



FAR REACHING STARK CHANGES ON THE HORIZON!?!

On July 2, 2007, the Centers for Medicare and Medicaid Services (“CMS”) issued “Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008” (the “Proposed Revisions”). While these Proposed Revisions are not the awaited Stark III regulations, and do not promulgate any final regulations, they are nevertheless noteworthy in that they contain extensive discussions by CMS of its concerns and thinking about a number of important subjects. Even if only some of CMS’s proposed revisions to the regulations were adopted, many presently common practices would be prohibited or restricted. Moreover, CMS is seeking comments and guidance on ways to further limit what it perceives to be abusive under the existing already restrictive Stark provisions.

In the “Physician Self-Referral Provisions” section of the Proposed Revisions, CMS discusses not only the Stark Law, but also Purchased Diagnostic Tests and Interpretations. In this section, CMS covers issues including the In-Office Ancillary Services Exception, per click payments, percentage-based arrangements, joint ventures with hospitals, and expanding the anti-mark up provisions for purchased tests. A few of the highlights are briefly summarized below.

Mark-Ups Prohibited on Purchased Technical & Professional Services. In prior pronouncements, CMS proposed to make changes to the Medicare Purchased Diagnostic Test or anti-markup rule, as well as changes to the definition of “centralized office” under the Stark Law. In the present Proposed Revisions, CMS proposes to expand the anti-markup rule to apply to both the technical component of purchased diagnostic tests and the professional component of purchased interpretations, and further propose to make such a rule applicable not only when the tests or interpretations are directly purchased, but also when they are obtained through a re-assignment from the actual provider of the service unless the performing supplier is a full-time employee. While CMS decided not to propose any changes to the definition of “centralized building” under the Stark Law, CMS did suggest that the anti-mark-up provision should apply in a centralized location and solicited comments on whether, or how, such should be implemented. This change could affect any group which provides diagnostic interpretation (e.g., imaging, lab) through its use of part-time employees or independent contractors.

Further Restrictions on In-Office Ancillary Services. In discussion of the in-office ancillary exception under the Stark Law, CMS expressed its concern that this exception was

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being applied to services that are not “closely connected to the physician practice.” Rather, in some cases, “core members of the group practice and their staff are never physically present” where the ancillary services are being performed, and the arrangement thus appears “to be nothing more than enterprises established for self referral” of Designated Health Services (“DHS”) covered under Stark. CMS also noted its concerns about potentially abusive arrangements in which a referral is made to a specialist who is an independent contractor of the group practice, and who then performs the service in a centralized building.

Despite its concerns, CMS declined to make a specific proposal, but instead solicited comments as to whether changes in Stark are necessary to address the concerns and, if so, what those changes should be. While CMS did not suggest specific changes, the areas in which it is seeking comments clearly indicates its concerns and suggest a likely limitation of currently permitted activity in the future. These include, without limitation,

1. Limiting therapy that meets the in-office ancillary exception to therapy provided on an “incident-to” basis.
2. Limiting ancillary service to only those needed at the time of an office visit.
3. Further changes to the definition of “same building” and “centralized location,” further limiting a group’s ability to utilize this exception.

Clearly, CMS is looking to further restructure what would be permitted under the existing exception. This is further evidenced in a recent article in the July 2007 issue of Health Executive which quotes Don Romano, Director of Technical Payment Policy at CMS, regarding the long anticipated Stark Phase III regulations. Romano states: “We usually don’t comment on specific proposals we have coming out. But it’s no secret we are going to be publishing Phase III soon...We are also proposing additional changes to our regulations through separate rule-making in the near future. Enforcement is up, and new regulations are coming. Providers should respond accordingly.” The article states that Phase III is expected to include a number of new provisions around block leasing arrangements with imaging and other facilities and clarify Stark exceptions and anti-kickback safe harbors for health IT.

Limitations on Per-Click Payments in Space and Equipment Leases. Previously, CMS made clear that, under the Stark Law, unit of service or per-click fees were generally permissible, if the fees were fair market value. Despite its prior pronouncements, CMS notes in the Proposed Revisions its ongoing concern that such fees are potentially abusive when the physician-lessor is paid every time he or she makes a referral to that location for use of that equipment. In such situations, the physician has “an incentive to profit from referring a higher volume of patients to the lessee.”

As a result, and “after reconsideration” of the issue, CMS is proposing that “space and equipment leases may not include unit of service based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor

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to the entity.” Notably, this proposal applies only to space and equipment rentals, and not to salary or payments for personal services.

No Percentage Leases/Management Fees with Referral Sources. CMS also noted that, while it has allowed percentage based compensation arrangements for compensating physicians for services they perform, percentage based arrangements were also being used for space and equipment rentals, which CMS believes are “potentially abusive.” As a result, CMS is proposing to clarify that percentage compensation arrangements may be used “only” for paying for personally performed physician services and that the percentage must be based on “the revenues directly resulting from the physician services . . .” This would prohibit use of percentage-based rental and management fees in States that currently permit such payment methodology.

Expansion of Covered Entities. CMS continues to state its concerns about services provided to hospitals and other providers under arrangement. CMS noted, for example, that it had received anecdotal reports of hospital-physician joint ventures that provide hospital imaging services formerly provided by the hospital directly. CMS reasons that many of the services provided by the joint venture were previously provided by the hospital alone and could continue to be provided by the hospital in some cases. CMS further noted that physician specialists who order services for their hospital patients set up joint ventures, frequently including as an owner a hospital to which the physicians refer patients. CMS worried that, in all of these cases, there was “no legitimate reason for these arranged for services other than to allow referring physicians an opportunity to make money on referrals for separately payable services.”

CMS then went further and, quoting a report from MedPAC, noted that physician ownership of “entities that provide services and equipment to imaging centers and other providers creates financial incentives for physicians to refer patients to these providers . . .” CMS stated that arrangements in which physicians “own leasing, staffing, and similar entities that furnish items and services to” DHS entities “raise significant concerns under the fraud and abuse laws” and appear to be “contrary to the plain intent of the physician self-referral law.”

CMS stated, however, that it is trying to determine the best approach to these issues, and noted that some of MedPAC’s concerns may be addressed in the upcoming “Phase III final rule.” Nevertheless, CMS is proposing to revise its definition of what constitutes a covered DHS entity under Stark to include both the entity that performs the DHS and the person or entity that submits claims or causes claims to be submitted to Medicare for DHS.

Stand in the Shoes. CMS is proposing to, in essence, collapse the indirect financial relationship concept when a DHS entity owns or controls another entity with which a physician has a financial arrangement. Under its proposal, in such cases, the physician would be deemed to have the same financial arrangement with the DHS entity as he or she has with the owned or controlled entity.

Other Miscellaneous Sub-Sections. Other miscellaneous sub-sections relating to various Stark Law issues include: Period of Disallowance for Noncompliant Financial Relationship;

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Obstetrical Malpractice Insurance Subsidies; Burden of Proof; Ownership or Investment Interest in Retirement Plans; and Alternative Criteria for Satisfying Certain Exceptions.

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While the Proposed Revisions are not the long awaited Stark Phase III regulations, they clearly indicate a desire by CMS to narrow permitted activity in the realm of self-referrals. Further, Phase III promises even further restrictions. If the Proposed Revisions were enacted, it will be necessary to modify and possibly unwind certain existing transactions. It is our understanding that Stark III is imminent. If you would like additional information, please do not hesitate to contact us at 516-393-2200.

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