

Per-click, under arrangement, mark-up, and other dirty words

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CMS Proposes Important Changes to the Stark Regulations

On July 2, 2007, while we were all busy looking for the Stark II Phase III regulations, which were due out a few months ago but have now been postponed indefinitely, the Centers for Medicare and Medicaid Services (CMS) released proposed revisions to the Medicare Physician Fee Schedule for 2008. Tucked within those 924 pages are 50 pages proposing major changes to the regulations under the Stark self-referral law.¹ The most significant of these are:

- The severe limitation (if not attempted elimination) of 3 popular models for physician involvement in the delivery of ancillaries:
 - “per-click” leases
 - markups on purchased diagnostic tests (both technical and professional components)
 - “under arrangement” deals between hospitals and physicians
- A general tightening of the “in-office ancillary” exception under Stark.

Other Stark-related issues addressed by CMS in this proposal include establishing burden of proof on a denied claim under Stark;

broadening of the Stark exception for obstetrical malpractice subsidies; clarification of the “period of disallowance” for noncompliant financial relationships; clarification of the Stark exception for physician investment in retirement plans; restrictions on use of percentage based compensation; broadening of the “stand in the shoes” theory for imputed compensation relationships; and alternatives for minor noncompliance under certain Stark exceptions.

Comments Due Soon

CMS will accept comments until August 31, 2007.² If you or your group are involved in or contemplating any arrangements that may be impacted by these proposals, you would be well advised to speak up.

Changes to Reassignment and Stark Rules Relating to Diagnostic Tests (Anti-Markup Provision)

CMS is now trying to correct what it sees as the gradual but pervasive degradation of the various Medicare billing rules and Stark regulations related to diagnostic tests. In this proposal, CMS takes direct aim at turnkey leases and other methods of “marking up” and profiting from purchased diagnostic tests, both technical and professional components.

Medicare rules currently prohibit the markup of the technical component of certain diagnostic tests that are performed by third-party sup-

pliers and billed to Medicare by a different provider. (This is known as the “purchased diagnostic test rule” or PDTR.) For the professional component, Medicare also restricts who may bill for the interpretation, but does not currently impose a markup prohibition. (This restriction is known as the “purchased interpretation rule” or PIR.) The problem with these rules is that CMS has been unclear on how or whether they apply in certain turnkey lease situations, which are now quite common in the industry. Further confusing matters is a relatively new reassignment exception allowing assignment (and hence markup) pursuant to any “contractual arrangement.” This new exception seemingly swallows the PDTR and PIR.

Lease companies and physicians have used the opportunity presented by this climate of uncertainty and entered into turnkey leases that permit physician groups to bill for (and profit from) services essentially provided by the lessor. From a Stark law perspective, these leases have been structured to meet the “in-office ancillary exception” by establishing the lease location in either the “same building” as the physician’s medical practice or in the “centralized building” for the performance of the tests.

CMS is concerned that these leases, and other arrangements that allow purchasers to mark up tests, are inconsistent with the intent of the Stark regulations and may lead to program abuse and overutiliza-

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tion. CMS attempted to address these issues in the 2007 Physician Fee Schedule, but backed off at the last moment. CMS now proposes to tighten up the PDTR, PIR, and the Stark regulations in 3 ways:

1. Impose an anti-markup provision on the technical component and the professional component of diagnostic tests, unless the performing supplier is a full-time employee of the billing entity. This will essentially prohibit turnkey leases involving leased technicians, and will largely remove the financial incentive to set up turnkey leases. The anti-markup rule for interpretations would not apply to independent labs.
2. Permit Medicare to be billed only for an amount that is net of any rent or similar payments that the supplier may have paid to the billing physician. For example, a test interpreter would be capped at billing Medicare \$50 (even though the fee schedule amount is \$100) if the interpreter paid the test supplier \$50 in rent. It is not clear how this rule would apply to bills for the technical component.
3. Apply an anti-markup provision to the technical component of diagnostic services performed in a “centralized building” (an alternative used by group practices to satisfy the Stark in-office ancillary exception). CMS is not sure if this will require a change to the Stark regulations (perhaps by changing the definition of “centralized building”) and is seeking comment on whether and how to effect such a provision.

In-Office Ancillary Services Exception (IOAE)

The IOAE is a very popular, but potentially abuse-ridden, Stark ex-

ception because it allows physicians to self-refer for the provision of most designated health services (DHS) when those services are provided ancillary to medical services provided by the physician (or the physician’s group). The IOAE imposes certain supervision and billing requirements, as well as location requirements (i.e., the DHS must be provided in the “same building” as the physician’s medical practice or in a “centralized building” used by the group for the provision of DHS). Increasingly, physicians are entering into leases and other arrangements in an attempt to meet the IOAE and thus bill for DHS such as lab, therapy, and radiology. These are often turnkey arrangements where a leasing company provides everything necessary for the provision of the DHS, and the physician provides nothing more than the patients and a lease payment. CMS describes these types of arrangements as “nothing more than enterprises established for the self-referral of DHS,” which, in its view of the world, are not closely-enough connected to the physician practice to satisfy the intent of the IOAE.

While CMS is quite concerned, it has not made a specific proposal to amend or limit the IOAE exception. Rather, it is soliciting comments on whether changes are necessary and how they should be implemented. For example, CMS is asking whether certain services should be excluded from the IOAE (much like DME is now excluded). CMS asks whether the definitions of “same building” and “centralized building” be changed and whether non-specialist physicians will be able to use the IOAE for specialty tests.

Per-Click Payments for Space and Equipment Leases

Just in case tightening the PDTR’s

anti-markup prohibition is not enough to curb what it perceives as abuse in the diagnostic testing industry, CMS is proposing to specifically prohibit the use of “per-click” payments under any space and equipment lease when the lessor is the referring physician. This is a turnaround from the 1998 Stark Phase I rulemaking, which allows per-click and other time-based leases so long as the payment is fair market value and does not change during the term of the lease in a manner that takes into account the volume or value of DHS referrals by the physician (either as lessor or lessee). CMS has given this issue another look and now believes that, at least in cases where the physician is the lessor, some per-click leases are structured so that a physician is rewarded for each referral he makes for DHS.

Accordingly, CMS is proposing that space and equipment leases may not include unit-based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity. For example, a physician could not lease an MRI to a hospital and receive a per-click fee each time the MRI is used to scan a patient the physician has referred to the hospital.

In addition, CMS is soliciting comments on whether it should prohibit time-based or per-click payments to an entity lessor by a physician lessee, to the extent that such payments reflect patients sent from the entity to the physician. CMS does not offer any examples of this seemingly odd situation. Moreover, CMS is silent as to the popular per-click lease arrangement where a leasing company leases to physician so that the physician can provide services to his own patients. Also not addressed are block leases. It is not clear from the CMS proposal whether these types of leases will still be allowed.

Ownership or Investment Interest in Retirement Plans

CMS proposes to limit the Stark regulation exception for physician ownership in retirement plans. Specifically, the revised exception would cover “an interest in a retirement plan offered to a physician or his or her immediate family member as a result of the physician’s (or family member’s) employment by the entity.” This revision is meant to address another perceived abuse, namely the situation where a physician’s retirement plan purchases an interest in a DHS entity, to which the physician refers. CMS believes that such an interest is an ownership interest in a DHS entity (i.e., it is not excepted under the retirement plan exception).

“Set in Advance” and Percentage-Based Compensation Arrangements

Several of the Stark compensation exceptions require that the compensation be “set in advance,” which brings up the issue of percentage compensation. CMS has flip-flopped quite a bit on this point over the years. Currently the Stark regulations allow percentage compensation arrangements with physicians, so long as the specific percentage formula is set forth in sufficient detail before the furnishing of the items or services, and the formula is not modified within the term of the arrangement in any manner that reflects the volume or value of referrals or other business between the parties.

CMS has become aware that percentage arrangements are being used not only as compensation for physician services, but also in space and equipment leases (e.g., rent based on a percentage of the revenues raised by the rented equipment and office space). CMS believes this is abusive and is therefore propos-

ing 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 those services and not on some other factor, such as a percentage of the savings by a hospital department unrelated to the physician services provided. This latter requirement could limit physician compensation under management contracts and gain-sharing arrangements.

Services Furnished Under Arrangement

As predicted by many commentators, it appears that CMS is closing the door on “under arrangement” deals involving DHS. In an under arrangement (UA) deal, a hospital (or other facility) contracts with another party (the “UA provider”) to operate a hospital program or department. The UA provider can be the physicians alone, or a joint venture formed by the hospital and the physicians. Typically, the services include all technical components (equipment, supplies, technicians) and perhaps also management and other services. The department or program is treated, for patient and payor purposes, as a hospital program, and the hospital pays the UA provider a fee (usually per-click).

In the 2004 Stark II Phase II rules, CMS essentially gave the green light to many physician/hospital UA deals, by clarifying that a physician’s relationship to the hospital (the DHS entity) in a UA deal is only a compensation relationship (and most likely an indirect one, at that). This interpretation is based on the fact that “entity” for Stark purposes is defined as the entity that bills for the DHS. In a UA deal, the entity that bills for the DHS is the hospital, and the physicians do not have an ownership interest in the hospital. Therefore, physicians

have been able to avoid the general Stark prohibition³ on owning a DHS entity to which the physician refers by instead having the physicians own the UA provider, which then contracts with the hospital.

CMS fears that UA deals have created risks of overutilization and other program abuse by creating a method to share hospital revenues with referring physicians. CMS points out that many of these UA services had previously been and could continue to be provided directly by the hospital, and thus, to CMS, there appears to be “no legitimate reason” for the UA deal other than to allow referring physicians an opportunity to profit. CMS is also concerned that the UA services are furnished in a less medically-intensive setting than a hospital, but billed at higher hospital rates (and also higher coinsurance and deductibles for patients).

To curb these perceived abuses, CMS is proposing to revise the definition of “entity” under the Stark Law. The revised definition would include both the person or entity that bills Medicare for DHS, as well as the person or entity that provides the DHS. Under this new definition, a physician-owned UA provider would be considered a covered “entity” (since it provides the DHS) and the physicians would therefore need to meet a Stark exception (and only limited exceptions are available for ownership interests). CMS is also asking for comments on whether it should instead adopt the definition of “entity” proposed by the Medicare Payment Advisory Commission, which is any entity “that derives a substantial proportion of its revenue from a provider of [DHS].” This definition seems to be even broader than that proposed by CMS.

“Stand in the Shoes” Theory

In the ever-confusing world of di-

rect versus indirect compensation relationships, CMS is again trying to provide some clarification. Specifically, CMS is proposing that, where a DHS entity owns or controls an entity to which a physician refers patients for DHS, the controlling entity will stand in the shoes of the entity to which the referrals are made and will be deemed to have the same compensation arrangements with the physician as the controlled entity. For example, a hospital would stand in the shoes of a medical foundation that it owns or controls. Thus if the foundation contracts with physicians for services, the physicians could not refer to the hospital unless a Stark exception was met that covers the foundation's relationship with the hospital. CMS warns commenters that they "should be mindful" that CMS may already have finalized a provision that treats physicians as standing in the shoes of their group practices. Needless to say, this proposal would expand the coverage of Stark II, as it would turn many arrangements that are currently considered "indirect" into "direct" ones.

Burden of Proof

CMS wants to add a new section to the Stark regulations that will clarify that the burden of proof will be on the billing provider in any appeal of a denial of payment for a designated health service, where the denial was made on the basis that the service was furnished pursuant to a referral prohibited under Stark.

Obstetrical Malpractice Insurance Subsidies

Perhaps the only good news in the proposal is CMS's contemplation of broadening the Stark exception for the provision of obstetrical malpractice insurance subsidies by hospitals. CMS is worried that patients

cannot get obstetrical care in some communities because of high obstetrical malpractice insurance rates, and that the current Stark exception is "unnecessarily restrictive." The existing exception requires that the obstetrician practice in a primary care Health Professional Shortage Area, among other requirements, and also incorporates the conditions in the relevant anti-kickback safe harbor.

CMS is therefore proposing to revise the exception in order to increase beneficiary access to OB care without creating a greater risk of program or patient abuse. CMS is proposing to rework the exception into 9 specific conditions, including 1 requiring either a HPSA or underserved area. CMS is soliciting comments on the revised exception.

Period of Disallowance for Noncompliant Financial Relationships

CMS is grappling with how to compute the "period of disallowance"—that is, the period during which a physician could not make DHS referrals to an entity and the entity could not bill for services provided pursuant to such referrals because a financial arrangement between the parties was covered by Stark but failed to satisfy the requirements of a Stark exception. CMS is struggling with cases where it is not clear when the relationship begins and ends, such as the case of a below-market lease that could be seen as an exchange for future referrals. For these unclear cases, CMS is soliciting comment on whether rules establishing the period of disallowance should or can be established (perhaps adopting a case-by-case approach, or deeming certain types of financial relationships to continue for a prescribed period of time).

CMS is also soliciting comment

as to whether the parties should be allowed to shorten the period of disallowance by unwinding the deal and returning prohibited compensation. CMS is also considering disqualifying parties (for a certain amount of time) from using an exception when an arrangement has failed to satisfy the requirements of that exception (one strike and you are out).

Alternative Method for Satisfying Certain Exceptions

What should happen when a physician and a DHS entity have entered into an arrangement that is substantively in compliance with a Stark exception but not in full technical compliance with a "minor" requirement, such as having a signature on a lease? CMS repeatedly states that it does not have discretion to waive Stark violations, but it is considering offering an "alternate method" for coming into compliance with certain exceptions. This alternate method would only be available for inadvertent violations that caused an agreement to fail to satisfy some procedural or "form" requirements.

The "alternate method" would come with its own requirements, of course. CMS is suggesting requirements such as self-disclosure to CMS, lack of the parties' knowledge of the violation at the time of the referral or the resulting claim, no risk of program or patient abuse, being within a certain time frame from the original noncompliance, and the arrangement not being the subject of an ongoing federal investigation, enforcement action or other proceeding. CMS is soliciting comments on whether and in what form such a policy should be adopted.

Summary

So, the winners under these CMS

proposals are OBs in rural areas and people who make minor mistakes when trying to meet a Stark exception. The losers are diagnostic test purchasers, per-click lease participants (at least when the lessor is a physician), and hospitals and physicians who are involved in UA arrangements. Those left in limbo (since they were not addressed) are block lease participants as well as per-click lease parties where the physician is both the lessee and the source of patients.

Of course, this is not the last word. CMS will take public comments on the proposals until August 31, 2007. We will then have to wait in suspense for the final rule, which could take years (although it is possible that at least some of the current proposals could be finalized

soon since they are currently part of the 2008 Physician Fee Schedule proposal.) This suspense is only heightened by the impending Stark II Phase III rules.

For the full text of the CMS proposals, go to www.cms.hhs.gov/physicianfeesched/downloads/CMS-1385-P.pdf?agree=yes&next=Accept.

Notes

1. Under the Stark law, a physician cannot refer to an entity—and the entity cannot bill—Medicare/Medicaid for designated health services (DHS) if the physician has a financial relationship (compensation or ownership) with the entity, unless a specific Stark exception is met. Some examples of DHS are clinical lab, radiology, occupational and physical therapy, home health, DME, pros-

thetics and orthotics, outpatient prescription drugs and hospital inpatient and outpatient services. For a further description of the Stark Law, its origins, and the exceptions to its prohibitions see Katayama AC, Lyons LA. Stark realities: coping with federal and state self-referral paranoia. *WMJ*. 1994; 631-636.

2. Comments can be e-mailed to www.cms.hhs.gov/eRulemaking or mailed (1 original and 2 copies) to CMS, Dept. of Health and Human Services, Attn: CMS-1385-P, PO Box 8018, Baltimore, MD 21244-8018. Please caption your comments “Physician Self-Referral Provisions” and refer to file code CMS-2385-P.
3. As with all Stark prohibitions, this prohibition applies unless an exception is met. For the ownership prohibition, there are few exceptions.

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