one (1) medical staff appreciation event each year.

Effective Date

Phase III will become effective on December 5, 2007. It should be noted, however, that in addition to the changes to the Stark Law from Phase III, CMS recently issued a draft 2008 Physician Fee Schedule. Included within the 2008 Physician Fee Schedule, there are additional proposed changes to the Stark Law, including changes to the indirect compensation definition and exception. The draft 2008 Physician Fee Schedule also proposes prohibiting “per-click” compensation in lease arrangements to the extent that the “per-click” charge reflects services provided to patients referred by the lessor to the lessee.

The Rogers Law Firm will continue to monitor the proposed 2008 Physician Fee Schedule and will provide updates accordingly. In the meantime if you have any questions or concerns with respect to Phase III of the Stark Law, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

Physician Payment Sunshine Act to be Filed in Congress

On September 6, 2007, Senators Charles Grassley (R-IA) and Herb Kohl (D-WI) announced that they will be introducing legislation in the United States Congress to require manufacturers of pharmaceutical drugs, devices and biologics to disclose the amount of money they give to doctors through payments, gifts, honoraria, travel and other means. The legislation, which is entitled The Physician Payment Sunshine Act (the “Act”) would apply to manufacturers with \$100 million or more in annual gross revenues. Pursuant to the Act, the Secretary of the United States Department of Health and Human Services would be required to create a website and post payment information in a clear and understandable manner to the public. Those manufacturers who do not post the required payment information, will be subject to penalties ranging from \$10,000 to \$100,000 per violation.

Senator Grassley commented on the Act by stating “[r]ight now the public has no way to know whether a doctor’s been given money that might affect prescribing habits. The bill is about letting the sunshine in so that the public can know. Whether it is dinner at a restaurant or tens of thousands of dollars or more in fees and travel, patients shouldn’t be in the dark about whether their doctors are getting money from drug and device makers.” The Act mirrors similar legislation in Minnesota, Vermont, Maine and West Virginia.

The Rogers Law Firm will continue to monitor the Act and provide updates accordingly.

CMS Revises Hospital CoP for Laboratory Services

The Centers for Medicare and Medicaid Services (“CMS”) recently issued an Interim Final Rule amending the Medicare Hospital Condition of Participation (“CoP”) for Laboratory Services. Specifically, the Interim Final Rule requires hospitals that transfuse blood and blood components to: prepare and follow written procedures for appropriate action when it is determined that blood and blood components the hospital received and transfused are at increased risk for transmitting the hepatitis C virus (“HCV”); quarantine prior collections from a donor who is at increased risk for transmitting HCV infections; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and extend the record retention period for transfusion-related data to ten (10) years. According to CMS, the intent of the Interim Final Rule is to aid in the prevention of HCV infection and to create opportunities for disease prevention that, in most cases, can occur many years after recipient exposure to a donor.

Policies and Procedures

The Interim Final Rule requires that a hospital establish policies and procedure for appropriate notification and documentation when it is determined that blood and blood components the hospital received and transfused are at increased risk for transmitting HCV. The policies and procedures must conform to federal, state and local laws, including requirements for the confidentiality of medical records and other patient information.

Quarantine of Prior Collections

The Interim Final Rule provides that if a hospital becomes aware of reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood components from previous donations in inventory. If a supplemental test or other follow-up testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine. If, however, the result of the supplemental test or other follow-up testing required by FDA is positive, the hospital must dispose of the blood and blood components and notify the transfusion recipients. If the supplemental test or follow-up testing is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine in accordance with indeterminate test results set forth in 21 CFR 610.46(b)(2), 610.47(b)(2) and 617.48(c)(2).

Notification of Transfusion Recipients

The Interim Final Rule states that if a hospital has administered potentially HIV or HCV infectious blood or blood components, or released such blood or blood components to another entity or individual, the hospital must take the following actions: (i) make reasonable attempts to notify the patient, or to notify the attending physician or the physician who ordered the blood or blood component and ask the physician to notify the patient that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling; (ii) if the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian or relative; and (iii) document in the patient’s medical record the notification or attempts to give the required notification.

Hospital Record-Keeping

The Interim Final Rule extends the record retention period for transfusion-related data to ten (10) years. The Interim Final Rule specifically states that the records must be kept for at least ten (10) years from the date of disposition in a manner that permits prompt retrieval. Furthermore, the hospital must have a fully funded plan to transfer these records to another hospital or entity if such hospital ceases operation for any reason.

The Interim Final Rule can be found in the August 24, 2007, edition of the *Federal Register*. The Interim Final Rule will become effective on February 28, 2008. However, hospitals should use the period before the effective date to update their applicable policies so that they are in compliance with the Interim Final Rule.

CMS Issues HIPAA Security Guidance

The Centers for Medicare and Medicaid Services (“CMS”) recently released a HIPAA Security Rule Guidance (the “Guidance”). The Security Rule is one of the administrative simplification provisions of the Health Insurance Portability and Accountability Act (“HIPAA”). The Security Rule sets forth regulations for how covered entities (e.g., hospitals, physicians) are to safeguard electronic protected health information (“EPHI”). The Security Rule applies to all covered entities which transmit EPHI. The purpose of the Guidance is to re-enforce some of the ways a covered entity may protect EPHI when it is accessed or used outside of the organization’s physical purview. The Guidance sets forth strategies that might be reasonable and appropriate for organizations that conduct some of their business activities through (1) the use of portable media/devices that store EPHI (i.e., flash drives); and (2) off-site access or transport of EPHI via laptops, personal digital assistance (“PDAs”) or home computers.

The Guidance points out that covered entities should be extremely cautious about allowing off-site use of, or access to, EPHI. Nevertheless, the Guidance acknowledges that there may be situations that warrant such off-site use or access, such as a home health nurse collecting and accessing patient data using a PDA or a laptop during a home health visit; a physician accessing an e-prescribing application on a PDA, while out of the office, to respond to patient request for refills; and a health plan employee transporting backup enrollee data on a media storage device to an off-site facility. The Guidance acknowledges that there may be other instances when such off-site use is appropriate. The Guidance emphasizes, however, that with any remote access to or use of EPHI, the covered entity should place significant attention on risk analysis and risk management strategies, policies and procedures for safeguarding EPHI and security awareness and training on the policies and procedures for safeguarding EPHI.

Risk Analysis and Risk Management Drive Policies

The Guidance states that once a covered entity has completed the analysis of the potential risks and vulnerabilities associated with remote access to, and off-site use of, EPHI, it must develop risk management measures to reduce such risk and vulnerabilities to a reasonable and appropriate level. The analysis of these risks should form the basis of policies and procedures designed to protect the covered entity’s EPHI. Covered entities should consider the following issues when developing or enhancing their policies concerning accessing, storing and transmitting EPHI:

- Data access policies and procedures should focus on ensuring that users only access data for which they are appropriately authorized. In particular, the Guidance states that remote access

to EPHI should only be granted to authorized users based upon their role within the organization and their need for access to EPHI.

- Storage policies and procedures should appropriately address all forms of media and devices which contain EPHI and which are beyond the covered entity's physical control.
- Transmission policies should focus upon the integrity and safety of EPHI sent over networks.

The Guidance points out that risk analysis and policy development will only be effective if there is an appropriate security workforce awareness and training program. The training should provide clear and concise instruction for accessing, storing and transmitting EPHI. Covered entities are encouraged to include in their workforce awareness and training programs the following: password management procedures; remove device/media protection (i.e., prohibit leaving such devices in unattended cars or public thoroughfares); and training on policies prohibiting the transmission of EPHI over open networks (including e-mail).

The Guidance also emphasizes the importance that security incident procedures specify the actions workforce members must take to mitigate harmful effects of a loss of EPHI via portable media. Such procedures may include securing and preserving evidence; managing the harmful effects of improper use or disclosure; and notification to affected parties. There should also be a sanction policy in place to appropriately discipline workforce members if they fail to comply with security policies and procedures of the covered entity related to off-site use of, or access to EPHI. The Guidance states that a covered entity should consider at least requiring employees to sign a statement of adherence to security policies and procedures as a prerequisite to employment.

If you have any questions or concerns regarding your entity's EPHI security policies and procedures, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

JCAHO Launches VAD Certification Program

On September 4, 2007, the Joint Commission on Accreditation of Health Care Organizations ("JCAHO") implemented a certification program for hospitals that perform Ventricular-Assisted Device ("VAD") surgery as destination therapy. A VAD is used to aide the pumping action of a weakened heart ventricle, a major pumping chamber of the heart. Hospitals that apply for VAD certification will receive a thorough on-site review by JCAHO. As appropriate, JCAHO will issue a hospital a Certificate of Distinction under the Joint Commission's Disease-Specific Care ("DAC") program for ventricular-assisted devices. The Center for Medicare and Medicaid Services ("CMS") will reimburse for VAD surgery as a destination therapy when it is performed at a JCAHO certified organization.

According to JCAHO, the VAD certification program will help standardize the care provided for heart patients who face limited treatment choices. VAD certification will be valid for two (2) years. CMS approved VAD programs have until March 27, 2009, to become certified.

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