Potential Impact of 2008 Medicare Physician Fee Schedule Proposed Rules on Imaging Arrangements
*By Thomas W. Greeson and Heather M. Zimmerman, Reed Smith LLP, Falls Church, VA**

On July 2, 2007, the Centers for Medicare and Medicaid Services (CMS) posted on its website the proposed updates to the Medicare Physician Fee Schedule (MPFS) for 2008 which, in addition to a sharp 9.9% decrease in payment,[1] include a number of significant revisions to the IDTF performance standards, purchased diagnostic test rule, and the physician self-referral prohibition that have the potential to significantly impact certain types of physician-owned imaging ventures.[2] This article summarizes the proposed updates and discusses the potential impact of the proposed rules on diagnostic imaging arrangements. We have included "blacklined" versions of the proposed regulatory changes to assist the reader's understanding of the proposed rules.

I. IDTF Performance Standards

As part of the 2007 MPFS updates, CMS expanded the conditions of participation for independent diagnostic testing facilities (IDTFs) to require that, at the time of enrollment or re-enrollment, the IDTF must certify that it meets a list of fourteen additional performance standards.[3] In late January, CMS issued a transmittal to update its Program Integrity Manual with the new IDTF enrollment standards that elicited substantial questions and criticism from the imaging industry.[4] In response to public comments and subsequent discussions with industry representatives, CMS rescinded the controversial transmittal and is now proposing, through notice and comment rulemaking, to revise several of the performance standards and add several new IDTF performance standards.

A. Liability Insurance – § 410.33(g)(6)

Currently, this standard requires that the IDTF "[h]ave a comprehensive liability insurance policy of at least $300,000 per location…." CMS is proposing to: i) delete the requirement that the policy list the serial numbers of all diagnostic equipment; ii) clarify that the liability policy must provide coverage at each location of at least $300,000 "per incident"; and iii) expand the standard as follows to require that the IDTF notify its Medicare administrative contractor (MAC) of any policy changes or cancellation and add its MAC as a certificate holder on the policy:

§ 410.33(g) ***Application certification standards.***
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6) Have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a nonrelative-owned company. ~~and list the serial numbers of any and all diagnostic equipment used by the IDTF, whether the equipment is stationary, in a mobile unit, or at the beneficiary's residence.~~ Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must –

(i) Ensure that the insurance policy must remain in force at all times and provide coverage of at least $300,000 per incident;

(ii) Notify the CMS designated contractor in writing of any policy changes or cancellations; and

(iii) List the CMS designated contractor as a Certificate Holder on the policy.

The stated rationale for requiring that IDTFs add their MACs as certificate holders is to enable the MACS to, at any time, directly verify with the IDTF's insurance underwriter and agent that the IDTF is maintaining the required liability insurance. It remains to be seen, however, whether insurance underwriters will be open to this idea of adding the government as certificate holder on an insurance policy since that could, theoretically, provide the government with contractual rights to indemnification or payment that it would not otherwise have. We anticipate there could be some resistance regarding this requirement.

B. Enrollment Changes – § 410.33(g)(2)

The current standards require an IDTF to report any changes to its Medicare enrollment application within 30 calendar days. In order to decrease the administrative burden of this requirement on both IDTFs and the MACs, CMS is proposing to revise the standard as follows:

§ 410.33(g) ***Application certification standards.***
* * * *

(2) Provides complete and accurate information on its enrollment application. ~~Any change in the enrollment information~~ Changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported to the designated fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days.

C. Beneficiary Questions & Complaints – § 410.33(g)(8)

CMS is proposing to expand performance standard (8) to require not only that the IDTF answer beneficiaries' questions and respond to their complaints but that the IDTF create and maintain on file at

the physical site of the IDTF (or home office for mobile units) documentation of these interactions with beneficiaries. The documentation must include:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) A summary of the complaint; the date it was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

D. Supervising Physician - § 410.33(b)(1)

In the final 2007 MPFS rule, CMS unintentionally appeared to expand the scope and responsibilities of the physician tasked with general supervision of the IDTF when it revised the existing requirement to state that the supervising physician must be responsible not only for quality-related oversight but also for "the overall administration and operation of the IDTFs… and for assuring compliance with applicable regulations." In response to public comments and negative industry feedback, CMS has acknowledged that its earlier rulemaking perhaps went farther than it should have and, as a result, CMS is proposing to entirely delete the controversial language and to amend its requirement limiting the number of IDTF sites that can be supervised by one physician as follows:

> **§ 410.33(b)** ***Supervising physician*****.** (1) Each supervising physician must be limited to providing supervision to no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests. ~~The IDTF supervising physician is responsible for the overall operation and administration of the IDTFs, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.~~

Although the text of the proposed regulation does not specifically state this, the preamble discussion clarifies that the three IDTF supervision limit is intended to apply to those physicians *providing general supervision services* (rather than direct or personal supervision services).

E. Enrollment Date – § 410.33(i)

Historically, the effective date of a new IDTF's enrollment has essentially been left to the discretion of the MAC and, in many cases, the effective date is set retroactively to cover a period when the IDTF was not enrolled with and may not have been operating in compliance with Medicare standards. In an effort to establish a more uniform enrollment standard and confirm that IDTFs are in compliance with the

Medicare standards prior to billing, CMS is proposing to add the following provision to the IDTF conditions of participation:

> **§ 410.33 (i)** ***Effective date of billing privileges.*** The effective date of billing privileges for a newly enrolled IDTF is the later of the following:
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> (1) The filing date of the Medicare enrollment application that was subsequently approved by a fee-for-service contractor; or
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> (2) The date the IDTF first furnished services at its new practice location;
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> (3) The filing date of the Medicare enrollment application is the date that the Medicare fee-for-service contractor receives a signed provider enrollment application that is able to process for approval.

Fortunately, this new rule would not entirely preclude IDTFs from retroactively billing for services, but it would limit the period of time for retroactive billing. Unfortunately, under this new rule an IDTF can be subject to a delayed enrollment date if the initial application is for any reason rejected by the MAC.

F. Prohibition on Sharing – § 410.33(g)(15)

Perhaps the most significant change in the IDTF performance standards is that CMS is proposing to add a new performance standard that states that, in order for an IDTF to satisfy the Medicare conditions of participation, the IDTF must certify that it:

> **§ 410.33(g)** ***Application certification standards.***
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> * * * *
>
> (15) Does not share space, equipment, or staff or sublease its operations to another individual or organization.

The purpose of this standard is supposedly to ensure that an IDTF's operations are separate and distinct from the operations of other entities so that CMS can confirm that the IDTF is operating in compliance with the Medicare conditions of participation. In addition, CMS noted that shared facility arrangements raise concerns under the physician self-referral prohibition and the federal anti-kickback statute.

CMS is proposing that the above standard apply only to fixed-base IDTF locations, but has requested public comment on whether this standard should also apply to mobile IDTFs. In its discussion of the proposed standard, CMS notes that it intends for the prohibition on sharing of office space to apply to shared waiting rooms and the prohibition on shared staff to apply to *supervising physicians*. We are unclear at this time as to how this prohibition on sharing supervising physicians could possibly be

implemented since, in many cases, the supervising physician of an IDTF is, in fact, an individual whose services are "shared" by an IDTF and that physician's own group practice. It is likely that CMS will need to further refine this standard in order to permit or address the sharing of supervising physicians.

If this standard is adopted, it would clearly eliminate the ability of an IDTF to enter into any type of sublease arrangement with a physician practice, a hospital (including "under arrangement" agreements), or any other individual or entity – regardless of whether the sublease was "per click," "block time," or any variation thereof.

II. Anti-Markup Provisions

A. Expanded to Purchased and Reassigned Interpretation Services

Under the Medicare "purchased diagnostic test" rule, also referred to as the "Anti-Markup Provision," if a physician 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 what the physician paid to purchase the test from the outside supplier.5 Currently, the Anti-Markup Provision does not apply to billings submitted for the professional component of a diagnostic test that a 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 also apply to any professional component services a physician purchases or obtains pursuant to a reassignment. After receiving public comments and reviewing the issue further, CMS determined that purchased diagnostic test and interpretation arrangements that permit the purchasing physicians to realize a profit from their referrals may lead to abusive overutilization of services. Therefore, CMS is proposing to eliminate this ability of a physician to profit from Medicare billings for professional component services that the physician either purchases under contract or obtains via reassignment from an outside supplier by closing the current loopholes in the PDT Rule and concurrently adding new provisions to the reassignment rule so that its requirements mirror those of the PDT Rule as indicated below.

§ 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.

B. Calculating a Supplier's "Net Charge"

In addition to expanding the Anti-Markup Provision to apply to professional component services, CMS is also 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, the Medicare fee schedule payment for the professional component of a Study is $50. A Radiologist agrees to pay Ortho Group $25 per Study for use of office space and computer workstation to perform professional interpretations. The Ortho Group agrees in return for the Radiologist's professional services to pay the Radiologist $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 essentially paying back $25 of the $50 pursuant to the lease agreement. As a result, the Ortho Group would be limited to billing Medicare $25 for the Radiologist's professional component services rather than a full $50.

C. Full-Time Employee Exemption

Perhaps the most controversial aspect of CMS' proposal to apply the Anti-Markup Provision to professional component services is the decision to apply the anti-markup prohibition to all technical and professional services performed by part-time employees and part-time or full-time independent contractors of a medical group. Thus, the only technical or professional services a medical group can mark-up are those performed by the group's *full-time employees*.

If this proposed revision to the reassignment rule is adopted, it would significantly impact the ability of radiology groups, IDTFs, and group practices with in-office imaging equipment to utilize independent contractor (and part-time employee) radiologists to perform professional interpretation services since these suppliers would be limited to billing Medicare no more than the amount actually paid to the radiologist even though the supplier must, in addition to paying the radiologist, also cover the costs and assume the business risk for billing for the radiologist's services. The end result is that the supplier

would actually lose money for each service performed by an independent contractor or part-time employee rather than breaking even or, preferably, making some measure of profit. This proposal will understandably generate a significant amount of public comment.

D. Elimination of Stark "On-Site" Interpretation Requirement

Under the current Stark rules, the exception for professional interpretation services when the referring physician has an investment interest in the entity to which he refers – and which bills for the Medicare/Medicaid service – is the "physician services" exception available to physician group practices. When an independent contractor radiologist performs a Stark designated health service (DHS) (such as the professional component of a radiology procedure) for a Medicare/Medicaid patient that is billed by the self-referring physician's group practice, the physician services exception requires that the performance of DHS services by the independent contractor radiologist must be provided on the group practice's premises. Otherwise, the independent contractor radiologist who reads remotely must bill separately for services to Medicare or Medicaid patients.

The proposed rules effectively exempt purchased or reassigned interpretation from the on-premises requirements of Stark. The rule would be amended to exclude physicians (or group practices) who bill for purchased diagnostic tests (technical component or professional component) in accordance with Stark rules from the definition of "entity" under § 411.351, which otherwise defines an "entity" as the party that bills Medicare for the DHS. Although still subject to the proposed anti-markup requirements, the purchased or reassigned interpretation service can be provided remotely, even when performed for Medicare or Medicaid patients whose referral of the technical component of the procedure by an investor in the group required compliance with the in-office ancillary services exception by the referring physician group. Separate billing will no longer be a requirement, although it will remain an option.

It is our expectation that CMS will also permit the entity purchasing the interpretation to bill its local Medicare contractor rather than the carrier where the interpretation was performed.

III. Significant Changes to the Stark Regulations

The Stark Law and its implementing regulations published by CMS generally prohibit a physician from referring a Medicare patient for the furnishing of a DHS by an entity with which the physician holds an ownership interest or has a compensation relationship.6 CMS previously expressed concern in the 2007 MPFS proposed rule regarding the potential for fraud, waste, and abuse of the Medicare program caused by the growth of so-called "pod" or "condo" laboratories. "Pod" laboratories are laboratories that are

located off-site from a physician's office (sometimes in another state) and operated entirely by an independent contractor physician pursuant to a reassignment arrangement for the purpose of performing pathology studies that will be billed globally by the ordering physician's office. Typically the physician's office pays the pod laboratory and the physician a fixed fee for diagnostic tests that is less than the global fee the physician is able to collect from the Medicare program when he/she bills for the test. CMS remains concerned that these arrangements may lead to the ordering of unnecessary tests, involve the payment of kickbacks and fee splitting between the parties, and possibly result in referrals that would otherwise be prohibited under the Stark Law. In an effort to protect the Medicare program from what CMS perceives to be a risk of abuse from pod laboratories and other similar contractual arrangements, CMS is proposing several significant revisions to the Stark regulations designed to curtail, if not entirely eliminate, certain types of arrangements.

A. Seeking Comments on "In-Office Ancillary Services" Exception

The "in-office ancillary services" exception generally permits a physician to order designated health services (including diagnostic radiology services) for his/her Medicare and Medicaid patients and then have the physician's practice perform and bill for the services without violating the prohibition on self-referrals if the physician is able to meet certain supervision, billing, and building requirements. This is the exception utilized by orthopedic, cardiology, neurosurgery and other non-radiology groups to place diagnostic imaging equipment in their office buildings and bill for imaging services performed for their patients.

In the 2007 MPFS proposed rule, CMS proposed to revise the "in-office ancillary services" exception to limit the ability of a specialist physician to become an independent contractor of a group, reassign his/her rights to payment to the group and subsequently perform the services in a "centralized building" that could be far removed from the group practice location and essentially not be in any way connected or integrated into the group's operations. CMS received many comments in response to its proposal stating that CMS needed to address not only professional services performed in a remote, centralized building but also services performed in the same building pursuant to a "turn-key" arrangement such as clinical laboratory or imaging service ventures.

CMS is not at this time issuing a specific proposal to revise the "in office ancillary services" exception. Instead, CMS is requesting public comments as to whether changes to this exception are necessary and, if so what changes should be made. CMS is particularly interested in receiving comments on:

(1) Whether certain services should not be protected under the exception (i.e., services that will not be used at the time of the patient's office visit in order to assist the physician with making a diagnosis or plan of treatment during the visit).

(2) Whether and, if so, how CMS should change the definition of "same building" and "centralized building."

(3) Whether non-specialist physicians should be permitted to use the exception to refer patients for specialized services that will be performed on equipment owned by the non-specialist physicians.

(4) Any other restrictions on ownership or investment in services that would curtail program or patient abuse.

B. Demise of "Per Click" Lease Payments

It is currently permissible under the Stark exceptions for space and equipment leases to structure the lease payments on a per-use or "per click" basis.7 In light of public comments regarding the potential for overutilization and abuse created by certain leasing arrangements, CMS has reconsidered the issue and is now proposing to revise the exceptions as follows to prohibit the use of per click lease payments in those situations where an entity owned by a physician leases space and/or equipment to another entity and the physician subsequently refers patients to that other entity for services:

> **§ 411.357(a)** ***Rental of office space.***
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> (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.
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> **§ 411.357(b)** ***Rental of equipment.***
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> (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.

For example, under the proposed rule it would not be permissible for a cardiology group or members of the group to purchase (either directly, or through a joint ventured leasing company) a 64-slice CT and

lease the CT to the hospital on a "per click" basis since the cardiologists will be referring patients to the hospital for cardiac CTA services. In order for the lease arrangement to qualify for protection under the exception, the lease payments would need to be a fixed, fair market value amount that would not change regardless of the number of studies the hospital actually performs (e.g., $10,000 per month).

In addition to prohibiting the use of per click payments to physician-owned leasing entities, CMS is soliciting comments on whether it should prohibit per click payments by a physician to an entity from which the physician leases space or equipment if that entity refers patients to the leasing physician. For example, such prohibition might apply in a situation where a radiology group owns a 64-slice CT scanner and leases the scanner to a cardiology group if that cardiology group refers patients to the radiology group for interpretation services.

C. Percentage-Based Compensation Restricted to Physician Services

In addition to eliminating "per click" lease fees, CMS is proposing to also eliminate the use of any type of percentage-based fees for office and equipment leases. Currently, the office space rental, equipment rental, and several other exceptions to the Stark Law require that the compensation amount be "set in advance." The regulations specify that compensation will be considered "set in advance" if "a specific formula for calculating the compensation is set in an agreement between the parties."[8] Thus, the existing regulations as currently promulgated permit payment of lease fees on a percentage compensation basis as long as the compensation formula and percentage amount are established in a written agreement.

Apparently, at the time CMS revised the "set in advance" requirement to permit percentage compensation arrangements its intent was solely to permit percentage compensation to be paid to physicians for providing physician services. CMS did not intend for the exception to apply to any and all other types of compensation arrangements, such as office and equipment leasing, since those arrangements can lead to overutilization of services and program abuse. In an effort to clarify the "set in advance" definition and enforce CMS' original intent for permitting percentage compensation arrangements, CMS is proposing to clarify the "set in advance" requirement as follows:

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

This proposal to change the "set in advance" requirement would essentially prohibit a physician group practice from receiving payment based on a percentage of collections or similar percentage-basis under an office lease, equipment lease, personnel lease, facility lease, billing service agreement, management services agreement, or any agreement other than a professional services agreement with a physician practice that refers patients to the radiology group (either directly or indirectly by referring patients to a hospital covered by the physician group). The only items or services for which the physician group could be paid on a percentage of collections are for professional services. As discussed above, compensation for lease of office space or equipment would need to be based on a fixed, aggregate amount (e.g. $X per month). Compensation for other non-professional services such as billing or management services could be paid as either a fixed, aggregate amount or as a time-based (e.g., $X per hour) or per-unit of service based (e.g., $X per study) payment.

D. Ownership or Investment Interest in Retirement Plans

The regulations currently specify that a physician does not have an ownership or investment interest in an entity that furnishes DHS solely by virtue of having an interest in that entity's retirement plan.[9] For example, a physician who is solely an employee of a medical practice and not a shareholder or owner is not considered to have an "ownership or investment interest" in the medical practice solely because the physician participates in the retirement plan.

It has been brought to CMS' attention that some physicians may attempt to abuse this exception by using their retirement plans to purchase entities that provide DHS and to which the physician then refers his or her patients for DHS. For example, a group of orthopedic surgeons participates in a retirement plan and that retirement plan invests its funds by purchasing an MRI center. The surgeons then refer their patients to the MRI center for imaging services and claim that they can do so without violating Stark because their investment is in a retirement plan – not the imaging center itself. In an effort to close this loophole and effect CMS' original intent that the exception only apply to legitimate, employer-sponsored retirement plans, CMS is proposing to clarify the definition of a "retirement plan" as follows:

411.354(b) Ownership or investment interest.

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(3) Ownership and investment interests do no 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;

E. Services Furnished "Under Arrangements"

Medicare generally permits a hospital, skilled nursing facility, home health agency, or hospice program to contract with a separate provider or supplier to obtain services for its patients "under arrangements." The hospital then bills and obtains reimbursement from Medicare for the services and pays the supplier a negotiated contract rate. For example, a group of cardiologists and radiologists form a joint venture (JV) to purchase a 64-slice CT scanner and open a cardiac imaging center on the hospital's campus. Rather than enrolling the JV as a supplier with Medicare and other payors, the JV enters into an "under arrangements" contract with the hospital pursuant to which the JV provides imaging services to registered hospital outpatients (some of whom were referred by the cardiologists) and the hospital bills for the services provided to Medicare beneficiaries under the Hospital Outpatient Prospective Payment System (HOPPS). The hospital, in return, pays the JV a negotiated contract rate for each study it performs. Although it may appear at first glance that the cardiologists are prohibited from referring Medicare patients to the JV for imaging services (i.e., DHS) since they have an ownership interest in the JV, those referrals would not, in fact, be prohibited since the "entity" to which the cardiologists are referring is actually the hospital - not the JV. This is because the Stark regulations narrowly define the term "entity" to mean the entity that submits a claim to the Medicare program. In an "under arrangements" scenario, the only entity submitting claims to Medicare is the hospital.

CMS notes in the preamble discussion to the 2008 MPFS proposed rule that, perhaps due in part to the recent Medicare payment reductions for imaging services performed in a non-hospital setting and surgical services performed in ambulatory surgery centers, these types of "under arrangements" contracts are proliferating, particularly with hospitals. CMS expressed concern with these types of "under arrangements" relationships with physician-owned entities for a number of reasons including: (1) risk that the arrangement encourages the physician-owners to over utilize services; (2) "[t]here appears to be no legitimate reason for these arrangements for services other than to allow referring physicians an opportunity to make money on referrals"; (3) in many cases, the services furnished "under arrangements" was previously provided directly by the hospital; and (4) the services furnished "under arrangements" to hospital patients are typically furnished in a less medically-intensive setting than a hospital but billed at the higher HOPPS rates. In fact, CMS explicitly states in the proposed rule that it believes arrangements structured so that referring physicians can own leasing, staffing, and similar

entities that do not, themselves, submit claims to Medicare for DHS but instead provide items and services to other entities that then bill for the DHS "raise significant concerns under the fraud and abuse laws" and are "contrary to the plain intent of the physician self-referral law."

In an attempt to prohibit these types of arrangements under which referring physicians supply items and services to entities that bill Medicare for DHS, CMS is proposing a significant and what will undoubtedly be a very controversial change to the Stark regulations. Specifically, CMS is proposing, as follows, to expand the definition of the "entity" to which a physician refers Medicare patients to include not only the entity that submits claims to Medicare for DHS, but also any person or entity that "performs the DHS":

§ 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~~.

This proposed revision to the definition of "entity" is perhaps the most significant with respect to imaging joint ventures that involve ownership by referring physicians since it appears that it would essentially bar referring physicians from participating in joint ventures that provide services under arrangement to hospitals or others.

Currently, a referring physician simply cannot hold an ownership interest in, for example, an IDTF that is enrolled in the Medicare program and to which that physician would refer Medicare patients for imaging services. An alternative model frequently used to deal with the Stark restrictions is that the referring physician would form a JV with other referring physicians, radiologists, and/or a hospital to purchase imaging equipment, lease office space, and establish an imaging center. The JV then leases the imaging facility to one or more entities such as a radiology group, a hospital, an IDTF, and/or physician practices located in the same building as the imaging facility (the Leasing Entity). Provided that the lease meets certain requirements of the indirect compensation exception to the Stark law, the referring physician could then refer his patients to the Leasing Entity since, although the entity is billing Medicare for the DHS, the referring physician does not have an ownership interest in that Leasing Entity.

Under the proposed revisions to the definition of "entity," it appears that the referring physician would not only be making referrals to the Leasing Entity, but may also be making referrals to the JV since the JV is arguably "the person or entity that performed the DHS." (Note: the term "performed" is not specifically defined so we assume that this will generate a considerable amount of discussion from the industry as to whether a leasing company actually "performs" DHS or merely leases its resources to another entity which then "performs" the DHS. Based on the preamble discussion, we presume CMS will take the former position). Significantly, there is no Stark exception that could be used to protect the referring physician's referrals of Medicare patients to a JV in which the physician has an ownership interest. The "in-office ancillary service exception" can only be used to protect a physician's Medicare referrals to his or her own medical practice – not to an imaging facility JV since it is not the physician's group practice.

As a result, *if the proposed rule is finalized* (including all of the proposed revisions to the IDTF standards and purchased diagnostic test rules described earlier), referring physicians would be significantly limited in their ability to provide imaging services to their own Medicare patients. We believe that referring physicians would primarily be limited to providing imaging services in one of two ways:

1. The referring physician or his/her group practice could acquire imaging equipment and operate the equipment within the group's office in a manner that satisfies all the requirements of the in-

office ancillary services exception to the Stark law. If the group contracts with a radiology practice for professional interpretation services, the group would be prohibited from marking-up any professional component charges to Medicare for those services.

2. The referring physician or his/her group practice could possibly lease the office space, imaging equipment and/or facility personnel from an entity that is not owned by the referring physician and that is not enrolled as a supplier with Medicare or any other third-party payor, provided that: (a) the group is able to perform imaging services at the facility in a manner that satisfies the requirements of the in-office ancillary services exception to the Stark Law; and (b) the lease is structured to meet all the requirements of the applicable office space rental, equipment rental, and/or personal services exceptions to the Stark Law including the requirement that the lease fee be "set in advance." "Set in advance" means that the lease fee cannot be "per click" nor can it be based on a percentage of collections. The lease fee would essentially need to be a fixed, periodic payment (e.g., $X per month). We note, however, that we are uncertain at this time whether this model would actually work since it is possible that CMS could still take the position that, even though the entity that owns the imaging facility is not enrolled as a "supplier" with Medicare, it is nevertheless, for purposes of the new PDT Rule, considered to be an "outside supplier." If the non-enrolled entity was deemed to be an "outside supplier" under the PDT Rule, the referring physician would be prohibited from marking-up the technical component services for Medicare patients, which could make the model financially untenable.

These proposed changes, if adopted, could be effective as early as January 1, 2008. The deadline for submitting comments is August 31, 2007.

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* Thomas W. Greeson can be reached at 703.641.4242, tgreeson@reedsmith.com and Heather M. Zimmerman can be reached at 703.641.4352, hzimmerman@reedsmith.com.

1 Congressional committees are reported to be working with organized medicine to halt the payments cuts. House lawmakers are considering a Medicare payment update of at least 0.5% in 2008 and 2009 and possibly replacing the sustainable growth rate with six separate service expenditure targets.

2 A copy of the proposed rule can be downloaded from the CMS website at http://www.cms.hhs.gov/physicianfeesched/downloads/CMS-1385-P.pdf?agree. The proposed rule is scheduled to be officially published in the *Federal Register* on July 12, 2007.

3 For a list of the fourteen performance standards, see 71 Fed. Reg. 69784 (Dec. 1, 2006) at http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/06-9086.pdf.

4 Transmittal 187, published January 27, 2007; rescinded February 16, 2007.

5 *See* 42 C.F.R. § 414.50.

6 *See generally* 42 U.S.C. § 1395nn and the CMS website on the Stark law at http://www.cms.hhs.gov/PhysicianSelfReferral/.

7 Although the extent Stark exceptions for space and equipment rental currently permit "per click" lease payments, it should be noted that "per click" lease payments do not satisfy the requirements of the corresponding space and equipment rental safe harbors under the federal anti-kickback statute.

8 42 C.F.R. § 411.354(d)(1).

9 42 C.F.R. § 411.354(b)(3)(i).