HEALTH CARE

Legal News Alert™

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Legal News Alert is part of our ongoing commitment to providing up-to-the minute information about pressing concerns or industry issues affecting our Health Care clients and colleagues.

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CMS Proposes Far-Reaching Stark Changes

On July 2, 2007, the Centers for Medicare & Medicaid Services (CMS) released a number of proposed and potentially far-reaching changes to the Stark regulations as part of its annual physician fee schedule update. (The long awaited Stark II, Phase III rules are not yet out, but are expected soon). The proposed Stark revisions would, among other things, prohibit certain **"per click" leases and percentage compensation** arrangements, eliminate many **"under arrangements" joint ventures**, and curtail use of the **in-office ancillary services** exception.

The proposed changes clearly result from CMS's frustration with what it perceives as a growing number of arrangements that permit physicians to profit from their referrals of ancillary services, while side-stepping or working around existing Stark restrictions. In short, **the proposed changes appear to be aimed at what CMS views as "loopholes"** in the existing rules.

The following are some of the more significant proposed changes:

"Per Click" Leases. The proposed rules would **prohibit per click and per unit rent** in space and equipment leases, to the extent the rental payments reflect services for patients referred by the lessor to the lessee.

Percentage Compensation. CMS now proposes **allowing percentage compensation only to pay for personally performed physician services, when the percentage is based upon revenues resulting from such services**. This change would prevent payments based upon a percentage of cost reductions achieved, or a percentage of revenue earned for meeting pay-for-performance goals, as well as many common expense sharing and management fee arrangements.

In-Office Ancillary Services. CMS asserts that this exception was initially meant to allow a limited range of services to be provided in physicians' offices that are "necessary to the diagnosis or treatment of the medical condition that brought the patient to the physicians' office." It expresses concern that the scope and complexity of services utilizing this exception is

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expanding and that there has been a "**migration of sophisticated and expensive imaging or other equipment to physician offices**," and some of these arrangements being "marketed to physicians over the internet." According to CMS, such services "furnished today purportedly under the in-office ancillary services exception are often not as closely connected to the physician practice." Although CMS appears to be frustrated by the trends it has identified in this area, it seems uncertain how best to address them. For now, CMS will "decline to issue a specific proposal for amending the in-office ancillary services exception" and instead seeks public comment on what changes should be made.

Under Arrangements. CMS continues to have concerns with services provided under arrangements to hospitals and other providers and asserts that "**there appears to be no legitimate reason'' for certain hospital/physician imaging joint ventures 'other than to allow referring physicians an opportunity to make money on referrals** for separately payable services' which 'were previously furnished directly by the hospitals, and in most cases, could continue to be furnished directly by the hospitals'". To address this issue, CMS proposes to change the definition of "entities" (that are prohibited from receiving referrals from physician owners) to include not just the hospital, which bills Medicare for the services provided under arrangement, but also the entity that "performs" the services under arrangement to the hospital. This would effectively **end the viability of many hospital/physician under arrangement joint ventures**.

Anti-Markup. The proposed changes would **prohibit physicians from marking** up the technical component or the professional interpretation of diagnostic imaging services that are purchased or **billed under reassignment**. CMS also proposes to prohibit marking up the technical component of diagnostic imaging services provided by a group practice in a "centralized building" and invites public comments on how to effect such a rule.

Burden of Proof. CMS proposes that on any appeal of a denial of payment based on a Stark violation, the **burden would be on the entity submitting the claim** to establish that the service was not furnished pursuant to a prohibited referral.

Alternative Criteria for Satisfying Exceptions. In a somewhat hopeful sign, CMS proposes to develop "alternative criteria" for situations that involve an inadvertent failure to meet one of the less substantive requirements of an applicable Stark exception. The example cited is a written agreement that sets forth the services to be furnished, provides for fair market compensation set in advance, and otherwise fully complies with an applicable exception, but mistakenly has not been signed by one or both parties. In these situations, parties may still be able to qualify for a Stark exception, if they self-disclose their situation to CMS, and CMS determines, at its sole discretion (and not subject to any appeal rights), that the failure was inadvertent, poses no harm of program or patient abuse, and meets certain other criteria.

What To Do Now

These changes are only proposed, so there is no immediate impact on existing arrangements. It is not yet known whether these proposed changes will become final and, if so, when. However, anyone contemplating an arrangement that involves any of the topics covered in the proposed rule changes is well-advised to consider ways to limit the potential effect on the arrangement if and when the proposed changes become final. Furthermore, a party to any current arrangement that would be affected by these proposed rule changes may wish to review their arrangement now, and consider alternatives should any of the proposed changes be ultimately enacted.

Finally, you may wish to consider submitting a formal comment letter to CMS in response to the proposed changes, or asking that such a submission be made by a trade association of which you are a member. Such comments are expected to be due by **August 31, 2007, but the actual date will depend on when the proposed regulations are published in the Federal Register**. For now, the proposed regulations are expected be published in the Federal Register on July 12, 2007.

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