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Special points of interest:

- **CMS finalizes anti-markup rule for diagnostic tests**
- **CMS uses payment rules to make regulatory changes**
- **CMS to institute collection of information on physician financial relationships with hospitals**

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MD LawAlert

Anti-Markup Rule: Where are we now?

By Gilbert F. Ganucheau, Jr.

Physicians who bill Medicare for diagnostic testing to their patients performed or supervised by other physicians may receive less reimbursement under the "Anti-Markup Rule" recently finalized by the Centers for Medicare and Medicaid Services ("CMS"). CMS has over the last couple of years taken steps to limit the amount it will pay for diagnostic testing that is performed either outside of the billing physician's office or performed or supervised by someone other than the billing physician. CMS has finalized the "Anti-Markup Rule" in the 2009 Medicare Physician Fee Schedule final rule.

CMS has had a long standing policy that a physician who purchases the technical component ("TC") of a diagnostic test from a supplier cannot "mark-up" the amount charged to the physician by the supplier and must pass on the actual cost to CMS. This "purchased test rule" requires the purchasing physician to pass on the costs of the TC directly to CMS with no additional charges or expenses related to the TC. And while there has been little guidance on exactly what constitutes a purchased test, the medical community has become fairly competent in following this rule.

In November of 2007, however, CMS extended the reach of the anti-markup rule to tests which do not meet the definition of a purchased test.

The expanded rule will prohibit a physician or supplier who orders a test from marking-up the TC or Professional Component ("PC") of any diagnostic test that is either performed outside of the

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Hospitals to Disclose Financial Relationships with Physicians

By David Dean Haynes, Jr.

Hospitals may soon be requested to disclose to CMS all financial relationships with physicians. In 2006, the Department of Health and Human Services ("DHH") conducted an informational survey of specialty hospitals and their competitors. The survey was a voluntary data collection tool to facilitate DHH's final report to Congress regarding specialty hospitals. DHH sent voluntary surveys to 130 specialty hospitals and to 322 competitor hospitals of those 130 specialty hospitals. Of ***all*** hospitals surveyed, 290 failed to respond.

In DHH's final report to Congress on specialty hospitals, it expressed its concern over the lack of response by the hospitals surveyed and stated its intention to implement a "regular disclosure process," which resulted in the development of the Disclosure of Financial Relationships Report ("DFRR") . The purpose of the DFRR is to collect information that will be subsequently used to analyze all investment/ownership interests and compensation arrangements between each hospital surveyed and its respective physicians to ensure compliance with the Stark law.

CMS proposes that the survey be completed and certified by the appropriate hospital

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Anti-Markup Continued

medical office space where a physician (or group) provides the full range of physician services or is purchased from an outside vendor. This rule prohibits a physician group that has an ancillary diagnostic service, such as a lab or imaging facility that would otherwise meet the same building requirement of the In-Office Ancillary Services Exception ("IOS") to the physician self-referral prohibitions of 42 USC 1395nn known as the Stark Law, from billing the full price of the test. The IOS exception allows group practices to own and refer patients for ancillary services when the ancillary services facility is located in the same building as that in which any physician of the group provides patient services or in a centralized building used by the group to render diagnostic services. This apparent conflict between the expanded anti-markup rule and Stark exception caused the industry great concern and eventually caused CMS to delay the implementation of the expanded anti-markup rule until further modifications were made.

On January 3, 2008, CMS published a notice delaying implementation of the new anti-markup provisions until January 1, 2009 but with two exceptions. First, the anti-markup prohibition will, as of January 1, 2008, continue to apply to the technical component of a "purchased diagnostic test" in the manner it had been prior to the recently promulgated rule.

The second exception is that, effective January 1, 2008, the new anti-markup provisions will be applicable to anatomic pathology diagnostic testing services if those services are furnished in space that: (1) is utilized by a physician group practice as a "centralized building" for purposes of complying with the physician self-referral rules; and (2) does not qualify as a "same building" as defined in CMS regulation. The second exception is designed to allow CMS to crack down on so-called "pod labs".

2009 Physician Fee Schedule

In the 2009 Physician Fee Schedule Final Rule, CMS revisited the Anti-markup rule and finalized a proposal it made in the 2009 PFS Proposed Rule. Under the final version of the Anti-Markup Rule, the Rule will apply to any purchased test and to any test performed or supervised by a physician that does not "share a practice" with the billing physician. The Rule provides two alternative tests to determine if the supervising or performing physician "shares a practice" with the billing physician.

Under the "substantially all test", if the performing physician furnished substantially all (at least 75%) of his professional services through the billing physician or group, the performing physician will be deemed to share a practice with the billing physician.

The second test is the "site of service test" in which only those services that are performed in the office of the billing physician will avoid the application of the anti-markup rule. "Office of the billing physician" includes separate space in the same building where the ordering physician regularly furnishes the full range of patient care services. The anti-markup rule will not apply to the TC of a test purchase from an outside supplier if the supplier is supervised by a physician located in the office of the billing physician. CMS has indicated that mobile vehicles, vans or trailers located in a parking lot are not considered to be in the billing physician's office for purposes of the rule.

Application of the anti-markup rule to billing for diagnostic testing must be considered when analyzing any arrangement for a physician or group to bill for tests that are performed by other suppliers or at facilities outside of the billing physician's office. Failure to bill appropriately for services covered by the anti-markup rule can result in serious consequences for the billing physician.

The Anti-Markup Rule will apply to any purchased test and to any test performed or supervised by a physician that does not "share a practice" with the billing physician. Failure to bill appropriately for services covered by the Anti-Markup Rule can result in serious consequences.

CMS Finalizes Stark Regulation Changes By: Gilbert F. Ganucheau, Jr.

The Ethics in Patient Referrals Act, 42 USC 1395nn, commonly known as the Stark Law, prohibits a physician from making referrals for certain "designated health services", including inpatient and outpatient hospital services, to an entity with which the physician has a financial relationship. The Stark Law also prohibits the entity from billing Medicare for services rendered pursuant to a prohibited referral. CMS recently made several changes in the Stark regulations that will affect physician relationships with Designated Health Services Entities. Numerous existing arrangements will have to be modified to comply with these changes.

PHYSICIAN STAND IN THE SHOES

CMS in Phase III of the Stark regulations provided that a physician stands in the shoes of his physician organization for purposes of determining if the physician had a direct or indirect financial relationship with a DHS entity. That rule was delayed as to physicians that are a part of a Academic Medical Center or a 501(c)(3) integrated health care system. CMS revised provisions of the rule to deem a physician who has an ownership or investment interest in a physician organization to stand in the shoes of that physician organization. Physician owners who do not receive the financial benefits of ownership or non-owner physician are not deemed to stand in the shoes of the organization, but are permitted to do so should they so chose.

PERIOD OF DISSALLOWANCE

CMS has established the time period in which a DHS entity that has a prohibited financial relationship with a physician is prohibited from billing for services referred by that physician. The start date of any period of disallowance is the date the prohibited financial relationship began. CMS has set the ending date of the disallowance period is no later than the following dates for the following relationships: a) for relationships that are non-compliant for reasons "unrelated" to compensation, the date the relationship becomes compliant; b) for relationships that are non-compliant due to payment of excess compensation, the date on which the excess compensation (plus interest, if applicable) is returned; or c) for relationships that are non-compliant due to payment of insufficient compensation, the date on which the "additional required compensation" (plus interest, if applicable) is paid.

PERCENTAGE–BASED COMPENSATION

CMS finalized changes to its interpretation of the term "set in advanced" to prohibit percentage based compensation formulae in the determination of rental charges for the lease of office space or equipment. In those circumstances, the rental charges must be set in advance and cannot be based on a percentage of revenues, collections or charges. CMS continues to be concerned over other arrangements in which the compensation is determined based on a percentage formula, but is only monitoring those arrangements at this time.

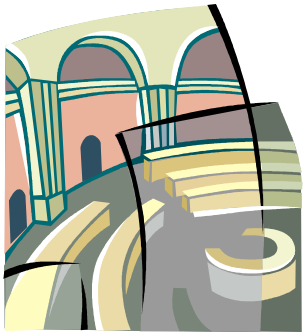
PER CLICK PAYMENTS IN LEASE ARRANGEMENTS

CMS also has prohibited per-click payments to physician lessors for services rendered to patients that were referred by the physician lessor. Several exceptions were revised to provide that unit-of-service rental payments are not allowed to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. This prohibition applies whether the physician is the lessor or is an owner or investor in an entity that is the lessor. The prohibition also applies to an entity lessor that refers patients to a physician lessee. This prohibition will become effective for lease payments after October 1, 2009.

SERVICES PROVIDED UNDER ARRANGEMENTS

CMS has changed the definition of "entity" that furnished DHS to include not only the entity that bills for the service, but also the entity that performs the service. Thus, a physician who has a financial relationship with an entity that provided DHS under an arrangement with a hospital, for which the hospital in turn bills, can no longer refer patients to the hospital for DHS. This change is also effective October 1, 2009.

CMS has adopted several changes to Stark regulations that will affect physician financial relationships.



Preparation for the DFRR (from Page 1)

official and returned within sixty (60) days. Untimely responses will trigger civil monetary penalties ($10,000 per day) unless good cause is shown. The DFRR will be a one-time collection, not an annual report, depending on the response from the surveyed hospitals. When warranted, CMS will provide the Office of Inspector General and the Department of Justice with the data collected.

The DFRR survey worksheet includes requests for various financial relationship information between a hospital and a physician from the cost reporting period 2006 only including but not limited to the following:

I. OWNERSHIP INFORMATION

- Hospital Characteristics
- Physicians that maintain direct ownership in the hospital
- Physicians that maintain indirect ownership
- Payments made to the hospital by direct owners
- Payment made to the hospital by indirect owners
- "Investment Reconciliation"
- If no physician owners (or family members), the ownership section of the DFRR is not applicable

II. COMPENSATION ARRANGMENTS

- **Rental of office space**
- **Rental of equipment**
- **Personal services agreement**
- **Physician recruitment**
- **For the above referenced compensation arrangements, a copy of the written agreement for such arrangement in force during 2006 must be provided**

III. ADDITIONAL COMPENSATION ARRANGEMENTS

- **Isolated transactions**
- **Remuneration unrelated to Designated Health Services**
- **Payments made by a physician**
- **Charitable donations**
- **Non-monetary compensation in excess of limits**
- **Medical staff incidental benefits in excess of limits**
- **Loan or loan guarantees made by the hospital on behalf of the physician or vice versa**

If a hospital (either a specialty hospital or a competitor of a specialty hospital) did not respond to the voluntary survey request in 2006 related to the specialty hospital report to Congress, it will receive a DFRR request when such is finalized. If a Medicare-participating hospital was not surveyed in 2006, it has approximately, a 1 in 50 chance of receiving a DFRR if/when finalized.

On December 19, 2008, CMS submitted the current DFRR to the Office of Management and Budget for review/approval and solicited comments from the healthcare industry that were due by January 20, 2009. The American Hospital Association ("AHA") is challenging the DFRR has a violation of the Paper Reduction Act because of the resources a hospital will consume to provide copies of certain agreements between physicians and that hospital. In addition, AHA is also challenging the DFRR as unsupported by the current reporting and disclosure requirements imposed by CMS. AHA has asked the Office of Management and Budget to deny authorization to proceed with the DFRR.

Due to the legislative process and the challenge to the DFRR by AHA, it is uncertain when a hospital can expect to receive a DFRR from CMS, if at all.

It is recommended that a hospital seek professional counsel if subject to a DFRR to ensure that it provides the appropriate information requested and/or does not provide information outside the scope of the DFRR.

David Dean Haynes, Jr. represents physicians in multiple areas, including partnership and corporate issues; compensation arrangements; recruitment and employment; regulatory issues such as Medicare and Medicaid compliance, including the Stark law and antikickback statute; the development of ancillary revenue arrangements, including specialty hospitals, ambulatory surgery centers, diagnostic imaging centers, diagnostic sleep centers, and medical office buildings; and capital formation mechanisms for such ancillary revenue arrangements,

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Kathleen L. DeBruhl & Associates is regional law firm with a national practice which represents the providers of health-care, and in particular physicians, regarding business and regulatory issues. The law firm has combined experience in all aspects of healthcare, including Medicare and Medicaid reimbursement, Stark and Anti-Kickback Compliance; Academic Medical Centers and Faculty Group Practices; development and joint venture contracting and financing; partnership and employment; Mergers and Acquisitions; Peer Review and hospital credentialing; professional licensing; regulatory and administrative proceedings; and dispute resolution including mediation, arbitration and litigation.

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