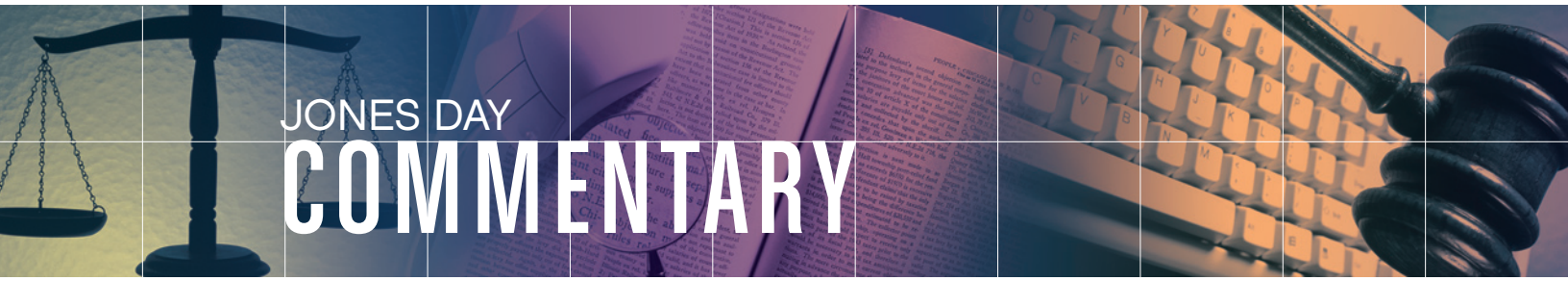
JONES DAY

AUGUST 2007



STARK ON THE FAST TRACK: SEPARATE RULEMAKING THREATENS MANY COMMON DEALS

On July 2, 2007, as part of its proposed update for the 2008 Medicare Physician Fee Schedule, the Centers for Medicare and Medicaid Services ("CMS") proposed substantial changes to the Stark Law regulations and the performance standards for independent diagnostic-testing facilities ("IDTFs"). If finalized in their current form, these proposals would eliminate many opportunities for physicians to maintain their practice incomes through hospital-physician arrangements, making them more inclined to become employed by hospitals or to pursue arrangements that exclude Medicare and Medicaid patients.

This *Jones Day Commentary* first summarizes these proposed changes and then illustrates the impact that these proposals would have (if finalized) on common hospital-physician arrangements. For quick reference, charts at the end of the *Commentary* compare these proposals with existing regulations. As CMS notes multiple times in the commentary accompanying these proposals, a separate final rule on the Stark regulations (the long-anticipated "Phase III" rules) is in process. In fact, the Phase III regulations cleared review by the Office of Management and Budget on August 20, 2007, and are expected to be released in the near future.

PART I: SUMMARY OF PROPOSED CHANGES

Proposed Regulations Would Eliminate Many "Per Click" Lease Arrangements

The proposed regulations would largely reverse CMS's interpretation of the "volume or value" standard as it applies to per-unit-of-service (or "per click") compensation arrangements. Presently, CMS allows "per click" compensation if the "per click" fee is fair market value for the services or items actually provided and does not vary during the course of the agreement based on designated health services ("DHS") or other referrals. CMS states that it now views these arrangements as "inherently susceptible to abuse," and it seeks to prohibit "per click" compensation in lease arrangements to the extent that the "per click" charge reflects "services provided to patients referred by the lessor to the lessee."

CMS Proposes to Limit Percentage Compensation to Physician Services

Similar to "per click" arrangements, Stark Law regulations currently permit percentage-based compensation, such as an equipment lease payment based on a percentage of the fee paid by the payor. CMS states that it intended to allow percentage-based formulas "only for compensating physicians for the physician services they perform. . . ." Accordingly, the proposed regulations would limit percentage compensation arrangements to paying for personally performed physician services and further limit any percentage payment to revenues derived directly from the physician services.

Proposed Definition of "Entity" Limits "Under Arrangements"

The proposed regulations would revert to a prior CMS proposal that the term "entity" would include persons or entities that perform (but do not bill for) DHS. This change effectively eliminates the provision of hospital services under arrangements by any entity in which physicians have an ownership interest, including a physician group practice. Similarly, CMS representatives have informally taken the position that a hospital may have no ownership interest in any entity that provides under-arrangement services. This informal interpretation, when considered with the proposed regulation, creates a curious question of who can provide under-arrangement services. Presumably, hospitals could turn to independent suppliers that have no physician investors or that have only physician investors who do not make any referrals to the hospital for Medicare- or Medicaid-reimbursable services. This likely will decrease the scope and, perhaps, the quality of under-arrangement services in areas where hospitals have few resources or alternatives.

Commentary Seeks Guidance on Collapsing Financial Relationships

CMS noted that commenters previously proposed allowing physicians to "stand in the shoes of their group practices" and fit within exceptions for direct compensation arrangements. CMS elected not to adopt this concept when it issued the Phase II regulations, but it now believes that such a rule is necessary. Accordingly, CMS proposes (without offering any regulatory language) to amend the definition of "compensation arrangement" to provide that:

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

CMS Targets In-Office Ancillary-Services Exception

The most onerous provision in the proposed regulations may be one that is not yet written. CMS has asked for comments on a number of issues relating to the in-office ancillary-services exception, revealing a desire to limit the availability of the exception, perhaps even in contradiction of the statute creating it. For example, CMS asked for comments on whether certain services should qualify for the exception and any other restrictions on ownership or investment interests in services that would curtail program or patient abuse.

CMS Again Targets Diagnostic Testing Through Sharing Restrictions, Markup Provisions

CMS proposed to use the 2008 Medicare Physician Fee Schedule to prohibit an IDTF from sharing space, equipment, or staff or from subleasing its operations to another individual or organization. Additionally, CMS proposes to revise Medicare billing rules to impose an anti-markup provision on both the technical and professional components of diagnostic tests performed by an outside supplier. In such cases, the physician or medical group will be paid the lesser of: (1) the supplier's net charge to the physician or medical group, (2) the billing physician's or medical group's actual charge, or (3) the Medicare fee schedule amount. This provision will apply regardless of whether the test or interpretation was purchased by the physician or medical group or its interpretation was reassigned to the physician or medical group billing for the test or interpretation. Significantly, the 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."

CMS Offers Other Proposals on Financial Relationships, Stark Law Enforcement

CMS also proposed other changes or sought comments regarding the exception for obstetrical malpractice insurance subsidies, retirement plan interests, the burden of proof for claims resulting from Stark Law-prohibited referrals, the period during which CMS may disallow claims as a result of Stark Law violations, and alternative methods of compliance with Stark Law exceptions. These additional proposals, as well as those discussed above, are addressed in the charts included in this *Jones Day Commentary*.

PART II: PROPOSED REGULATIONS DRAMATICALLY AFFECT HOSPITAL-PHYSICIAN ARRANGEMENTS

These proposed regulations, if finalized in their present form, would dramatically affect many existing hospital-physician arrangements. As discussed below, hospitals should begin evaluating each of their existing arrangements with physicians for compliance with the proposed regulations, given that CMS has proposed January 1, 2008, as the effective date for these regulations.

Turnkey Supplier Joint Ventures

This particular joint venture usually involves the creation by physicians and a hospital of a limited liability company that serves as a turnkey supplier of space, equipment, and personnel (*e.g.*, MRI, 64-slice CT, linear accelerator services) to a single group practice or multiple group practices that are located in the same building. In many of these ventures, the group practice will lease space, equipment, or personnel to the joint venture or utilize its own personnel to bill for the service. Likewise, for administrative convenience, the turnkey fee is often set as a percentage of the global fee paid by the payor.

Given the proposed regulatory changes, the joint venture would need to charge the group practices receiving the turnkey service the Medicare fee schedule amount to avoid application of the anti-markup rule. Any leasing of space or equipment by the group practice to the joint venture would result in a reduction of the fee paid to the group practice by Medicare under the anti-markup rule. Thus, any space or equipment that is leased by the joint venture would need to be leased from the hospital or a third party (which may require reconfiguring any leases that are currently in place with a group practice).

As written, the anti-markup provision would effectively require the turnkey supplier to provide all aspects of the supplied service to the group practice because the group practice would be limited to receiving reimbursement equal to the supplier's net charge to the group practice. Thus, for example, the group practice should have the supplier provide billing services (perhaps using the group practice's own billing staff under a leased employee arrangement) and bundle the cost of those services into the supplier's charge to the group practice. Otherwise, if the group practice does the billing for the service on its own, it would not be able to recoup its costs from Medicare due to the payment restriction. This would seem to be an unintended consequence of the proposed anti-markup provision, and one hopes it will be revised as a result of the comment process. To fix this unfortunate result, CMS would merely need to revise the anti-markup provision to apply only to the portion of the service supplied by the turnkey supplier.

While generally the proposed rule would preclude the use of a percentage of the global fee payment methodology and per-unit-of-service fee arrangements for the leasing of space or equipment, it would appear that such payment arrangements still would be permitted in cases where the subject services meet the requirements of the in-office ancillary-services exception to the Stark Law. This issue will need to be followed closely, as CMS may elect to foreclose the use of such payment arrangements for in-office ancillary services through Phase III or after analyzing the comments to the proposed rule.

Given the proposed change to the IDTF regulations, the joint venture would not be permitted to function as an IDTF with respect to referrals from non-group practice sources.

Cardiac Catheterization Services "Under Arrangements"

Under this model, a joint venture is created by physicians and a hospital to operate an IDTF that provides diagnostic

cardiac catheterization services directly and interventional cardiac catheterization services to hospital patients "under arrangements."

Given the proposed regulatory changes, the IDTF would no longer be permitted to provide interventional cardiac catheterization services to hospital patients "under arrangements" because the IDTF would be considered an "entity" to which the physician owners of the IDTF are referring hospital services that are Stark Law DHS, and no Stark Law exception would apply to this direct ownership interest (unless the IDTF is a rural provider).

Indeed, for the same reason, it would appear that the change to the definition of "entity" would eliminate the provision of any hospital services "under arrangements" by any entity in which physicians have an ownership interest, including a physician group practice (unless the entity is a rural provider). Going forward, with those two exceptions, only non-physician-owned suppliers would be able to provide services to hospital patients under arrangements.

Cath Lab/MRI/CT Supplier Arrangement

Under this model, the hospital leases space, diagnostic equipment, and personnel to a physician group on a turnkey service basis, and the group uses the same to provide diagnostic services to patients of the group.

The proposed anti-markup regulation would preclude the group from billing Medicare for any amount in excess of the amount that the hospital charges the group. If the hospital provides only the space and equipment and not the personnel, then the anti-markup rule may not apply because the test would not be "performed" by a supplier.

Equipment/Space Leasing Arrangements

Under these types of arrangements, physicians lease either space or equipment to the hospital and are paid on a per-unit-of-service basis, even if the physician has referred the patient to the hospital for the use of the equipment/space.

The proposed regulations would preclude the use of per-unit-of-service rental payments if such charges reflect the services provided to patients referred by the physician lessor to the hospital lessee (which is true in most cases where this type of payment methodology has been employed).

Gainsharing

Under gainsharing models, the hospital pays participating physicians a percentage of the hospital's cost savings that result from the gainsharing activities.

Given CMS's comments in the preamble to the proposed regulations and the change to the regulation itself, a percentage of cost-savings payment methodology would not be considered to be "set in advance." While this would preclude the application of the Stark Law personal services and fair-market-value exceptions, the indirect compensation arrangement exception may still protect such payments (although CMS suggested it may have already taken steps to severely restrict the use of the indirect compensation arrangement exception in the Phase III rule).

STRATEGIC IMPLICATIONS OF THE PROPOSED REGULATIONS

The proposed regulations would eliminate many opportunities for physicians to maintain their practice incomes. This is likely to make physicians more inclined to become employed by hospitals. It may also lead many physicians to pursue imaging centers and other types of joint ventures that serve only commercial insureds—and not Medicare and Medicaid beneficiaries.

One integration model that would not be affected by the proposed regulations is the comanagement model. This model often involves the formation of a hospital-physician joint venture to manage a hospital department. This model, which is already under consideration by many hospital systems around the country, will likely gain new proponents in the physician community. It should also be noted that while the proposed regulations do not hinder the development of whole hospitals, Congress recently has considered changes to the Stark Law itself that would eliminate the whole-hospital exception.

The following is a link to the CMS announcement: http://www.cms.hhs.gov/PhysicianFeeSched/PFSFRN/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=4&sortOrder=ascending&itemID=CMS1200867

COMMENT PERIOD AND EFFECTIVE DATE

The proposed rule was published in the July 12, 2007, Federal Register, and comments regarding the proposed rule will be accepted until August 31, 2007 (September 7, 2007, for the alternative method of compliance portion). CMS has stated that a final rule will be published sometime this fall and that the final rule will be effective for services furnished on or after January 1, 2008.

Proposed Stark Law Regulations		
Regulation Topic	**Existing Regulation (If Any)**	**Proposed Regulation**
"Set in Advance" (Percentage-Based Compensation)	Percentage-based compensation is considered set in advance if the formula for calculating it is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid.	CMS has proposed clarifying that percentage compensation arrangements may be used to pay for personally performed physician services only and must be based on the revenues directly resulting from the physician services, rather than other factors, such as percentage of the savings generated in a hospital department.
"Per Click" Lease Arrangements	"Per click" compensation will be deemed not to take into account the volume or value of referrals if the compensation is fair market value for the services or items actually provided and does not vary during the course of the agreement in any manner that takes into account referrals of DHS or other business generated by the referring physician.	The proposed rules would disallow "per click" arrangements to the extent that the lease charges reflect services to patients referred by the lessor to the lessee. CMS has requested additional commentary on whether it should impose a corresponding prohibition on "per click" arrangements for referrals from the lessor to a physician lessee.
Under Arrangements	CMS interprets the term "entity" as only the person or entity that bills Medicare for the DHS, and not the person or entity that actually performs the DHS. This interpretation allows a physician to have an ownership interest in a joint venture that provides services to the hospital under arrangements.	CMS has proposed that the term "entity" include both the person or entity that performs the DHS as well as the person or entity that bills Medicare for the DHS. This change would prohibit physician ownership in joint ventures that provide services to hospitals under arrangements, unless the entity is a rural provider.
In-Office Ancillary-Services Exception	Exception allows physicians or group practices to provide DHS (other than most DME and parenteral and enteral nutrients, equipment, and supplies) if the provision of such services satisfies supervision, building, and billing requirements.	CMS has solicited comments on: • Whether certain services should not qualify for the exception. • Whether it should modify the definitions of "same building" and "centralized building" and if so, how. • Whether nonspecialist physicians should use the exception to refer patients for specialized services involving equipment owned by the nonspecialists. • Any other restrictions on ownership or investment in services.
Collapsing Financial Relationships	CMS must presently respect corporate formalities, such as separately organized limited liability companies or corporations.	CMS has proposed that, where a DHS entity owns or controls an entity to which a physician refers patients for DHS, the DHS entity would "stand in the shoes" of the entity that it owns or controls and would be deemed to have the same compensation arrangements with the same parties and on the same terms as the entity that it owns or controls.
Obstetrical Malpractice Insurance Subsidies	Current exception requires that the subsidy meet all elements of the safe harbor to the Federal Anti-Kickback Statute.	CMS has not proposed any specific revisions to the exception for obstetrical malpractice insurance subsidies. Instead, CMS is seeking comments on what provisions of the safe harbor are necessary to safeguard against program or patient abuse.
Retirement Plan Interests	Ownership and investment interests do not include an interest in a retirement plan.	CMS has proposed modifying the retirement plan exclusion to tie it more directly to employment relationships. Accordingly, the proposed rule would exclude interests in a retirement plan only if offered to the physician (or his or her immediate family member) through the physician's (or family member's) employment.

Proposed Stark Law Regulations (Continued)		
Regulation Topic	**Existing Regulation (If Any)**	**Proposed Regulation**
Burden of Proof	No rule presently exists on who carries the burden of proof for establishing that a claim for DHS resulted from a prohibited referral.	After a claim is denied for Stark Law violations, the burden of proof would be on the entity submitting the claim for payment to establish that the claim did not result from a prohibited referral. CMS states that this rule is consistent with its policy regarding claim denials in general.
Noncompliant Financial Relationships	No existing rule clearly states the period during which CMS will disallow claims for DHS when a financial relationship fails to comply with an exception.	CMS has not proposed any specific rule but states that, generally, the period of disallowance would begin on the date that the financial relationship failed to comply with an exception and end on the date that the financial relationship ended. CMS has specifically requested comments on instances in which it may be difficult to determine when a noncompliant financial relationship ends.
Alternative Methods of Compliance	No rule presently exists by which parties may cure technical violations of the Stark Law that result from a failure to adhere to form requirements, such as the failure to obtain signatures on a lease agreement.	CMS has solicited comments on whether it should adopt rules allowing for alternative methods of compliance for technical violations of form. Significantly, CMS has indicated that, if it adopts such a rule, parties must inform CMS of the violation and allow CMS to determine in its sole discretion (with no appeal) whether the violation resulted from a failure to follow form requirements as opposed to more substantive violations, such as failure to pay consistent with fair market value.

Proposed IDTF Regulations		
Regulation Topic	**Existing Regulation (If Any)**	**Proposed Regulation**
Sharing of Space, Equipment, or Personnel	No rule prohibits the sharing of space, equipment, or personnel.	CMS has proposed a requirement that an IDTF must "not share space, equipment, or staff or sublease its operations to another individual or organization."
Anti-Markup Provisions for Purchased Diagnostic Tests	Imposes an anti-markup provision on the technical component of a purchased diagnostic test.	Imposes an anti-markup provision on both the technical and professional components of purchased diagnostic tests, limiting reimbursement to the lesser of the supplier's net charge, the physician's actual charge, or the fee schedule amount for the test. Significantly, "net charge" must be determined without regard to any charge intended to reflect the cost of equipment or space leased to the outside supplier by or through the billing physician or medical group.

LAWYER CONTACTS

For further information or to discuss the effect of the proposed changes on your existing and planned hospital-physician joint ventures, leases, and other arrangements, or for assistance in submitting comments on these proposed changes, please contact your principal Firm representative or one of the lawyers listed below. General e-mail messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com.

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