

TO: HEALTH CARE CLIENTS

DATE: July 24, 2007

RE: Update on Important Stark Law Developments: CMS Proposes Regulatory Changes, Solicits Comments on Other Key Related Issues, and Will Mandate Disclosure of Certain Hospitals' Financial Relationships

I. INTRODUCTION

By one measure, the Stark Law has just turned eighteen years old. This legislation, informally named after its chief legislative sponsor, Representative Fortney "Pete" Stark (D-CA), was originally enacted as part of the Omnibus Budget Reconciliation Act of 1989, about eighteen years ago (with an effective date of January 1, 1992). The Stark Law, as amended, prohibits a physician from making referrals to an entity, with which the physician or an immediate family member has a financial relationship, for the furnishing of specified "designated health services" ("DHS") under Medicare, unless an exception applies.¹ The Stark Law, with its numerous sets of proposed and final regulations, has developed gradually, in stages and, like most eighteen-year olds, remains a work in progress.

The Centers for Medicare & Medicaid Services ("CMS") bears primary responsibility for implementing the Stark Law. In so doing, CMS coordinates, to a significant degree, with the Department of Health and Human Services' ("HHS") Office of Inspector General ("OIG"). Past major regulatory Stark Law initiatives have appeared as stand-alone Stark regulations and/or proposed regulations.² Consistent with that approach, on June 14, 2007, CMS announced that it has sent a final Stark rule (referred to informally as "Stark III") to the Office of Management and Budget ("OMB") for regulatory review. That rule likely will finalize a number of Stark Law provisions that have not yet been addressed (e.g., referrals for certain Medicaid-covered services)

¹ See 42 U.S.C. § 1395nn. Reed Smith has prepared a series of client memoranda analyzing the various regulatory developments implementing the Stark Law. These memoranda are available through our office.

² Prior stages of Stark Law and regulatory developments have been dubbed Stark I, Stark II (Phase I), and Stark II (Phase II).

and also will address issues raised by the many public comments received on the Stark II (Phase II) regulations published in the Federal Register on March 26, 2004.³

However, for the past two years, CMS also has opted to tackle certain tough Stark issues in another rulemaking context: the proposed update to the Medicare Physician Fee Schedule (“MPFS”). In certain cases, the Stark Law rules are intertwined with Medicare reimbursement rules and, thus, must be considered together to understand the permissibility of certain arrangements. Understanding the interplay of these complicated rules can be challenging but is essential for maintaining regulatory compliance.

On July 2, 2007, CMS posted on its website, as a proposed rule, the 2008 MPFS update,⁴ which includes several important and potentially far-reaching proposed amendments to current Stark regulations. This mechanism of using the MPFS for addressing important, complex Stark issues has added strength to the accelerating currents, and cross-currents, of change and development on the Stark Law front. Further, CMS is seeking public comment on several additional Stark-related topics for which no rule change is yet being formally proposed (but may well be reflected in later rule changes). Public comments to CMS on most of the proposed rules and related topics are due no later than August 31, 2007. Due to a publishing error, the deadline for commenting on CMS’s proposed “alternative criteria for satisfying exceptions” (discussed herein in Section II (K)) was extended to September 7, 2007.

Finally, there is growing evidence that federal audit activity of Stark Law compliance will increase in the hospital/physician relationship context. CMS recently announced in the Federal Register⁵ that the agency will seek mandatory disclosure from approximately 500 hospitals, located in approximately fifteen states, of hospital/physician financial relationships subject to the Stark Law. This mandatory reporting/disclosure initiative follows CMS’s prior attempt to obtain voluntary hospital compliance with a similar request for information focused primarily on specialty hospitals and their competitors. Disappointed with the number of hospitals that responded voluntarily, CMS will be requiring reporting of physician financial relationships from the selected hospitals, thereby turning up the heat by increasing its scrutiny of Stark issues involving physician-hospital financial relationships.

³ 69 Fed. Reg. 16,054 (2004).

⁴ 72 Fed. Reg. 38,122 (2007).

⁵ 72 Fed. Reg. 28,056 (2007).

In our view, the important Stark-related developments described in this memorandum, together with the expected promulgation of the Stark III rule in the near future and the impending mandatory hospital reporting activity, are clear indications that Stark Law issues are increasingly “coming of age” and becoming more of a compliance priority for CMS and perhaps also for federal enforcement agencies. Entities subject to the Stark Law that could be affected by these developments should consider submitting comments to CMS. At the very least, such providers should continue to be vigilant in their Stark compliance efforts.

II. PROPOSED AMENDMENTS TO STARK REGULATIONS AND SOLICITATION OF COMMENTS

The 2008 MPFS includes eleven separate, sometimes interrelated, Stark Law topics. Six of these topics are set forth as proposed rule changes (*i.e.*, amendments to existing Stark regulations). For the remaining five topics, CMS is not currently proposing a formal rule change, but instead is soliciting public comment on them. We believe these CMS-driven Stark initiatives are as significant as any that have been introduced in many years. Our memorandum first discusses the six topics presented as proposed amendments to current rules (sections “A” through “F”), then addresses the five significant Stark issues not subject to a formal rulemaking proposal (sections “G” through “K”), but on which public comment is being sought.

Many of these eleven Stark topics are quite complex and, if finalized, of substantial practical significance. Some constitute a reversal of existing CMS positions that would effectively narrow considerably the types of leasing arrangements and joint venture structures that currently are permissible. CMS’s treatment of most of these Stark topics apparently reflects CMS’s view that it has learned some lessons over the years that need to be addressed. In a press release relating to the 2008 MPFS, CMS expresses its intent “to close loopholes that have made the Medicare program vulnerable to abuse.” Because of their potentially far-reaching implications, we summarize below these proposed Stark rules and related topics and provide commentary on selected aspects of CMS’s treatment of these Stark Law issues.

A. Expansion of the “Anti-Mark Up” Restrictions for Purchased Diagnostic Tests

This section addresses CMS’s significant proposal to expand its “Anti-Markup Provision” to the professional component of diagnostic tests. It will be of interest primarily to physicians, group practices, medical faculty practice plans, practice management companies, third-party billing companies, and those who represent or counsel such clients. These proposed

rule changes affect two Medicare reimbursement regulations (*i.e.*, the “purchased diagnostic test” rule and the “reassignment” rule), rather than changes to a Stark rule. However, CMS had previously considered a Stark rule amendment to achieve the same policy results as this proposed rule, which would have modified the definition of “centralized building” used in the “in-office ancillary services” exception. CMS could revisit that approach in the future if it determines it needs to further supplement the reimbursement rule changes proposed here in the 2008 MPFS.

1. Expanded to Cover Professional Component Services

Under the Medicare “purchased diagnostic test” (“PDT”) rule, also referred to as the “Anti-Markup Provision,” if a physician (or medical group) bills Medicare for the technical component of a diagnostic test performed by an outside supplier, the physician is essentially prohibited from “marking up” the charges submitted to Medicare for the technical component services above the amount the physician actually paid to purchase the test from the outside supplier.⁶ Specifically, the PDT rule provides that if a physician bills for the technical component of a diagnostic test purchased from an outside supplier, the physician will be paid the lowest of:

- (i) The supplier’s net charge to the physician.
- (ii) The physician’s actual charge.
- (iii) The fee schedule amount for the test that would be allowed if the supplier billed directly.

Currently, the Anti-Markup Provision does not apply to any Medicare claims a physician submits for the professional component of a diagnostic test which the physician either purchases under a contract or obtains pursuant to a reassignment from another physician or group practice.

In the 2007 MPFS proposed rule, CMS solicited public comment on expanding the Anti-Markup Provision to apply also to the professional component of a diagnostic test if a physician either purchases those services from an outside physician or supplier or obtains the services pursuant to a reassignment from an outside physician or supplier. After reviewing the public comments, CMS determined that purchased diagnostic test and interpretation arrangements that permit purchasing physicians to realize a profit from their referrals for diagnostic testing may lead to abusive overutilization of services. Therefore, CMS is proposing to eliminate the ability of a physician to profit from Medicare billings for the professional component of diagnostic tests

⁶ See 42 C.F.R. § 414.50.

if the physician either purchases the services under contract or obtains the services via reassignment from an outside supplier by expanding the Anti-Markup Provision of the PDT Rule to apply to the professional component of diagnostic testing services, and concurrently adding new provisions to the Medicare reassignment rules so that the anti-markup prohibition also applies to reassigned professional component services.⁷

2. Calculating a Supplier's "Net Charge"

In addition to expanding the Anti-Markup Provision to apply to professional component services, CMS is attempting to prevent "gaming" of the Anti-Markup Provision by clarifying that a "supplier's net charge" cannot include any charge the supplier incurs as a result of leasing equipment or space from the physician or medical group that will be billing for the supplier's services. For example, assume the Medicare fee schedule payment for the professional component of a MRI study is \$50. A radiologist agrees to pay an orthopedic group \$25 per study to use the group's office space and computer workstation to perform professional interpretations of its MRI studies. The group agrees compensate the radiologist for his professional services at a rate of \$50 per study. For purposes of the PDT Rule, the radiologist's "net charge" to the Ortho Group for the professional services would not be the \$50 the radiologist was paid but, instead, \$25 since the radiologist is paying the orthopedic group \$25 to use its office space and computer workstation. As a result, the orthopedic group would be limited to billing Medicare \$25 for the radiologist's professional component services rather than a full \$50 and, therefore, would only be paid \$25 by Medicare rather than the full fee schedule amount of \$50.

3. Definition of "Outside Supplier"

Perhaps the most controversial aspect of CMS's proposal to expand the scope of the PDT Rule and its Anti-Markup Provision is the proposal to define the term "outside supplier" to mean any person or entity other than a full-time employee. As a result, if the technical and/or professional component of a diagnostic test is performed by a part-time employee, part-time independent contractor, or full-time independent contractor, that service will be subject to the Anti-Markup Provision. Thus, the only technical or professional component service of a diagnostic test that a physician or medical group could mark-up are those performed by full-time employees.

⁷ A blacklined version of CMS's proposed regulatory changes addressed in this memorandum, including the PDT Rule and reassignment rule changes, is included in Appendix A.

If this proposed revision to the PDT Rule is adopted, it would significantly impact the ability of medical groups to utilize part-time employee and independent contractor radiologists, pathologists, or other physicians to perform professional interpretation services since the medical groups would be limited to billing Medicare no more than the interpreting physician's "net charge," even though the medical group must, in addition to paying the interpreting physician, cover the overhead costs and assume the business risk for billing for the services.

4. Reed Smith Comments/Questions

CMS has proposed these changes due to its concern regarding physician group practices or other suppliers being able to procure diagnostic testing services as a profit center that could lead to Medicare overutilization. The details of the current CMS proposal to implement a system to address that concern, however, raises the following issues:

a. *How will "net charge" be calculated if:*

- The lease payments are a fixed amount rather than per test (e.g., \$500 per month)?
- The compensation paid to the supplier for the technical or professional component services is based on a fixed fee rather than per test payment?

b. *Issues Regarding "Outside Supplier"*

- For employees or contractors who are paid on a salaried or hourly basis, how do you determine what the "net charge" is per test performed?
- Does "net charge" for employees take into account benefits in addition to salary?
- When calculating "net charge" can you take into account overhead costs such as billing costs and bad debt?
- How will "full-time" employee be defined?

B. Burden of Proof

1. Provider's Burden to Prove Compliance

CMS proposes adding a new section 411.353(g) to the existing Stark regulations that would "clarify" the burden of proof when a provider appeals a claim that was denied payment because the DHS allegedly arose from a prohibited referral. The regulations were previously silent on this subject. The new language states that "the burden is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral

(and not on CMS or its contractors to establish that the service was furnished pursuant to a prohibited referral).”⁸ CMS notes that the new section is consistent with the agency’s policy for claims denials generally.

2. Reed Smith Comments/Questions

If this provision is finalized, proper document retention and recordkeeping policies will assume even greater importance since, when challenged by CMS, providers will have to prove their compliance with the Stark Law’s requirements to an independent adjudicator rather than CMS having to prove guilt. In other words, once CMS alleges through a claims denial that a Stark violation has occurred, the burden will shift to the provider to prove otherwise.

The proposed language does not specify whether the provider will have to prove compliance with all components of the relevant Stark exception or (more logically) only the portion of the exception that CMS believes was not satisfied if CMS has specified that alleged Stark compliance deficiency. For instance, many Stark exceptions require compliance with the federal anti-kickback statute. That means the provider must prove that the arrangement meets a safe harbor, received a favorable OIG advisory opinion, or otherwise does not violate the anti-kickback statute. Absent full safe harbor compliance or issuance of a favorable advisory opinion, the provider would surely face a significant challenge to “prove a negative” under uncertain anti-kickback statute standards – that the arrangement does not violate the anti-kickback statute. The burden on the provider will be substantially greater if compliance with this law needs to be proven each time there is an appeal of an alleged Stark violation. Furthermore, CMS does not normally determine compliance with the anti-kickback statute and, under the current proposal, would not be subject to any particular standards or procedures for explaining and justifying its findings in response to a provider’s appeal of a Stark-related claims denial.

Among the Stark general exceptions and compensation arrangement exceptions that require compliance with the anti-kickback statute are those applicable to the following arrangements:

- In-office ancillary services
- Academic medical centers
- Implants furnished by an ASC

⁸ 72 Fed. Reg. 38,122, 38,224 (Jul. 12, 2007) (Parenthetical language in original.).

- Provision of EPO in a dialysis facility
- Contacts following cataract surgery
- Intra-family referrals
- Personal services arrangements (general reference)
- Physician recruitment
- Charitable donations by a physician
- FMV compensation exception
- Medical staff incidental benefits
- Indirect compensation
- Professional courtesy
- Retention payments in undeserved areas

Given the considerable uncertainties of proving anti-kickback statute compliance (an intent-based statute), affected parties may want to comment to CMS that additional clarification is needed on this point.

C. Unit-of-Service (Per-Click) Payment in Space and Equipment Leases

1. Overview of Proposed Regulatory Modifications

Current Stark exceptions for space and equipment leases (and personal services) permit payment based on a “per-click” basis (*i.e.*, a per-use or per-service fee). However, in the 2008 MPFS, CMS notes that it is “concerned with lease arrangements that are structured so that a physician is rewarded for each referral he or she makes for DHS.” As such, CMS proposes to modify the existing Stark exceptions for space and equipment leases (but not personal services), by supplementing existing requirements for lease payments (namely, fair market value and the prohibition on any variance per referrals or business generated between the parties). Specifically, CMS proposes to add the following provision to the space and equipment lease exceptions:

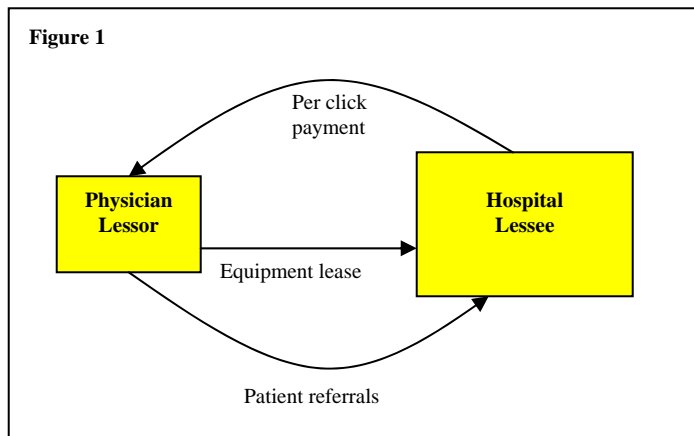
Per unit-of-service rental charges are not allowed to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

In making this proposal, CMS notes that it believes that “such arrangements are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee. . . .” This represents a reversal of CMS’s current regulatory position: although CMS originally would have prohibited such arrangements, CMS changed its mind in the final 2001 Stark II (Phase I) regulations and expressly stated that, in connection with space and equipment leases, it would permit “time-based or unit-of-service-based payments, even when the physician receiving the payment has generated the payment through a DHS referral.”⁹ CMS acknowledged that one reason it reached this conclusion was because the Stark Law’s legislative history showed that Congress intended to permit time-based and unit-of-service arrangements.¹⁰

In addition, CMS requests comments on whether it should impose the same restriction on leasing arrangements that flow in the other direction (*i.e.*, where the DHS entity is the lessor). Specifically, CMS asks whether it should prohibit “time-based or unit-of-service-based payments to an entity lessor by a physician lessee, to the extent that such payments reflect services rendered to patients sent to the physician lessee by the entity lessor.”

2. Reed Smith Comments/Questions

CMS provides an example of the type of arrangement it disfavors and that would be prohibited under the proposed modification. Under the scenario presented by CMS, a physician leases equipment (that the physician owns) to a hospital on a per-click basis. Thus, the physician receives a lease payment each time the physician makes a referral to the hospital for use of the equipment. See Figure 1.



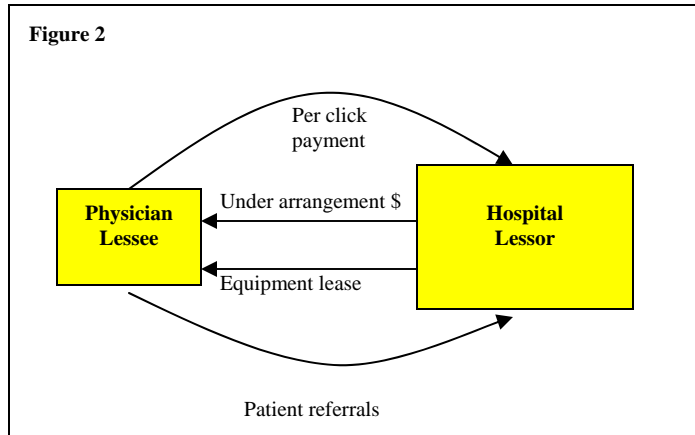
⁹ 66 Fed. Reg. at 876.

¹⁰ Id.

As currently proposed, the changes to the regulation would only apply to individual physician lessors. This has two important implications. First, it would not impact arrangements between a physician group and a hospital — as always, this type of arrangement would be subject to an analysis under the definition (and exception) for indirect compensation arrangements (and therefore the lease exceptions would not apply). We note, however, that this could potentially change based on CMS’s comments regarding physicians “standing in the shoes” of their group practices. (Although no proposed changes are included with the current rulemaking; see the discussion below at Section J.) To the extent CMS collapses the relationship between a physician and his or her group, the space and equipment rental exceptions would have a much broader application, and many arrangements would need to be restructured to comply with the applicable lease exception. (Some arrangements may already be structured to comply (or substantially comply) with the anti-kickback law safe harbor for leases, but this may not be sufficient for Stark Law compliance.)

As suggested above, CMS is essentially doing a policy “flip-flop” with its proposal changes to the lease exceptions. While recognizing that the Stark Law’s legislative history would permit many “per click” arrangements even when the physician-lessor is the referral source, CMS proposes to prohibit such leases by invoking its statutory authority (in the Stark exception for lease arrangements) to impose regulatory requirements to protect against abuse. We believe this raises a potentially significant legal issue, namely, whether CMS can legally utilize this general regulatory authority from the lease exception to impose a restriction that is flatly inconsistent with the Stark II conference report which clearly states Congress’s intent to allow “per click” arrangements as long as the amount of the per-click rates does not fluctuate during the contract period based on the volume or value of referrals between the parties.

Second, the proposed restrictions on per-click payments would not apply where the hospital (or other DHS entity) is the lessor. As noted above, CMS has only solicited comments on this point. However, CMS includes an example of the type of hospital-physician leasing arrangement that it finds suspect: A hospital leases an MRI machine (that it owns) to a physician (lessee) on a per-click basis. Under these circumstances, CMS asserts that the physician only “rents the MRI machine from the hospital when the physician refers a patient for an MRI and then provides the facility portion of the MRI services under arrangements with the hospital.” Under these circumstances, the physician “benefits financially and the arrangement could provide an incentive for overutilization or other program abuse.” See Figure 2.



Although not entirely clear, CMS appears to be identifying a situation where the physician would provide MRI services to the hospital under arrangement, the hospital would pay the physician for any services provided under arrangement (which would include payment for the leased MRI over and above the rental amount) and therefore financially benefit from the arrangement. That said, CMS’s solicitation of comments appears to be (at least potentially) broader in application, in that it would prohibit all per-click leasing arrangements where the DHS entity is the lessor and a physician is the lessee.

D. Ownership or Investment Interest in Retirement Plans

1. Narrowing the Ownership Exception

Currently, Section 411.354(b)(3)(i) excludes an “interest in a retirement plan” from the definition of ownership and investment interests. CMS proposes to tighten this exception in response to comments noting that some physicians appeared to be abusing it. CMS reports that it received information indicating that, contrary to the agency’s intent, some physicians are using retirement plans to purchase DHS entities to which the physicians refer patients. If finalized, the exception would apply only to ownership or investment interests in a retirement plan offered by an entity to a physician or immediate family member as a result of the physician’s employment with the entity. It would not extend to any DHS entity in which the employer’s retirement plan invests.

2. Reed Smith Comments/Question

An example of the perceived abuse that this change is designed to avoid would be a scenario in which Dr. Adams is an employee of Bayside Clinic but participates in a retirement plan which owns shares in Covese Imaging, Inc. Dr. Adams then refers patients to Covese

Imaging. The new regulation is intended to ensure that Dr. Adams' ownership interest in Coveseide Imaging, through the retirement plan's investment, would not be subject to the ownership exception for retirement plans. However, any interest Dr. Adams has in Bayside Clinic by virtue of the retirement plan would still be excluded from the definition of ownership and investment interests under the new language.

E. Set-In-Advance and Percentage-Based Compensation

1. Limiting Use of Percentage Arrangements

CMS proposes to reverse course and to rein in substantially the permissible use of percentage arrangements under the Stark Law.

Several important Stark exceptions require that compensation be “set in advance” (see, e.g., office and equipment leases, personal service arrangements, FMV compensation, and academic medical center arrangements with physicians). As part of the Stark regulations’ “special rules on compensation,” CMS has long grappled with how to treat percentage arrangements under the “set in advance” requirement. In the 2001 final Stark regulations (Phase I), CMS stated that percentage arrangements based on a “fluctuating or indeterminate amount” (e.g., percentage of revenues or collections) were not set-in-advance and, thus, not permissible under Stark. However, responding to pressure from segments of the provider community, CMS suspended implementation of that restriction on percentage arrangements. In the 2004 Phase II regulations, CMS changed its prior Phase I position by allowing most types of percentage arrangements, as long as the formula was specified prospectively, was objectively verifiable, and did not change during the contract period based on the volume or value of the physician’s referrals or other business generated.

Now, in the 2008 MPFS proposal, CMS would only permit a DHS entity to have a percentage arrangement with a referring physician when the percentage is based exclusively on revenues generated from the physician’s personally performed services. CMS explained that it is proposing this more restrictive approach because of what it perceives as potentially abusive arrangements involving percentage-based equipment and office leases, or other payments not related to the physician services provided.

2. Reed Smith Comments/Questions

CMS obviously is struggling over the percentage arrangement issue, as evidenced by its several, significant changes of heart about percentage arrangements. If enacted as proposed, this change would effectively require fixed-fee equipment and space leases between referring physicians and DHS entities. It also would severely restrict relatively common forms of percentage management agreements and facility service agreements in the joint venture context.

Taken together with the proposed restrictions on “per click” arrangements described above, CMS appears to be trying to force most contractual arrangements (other than personal service arrangements) into a flat-fee model. It is unclear whether CMS’s most recent thinking on these issues (after several course reversals) represents the best way to balance real-world contracting models against the legitimate need to prevent abuse. It is also unclear why CMS considers percentage arrangements to be more inherently suspect than any other variable fee structure. It may also be the case that mandating flat-fee contractual arrangements in certain management and other business contexts is akin to trying to force a round peg into a square hole.

Providers potentially affected by this proposal should assess the contractual restructuring that would be required and, if troubled by that prospect, consider submitting comments to help further refine CMS’s understanding of these arrangements.

F. Services Furnished “Under Arrangements”

1. Sweeping New “Entities” Into Stark Law

CMS proposes to make a significant change to the definition of “entity” in order to prevent so-called “under arrangements” joint ventures that have referring physicians as owners. In recent years, these “under arrangements” joint ventures have been formed to furnish imaging, ambulatory surgery, cardiac catheterization and other services to hospitals. At present, CMS interprets the definition of “entity” as including only the person or entity that bills Medicare for DHS, but not the person or entity that performs the DHS (if that person or entity is not also billing Medicare). CMS now proposes to extend “entity” to the person or entity that performs the DHS. The proposed definitional change is ambiguous, however, and would leave unclear whether vendors to DHS providers would be subject to the Stark Law merely because their goods or services comprise part of a DHS billed by their customer (see commentary below).

The Medicare statute permits providers, such as hospitals, rural primary care hospitals, skilled nursing facilities, home health agencies, and hospices, to furnish services to beneficiaries “under arrangements” with third party vendors. The vendor has a contractual relationship with the provider, and the provider (but not the vendor) bills for the services. Regulatory guidance concerning permissible “under arrangements” scenarios has tended to focus on the provider’s ultimate responsibility for the services performed by an “under arrangements” vendor.

CMS is concerned that hospital outpatient services furnished by an “under arrangements” vendor owned by referring physicians creates a risk of overutilization. CMS states that there may be no legitimate reason for such an arrangement other than allowing a physician to make money on referrals, particularly where the services furnished by the joint venture were previously directly furnished by the hospital. In addition, CMS expresses concern that the “under arrangements” services might be furnished in a less medically-intensive setting but billed at higher outpatient hospital PPS rates.

In its March 2005 Report to Congress, the Medicare Payment Advisory Commission (“MedPAC”) recommended changes to prohibit physician referrals by a physician who has an ownership in an entity “that derives a substantial proportion of its revenues from a [DHS] provider.” CMS goes further, however, by proposing that the term “entity” be defined to include not only the entity that submits claims to Medicare for DHS, but also the person or entity that “performs the DHS” or causes claims to be submitted. The aim of this change is to prohibit a physician owner of an “under arrangements” vendor from referring for the joint venture’s services.

2. Reed Smith Comments/Questions

Here is an example of an arrangement we believe remains unresolved under CMS’s proposed changes for “under arrangements.” Assume an orthopedic surgeon has an ownership interest in a manufacturer of spinal implants. The manufacturer sells its implants to the hospital where the surgeon performs his or her surgeries. How would the definitional change of “entity” affect Stark Law compliance for the manufacturer?

It is unclear whether the manufacturer would be considered an entity that is subject to the Stark Law. The proposed definition would extend the definition of entity to an entity that “performs the DHS.” Inpatient and outpatient hospital services are DHS, and spinal implants may be part of a DHS furnished to Medicare patients and billed by the hospital. If interpreted

this broadly, the proposed change could extend the Stark Law to a large number of entities not previously subject to its prohibitions.

G. In Office Ancillary Services Exception

1. Soliciting Comments On Requisite Nexus to Physician's Core Practice

The Stark Law's in-office ancillary services exception allows a physician to furnish (and financially benefit from referrals for) many ancillary services. There are conditions, however, such as supervision, location, and billing requirements that, in effect, seek to ensure that the ancillary services are furnished as an integral part of the physician's medical practice. In the Preamble to the 2008 MPFS, CMS expresses concern that this exception is being used to allow referring physicians to benefit financially from referrals for ancillary services that are "often not as closely connected to the physician practice." According to CMS, this exception is intended to allow group practices to provide their patients with ancillary services required for "the diagnosis or treatment that brought the patient to the physician's office."

CMS cites the example of pathology laboratory services that are not physically located near any of a physician practice's offices, for which professional interpretations are performed by a contractor pathologist with virtually no relationship with the practice, and in some cases using technologists employed by an entity unrelated to the physician practice. CMS suggests that the core members of the group practice and their staff should be involved in contracted services delivered under the in-office ancillary services exception. Even where the ancillary services are furnished in the same building where physician services are performed, CMS says that "there may be very little interaction between the physicians who treat patients and the staff that provide the ancillary services." CMS expresses particular concern over "the proliferation of in-office laboratories and the migration of sophisticated and expensive imaging or other equipment," and "turn-key" operations for in-office laboratories and other ventures. (See commentary below.) In this sense, CMS is embracing the theme articulated by the OIG in its April 2003 Special Advisory Bulletin on Contractual Joint Ventures.

CMS solicits comments as to whether changes are needed to the in-office ancillary services exception to curtail program or patient abuse. Specifically, CMS asks whether some services should not qualify for the exception (including therapy not billed under the "incident to" rules, and services not needed at the time of the office visit in order to assist the physician in his diagnosis or plan of treatment), whether changes to the "same building" and "centralized

building” definitions are warranted, and whether nonspecialist physicians should be able to use the exception for specialty services involving the use of equipment owned by the nonspecialists.

2. Reed Smith Comments/Questions

Assume an orthopedic physician practice contracts with an imaging company to furnish MRI and radiation technologists in unused space in the same building where the physician practice has its main office. The imaging company arranges for a contractor radiologist to supervise and interpret the studies. The physician practice bills for the imaging services, and pays the imaging company on a “per click” basis. Would this arrangement be affected by the Proposed Rule?

CMS is not proposing any changes that would affect this arrangement; however, some of CMS’s discussion indicates that CMS may be concerned about aspects of this arrangement. In particular, if the imaging center is operated independently from the physician practice by contractors, CMS may view the arrangement as being of a type not intended to be permitted by the Stark Law. Be on the lookout for future proposed changes, and evaluate the arrangement in light of the OIG’s concerns about contractual joint ventures.

H. Obstetrical Malpractice Insurance Subsidies

1. Possibly Broadening the Exception

The current Stark regulations exempt from the definition of a “financial relationship” certain subsidies of obstetrical malpractice insurance.¹¹ To qualify for this exception, the subsidy must satisfy the OIG’s Anti-Kickback Statute safe harbor for obstetrical malpractice insurance subsidies.¹² In the preamble to the 2008 MPFS, CMS expressed concern that the exception for these subsidies is “unnecessarily restrictive; that is, ...[the] exception does not allow for certain obstetrical malpractice insurance subsidies that may be provided without a risk of program or patient abuse.” Citing anecdotal evidence that difficulties obtaining malpractice insurance have caused obstetricians to leave certain states for other practice locations, CMS is soliciting comments on the extent of the problem and how the exception could be broadened.¹³

11 42 C.F.R. § 411.357(r).

12 See 42 C.F.R. § 1001.952(o).

13 See 72 Fed. Reg. 38,122, 38,182 (Jul. 12, 2007).

CMS specifically mentions a requirement found in the anti-kickback safe harbor that “75 percent of the physician’s obstetrical patients treated under the coverage of the malpractice insurance will either reside in a HPSA [Health Professional Shortage Area] or a medically-underserved area or be part of a medically-underserved population” as one requirement that should perhaps be changed. CMS, though, notes its preference for “bright-line requirements,” which suggests that the agency may retain some numeric threshold in this area.¹⁴

The agency also “proposes” (but does not offer specific language) listing the conditions that it believes are necessary to “safeguard against program or patient abuse” in the Stark regulations. The agency suggests:

- A requirement for a written agreement between the parties;
- Physician certification (or, in subsequent years, actual data indicating) that a specified percent of the physician’s obstetrical patients treated under the coverage of the subsidized malpractice insurance will either reside in a HPSA or medically-underserved area or be part of a medically-underserved population;
- Location of the entity making the malpractice insurance premium subsidy payment;
- Location of the medical practice of the physician receiving the malpractice insurance subsidy payment;
- A requirement that the payment not be conditioned on the physician making referrals to, or otherwise generating business for, the entity;
- No restriction on the physician establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity;
- A requirement that the amount of the payment may not vary based on the volume or value of any previous or expected referrals to or business otherwise generated for the entity by the physician;
- A requirement that the physician must treat obstetrical patients who receive medical benefits or assistance under any federal health care program in a nondiscriminatory manner;
- A requirement that the insurance is a bona fide malpractice insurance policy or program, and the premium, if any, is calculated based on a bona fide assessment of the liability risk covered under the insurance;

14 See id.

CMS also suggests an additional requirement that the subsidy not violate the anti-kickback statute or “any other Federal or State law or regulation governing billing or claims submission.”¹⁵

2. Reed Smith Comments/Questions

It is refreshing to see a CMS proposal to broaden a Stark exception. Most of these possible requirements resemble the requirements found in the anti-kickback statute safe harbor. Thus, the primary effect of this proposal may an expansion of the geographic scope of the existing Stark exception.

I. Period of Disqualification for Noncompliant Arrangements

1. Seeking Clarification of Stark Sanction Period

In response to a previous rulemaking, CMS received comments regarding the period a physician would be disqualified from referring DHS to the entity and the entity could not bill Medicare in instances where a financial arrangement failed to satisfy the requirements for a Stark exception. While CMS is not making any proposals for delineating the period of disqualification, the agency seeks comments on how, to the extent practicable, such a period might be determined.

In instances where it is clear when the relationship begins and ends, CMS believes that the period of disallowance begins and ends on those dates. There are a variety of instances, however, when it is not clear when a relationship begins and ends. For example, a lease that is substantially below fair market value might be viewed as being consideration for future referrals even after the end of the lease term. As such, CMS seeks comment as to whether these situations should be evaluated on a case-by-case basis or if certain types of financial relationships should be deemed to continue for a certain period of time. Additionally, CMS seeks comment as to whether the parties could limit the period of disqualification by reforming the relationship and returning prohibited compensation. If adopted, such an accommodation would only be available to parties whom CMS determines did not know, or have reason to know, that they were out of Stark compliance. Finally, CMS seeks comment as to whether parties should be barred for an additional period of time from relying upon an exception when they clearly failed to satisfy its terms.

¹⁵ Id.

2. Reed Smith Comments/Questions

Given the variety of Stark exceptions and the multiple types of physician/entity relationships in the marketplace, it appears difficult to develop any “bright line” tests for a period of disqualification. For example, the Stark exception for isolated transactions raises issues similar to the below value lease example provided by CMS, but the specific facts of the transaction likely would dictate the applicable disqualification period. With respect to a bar on use of an exception, if parties were prohibited from relying upon an exception for a period based upon failure to satisfy its terms, it is unclear whether the bar should be applied to only those parties or to each party in any relationship for the period.

J. “Stand In The Shoes”

1. Movement Toward Analyzing Physician Arrangements As “Direct” Rather Than “Indirect”

CMS invokes the “stand in the shoes” concept to suggest the possible restructuring of the required Stark analysis in assessing arrangements involving multiple parties/entities. In general, the Stark Law requires that direct compensation arrangements between a referring physician and a DHS entity must satisfy one of the direct compensation arrangement exceptions. Conversely, if there is one or more additional persons or entities in the chain of financial relationships linking the referring physician to the DHS entity, then the physician/DHS entity’s financial relationship is usually considered “indirect” (unless that entity is the referring physician’s wholly-owned professional corporation – the physician’s “alter ego”). In that case, a different definition – the one for “indirect compensation arrangements” – must be assessed to determine if the parties have a financial relationship. If so, the exception for indirect compensation arrangements must be satisfied. Considerable ambiguity can exist as to whether an arrangement meets the Stark Law’s definition of “indirect compensation arrangement” and, if it does, whether the indirect compensation arrangement exception applies. Assessment of these issues involves, among other things, a “knowledge” element that can further “muddy the waters.”

In the 2008 MPFS, CMS states that it is proposing a Stark rule change, but it does not supply any proposed language (at least on the CMS website edition). Further, CMS indicates that it will likely address whether a physician should be considered to be “standing in the shoes” of his or her medical group in the upcoming Stark III regulations. (That is a very important issue which should be closely monitored.) In the MPFS context, CMS’s focus is on the “DHS entity” side of the equation. Simply stated, CMS is soliciting comment on its proposal that:

[W]here a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS entity would stand in the shoes of the entity that it owns or controls and would be deemed to have the same compensation arrangements with the same parties and on the same terms as does the entity that it owns or controls.

2. Reed Smith Comments/Questions

While we commend CMS for its efforts in trying to clarify the Stark method for assessing contractual arrangements with multiple parties, CMS's current proposal for the "DHS-end" of the chain of financial relationships remains quite confusing. In the CMS example, if a hospital-owned medical foundation/clinic contracts with a physician to provide physician services at a clinic the foundation owns, then the hospital would "stand in the shoes" of the medical foundation. Accordingly, the hospital would be "deemed" to have a direct compensation relationship with the contractor physician.

Although we understand that CMS may be seeking to convert certain arrangements from "indirect" to "direct" for purposes of determining compliance with a Stark exception, the example given in the MPFS is confusing. For example:

- Would the entity contracting directly with the physician (here, the medical foundation) have to be a DHS provider for the analysis to apply? CMS's preamble commentary suggests "yes," but the example (involving the provision of "physician services") suggests "no."
- If the hospital and clinic are collapsed, would each of them separately have to qualify for a compensation arrangement exception (*e.g.*, a personal services arrangement ("PSA")) with the physician, or only one of them? Would the answer differ based on whether the physician refers only to the clinic for DHS, or refers to both the clinic and the hospital?
- If the referring physician has a medical director agreement with the clinic that meets the PSA exception, would the same physician also be deemed to have the same PSA exception with the hospital even if he/she provided no services to the hospital?

At the end of the day, it seems clear that CMS wants to move the Stark analysis away from the ambiguities of the "indirect compensation" analysis. However, we believe much work remains to be done if this shift is to result in a clear, "bright-line" rule, which must be the goal.

K. Alternative Criteria For Satisfying Certain Exceptions

1. Proposed Relief For Inadvertent Errors and Minor Stark Violations

In response to previous rulemaking, CMS received comments regarding “technical” violations of the Stark Law and that innocent or trivial violations could result in draconian penalties. For example, a missing signature on a lease agreement or personal services arrangement otherwise satisfying a Stark exception could result in an entity being required to repay Medicare revenue for all services provided to patients referred by the physician who is a party to the non-compliant lease or personal services arrangement during the term of the agreement. CMS states that it does not have discretion to waive violations of the Stark Law, as it is a strict liability statute. Nonetheless, CMS is considering amending certain Stark exceptions to provide an alternative method for satisfying the exception in instances where there has been an unintentional violation of a procedural or “form” requirement of the exception.

If such an amendment were adopted, the alternative method for Stark compliance would apply if: (i) the parties self-disclose the violation to CMS; (ii) CMS determines that the arrangement otherwise satisfies the exception; (iii) the failure to meet all the exception’s requirements was inadvertent; (iv) the parties did not have knowledge that one of the procedural or form requirements were not satisfied; (v) the parties either have brought the arrangement into full compliance with the exception or have terminated the relationship; (vi) the arrangement does not pose a risk or program or patient abuse; (vii) no more than a set period of time has elapsed since the time of noncompliance; and (viii) the arrangement is not the subject of an ongoing federal investigation. Further, CMS would have sole discretion to determine whether the alternative criteria were satisfied, and there would no appeal or review of CMS’s determination.

2. Reed Smith Comments/Questions

CMS is seeking comment as to whether such an alternative compliance method policy should be adopted and how it would be implemented. While the issue of technical non-compliance has been a persistent enforcement issue under the Stark Law, the alternative compliance policy raises several additional issues. For example, entities utilizing such an alternative compliance method would have to self-disclose the issue, would be subject to CMS’s sole authority (without any appeal rights), and essentially would waive any defenses otherwise available. Further, entities could be subject to extensive discovery (including disclosure of electronic mail correspondence and draft agreements) as CMS seeks to determine whether noncompliance with a procedural or form requirement was inadvertent. Moreover, as there

would be no established time-frames for CMS's response, entities could potentially increase their exposure under the federal False Claims Act. Finally, while CMS states that the same "knowledge" standard utilized in the False Claims Act would be applied, it is unclear how entities could demonstrate that they did not know and should not have known that, for example, a signature was missing on a lease or personal services agreement. Once the disclosure is made the matter could take on a life of its own.

In short, although CMS should be commended for trying to find a reasonable, balanced way to handle minor, inadvertent Stark violations, the method described in the 2008 MPFS includes many dangers and potential pitfalls for providers – especially those related to the unprotected disclosure, without procedural safeguards, of potential Stark compliance problems to CMS.

III. CMS'S MANDATORY HOSPITAL DISCLOSURE INITIATIVE

CMS is preparing to e-mail the Disclosure of Financial Relationship Report ("DFRR") form to 500 acute care and specialty care hospitals around the country to examine their compliance with the Stark Law in what may be the first step in an expanding self-reporting approach to Stark compliance oversight.

Notice of the new plan was published in the May 18, 2007 Federal Register (72 Fed. Reg. 28,056) and is targeted for completion by the end of September. The plan to collect information began with a voluntary survey sent to 130 specialty hospitals and 322 general acute-care hospitals. Because only 64 specialty hospitals and 76 acute-care hospitals responded, CMS has stepped-up its information-collection efforts. The low response rate raised concerns about "potential tainted relationships" which led CMS to plan a "regular disclosure process," according to its Specialty Hospital Final Report to Congress in 2006.

The new form is mandatory and penalties for non-compliance are severe. For each day after the 45 day response deadline, CMS can impose civil monetary penalties of up to \$10,000. The authority for this program, as set out in the cover letter sent to hospitals required to respond, is Section 1877(f) of the Social Security Act (a section of the Stark Law that essentially had been put on "hold"). This provision allows the Secretary to collect, in such form, manner, and at such times as the Secretary shall specify, "information concerning [an] entity's ownership, investment, and compensation arrangements."

The forms require detailed information about hospital-physician relationships such as space and equipment rentals, personal services arrangements, physician recruitment, stock equity, secured debt and capital equipment. On completion, the forms must be signed by the CEO, a CFO or other “appropriate official” who must certify the accuracy of their contents. A Program Safeguard Contractor under contract with CMS will compile and analyze the results.

On the basis of these results, CMS will decide whether to collect this data from all Medicare-participating hospitals. Other alternatives CMS is considering include staggering reporting or concentrating only on certain types of relationships. This initial CMS project holds the potential to bring about significant changes in auditing and possibly enforcement of Stark compliance. For more information including a list of hospitals, see www.cms.hhs.gov/physicianselfreferral/06a_dra_reports.asp? (Click on “Specialty Hospital Final Report to Congress”; Appendix Two is the list of hospitals required to participate.)

* * * * *

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The contents of this Memorandum are for informational purposes only, and do not constitute legal advice.

APPENDIX “A”
Blacklined Version of Proposed Modifications to
Stark Regulations and Purchased Diagnostic Test Rule

§ 414.50 (PDT Rule)

(a) General rule. (1) For services covered under section 1861(s)(3) of the Act and paid for under part 414 of this chapter (other than clinical laboratory tests paid under section 1833 (a)(2)(D) of the Act, which are subject to the special rules set forth in section 1833(h)(5)(A) of the Act), ~~this part 414 subpart A~~, if a physician or medical group bills for the technical or professional component of a diagnostic test that was performed by an outside supplier, the payment to the physician or medical group (less the applicable deductibles and coinsurance) for the technical or professional component of the test may not exceed the lowest of the following amounts:

- (i) The supplier’s net charge to the physician or medical group.
- (ii) The physician’s or medical group’s actual charge.
- (iii) The fee schedule amount for the test that would be allowed if the supplier billed directly.

(2) This provision applies regardless of whether the test or its interpretation was purchased by the physician or medical group billing for the test or the interpretation, or whether the right to bill for the test or its interpretation was reassigned to the physician or medical group billing for the test or interpretation.

(3) For purposes of paragraph (a) of this section –

- (i) The physician’s or other supplier’s net charge must be determined without regard to any charge that is intended to reflect the cost of equipment or space leased to the outside supplier by or through the billing physician or medical group.
- (ii) An outside supplier is someone other than a full-time employee of the billing physician or medical group.

(b) Restriction on payment. (1) The physician or medical group must identify the supplier and indicate the supplier’s net charge for the test. If the physician or medical group fails to provide this information, CMS makes no payment to the physician or medical group and the physician or medical group may not bill the beneficiary.

(1) (2) Physicians and medical groups that who accept Medicare assignment may bill beneficiaries for only the applicable deductibles and coinsurance.

(2) (3) Physicians and medical groups that who do not accept Medicare assignment may not bill the beneficiary more than the payment amount described in paragraph (a) of this section.

42 C.F.R. § 424.80 (d) -*Reassignment to an entity under an employer-employee relationship or under a contractual arrangement.*

* * * *

(3) Reassignment of the technical or professional component of diagnostic test services. If a physician or medical group bills for the technical or professional component of a diagnostic test covered under section 1861(s)(3) of the Act and paid for under part 414 of this chapter (other than the clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to special rules set forth in section 1833(h)(5)(A) of the Act), following a reassignment from a physician or other supplier who performed the technical or professional component and who was not a full-time employee of the billing physician or medical group at the time the service was performed, each of the following conditions must be met:

(i) The payment to the billing physician, or medical group, less the applicable deductibles and coinsurance, may not exceed the lowest of the following amounts:

(A) The physician's or other supplier's net charge to the billing physician or medical group. The physician's or suppliers net charge must be determined without regard to any charge that is intended to cover or address the cost of equipment or space leased to the physician or the other supplier by or through the billing physician or medical group.

(B) The billing physician's or medical group's actual charge.

(C) The fee schedule amount for the service that would be allowed if the physician or other supplier billed directly.

(ii) The physician or medical group billing for the test must identify the physician or other supplier that performed the test and indicate the supplier's net charge for the test. If the physician or medical group billing for the test fails to provide this information, CMS will not make any payment to the physician or medical group

billing for the test and the billing physician or medical group can not bill the beneficiary.

(iii) To bill for the technical component of the service, the physician or medical group must directly perform the professional component of the service.

§ 411.357(a) *Rental of office space.*

* * * *

(5) The rental charges over the term of the agreement are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. Per unit-of-service rental charges are not allowed to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

§ 411.357(b) *Rental of equipment.*

* * * *

(4) The rental charges over the term of the agreement are set in advance, consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. Per unit-of-service rental charges are not allowed to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

§ 411.354(d) *Special rules on compensation.*

* * * *

(1) Compensation will be considered “set in advance” if the aggregate compensation, a time-based or per unit of service based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the agreement in any manner that reflects the volume or value of referrals or other business generated by the referring physician. Percentage-based compensation, other than compensation based on revenues directly resulting from personally performed physician services (as defined in § 410.20(a)), is not considered set in advance.

411.354(b) *Ownership or investment interest.*

* * * *

(3) Ownership and investment interests do not include, among other things –

(i) An interest in an entity that arises from a retirement plan offered by that entity to the physician or immediate family member through the physician's or immediate family member's employment with that entity;

§ 411.351 Definitions

* * * *

Entity means –

(1) A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, not-for-profit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it–

(i) Is the person or entity that has performed the DHS, or

(ii) Presented a claim or caused a claim to be presented for Medicare benefits for the DHS.

~~(i) Is the person or entity to which CMS makes payment for the DHS, directly or upon assignment on the patient's behalf; or~~

~~(ii) Is the person or entity to which the right to payment for the DHS has been reassigned pursuant to Sec. 424.80(b)(1) (employer), (b)(2) (facility), or (b)(3) (health care delivery system) of this chapter (other than a health care delivery system that is a health plan (as defined in Sec. 1001.952(l) of this title), and other than any managed care organization (MCO), provider sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees).~~

(2) For purposes of this subpart, "entity" includes a health plan, managed care organization (MCO), provider sponsored organization (PSO), or independent practice association (IPA) that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to Sec. 424.80(b)(1) and (b)(2) of this chapter, with respect to any designated health services provided by that supplier; "entity" does not include a health care delivery system that is a health plan (as defined in 1001.952(l) of this title), or any MCO, PSO or IPA with which a health plan contracts for services provided to plan enrollees.

(3) For purposes of this subpart, "entity" does not include a physician's practice when it bills Medicare for a diagnostic test in accordance with Sec. 414.50 of this chapter (Physician billing for purchased diagnostic tests) and section 30.2.9 of the Internet –Only Manual, Pub. 100-04, Chapter 1, General Billing Requirements. ~~3060.4 of the Medicare Carriers Manual (Purchased diagnostic tests), as amended or replaced from time to time.~~