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Julie A. Knutson, Editor

Special Stark Edition:
CMS Publishes Significant Rule Changes to Stark

On August 19, CMS published *final* rules amending Stark in ways that are both helpful and chilling. Many of the changes go to the heart of hospital-physician and physician-physician relationships and will affect many existing, pending, and planned transactions and business structures. The following is a brief summary of several of the most significant changes affecting transactional relationships.

1. CMS reverses course and permits amendment of leases and agreements.

In comments to Phase III, CMS had stated that space and equipment leases and personal service agreements will fail to meet the "set in advance" standard and therefore will fail to fit the necessary exception if they are *amended* with respect to the space, equipment, or services and corresponding rent or fees during their term. CMS commented that parties needed to terminate existing agreements (assuming they had been in effect a year or longer) and enter into new agreements in order to incorporate new space, equipment, or service terms.

CMS has now reversed this position. Amendment of space, equipment, and service terms during the term of agreements will be permissible so long as: (i) the applicable terms of the underlying exception continue to be satisfied; (ii) the amended rent or fee is determined (and documented) in advance of being implemented; (iii) the formula for the additional rent or fees is objectively verifiable and does not take into account the volume or value of referrals; and (iv) the amended rent or fee terms will be in effect for a year or longer. Moreover, CMS states this approach is applicable in all exceptions that include a set in advance requirement. This is a very favorable development that makes drafting arrangements simpler and also reduces the risk of inadvertent violations.

2. Stand-in-the-shoes is sensibly narrowed.

The stand-in-the-shoes rule, which made its debut in Phase III, states that if the only intervening party between a referring physician and an "entity" covered by Stark is the physician's "practice organization,"

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the physician is *deemed to have the same financial relationship with the entity that his or her practice organization has.* It looks at the financial relationships between the practice organization (often the captive clinic affiliate in an integrated delivery system or academic medical center setting) and the entity (often a hospital in the integrated delivery system or academic medical center setting) and requires that they all fit an exception for *direct* financial relationships. However, fund transfers and support payments among entities that do not fit exceptions are commonplace in integrated delivery system and academic medical center settings. CMS seemed to recognize that the rule had unintended consequences when it delayed its effectiveness for one year.

Now the stand-in-the-shoes rule has been substantially narrowed. First, it carves out any financial relationship that fits within the broad exception for academic medical centers.[1] Second, its mandatory effect is now limited to physicians who have an "ownership or investment interest" in their practice organization. Moreover, *"ownership and investment interest"* does not include physicians whose ownership or investment interest is "titular only," defined as:

> "An ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment."

This new requirement of an ownership or investment interest applies in all settings, not just within an integrated delivery system or academic medical center C. The result is that *many fewer* relationships will trigger stand-in-the-shoes treatment and require an exception for direct financial relationships. Note, however, that many relationships newly excluded from stand-in-the-shoes treatment because of this physician ownership condition will *still need to be analyzed as possible indirect compensation arrangements.*

In an interesting twist, the final rule also *allows* physicians who do not have an ownership interest in their practice organizations to choose to be treated under the stand-in-the-shoes rule. This would only be done if, in an unusual case, it is easier to fit a direct exception for the relationship between the physician organization and the entity than to meet the exception for indirect compensation arrangements.

This new iteration of the stand-in-the-shoes rule becomes effective October 1, 2008. The current moratorium is not being extended. The original grandfathering provisions remain in place.

3. "Under arrangement" transactions are severely limited.

In a much anticipated move, the final rule amends the definition of "entity" in Stark to include not only the entity that bills Medicare for designated health services, but also the entity that *performs* them – the classic "under arrangement" or "performing" entity. The definition is amended to include "the person or entity that has *performed* services that are billed as DHS …." The amendment is effective October 1, 2009, meaning that there is more than a year to anticipate and plan for this change.

The effect is dramatic. First, under arrangement services are by definition "hospital services" and therefore designated health services. Second, the under arrangement entity – the physician owned or co-owned entity, including even the physician's own group medical practice, that contracts to perform and sell services

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[1] *AMC exception at 42 C.F.R. 411.355(e).*

under arrangement – is now an "entity" covered by Stark. Therefore, before physician owners may refer services to these under arrangement entities, their ownership interest in them must be placed into a Stark exception for ownership or investment interests. The problem is that *there is no apparent exception* for physician ownership of an "entity" in an urban (MSA) area. The only potentially applicable exception is limited to "rural" areas.

The good news is that these changes have been anticipated for over a year; the bad news is that they are here. Under arrangement relationships have been an exceedingly flexible tool for hospitals and have allowed hospitals to save substantial capital by not having to acquire each diagnostic modality on its own. This change removes a major subset of potential investors in those modalities in all but rural settings.

4. Space and equipment leases – the end of percentage-based rental formulas.

CMS has amended four Stark[2] exceptions to state that space and equipment leases will no longer meet the applicable exceptions to the extent rental charges are based on:

> "a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or the business generated in the office space."

Nearly identical text applies to equipment rentals. This change is not tied to business generated from referral among the parties. It applies to all space and equipment rentals that need an exception. Percentage formulas apportioning rent based on relative square footage in the building or apportioning taxes and utilities will still be permitted.

Importantly, this rule change does not affect percentage-based compensation formulas for "personally performed" services. Use of a percentage-based formula in service arrangements is subject to other restrictions – for example, cannot reflect the volume or value of referrals or other business generated between the parties and must be tied to personally performed services – but there is no per se prohibition on their use.

5. Per-click rental arrangements are severely curtailed.

In a closely-related change, CMS has amended the same four Stark exceptions to state that space and equipment leases will no longer meet the applicable exceptions to the extent rental charges are based on:

> "per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties."

In this change, only those per-click or per-unit-of-service charges that reflect the volume or value of services referred "between the parties" are covered. However, referrals going both ways are covered.

With respect to both the elimination of percentage-based rental formulas and certain per-unit-of-service rental formulas, CMS acknowledges that many transactions may need to be restructured. In the preamble CMS states:

> "We recognize that the revisions [prohibiting percentage and certain per-click rental arrangements] may require restructuring or termination of arrangements for the rental of office space and equipment. We expect that the delayed effective date [to October 1, 2009] will provide parties with sufficient time to review

Use of a percentage-based formula in service arrangements is subject to other restrictions...

[2] *The rule change applies to the exceptions for space and equipment leases, fair market value compensation transactions (which can include an equipment lease component), and indirect compensation arrangements.*

existing arrangements and restructure them as necessary."

There is no grandfathering; parties are expected to identify and restructure by October 1, 2009.

6. Period of disallowance – the worst of the worst.

Perhaps the most chilling aspect of the new rules is where CMS attempts to clarify the period of disallowance – the period during which a physician's referrals of DHS payable under Medicare are disqualified and therefore cannot be billed to Medicare (or anyone else).

First, CMS notes that disallowance of a referral is measured as of *the date of the referral*. There are generally no retroactive "fixes" you can implement today that can cure a past period of disallowance. That is not new or unexpected. Where the new rules have its most negative impact, however, is on what you must do to fix your relationship *prospectively*. You must fix the past deficiencies in order to *prospectively* end the period of disallowance.

The new rule provides that the period of disallowance ends no later than:

- if the noncompliance is <u>not</u> related to the payment of compensation, such as where the parties neglect to create a written agreement, the date that the financial relationship satisfies all of the requirements of an applicable exception; or
- if the noncompliance is related to the payment of compensation, the date on which all excess compensation is repaid to the party that paid it, or the date on which all deficiencies are repaid to the party to which owed. Here it is not enough to put the relationship on a firm fitting prospectively. Past overpayments or underpayments must be paid or collected.

Assume a hospital enters into a five-year lease with a surgeon. In month 7 it is determined that the rent being charged is below fair market value or is based on an improper rental formula. The effect is:

- All of the surgeon's referrals for the prior six months are disallowed. There is nothing that can be done to fix that problem retroactively.
- The financial relationship framed by the lease remains out of compliance until the physician pays the rental deficiency.
- Even this repayment, however, does not cure that past non-compliance; it is merely a prerequisite to ending the period of disallowance prospectively – for month 7 and thereafter.

The hospital in this example has <u>no</u> good options. It can terminate the lease and enter into a new one. That ends the period of disallowance as to the original lease. But this step assumes the surgeon acquiesces in the lease termination and adjusted rent or that you have the unilateral right under the lease to take these steps. Alternatively, the hospital can "require" the physician to immediately "repay" the shortfall in rent and amend the lease to correct the formula – even though the lease is a binding document and already specifies rent. Alternatively, the hospital can terminate the lease and evict the surgeon when he won't agree to the first two alternatives. This takes months, if it is permissible at all, and the period of disallowance is building. Finally, the hospital in this example can suspend privileges and cease accepting referrals. This will not halt the period of disallowance, but would cut off the number of disallowed referrals.

Expand this concept to reach all financial

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relationships between physicians and Stark entities. There will rarely be an immediate, workable alternative that can limit the damage prospectively. All of this highlights the fact that there is no safeguard as important as having a documented basis for the fair market value rent or fee before the contract is implemented and having each financial relationship identified and analyzed for compliance with an applicable Stark exception.

7. Alternative compliance for missing signature.

CMS has added a helpful, though limited, alternative in cases where the noncompliance relates solely to the lack of obtaining a required signature. It only applies to exceptions where a signed written agreement is required. The new rule provides a limited period of time in which to obtain the required signature after the fact. Correction (in the form of obtaining the required signature) must occur within 30 days of the start of the agreement in the case of an intentional or knowing failure and within 90 days in the case of an inadvertent failure. The exception may be used only once each three years with respect to the same referring physician.

There are more rule changes not reported above. They appear to have less immediate application. We will cover them in future articles, along with other changes in the pipeline. Here we have attempted to discuss changes with immediate and wide-spread application in common health care relationships.

Conclusion

CMS reaffirms that Stark is a "strict liability statute." Compliance turns on meeting highly technical rules. Experience increasingly shows that physicians and entities need to do everything in their power to identify covered financial relationships in advance and 100% of the time and them analyze and structure them carefully within ever evolving rules.

Alex M. (Kelly) Clarke

Save the Date!

The 20th Annual Health Law Forum will be held on Friday, November 21, 2008 at the Marriott Regency in Omaha.

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