

CMS Finalizes Significant Changes to Stark Regulations

On July 31, as part of the Hospital Inpatient Prospective Payment System Update, the Centers for Medicare & Medicaid Services (CMS) finalized numerous previously proposed amendments to the Stark regulations. Some of these amendments will require hospitals and physicians to dismantle or overhaul many existing arrangements. Parties especially should inventory under arrangements and leasing agreements—even indirect leasing agreements that do not involve DHS—to ensure compliance upon the rules' effectiveness.

- **Under Arrangements.** Effective October 1, 2009, the definition of “entity . . . furnishing DHS” will include entities that perform DHS, not just entities that submit claims for DHS. This will cause physician practices and other entities that provide services under arrangements with hospitals to be deemed to be furnishing DHS. This will prohibit physicians having ownership interests or compensation arrangements with such practices from making referrals for the under arrangements services, or for other DHS, unless the physicians' relationships with the billing hospital and the practice satisfy the terms of an exception. While employees or contractors of physician groups providing services under arrangements may be able to qualify for an exception, exceptions available to group owners are limited.
- **Percentage-Based or Per-Click Compensation in Leases.** Effective October 1, 2009, the lease exceptions, fair market value exception, and indirect compensation exception will prohibit the use of percentage-based (i.e., percent of billings or collections) or per-click compensation in space or equipment leases between physicians and DHS entities—or in certain circumstances between two entities interposed in a chain of relationships between physicians and DHS entities (e.g., between a physician-owned leasing company and a hospital-owned ambulatory surgery center), even if the leases do not directly involve DHS. Limited at this time to leases, the amendment will not affect gain-sharing or other non-lease compensation arrangements.
- **Stand in the Shoes.** Effective October 1, 2008, physicians who do not have a bona fide ownership interest in a physician organization—i.e., groups' employees, contractors, and those having only “titular” ownership interests, such as nominee shareholders of controlled PCs—no longer will be required to “stand in the shoes” of their physician organizations, and so may utilize the indirect compensation exception as available prior to the 2007 Phase III rules. This will increase the flexibility of hospitals' relationships with groups having only nominal ownership structures, particularly with respect to mission support payments and subsidies.
- **Period of Disallowance.** Effective October 1, 2008, the Stark regulations will define the maximum period during which referrals and associated billings are barred due to noncompliance. In brief, the Stark bar may extend from the date of noncompliance until complete cure, which is deemed to be the date that non-financial noncompliance is corrected (e.g., lease is signed), excess compensation is refunded (e.g., physician returns compensation above fair market value), and insufficient compensation is paid (e.g., physician pays shortfall of rent below fair market value). Barring physicians' referrals and hospitals' billings for the full period from noncompliance until cure, this could lead to extended prohibition periods if noncompliance is not promptly cured (e.g., if a physician does not return excess compensation), and could preclude parties from making retroactive corrections in the event of inadvertent non-compliance. As indicated, the rule defines the maximum period of disallowance; in commentary, CMS noted that the rule “does not prevent parties from attempting to demonstrate that the period of disallowance ended on some earlier date.”

- **Alternative Method of Compliance.** Effective October 1, 2008, arrangements that fail to satisfy a Stark exception solely due to noncompliance with a signature requirement may satisfy a new alternative method for compliance. Parties that “inadvertently” fail to sign an agreement prior to commencement may sign within 90 days and remain compliant. If parties’ failure to sign is not “inadvertent” (e.g., if a physician and hospital agree to sign a services agreement after services begin), they must sign within 30 days of commencement to remain in compliance.
- **Obstetrical Malpractice Subsidies.** Effective October 1, 2008, the availability of the exception for obstetrical malpractice insurance subsidies will be expanded in designated underserved and rural areas.
- **Interests in Retirement Plans.** Effective October 1, 2008, any physician who, through an employer-based retirement plan, indirectly holds an interest in a DHS entity in which the plan invests will be considered to have an ownership or investment interest in that DHS entity.
- **Burden of Proof.** Effective October 1, 2008, a DHS entity appealing a denial of a payment based on the Stark law will bear the initial burden of proof during all appellate proceedings to show that the service was not furnished pursuant to a prohibited referral.
- **Miscellaneous.** Indicating commenters’ nearly unanimous opposition, CMS determined not to finalize its earlier entity-side “stand in the shoes” proposal.

As indicated above, the effective dates of the amendments vary. They are summarized below:

Effective October 1, 2008

- Revision to “Stand in the Shoes”
- Period of Disallowance
- Alternative Method of Compliance
- Obstetrical Malpractice Subsidies
- Interests in Retirement Plans
- Burden of Proof

Effective October 1, 2009

- Under Arrangements
- Percentage-Based or Per-Click Compensation

If you have any questions about the Stark amendments, please contact your regular Ropes & Gray attorney.

The Hospital Inpatient Prospective Payment System Update is available on display prior to publication in the Federal Register at <http://edocket.access.gpo.gov/2008/pdf/E8-14949.pdf>. Discussion of the Stark amendments begins on page 970, and the text of the Stark amendments begins on page 1231.

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