

Stark III – Nine Areas of Concern



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These proposed Stark III Rules tend to tighten up restrictions rather than add additional opportunities.

The Center for Medicare and Medicaid Services (“CMS”), on July 2nd, published their thoughts relating to the impending Stark III Rules. In addition to certain specific proposed rules, CMS solicited comments on several areas of concern. These proposed Stark III Rules tend to tighten up restrictions rather than add additional opportunities. While many of the proposed changes make sense given ongoing potentially abusive activities, the changes will not be viewed as physician-friendly. Nine of the key concepts that come out of the new proposed Stark rules from July 2nd are as follows:

1. **Anti-Markup Rules.** Currently, several types of imaging services are subject to certain anti-markup rules. For example, a physician cannot purchase an image or a MRI, and resell it to Medicare or Medicaid and profit from such resale. CMS proposed to expand the anti-markup restrictions to apply to a wider variety of services.

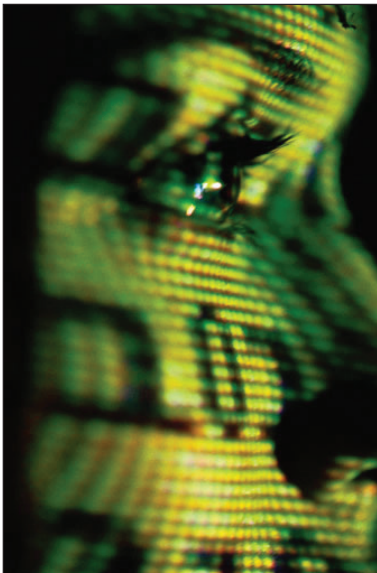
The Purchased Diagnostic Test Rule, or Anti-Markup Rule, currently only applies to the purchased technical component of an imaging service, not to a purchased professional component (that is, a purchased interpretation). CMS published proposed regulations that would subject the professional component of a purchased test to the Anti-Markup Rule as well. Further revisions proposed by CMS include:

- a. The Anti-Markup Rule will be expanded to apply to all arrangements that do not involve reassignment from a full-time employee of the billing entity. That is, billing entities that receive reassignment from part-time employees or independent contractors have the amount they can bill for such professional services limited by the new Anti-Markup Rule.
- b. The performing physician’s net billed charge to the billing entity cannot include any space or equipment lease payments from the performing physician to the billing entity. That is, the new rules will prevent a leasing physician from “charging back” his lease costs to the billing entity in order to inflate his “net charge.”
- c. The anti-markup provision would not apply to the professional component of tests ordered by independent labs, as CMS believes that tests ordered by independent labs do not carry a significant risk of abuse.
- d. CMS is also soliciting opinions as to whether it should apply the Anti-Markup Rule to the technical component provided in the “centralized building” used by a practice pursuant to the in-office ancillary services exception to the Stark Act. However, this restriction is not included among the proposed revisions.

2. **In-Office Ancillary Services.** The commentators express concern with the use of the “centralized building” requirement under the in-office ancillary services exception to the Stark Act. Generally, physicians can provide designated health services through their practice at either a location where they regularly practice (as defined more fully in the

Stark regulations) or at a “centralized building” location. CMS raised concerns that many physician groups are using a centralized building location to meet the in-office ancillary services exception, but really have almost no resources there. That is, the group simply outsources the various components of the testing to contractors who have virtually no relationship to the group practice. CMS outlined the original intent of the in-office ancillary services exception and then observed:

However, services furnished today purportedly under the in-office ancillary services exception are often not as closely connected to the physician practice. For example, pathology services may be furnished in a building that is not physically close to any of the group practice’s other offices, and the professional component of the pathology services may be furnished by contractor pathologists who have virtually no relationship with the group practice (in some cases, the technical component of the pathology services is furnished by laboratory technologists who are employed by an entity unrelated to the group practice). In other words, the core members of the group practice and their staff are never physically present in the contractor pathologist’s office. Similarly, the contractor pathologists do not participate in any group practice activities: they attend no meetings (except for phone calls about individual patients), and do not obtain retirement or health benefits from the group practice. In sum, these types of arrangements appear to be nothing more than enterprises established for the self-referral of DHS.



In previous pronouncements, CMS has contemplated several methods of tightening up the in-office ancillary services exception, such as:

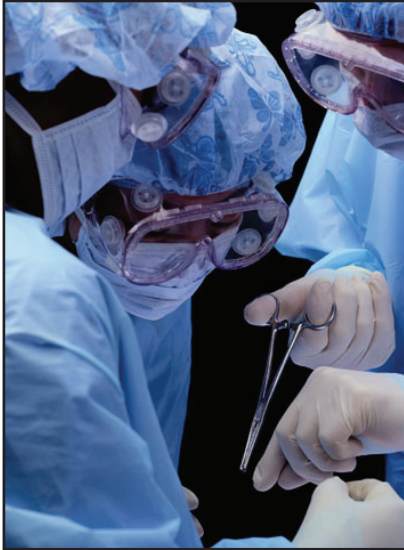
- a. require a minimum size centralized building;
- b. require that all or substantially all of the equipment needed to perform the ancillary services is permanently located in the centralized building space; and/or
- c. require that a group have a full time employee or substantially full time presence at the centralized building.

In the July 2nd publication, CMS requested opinions regarding several additional suggestions designed to curb abuse under the in-office ancillary services exception. CMS requested options on:

- a. whether certain services prone to abuse by outsourcing, such as complex laboratory services, should lose protection of the in-office ancillary services exception;

- b. whether CMS should adopt changes to the definition of “centralized building,” such as those changes suggested above; and
- c. whether the protection of the in-office ancillary services exception should apply to non-specialists who refer for specialist services using equipment that is owned by the non-specialists.

At this point, CMS has determined that its additional rules related to the Anti-Markup Rule may sufficiently address this concern and declined to issue new requirements for the in-office ancillary services centralized building requirement.



3. Under Arrangements. The Center for Medicare and Medicaid Services broadly took a strong stance against “under arrangements” models. CMS acknowledges that under arrangements procedures are increasing and are likely to continue to increase with respect to services furnished after January 1, 2008, as Medicare will pay ambulatory surgery centers approximately 65% of the payment made for the same procedure in a hospital, or under arrangements with a hospital. CMS has essentially stated that most of the existing under arrangements per-click models would be deemed illegal under the new Stark III Rules.

The specific revision proposed by CMS would directly attack the basis of the “under arrangements” model. The Stark Act prohibits physicians from making referrals for a designated health service to an entity in which the physician (or a family member) has a financial relationship. The Stark Act previously defined the “entity” as the person or entity that presented the claim to Medicare, not the person or entity actually performing the designated health service. Therefore, the physician could have a financial relationship with the entity performing the service (such as a joint venture) but not with the entity billing for the service (such as a hospital) without implicating the Stark Act. The proposed rules have expanded the definition of “entity” to include either the person or entity that presented the claim to Medicare *or* the person or entity actually performing the designated health service. Therefore, a relationship with either type of entity will implicate the Stark Act prohibitions.

4. Percentage Based Compensation. CMS assessed different percentage-based relationships in the provider community. CMS decided that percentage-based relationships may still be acceptable to determine payments for direct physician services, but percentage-based payments would not be acceptable for other types of exceptions under the Stark Act. For example, CMS determined that percentage-based equipment and office space leases present the

potential for program abuse. Percentage-based management agreements that go beyond direct physician services could be abusive as well. CMS stated:

Despite our intent that percentage compensation arrangements could be used only for compensating physicians for the physician services they perform, it has come to our attention that percentage compensation arrangements are being used for the provision of other services and items, such as equipment and office space that is leased on the basis of a percentage of the revenues raised by the equipment or in the medical office space. We are concerned that percentage compensation arrangements in the context of equipment and office space rentals are potentially abusive. We note that section 1877(e)(1)(A)(vi) of the Act, which respect to office space rentals, and section 1877(e)(1)(A)(vi) of the Act, which respect to equipment rentals, allow us to impose requirements on office space and equipment rental arrangements as needed to protect against program or patient abuse. Although we are concerned primarily with percentage compensation arrangements in the context of equipment and office space rentals, we believe that there is the potential for percentage compensation to be utilized in other areas as well.



In order to address this situation, CMS proposed to clarify that percentage compensation arrangements:

- a. may only be used for paying for personally performed physician services, and
- b. must be based on the revenues directly resulting from the physician services rather than based on some other factor (such as a percentage of the savings by a hospital department, which is not directly or indirectly related to the physician services provided).

5. **Burden of Proof.** The new rules propose that the burden of proof showing that a physician meets a Stark Act exception fall on the physician or the party ordering or billing for the designated health services, and not on the government. This proposed rule clarifies that it is not CMS's responsibility to prove that a provider has violated the Stark Act prohibitions. Rather, a provider bears the burden of proof in showing that an exception is met or that a particular arrangement does not implicate a designated health service.

6. **Obstetrical Malpractice Insurance Subsidy.** CMS has already provided an exception for a subsidy for a physician's obstetrical malpractice insurance coverage. CMS has not proposed any rules to revise or eliminate this exception. However, CMS is soliciting opinions as to whether certain elements should be added in order to provide more stringent requirements to meet this exception. These elements include the necessity of a written agreement, physician certification that a certain percentage of patients reside in a medically underserved area, and the requirement that the

subsidy not be based on referrals from the physician or vary due to the volume or value of referrals from the physician. In general, these new requirements would make it more difficult to meet the exception required to provide a subsidy for obstetrical malpractice insurance coverage.

7. **Per-Click Leases.** The proposed rules also provide certain limitations on per use or “per-click” space and equipment leases. Stark Act regulations specifically provide that per-click arrangements can be considered “set in advance” for the purposes of the space and equipment lease exceptions. CMS proposed language that would prohibit a physician lessor from making referrals to an entity lessee, as this seems to CMS to pose a clear risk of abuse. CMS stated:



After reconsidering the issue, we are 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 to the entity. We believe that such arrangements are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee, and we would disallow such per-click payments, using our authority under section 1877(e)(1) of the Act, even if the statute does not expressly forbid per-click payments to a lessor for patient referred to the lessee.

The proposed language in the equipment and space lease exceptions reads: “Per unit-of-service rental charges are not allowed to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.” In addition to the limitation provided in the proposed regulations, CMS is also soliciting opinions as to whether per-click leases should be prohibited between entity lessors (such as a hospital) and physician lessees. The new rule will effectively eliminate per-unit or per-click leases for space and equipment rentals.

8. **Stand in the Shoes.** Under the original Stark Rule, there was an argument that certain indirect compensation relationships would not violate the Stark Act. For example, a hospital might own a clinic or foundation, and that clinic or foundation would employ physicians. The relationship between the hospital and the employed physicians, in this example, was indirect so as to not implicate the Stark Act. CMS determined that some of these relationships may be abusive:

We believe that it is necessary to collapse the type of relationship discussed above to safeguard against program abuse by parties who endeavor to avoid the application of the physician self-referral requirements by simply inserting an entity or contract into a chain of financial relationships linking a DHS entity and a referring physician.

Under the proposed rule, the hospital owner of the clinic or foundation would “stand in the shoes” of the clinic or foundation and the relationship between the physicians and the foundation or clinic would need to meet a Stark exception as though the hospital were a direct employer of the physicians.

9. **Other Issues.** The proposed CMS requirements, in addition to touching on the issues described above, also impose a number of additional technical requirements and requests for further discussion. Some of these items deal with CMS’ views regarding inadvertent violations of the Stark Act and the manner of curing inadvertent violations. Certain other items deal with other compliance rules.

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Overall, the new Stark rules show an increased tendency of the government to crack down on what they view as abusive use of certain Stark exceptions.