PUBLICATION

Proposed Stark Law Revisions Could Affect Many Existing Business Arrangements Between Physicians And Hospitals And Other Providers

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On July 2, 2007, The Centers for Medicare & Medicaid Services (CMS) issued its proposed updates to the Medicare Physician Fee Schedule (MPFS) for fiscal year 2008. The updates, published at 72 Fed. Reg. 38122 (July 12, 2007), propose a 9.9% decrease in Medicare physician fee payments, relative value unit (RVU) changes, and other changes which would result in a decrease in Medicare payments for all physician specialties other than anesthesiology, which would receive an increase.

More importantly, the MPFS also proposes revisions to the Stark Law, 42 U.S.C. § 1395nn, that could affect existing business arrangements, particularly joint ventures involving services provided under arrangements, and percentage-based and "per-click" compensation arrangements. Several other minor changes to the Stark Law are proposed, and CMS solicits comments on a number of other possible revisions that would also affect existing business arrangements. The MPFS also makes major changes to the anti-markup provisions of Medicare's purchased diagnostic test rule.

Examples of transactions and arrangements which would be impacted by the proposed rule changes are:

Under Arrangements Transactions with Hospitals

- Physician Group provides PET scan machine and personnel to Hospital and Hospital bills the service
- Joint Venture of Cardiology Group and Hospital develops Cardiac Imaging Center and provides services to Hospital patients where Hospital bills

Per Click Space and Equipment Lease

- Physician leases MRI to Hospital at "per click" lease rate and Physician refers patients to Hospital for MRI services
- Physician owned entity leases equipment to IDTF and receives "per click" payment every time physician uses the machine
- Cardiology group leases CT equipment to Hospital and is paid on a "per click" basis

Percentage-based Compensation Arrangements

- Physician or Physician-owned entity provides items or services to Hospital under billing agreement, management agreement, or employee lease agreement and is paid based on a percentage of net revenue, percentage of collections or a percentage of costs
- Turn key lease or service arrangements for space, equipment and personnel with any DHS Provider where Physician or Physician-owned entity receives percentage compensation

If adopted, the proposed revisions become effective as early as January 1, 2008. The scope of revisions proposed in the MPFS is interesting, given CMS's one-year delay in the deadline to issue Stark III regulations that was announced in March 2007. Comments made by CMS in the preamble to the proposed Stark Law

revisions, together with the manner in which CMS discusses possible revisions for which it solicits comments, suggest that Stark III may also contain significant revisions affecting existing arrangements.

Analysis of Proposed Rules

Services Furnished "Under Arrangements"

CMS expresses its concern about hospital-physician joint ventures providing services formerly provided by the hospital directly, stating "there appears to be no legitimate reason for these arranged-for services other than to allow the referring physicians an opportunity to make money on referrals for separately payable services." CMS also notes that services furnished under arrangements to a hospital are furnished in a less medically intensive setting than the hospital, but billed at higher outpatient hospital Prospective Payment System (PPS) rates, resulting in unnecessary costs to the Medicare program and beneficiaries.

To address this perceived abuse, CMS proposes to revise the definition of "entity" under the Stark Law so that the term not only covers the person or entity that presents claims to Medicare for Designated Health Services (DHS), but also the person or entity that provides the DHS or causes a claim to be presented for the DHS. Just what constitutes causing a claim to be presented is not clear.

The effect of this proposed revision would be that physician investors in a joint venture that provides DHS to a hospital under arrangements would be precluded under the Stark Law from making referrals for Medicare DHS to the joint venture, and the hospital receiving the services under arrangements could not bill Medicare for DHS resulting from those referrals.

This proposal is in part a reaction to the Medicare Payment Advisory Committee's (MedPAC) March 2005 Report to Congress, in which MedPAC recommended that the definition of physician ownership in the Stark Law be revised to include "interests in an entity that derives a substantial proportion of its revenue from a provider of designated health services." An example of the type of interest that would be affected by the MedPAC proposal is physician ownership of a company that derives a substantial proportion of its revenue from the lease of equipment to imaging centers.

CMS solicits comments on whether it should adopt the MedPAC "substantial proportion of revenue" test, either in combination with CMS's proposal to redefine the term "entity" or instead of that proposal.

Unit-of-Service ("Per Click") Rentals

CMS proposes to revise the space and equipment rental exceptions by prohibiting unit-of-service payments to a physician when (1) the physician leases the space or equipment to a DHS entity; and (2) the DHS entity uses the leased space or equipment to furnish services to patients referred by the physician-lessor.

According to CMS, per-click lease arrangements are inherently susceptible to abuse because the physician-lessor has an incentive to profit from referring a higher volume of patients to the DHS entity-lessee.

CMS solicits comments on whether it should prohibit per-click payments when the lessor is the DHS entity and the lessee is the physician.

Percentage-Based Compensation Arrangements

CMS indicates that it intended that percentage compensation arrangements "could be used only for compensating physicians for the physician services they perform," and notes that percentage compensation

arrangements are being used for equipment and office space. An example would be where rental is based on a percentage of revenues raised by the equipment or in the office space.

As a result, the MPFS proposes to clarify that percentage compensation arrangements (1) may be used only for paying for personally performed physician services; and (2) must be based on the revenues directly resulting from the physician services rather than based on some other factor, such as a percentage of savings by a hospital department (which is not directly or indirectly related to the physician services provided).

Standing In The Shoes

The MPFS contains CMS's proposal to address the difficult subject of indirect financial relationships on the DHS entity side of physician-DHS entity financial relationships. The proposed amendment provides that a DHS entity which owns or controls an entity to which a physician refers Medicare patients for DHS would be deemed to "stand in the shoes" of the entity it owns or controls, so that the DHS entity is further deemed to have the same compensation arrangements with the same parties and on the same terms as does the entity it owns or controls.

The example provided by the CMS is a hospital that owns or controls a medical foundation that contracts with a physician to provide physician services as a clinic owned by the medical foundation. Under the proposed rule, the hospital would be deemed to stand in the shoes of the medical foundation and to have a direct financial relationship with the physician contractor.

One issue raised in the proposal is that DHS entities owned by another DHS entity represent only one of the relationships that, under the current regulations, would create an indirect compensation relationship. Whether the proposal will be extended to other indirect compensation relationships is unknown.

Another issue raised is the definition of "control" that could be applied by CMS. A hospital may possibly be deemed to control, and therefore stand in the shoes of, the joint venture, with a potentially disastrous effect on joint ventures otherwise relying on an indirect compensation exception between the hospital and physician owners of the joint venture.

However, CMS solicits comments on whether the "stand in the shoes" approach should be extended to other types of financial relationships. Based on conversations with CMS and commentary in the preamble to the proposed MPFS, it appears CMS is considering a change to the Stark Law that would treat physicians as standing in the shoes of their group practices or other physician practices. CMS makes the coy statement:

[C]ommenters should be mindful that we may finalize (or may have already finalized) a provision that treats physicians as standing in the shoes of their group practices or other physician practices.

This would severely limit application of the indirect compensation exception.

In-Office Ancillary Services Exception

One of the most frequently used exceptions to the Stark Law is the exception for in-office ancillary services (IOAS) furnished by group practices and sole practitioners. CMS believes that Congress intended for the IAOS exception to:

"allow for the provision of certain services necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office."

CMS expresses its concern that services "purportedly" furnished under the IAOS exception are often not closely connected with the physician practice. As an example, CMS cites pathology services furnished in a building that is not physically close to a group practice's other offices, by contractor pathologists who have "virtually no relationship with the group practice." In these cases, according to CMS, the core members of the group practice and their staff may never be "physically present in the contractor pathologist's office," and the contractor pathologist neither participates in any group practice activities nor obtains retirement or health benefits from the group practice. CMS says these arrangements "appear to be nothing more than enterprises established for the self-referral of DHS." CMS also expresses concerns that the IOAS exception "enables physicians to order and then subsequently perform ancillary services instead of making a referral to a specialist."

Although CMS declines to propose an amendment to the IOAS exception, it solicits comments on (1) whether certain services should not qualify for the exception (such as therapy services that are not provided on an incident-to basis, and services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment); (2) whether CMS should make changes to the definitions of "same building" and "centralized building;" (3) whether nonspecialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the nonspecialists; and (4) any other restrictions on the ownership or investment in services that would curtail program or patient abuse.

Period of Disallowance For Noncompliant Financial Relationships

Where there is a prohibited financial arrangement under the Stark Law, the statute and regulations have never specifically addressed the period during which a physician cannot refer DHS to an entity and the entity cannot bill Medicare DHS resulting from an improper referral from that physician.

CMS make no proposal, but solicits comments on:

- How to set forth the period of disallowance for arrangements that implicate, but fail to satisfy the requirements of, one or more of the exceptions to the Stark Law;
- Whether, with respect to types of noncompliance for which it is not clear when a financial relationship ended, CMS should always employ a case-by-case approach, or deem certain types of financial relationships to continue for a prescribed period of time;
- Whether CMS should allow the period of disallowance to terminate where the parties have returned, or paid back the value of, the consideration (a standard which, in our experience, previously has been informally discussed by the CMS in connection with the settlement of investigations); and
- Whether CMS should impose a period of disqualification from using an exception where an arrangement has failed to satisfy the requirements of that exception.

Burden of Proof

The MPFS proposes that, if payment is denied on the basis that a service was provided pursuant to a referral prohibited by the Stark Law, the burden of proof is on the entity that submitted the claim for payment to show the service was not furnished as a result of a prohibited referral.

Retirement Plans

Under current regulations, interests in retirement plans are excluded from the Stark Law's definition of ownership and investment interests. The MPFS proposes that ownership and investment interests include an interest in a retirement plan offered by the entity to the physician or immediate family member as a result of the physician's or immediate family member's employment by the entity. CMS announced that it never intended to

exclude from the definition of ownership or investment interests an interest in a DHS entity that results from a physician's (or immediate family member's) participation in a retirement plan that purchases an interest in a DHS entity.

Alternative Criteria For Satisfying Exceptions

In the MPFS, CMS responds to a comment stating that it should exercise discretion in pursuing minor violations and the failure to meet procedural requirements of an exception to the Stark Law. The example given is failure to obtain all required signatures prior to the commencement of an agreement for personal services.

CMS notes that it "do[es] not have the authority to waive violations of the physician self-referral statute or regulations." However, CMS announces that it is considering whether to provide an alternate method for satisfying Stark Law exceptions. As contemplated by CMS, the proposed method would address only inadvertent violations in which an agreement "fails to satisfy the procedural or 'form' requirements of an exception to the [Stark Law] statute or regulations." The alternative criteria for compliance would not apply to compensation that is not fair market value, is related to the volume or value of referrals, or is not set in advance.

The proposed revision provides that an arrangement that does not meet all of the existing prescribed criteria of an exception would nevertheless be deemed to meet the exception if:

1. The facts and circumstances of the arrangement are self-disclosed by the parties to CMS;
2. CMS determines that the arrangement satisfied all but the prescribed procedural or "form" requirements of the exception at the time of the referral for DHS at issue and at the time of the claim for such DHS;
3. The failure to meet all the prescribed criteria of the exception was inadvertent;
4. The referral for DHS and the claim for DHS were not made with knowledge that one or more of the prescribed criteria of the exception were not met (using the knowledge standard applicable under the False Claims Act);
5. The parties have brought (or will bring as soon as possible) the arrangement into complete compliance with the prescribed criteria of the exception or have terminated (or will terminate as soon as possible) the financial relationship between or among them;
6. The arrangement did not pose a risk of program or patient abuse;
7. No more than a set amount of time had passed since the time of the original noncompliance with the prescribed criteria; and
8. The arrangement at issue is not the subject of an ongoing Federal investigation or other proceeding (including, but not limited to, an enforcement matter).

In addition, CMS states that any alternate method it adopts for satisfying Stark Law exceptions must not violate the Federal Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

CMS contemplates that any proposed alternative criteria would apply only in the case of an innocent or unintentional mistake and the referral for DHS and the claim for DHS were made without knowledge that the arrangement failed to meet the strict criteria of the applicable exception. CMS cautions that, even if it adopts alternative criteria for satisfying exceptions, it intends that a claim submitted with knowledge that the applicable Stark Law exception was not met would violate the Stark Law and could be found to be a violation of the False Claims Act.

CMS solicits comments on a wide-ranging list of issues regarding an alternate compliance method policy, including the exceptions to which the policy should apply, the conditions that must be met to achieve alternate

compliance, the maximum length of time that parties may be in inadvertent noncompliance with an exception and still be able to avail themselves of the alternative compliance method, and whether CMS should require documentary proof of the parties' intent to contract (through memoranda, electronic mail, or otherwise) in the case where the parties failed to obtain a necessary signature for a contractual arrangement.

Obstetrical Malpractice Insurance Subsidies

The MPFS proposes to revise the obstetrical malpractice insurance subsidy exception under the Stark Law, which CMS says may be unnecessarily restrictive. CMS seeks comments on how the exception should be changed without creating a risk of program or patient abuse.

Comments should address the requirements that would be appropriate to include in the exception for malpractice insurance subsidies. In particular, CMS seeks comments as to whether the following requirements would be appropriate:

- 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 Health Professional Shortage Area 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; and
- 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.

In addition, CMS states that any revised obstetrical malpractice insurance subsidy exception must not violate the Federal Medicare Anti-Kickback Statute.

CMS proposes revisions to Medicare reassignment rules and the Stark Law to remove the financial incentive for most providers to purchase either the professional or technical components of diagnostic tests. Under the proposed revisions, the anti-mark-up provision would apply to both professional and technical components of diagnostic tests billed by a physician or group practice but performed by someone other than a full-time employee of the billing physician or group practice. The prohibition on marking up the cost of diagnostic tests would apply to any component performed by an outside supplier, regardless of whether the billing physician purchases the component or receives a reassignment of the right to payment for the component.

To prevent what CMS refers to as "gaming" the anti-markup provision, any equipment or space rental amounts paid by the supplier of the component to or through the billing physician or entity must be subtracted from the charge for the component to determine the charge that may not be marked up to Medicare. For example, if a physician pays $100 for a diagnostic test, but leases equipment to the supplier and receives a $75 per-test

rental payment, then the cost to the physician to purchase the diagnostic test would be only $25 (or $100 less $75).

CMS does not address how this revision may apply when the physician employed part-time or independent contractor physician of a group practice interprets a diagnostic test.

CMS indicates that it will not apply the anti-markup provision when an independent laboratory orders the professional component of a diagnostic test because it believes these arrangements pose minimal risk of abuse.

If adopted as proposed, this revision to the anti-markup provision will have a profound effect on many existing business arrangements.

Independent Diagnostic Testing Facilities

Finally, among other substantive proposals, the MPFS proposes revisions and clarifications to existing Independent Diagnostic Testing (IDTF) performance standards. The proposed revisions to IDTF standards would prohibit an IDTF from sharing equipment, space or staff, or from subleasing its operations to another individual or organization. A proposed revision to the liability insurance standards requires that IDTFs add their CMS-designated contractor as a certificate holder on the liability insurance policy, and provides that IDTFs will receive no reimbursement for services rendered during a period that the required insurance coverage is not in place, even if through an inadvertent or technical lapse.

Summary

The revisions to the Stark Law proposed in the MPFS represent the most restrictive action taken with respect to a physician's financial relationship with a DHS since the initial Stark II legislative action. The scope of additional limitations on which CMS has solicited comments, together with the impending March 2008 deadline for CMS to issue Stark III regulations, suggest that even more restrictive action may be taken.

We recommend that all physicians and health care providers consider their existing business arrangements in light of the proposed revisions to determine if the arrangements are affected and, if so, how they must be restructured if the proposed revisions are adopted. CMS is accepting comments on the proposed revisions through August 31, 2007.