CMS Issues Final Phase III Regulations – Significant Impact on Physician-Hospital and Physician-Driven Relationships



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he Center for Medicare and Medicaid Services ("CMS"), on September 5th, published a final rule implementing Phase III of Part II of the Stark Act (the "Stark III Regulations").¹ CMS, in addition to revising certain elements of the Stark Act, responded to commentary regarding the elements it had changed and the elements still under consideration for revision. Generally, the Stark III Regulations tend to tighten up restrictions rather than add additional opportunities. While many of the revisions to the Stark Act restrictions make sense given ongoing potentially abusive activities, the changes will not be viewed as physician-friendly. The Stark III Regulations are effective as of December 4, 2007. With only a few exceptions, all financial relationships subject to the Stark Act prohibitions must be compliant with a Stark Act exception at that time.

The Stark III Regulations reflect actual changes made by CMS regarding the Stark Act and physician referral issues. The 2008 Medicare Physician Fee Schedule (the "MPFS"), 2 published by CMS on July 12th, presents additional concerns and considerations applicable to certain provisions of the Stark Act in the form of proposed regulations and requests for comments. These items may or may not ultimately be adopted into law.

This article sets forth an overview of the key revisions presented in the Stark III Regulations and the MPFS. Each of the key points contains a description of the revision and a brief discussion on the impact of this change on physicians and their practices.

I. Stark II Phase III

The key provisions of the Stark III Regulations and a short summary of each are as follows:

1. "Stand in the Shoes": A physician's relationship with an entity providing designated health services (such as a hospital) through a direct single intervening physician organization (such as a group practice) may no longer take advantage of the favorable provisions of the Stark Act's indirect compensation exception. The physician is deemed to "stand in the shoes" of his or her physician organization. Therefore, the relationship between the physician organization itself and the entity providing designated health services must meet a Stark Act exception.

The Stark III Regulations, in making this change, tighten a bit the indirect compensation exception. The indirect compensation exception is still available for compensation relationships where there is more than one entity between the provider of designated health services and the physician, so long as the physician is paid in a manner that does not reflect the volume or value of referrals to the entity providing the designated health services.

2. Shared Space: To the extent a physician or practice utilizes the Stark Act's in-office ancillary services exception to provide designated health services to patients (such as imaging or clinical lab services), such services must truly be provided in office or must be leased on a block-time basis, rather than a per-click basis.

⁷² Fed. Reg. 51012 et seq. (September 5, 2007)

^{2 72} Fed. Reg. 38122 et seq. (July 12, 2007)

- 3. Independent Contractors: Group practices which obtain the services of an independent contractor physician (such as a pathologist or radiologist) in connection with the provision of designated health services must contract with that physician directly. Contracting with the physician's practice or a staffing service will not allow the group practice to bill for the independent contractor's services as a "physician in the group practice."
- 4. Recruited Physicians: Group practices which accept economic assistance for the recruitment of a physician must abide by certain new accounting rules which have been tightened and must abide by certain restriction which have been loosened as to non-competition items.
- 5. Academic Medical Centers: The Stark III Regulations make some clarifications to the academic medical center exception. The academic medical center exception as a whole provides greater latitude as to specific compensation payments as long as the aggregate compensation paid is at fair market value. Key clarifications are (i) the requirement to aggregate physician faculty member compensation relationships in order to determine fair market value, and (ii) the method for counting faculty member physicians.
- 6. Productivity Bonuses: The Stark III Regulations permit payment of a productivity bonus to a physician for income directly derived from designated health service referrals that are "incident to" the physician's performance of services. Because this benefit is limited to productivity bonuses but not profit sharing, and because referrals truly "incident to" the physician's referrals are generally few, this expansion is of limited practical effect.
- 7. Fair Market Value: The Stark Act's fair market value exception has been expanded to include arrangements whereby a physician makes payments to an entity providing designated health services (such as a payment for health services), and not just to situations where an entity makes payments to a physician (such as a medical director agreement).
- 8. Amendments: The Stark III Regulations clarified that amendments to agreements implicated by the Stark Act are acceptable so long as the economic elements of the agreement (such as the rate of physician compensation or the square footage of a lease) remain materially unchanged by the amendment.
- 9. Holdovers: The Stark III Regulations specifically allow for month-to-month holdover payments after the expiration of a rental agreement or a personal services arrangement (such as an agreement with a pathologist or radiologist) for up to six months and so long as the terms and conditions of the expired agreement do not change during the holdover period.
- Other Issues: The Stark III Regulations provide additional clarifications and minor revisions which provide some practical advice regarding nonmonetary compensation, compliance training and professional courtesy.

1. "Stand in the Shoes"

a. Changes to the Indirect Compensation Arrangement Definition and Exception

CMS, in an attempt to "clos[e] an unintended loophole in the definition of indirect compensation arrangement" thereby "reduce[ing] the risk of fraud and abuse" has amended the Stark Act to expand the "stand in the shoes" concept to group practices and other physician organization when applying the rules for direct and indirect compensation relationships.³ Essentially, as a result of the change, compensation relationships between entities providing designated health services and group practices or other physician-owned entities where there is one link between the physician and the entity providing designated health services will be treated as a compensation relationship directly between the entities and the physician for purposes of the Stark Act.

The Stark Act defines the types of financial arrangements which are subject to the physician referral prohibition. It draws a distinction between direct and indirect compensation relationships, with different exceptions available for each.4 Generally speaking, the exceptions available for direct compensation relationships have stricter requirements than the exception for indirect compensation relationships. Prior to the Stark III Regulations, direct compensation relationships were those between an entity providing designated health services and a referring physician, such as a lease between a hospital and a physician. CMS had also adopted a "stand in the shoes" rule pursuant to which a compensation relationship between an entity providing designated health services and a physician's whollyowned professional corporation was deemed to be a direct compensation relationship. The Stark III Regulations have further expanded the "stand in the shoes" concept to include "physician organizations" such as a referring physician's professional corporation, physician practice or group practice. Therefore, "when a physician stands in the shoes of his or her physician organization, he or she will be deemed to have the same compensation arrangement (with the same parties and on the same terms) as the physician organization has with the DHS entity."6 Therefore, under the Stark III Regulations, any compensation relationship between an entity which provides designated health services and a physician group practice or other physician owned entities will be deemed a direct compensation relationship and must meet a Stark Act exception as though the physician were a directly contracting party.

The regulations also make clear that the "parties" covered by the "stand in the shoes" concept include all physician members, employees and independent contractors of a physician organization, and thus each of these individuals must comply with an applicable Stark exception. CMS offered this example:

[I]f a DHS entity leases office space to a group practice, the lease will be deemed to be a direct compensation arrangement with each physician in the group practice, and the lease will need to

^{3 72} Fed. Reg. 51026

^{4 42} C.F.R. § 411.354

^{5 72} Fed. Reg. 51028

⁶ Id.

fit in the exception for rental of office space in § 411.357(a) if the DHS entity wants to submit claims for DHS referrals from those physicians.⁷

As of December 4, 2007, all compensation arrangements must be analyzed under the "stand in the shoes" provisions in order to determine whether a direct or indirect compensation relationship exists, and what corresponding exceptions may be available. However, the Stark III Regulations have established a transition period whereby any arrangements that were in existence prior to September 5, 2007 (the publication date of the Stark III Regulations) need not be amended during the original term of the arrangement or the current renewal term. Such arrangement may continue to use the indirect compensation exception as though the revised "stand in the shoes" requirement does not apply, but only for the duration of the current term.⁸

b. Impact of Change

The expansion of the "stand in the shoes" concept will likely have significant implications on the structure of arrangements between physicians and entities providing designated health services. Whereas prior to the Stark III Regulations, an arrangement between a physician group practice and a hospital arguably only needed to satisfy the more liberal indirect compensation exception, now these arrangements must meet all of the requirements of the direct compensation arrangement exceptions. For example, an agreement between a hospital and a group of physicians for the provision of hospitalist services must now meet all of the requirements to the personal services exception to the Stark law.

The changes to the "stand in the shoes" concept may also have a significant impact in the academic medical center ("AMC") setting. For example, if the hospital component of an AMC is an organization separate and distinct from the university and operates a faculty practice plan as part of the university's medical school, prior to the Stark III Regulations, any financial relationship between the hospital and the university, with respect to the physicians, would be indirect. Now, the arrangement needs to meet either the tests applicable to a direct relationship or the more liberal tests applicable to an academic medical center. These relationships will no longer be able to meet the indirect compensation exception. The aggregate compensation from the hospital to the practice plan or similar entity must be at a fair market value in order to meet a Stark exception. Additionally, compensation to the individual physicians must not be based on the volume or value of referrals by a physician to the hospital.

2. Shared Space Issues

a. Clarification of the "Same Building" Requirement

The in-office ancillary services exception to the Stark Act permits physicians and group practices to order and provide many designated health services truly ancillary to medical services. Ancillary services provided by physicians or their practices may include lab services and imaging services. These ancillary services must be provided in the "same building" where the physician or the physician's practice routinely

⁷ Id.

⁸ Id.



provides the full range of medical services. That is, in the building where the ancillary designated health services are provided, the physician or group practice must spend at least some minimum number of hours providing medical services unrelated to the furnishing of designated health services.⁹

CMS acknowledges that the in-office ancillary services exception is "one of the most important exceptions to the physician self-referral prohibition." In the Stark III Regulations, CMS made no substantive changes to this exception, but responded to many comments regarding this exception's implementation. One commenter asked whether the costs and administration of a facility offering designated health services (such as an imaging suite or clinical laboratory) could be shared by several practices within the same building simultaneously. CMS responded by stating that the practices must enter into separate leases for blocks of time with the designated health services facility. Specifically, CMS responded:

A physician sharing a DHS facility in the same building must control the facility and the staffing (for example, the supervision of the services) at the time the designated health service is furnished to the patient. To satisfy the in-office ancillary services exception, an arrangement must meet all of the requirements of § 411.355(b), not merely on paper, but in operation. As a practical matter, this likely necessitates a block lease arrangement for the space and equipment used to provide the designated health service. Shared facility arrangements must be carefully structured and operated (for example, with respect to billing and supervision of the staff members who provide DHS in the facility). We note that common peruse fee arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary services exception and may implicate the antikickback statute.11

Despite the lack of substantial change to the in-office ancillary services exception, CMS indicated that it is carefully reviewing whether certain types of designated health services should be subject to protection under this exception at all. CMS stated: "We are considering whether certain types of arrangements, such as those involving in-office pathology labs and sophisticated imaging equipment, should continue to be eligible for protection under the in-office ancillary services exception." An increasing number of practices, particularly larger practices, utilize the in-office ancillary services exception to provide lab and imaging services to their patients. CMS' intent is to assure that the group is truly the provider of such ancillary services.

⁹ The specific number of minimum hours is based on which of three alternative tests the physician or group practice elects to use to satisfy the "same building" element of the exception. See 42 C.F.R. § 411.351.

^{10 72} Fed. Reg. 51032

¹¹ ld. at 51033

¹² Id. at 51034

b. Impact of Change

To the extent a physician or his or her practice utilizes the in-office ancillary services exception to provide designated health services to patients (such as imaging for CT/MRI procedures or a clinical laboratory for lab services), the Stark III Regulations emphasize that such services must be leased on a block-time basis, rather than a per-click basis. A physician or group must provide independent control and staffing pursuant to a block-lease structure. This means that the physician or practice takes on the economic risk of underutilization during the block of time. If an imaging facility is only used twice a day by a practice under a per-click lease arrangement, it is the imaging provider that suffers from the lost utilization. However, if the imaging facility is only used twice during a day when it is block-leased exclusively by the practice, it is the practice that suffers from the lost utilization. Therefore, the Stark III Regulation's emphasis on block leasing over per-click arrangements is intended to help assure the practice is the provider and as a consequence may subject physicians and their practices to greater economic risk.

Furthermore, physicians and groups relying upon per-click lease arrangements should monitor future CMS guidance on this issue. In addition to the potential revisions discussed in the Stark III Regulations regarding the in-office ancillary services exception, the Medicare Physician Fee Schedule for 2008 proposed (but did not enact) several revisions regarding the use of per-click leases with respect to the space and equipment rental exceptions.

3. Independent Contractor Contract Requirements

a. Changes to the Definition of "Physicians in a Group Practice"

An independent contractor physician who qualifies as a "physician in the group" is eligible for protection under the physician practice exception and the in-office ancillary services exception, and services performed by the independent contractor can be billed directly by the group practice. In the Stark III Regulations, CMS has further restricted arrangements whereby an independent contractor will be deemed a "physician in the group practice" by adding the requirement that contracts for the provision of services be directly between the independent contractor physician and the group practice. Contracts between the group practice and another entity, such as a staffing company, do not establish the independent contractor as a "physician in the group practice." Therefore, the group practice is not able to accept reassignment of services from the performing physician and bill for those services.

While CMS includes such independent contractors as "physicians in the group practice," it explicitly declined to extend the definition of "physicians in the group practice" to other types of employment relationships, including leased or borrowed physicians who are employees or independent contractors of another entity. CMS explained this distinction, stating:

Group practices receive favorable treatment under the physician self referral law with respect to physician compensation. Accordingly, we believe that, in order to qualify as a group practice and receive such favorable treatment, the



group practice's physicians must have a strong and meaningful nexus to the group practice. An independent contractor in direct contractual privity with a group practice has such a nexus; employees leased from other entities do not. We believe this justifies excluding a leased employee from being a "physician in the group practice," contrary to the commenter's assertion that there is no distinction between an independent contractor and a leased employee.¹³

CMS also declined to remove the condition that an independent contractor be considered a "physician in the group practice" only when he or she is performing services on the group practice's premises. The basis for this request was the change in the reassignment provisions which were part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which permitted independent contractor physicians to reassign their claims to a group practice for services performed off-premises. In response, CMS stated that while the Medicare program is "allowed to make payment to an entity that has received reassigned payments pursuant to a contractual arrangement" it is not required to honor those contractual arrangements it believes are "potentially abusive." CMS further stated that an independent contractor physician is considered a physician in the group practice "only when he or she is performing services in the group practice's facilities and, thus, has a clear and meaningful nexus with the group's medical practice."

b. Impact of Change

Direct employment of radiologists or pathologists (rather than engagement of radiologists or pathologists as independent contractors) is not affected by this revision. However, to the extent radiologists and pathologists are not employees of a group, the group may need to alter how it contracts for radiology or pathology services. For example, rather than contract with a group of radiologists to help perform imaging services, the group would need to contract directly with a radiologist in order for the group to bill for the services and as long as the service is to be provided by the group. This is also true when a group practice contracts with a pathologist to assist with lab services.

4. The Recruitment Exception

a. Changes and Clarification to the Exception

The Stark III Regulations make various changes to the physician recruitment exception to both clarify and revise the specific details of the exception. Generally, remuneration paid by a hospital or federally qualified health center to a physician to induce such physician to move to an area served by the hospital and relocate his or her practice qualifies for the recruitment exception if, (i) the arrangement is in writing, (ii) the physician is not required to refer patients to the hospital, (iii) the amount of remuneration does not take into account volume or value of referrals, and (iv) the physician is allowed to establish staff privileges at any other

¹³ Id. at 51018

¹⁴ Id. at 51017

¹⁵ ld.

hospitals and refer business to any other entities. ¹⁶ If the remuneration is paid by the hospital to a group practice to subsidize the recruitment of a physician who will join the group practice and serve the hospital, the exception further requires that (i) the written agreement to be signed by the recruited physician, the hospital and the group practice, (ii) the group practice only be provided actual costs incurred in the recruitment, (iii) any income guarantee made by the hospital to the recruited physician paid to the group practice only cover actual additional incremental costs attributable to the recruited physician, (iv) the hospital maintain records of the pass-through payment for 5 years, (v) the remuneration paid not take into account volume or value of referrals of the recruited physician or the physician practice, (vi) any non-competition provision imposed on the recruited physician not be an unreasonable restriction, and (vii) the arrangement not violate the anti-kickback statute. ¹⁷

The Stark III Regulations make a variety of changes to the recruitment exception, such as expanding the exception to cover recruitment by rural health clinics and changing how the "geographic area served by the hospital" is determined. The Stark III Regulations also clarified that "relocation" requires a physician to move his or her medical practice from outside to inside the geographic area served by the hospital and either (i) move his or her practice at least 25 miles or (ii) derive at least 75% of his or her practice revenue from new patients.¹⁸

CMS made additional changes that directly impact how group practices may interact with a recruited physician. Generally, when a hospital recruits a physician to relocate, the physician joins a new group practice. The group practice members, to a great degree, often provide services at and admit patients to the hospital. Previously, physician practices were prohibited from imposing non-competition covenants on recruited physicians. However, CMS has revised this complete ban to only prohibit practices from "unreasonably restricting" the recruited physician's ability to practice medicine in the geographic area serviced by the hospital. CMS stated that the following restrictions are allowable:

- 1. restrictions on moonlighting;
- 2. prohibitions on soliciting patients and/or employees of the physician practice;
- 3. requiring a recruiting physician to treat Medicaid and indigent patients;
- 4. requiring that a recruited physician not use confidential or proprietary information of the physician practice;
- 5. requiring the recruited physician to repay losses of his or her practice that are absorbed by the practice in excess of any hospital recruitment payments; and

^{16 42} CFR § 411.357(e)(1)

¹⁷ Id. at § 411.375(e)(4)

^{18 72} Fed. Reg. 51048

6. requiring the recruited physician to pay a predetermined amount of reasonable damages (that is, liquidated damages that are not "significant or unreasonable") if the physician leaves the physician practice and remains in the community.¹⁹

CMS's reason for limiting the use of non-competition provisions was:

[i]ntended to discourage physician practices that recruit physicians using hospital funding from making it so difficult for a recruit physician to remain in the community and fulfill his or her commitments under the recruiting agreement with the hospital.²⁰

CMS noted, however, that categorically prohibiting physician practices from imposing non-competition provisions may cause the unintended effect of making it more difficult for hospitals to recruit physicians. Therefore, any restrictions on a recruited physician's practice must not be unreasonable.

CMS also clarified that the physician group could not allocate more than its actual, additional incremental costs associated with the recruited physician in the hospital's income guarantee. The Stark III Regulations clarify that the following costs can be included in "recruiting expenses": tail insurance covering the physician's prior practice, headhunters, and travel expenses during the recruiting period, among others. However, the cost of time spent by the physician group in recruiting is not included in the expenses that may be covered by the income guarantee.²¹ The Stark III Regulations provide the following:

In the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician practice, or directly to a physician who joins a physician practice, the following additional conditions must be met:

- (i) The written agreement in paragraph (e)(1) is also signed by the party to whom the payments are directly made.
- (ii) Except for actual costs incurred by the physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician.
- (iii) In the case of an income guarantee of any type made by the hospital to a recruited physician who joins a physician practice, the costs allocated by the physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician. With respect to a physician recruited to join a physician practice located in

¹⁹ Id. at 51053-54

²⁰ Id. at 51054

²¹ Id. at 51051

a rural area or HPSA, if the physician is recruited to replace a physician who, within the previous 12-month period, retired, relocated outside of the geographic area served by the hospital, or died, the costs allocated by the physician practice to the recruited physician do not exceed either—
(A) The actual additional incremental costs attributable to the recruited physician; or (B) The lower of a *per capita* allocation or 20 percent of the practice's aggregate costs.

- (iv) Records of the actual costs and the passedthrough amounts are maintained for a period of at least 5 years and made available to the Secretary upon request.
- (v) The remuneration from the hospital under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.
- (vi) The physician practice may not impose on the recruited physician practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital.
- (vii) The arrangement does not violate the antikickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.²²

b. Impact of Change

The changes in the recruitment exception should make it easier for practices and hospitals to work together to recruit new physicians to a community.

The changes in the recruitment exception will allow group practices to impose some level of restriction on such physicians as specifically noted and permitted in the Stark III Regulations. The rules also clarify certain rules required in accounting for expenses related to recruitment and as to calculation of income guarantees.

5. Academic Medical Centers

a. Changes to the Exception for Academic Medical Centers

The Stark III Regulations, in addition to the "stand in the shoes" change and possible impact discussed previously, presented some minor clarifying changes to the Academic Medical Center ("AMC") exception to the Stark Act with respect to the conditions on the compensation paid to AMC physicians and the definition of an "academic medical center." CMS also clarified issues related to the qualification of newly-affiliated hospitals as AMCs and the application of the indirect compensation arrangement exception in the AMC setting.

In order to qualify for the AMC exception, the compensation paid by the AMC to faculty physicians must meet specific conditions. In response to confusion about these specific conditions (notably, whether compensation paid by each component of the AMC must be fair market value), CMS outlined the required conditions for faculty physician compensation as follows:

- 1. The actual dollar amount of the referring faculty physician's compensation need not be set in advance, but rather it is sufficient for the contribution of each component of the AMC to the aggregate compensation satisfy the set in advance requirements;²³
- 2. If a faculty physician is paid by more than one component, each payment arrangement must not take into account volume or value of referrals or other business generated within the AMC; and
- 3. The total aggregate compensation paid to the faculty physician cannot exceed fair market value.²⁴

This clarification that the compensation paid by each single component is not required to comply with fair market value; rather, all compensation in the aggregate cannot exceed fair market value.

Included in the definition of an "academic medical center" for purposes of this exception are "one or more affiliated hospitals in which the majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admission is made by physicians who are faculty members."²⁵ The Stark III Regulations clarify how an affiliated hospital should count courtesy staff when calculating the "majority" discussed above. CMS stated:

We are modifying § 411.355(e)(2)(iii) to clarify that, if a hospital elects to include or exclude a physician holding a particular class of privileges (for example physicians holding courtesy privileges), the hospital must include or exclude, respectively, all individual physicians with the same class of privileges at the affiliated hospital when determining whether the majority of



²³ These requirements are outlined in § 411.354(d)

^{24 72} Fed. Reg. 51037

²⁵ Id. at 51090

the physicians on its medical staff are faculty members of the affiliated medical school or are on the faculty of the educational programs at the accredited academic hospital.²⁶

Therefore, in determining whether a hospital meets the physician-majority test of the AMC definition, the hospital must consistently include or exclude physicians holding a particular class of privileges. In a related action, CMS declined to institute a transition period for newly-affiliated hospitals that fail to meet the above discussed majority tests, even if such hospital is in the process of increasing the number of physicians on its medical staff who are faculty members. CMS took a hard line, stating, "the regulation is clear that all conditions must be met at the time the referral is made."²⁷

Finally, a commentor requested clarification on the applicability of the indirect compensation arrangements exception in the AMC setting. While CMS confirms that the indirect compensation arrangement may apply to arrangements involving AMCs and physicians, the commentary and the rule do not expand on this application.²⁸

b. Impact of Change

The Stark III Regulations do not make substantive changes to the AMC exception, but rather clarify some of its provisions. Compensation relationships between AMCs and faculty physicians and practices vary widely, from a straight salary paid by the faculty group practice to situations where portions of the physician's salary and other income come from separate components including the university, hospital, and others. The Stark III Regulations clarify that the purpose of the AMC exception is to protect compensation received by physicians from all components of the AMC, not only to compensation from the component with which he or she has an employment relationship. Therefore, the AMC need not determine if each component providing compensation to a faculty physician is complying with fair market value, but rather the aggregate compensation paid to faculty physician paid by the AMC must not exceed fair market value. Rather than looking solely at his or her salary from his or her primary employer, faculty physicians should scrutinize their total compensation received from any component of the AMC to ensure that it does not exceed fair market value.

The Stark III Regulations also clarify that when counting physicians for purposes of determining whether a majority of the physicians on the staff of a hospital are faculty members, the AMC must be consistent in either including or excluding courtesy staff members for purposes of calculations. AMCs should verify whether the hospital staff meets the majority test.

²⁶ Id.

²⁷ Id. at 51038

²⁸ Id.

6. Productivity Bonuses and "Incident to" Referrals

a. Compensation to Physicians in a Group Practice

The current Stark Act regulations prohibit compensation payments to members of a group practice based on the volume or value of a physician member's referrals.²⁹ However, the regulations contain an exception that allows profit sharing and productivity bonuses based *indirectly* on referrals of designated health services, as follows:

A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services that he or she has personally performed (including services "incident to" those personally performed services as defined in § 411.351), provided that the share or bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician.³⁰

In the Stark III Regulations, CMS has clarified that although profit sharing may not be directly based on referrals, it is appropriate to provide physicians with productivity bonuses based directly on the physician's performance of services and on services "incident to" the physician's performance of services. As a result, the Stark III Regulations revise the language provided above to read:

A physician in the group practice may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician. A physician in the group practice may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).31

This revised language permits payment of a productivity bonus to a physician based on referrals for designated health services "incident to" the physician's performance of services (such as physical therapy or outpatient prescription drugs), but not referrals for other designated health services (such as diagnostic tests or hospital admissions).³² Unfortunately, few designated health services are clearly and directly "incident to" a physician's services, so this benefit is of little practical effect. Furthermore, profit shares, which encompass income from a large variety of services, may not be distributed to a physician in a way that directly relates to the physician's referrals.

^{29 42} C.F.R. § 411.352(g)

³⁰ Id. at § 411.352(i)(1)

^{31 72} Fed. Reg. 51023

³² Id. at 51024

b. "Incident to" Referrals

The Stark Act does not provide an independent definition for referrals that are provided "incident to" a physician's personally performed services. Instead, the Stark Act definition refers to Medicare coverage and payment rules, as follows:

"Incident to" services means those services that meet the requirements of section 1861(s)(2)(A) of the Act, 42 CFR § 410.26,³³ and section 2050 of the Medicare Carriers (CMS Pub. 14-3), Part 3 – Claims Process, as amended or replaced from time to time.³⁴

In order to conform the Stark Act definition to the Medicare coverage and payment rules, the Stark III Regulations have revised this definition to apply not just to "services" but to "services and supplies". 35

CMS stated that this tie to the Medicare rules is appropriate and rejected a comment to separate "incident to" services for Stark purposes and "incident to" services for the purposes of Medicare billing. Although income from "incident to" services derives from a referral, CMS stated that this income may be appropriately calculated in a physician's compensation. CMS commented:

We do not believe that our "incident to" billing rule in § 410.26 is inconsistent with the language of section 1877(h)(4)(B)(i) of the Act. Although "incident to" services are referrals for purposes of section 1877 of the Act, we believe that the Congress intended that these services nonetheless may be considered when calculating a physician's productivity bonus. For those services that are appropriately billed "incident to" under current Medicare rules, the group practice physician to whose personally performed services the "incident to" services are incidental (that is, the ordering physician) may be paid a productivity bonus or profit share consistent with the special rules for such compensation set forth in § 411.352(i).36

This reference is to the Medicare regulations which provide, at 42 C.F.R. §410.26(b): Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).

⁽¹⁾ Services and supplies must be furnished in a noninstitutional setting to noninstitutional patients.

⁽²⁾ Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.

⁽³⁾ Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).

⁽⁴⁾ Services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner).

⁽⁵⁾ Services and supplies must be furnished under the direct supervision of the physician (or other practitioner). The physician (or other practitioner) directly supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

⁽⁶⁾ Services and supplies must be furnished by the physician, practitioner with an incident to benefit, or auxiliary personnel.

⁽⁷⁾ A physician (or other practitioner) may be an employee or an independent contractor.

^{34 42} C.F.R. § 411.351

^{35 72} Fed. Reg. 51081

³⁶ Id. at 51016

c. Impact of Change

The Stark III Regulations now specifically permit productivity bonuses based on referral of designated health services, but only for those services that are "incident to" a physician's personally performed services. However, only income from those services truly "incident to" the physician's performance of services (such as administration of drugs) may be included in such a productivity bonus. Income derived from referrals for services that are not "incident to" the physician's personally performed services (such as hospital admissions, research for labs or imaging services, or diagnostic tests to determine whether other conditions exist) may not be directly distributed as a productivity bonus. Income from services not truly "incident to" a physician's services must instead be indirectly allocated to physicians (such as in the same manner as overall profits).

Overall profits cannot be directly based on a physician's referrals for designated health services, and must be indirectly based on income derived from such referrals (such as, by being pooled and then distributed pro rata to all owners). Group practices should review profit sharing and productivity bonus formulae for compliance with the Stark Act.

7. Fair Market Value Safe Harbor and Exception

a. Elimination of the Fair Market Value Safe Harbor as a Means of Demonstrating Compensation Fairness

The last phase of the Stark Act had created a "safe harbor" in the definition of "fair market value" for hourly payments to physicians for their personal services. Although acknowledging that several methods of calculating fair market value exist, pursuant to this provision, CMS would automatically deem the following compensation calculation methodologies to be fair market value: (i) an hourly payment less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, and (ii) the 50th percentile national compensation level based on one of several specified, recognized surveys. CMS received numerous objections to the prescriptive nature of these methodologies from commentors urging more flexibility, as well as complaints about the unavailability of the surveys identified in the safe harbor, and thus has eliminated the safe harbor. However, CMS emphasized that it will continue to scrutinize the fair market value of arrangements and that reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value of physician compensation.37

In response to specific comments, CMS made two additional noteworthy statements regarding the fair market value hourly rate compensation. While a fair market value rate may be used to compensate a physician for both clinical and administrative work, CMS specifically noted that there may be a distinction between the rate paid to a physician for administrative work as opposed to the rate paid to a physician for clinical work. Finally, CMS confirmed that a fair market value hourly rate could be used to determine an annual salary, provided that the hourly multiplier used to calculate such salary accurately reflected the number of hours a physician actually worked.³⁸



⁷ Id. at 51015

³⁸ Id. at 51016

b. Expansion of the Fair Market Value Exception

Prior to the issuance of the Stark III Regulations, the fair market value exception protected arrangements whereby an entity providing designated health services paid compensation to a physician, family member of a physician, or group of physicians for the provisions of items or services if the arrangement met five specific requirements. The Stark III Regulations expand the fair market value exception to also include compensation made from a physician to an entity providing designated health services. Therefore, the fair market value exception now covers payment made from the entity to a physician, as well as from the physician to an entity, provided:

- 1. The arrangement is set out in a writing signed by the parties describing the items or services;
- 2. The writing sets out a timeframe for the arrangement;
- 3. The writing specifies the compensation, which must be set in advance, consistent with fair market value, and not determined in a manner that takes into account volume or value of the physician's referrals;
- 4. The arrangement is commercially reasonable and furthers the legitimate business purpose of the parties; and
- 5. The arrangement does not violate the anti-kickback statute or involved the promotion of any business arrangement that violates state or federal law.³⁹

In addition, the Stark III Regulations clarify that the fair market value exception does not apply to the leases of office space, but that such arrangements must fit the stricter lease of office space exception.⁴⁰ CMS stated,

[B]ecause space leases have been subject to abuse, we believe that the use of the fair market value compensation exception for space leases may pose a risk of program or patient abuse.⁴¹

c. Impact of Change

Because the fair market value safe harbor was voluntary and due to the difficulty in using the specific "safe harbor" methodologies provided, many compensation arrangements did not utilize the safe harbor for physician hourly wages. As a result, the elimination of the safe harbor should not be of major consequence. Parties should be aware that compliance with either of the two methodologies will no longer be sufficient to prove fair market value compensation. However, use of these methodologies would still help prove that a compensation relationship complies with fair market value if ever challenged.

The change to the fair market value exception has a much larger impact. By expanding the fair market value exception to include payments by

³⁹ Id. at 51059

⁴⁰ Id.

⁴¹ Id.

a physician to an entity providing designated health services, CMS has effectively eliminated the payment by physician exception. This should overall make it easier to analyze relationships and Stark Act exceptions. The distinction between the two exceptions is important as the conditions for qualification under the fair market value exception are more cumbersome than that payment by physician exception. Physicians should note that the purchase of health care services from an entity providing designated health services must satisfy all of the requirements of the fair market value exception, including but not limited to a written agreement, signed by the parties, with compensation set in advance. However, the fair market value exception can not be used for lease of space agreements, thus any traditional or time-block lease arrangement must comply with the lease of space exception.

8. Amendments

a. Amendments to Compensation Arrangements

Many compensation arrangement exceptions to the Stark Act, such as the personal services exception and the rental of office space and equipment exceptions, have certain similar requirements. For example, all three exceptions require that the compensation rate or rental rate be "set in advance," that the rate be at a fair market value, that the rate not vary due to the volume or value of referrals, and that the agreement be for a term of at least one year (if the agreement is terminated within the first year, the parties may not enter into a substantially similar agreement until the first year of the original term has expired). These conditions have raised questions pertaining to amendments of agreements protected by these exceptions during the first year of the agreement.

In the Stark III Regulations, CMS provided some clarification regarding these types of amendments. Regarding the "set in advance" requirement, CMS reiterated that this requirement does not mandate a fixed rate, but also encompasses a fixed time-based or unit-of-service-based methodology that permits calculation of the rate during the term of the agreement (such as certain percentage-based compensation rates). CMS clarified that: "amendments are permissible under the 'set in advance' definition if they are made for *bona fide* reasons unrelated to the volume or value of referrals or other business generated between the parties. However, parties must still satisfy all requirements of an exception, including any requirements bearing on amendments of agreements."⁴²

Regarding amendments to agreements for rental of office space or equipment, CMS provided the following specific guidance:

[R]ental charges for the rental of office space and equipment must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. In addition to these and other requirements, the written agreement must provide for at least a 1-year term. An amended lease agreement must comply with these four criteria, as well as the remaining conditions of

the exception. Changes to the rental charges (including changes to the methodology for calculating the rental charges) and changes to certain other terms that are material to the rental charges (for example, a change to the amount of space rented) may jeopardize compliance with one or more of these four criteria [...].

Parties may amend a lease agreement multiple times during or after the first year of its term, provided that the rental charges are not changed and all other requirements of the exception are satisfied. However, changes to terms that are material to the rental charges, such as the amount of space leased, may cause the rental charges to fall out of compliance with the fair market value and "volume and value of referrals" requirements. For example, if the original rental charges were \$5,000 per month for 200 square feet of space and the amended lease added 100 square feet of space but did not require additional payment beyond the original monthly payment of \$5,000, the rental charges under the new agreement likely would not be consistent with fair market value and may take into account the volume or value of referrals or other business generated between the parties.

An amended agreement need not continue for an additional 1 year following its amendment if the original termination date of the agreement would occur sooner. Rather, because the exceptions in § 411.357(a) and (b) require a term of 1 year from the inception of the lease or rental agreement, the amended agreement may terminate upon the original expiration date, provided that the original term of the agreement is at least 1 year. As we noted above, rental charges may not be amended.⁴³

b. Impact of Change

A physician or group wishing to amend a compensation agreement protected by a Stark Act exception (including a personal services arrangement, a space rental agreement, or an equipment rental agreement) should identify the specific terms that are being amended. To the extent that solely non-economic terms are being amended, the amendment is likely acceptable and permitted under the Stark III Regulations' guidance. However, amendments that alter the economic terms of the agreement

(such as changes in compensation, rental rates, or the specific space or items being leased) should be analyzed to confirm that the amended economic terms continue to reflect fair market value.

Although non-economic amendments are generally acceptable under the guidance provided in the Stark III Regulations, no amendment should be made that would reflect the volume or value of physician referrals. In addition, the amended agreement must continue to fit within an appropriate exception to the Stark Act.

9. Holdover Payments

a. Space and Equipment Rental Exceptions

The space and equipment rental exceptions to the Stark Act currently provide that, immediately upon termination of an existing lease agreement of at least one year, a "holdover" month-to-month lease upon the same terms is permitted, so long as the duration of the lease holdover is for not more than six months. Generally, this "holdover" period is intended to keep parties that are winding down an otherwise-proper lease agreement (such as, by taking actions to evict a tenant) from falling out of compliance with the Stark Act. In the Stark III Regulations, CMS discussed whether a rental premium is appropriate, or whether a rental premium would violate the requirement that such a holdover be on the same terms as the expired lease. CMS stated:

We agree that lessors can charge a holdover rental premium, provided that the amount of the premium was set in advance in the lease agreement (or in any subsequent renewal) at the time of its execution and the rental rate (including the premium) remains consistent with fair market value and does not take into account the volume or value of referrals or other business generated between the parties.

b. Personal Service Arrangements Exception

The Stark III Regulations also establish a similar holdover period in the personal service arrangements exception in order to protect arrangements that have fallen out of compliance. CMS stated:

[W]e are establishing a 6-month holdover provision for personal service arrangements that otherwise meet the requirements in [the personal service arrangements exception]. We believe that this provision, along with the holdover provisions already available in the exceptions for the rental of office space and equipment [...], should provide adequate relief to parties to arrangements of these types that would otherwise temporarily fall out of compliance with the physician self-referral law.⁴⁴



c. Impact of Change

Although a physician or group may temporarily rely upon a holdover period upon the expiration of a rental agreement or personal service arrangement (such as an agreement for professional services), the same terms and conditions will apply for the duration of the holdover period. Furthermore, the Stark III Regulations permit a premium during the time of such holdover, as long as the premium is set forth in the agreement.

9. Minor Revisions from the Stark III Regulations

The Stark III Regulations present additional clarifications and minor revisions which provide some practical advice to be used in operations. These practical tips implicate the Stark Act exceptions regarding nonmonetary compensation, compliance training and professional courtesy.

a. Nonmonetary Compensation Exception

The Act provides that nonmonetary compensation that does not exceed \$300 per year (adjusted annually for inflation) does not create a compensation arrangement if (i) the compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician;(ii) the compensation is not solicited by the physician or the physician's practice; and (iii) the compensation arrangement does not violate Federal or state law.⁴⁵ This exception was broadened as follows:

This Phase III final rule makes two substantive changes to § 411.357(k): (1) The revised exception allows physicians to repay certain excess nonmonetary compensation within the same calendar year to preserve compliance with the exception; and (2) the revised exception allows entities, without regard to the dollar limitation in § 411.357(k)(1), to provide one medical staff appreciation function (such as a holiday party) for the entire medical staff per year. We are also clarifying that the aggregate limit in § 411.357(k)(1) is to be calculated on a calendar year basis.⁴⁶

b. Compliance Training Exception

The current Stark Act provides an exception for compliance training provided to a physician (or a physician's office staff) by any entity offering designated health services (such as a hospital).⁴⁷ Previously, this compliance training exception excluded any program for which continuing medical education ("CME") credit was available. The Stark III Regulations broadened this exception to include programs that offer CME

^{45 42} C.F.R. § 411.357(k)

^{46 72} Fed. Reg. 51058

^{47 42} C.F.R. § 411.357(o)

credit, so long as compliance training predominates. ⁴⁸ On-line training also meets this exception, so long as such training is accessed locally by the physician. ⁴⁹ This expands the opportunities for compliance training available to physicians from local hospitals.

c. Professional Courtesy Exception

The last phase of the Stark Act created an exception for the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff. To qualify for the exception, the arrangement must meet the following conditions: (i) the professional courtesy is offered to all physicians on the entity's bona fide medical staff or in the entity's local community without regard to the volume or value of referrals or other business generated between the parties; (ii) the health care items and services provided are of a type routinely provided by the entity; (iii) the entity's professional courtesy policy is set out in writing and approved in advance by the governing body of the health care entity; (iv) the professional courtesy is not offered to any Federal health care program beneficiary without a good faith showing of financial need; (v) if the professional courtesy involves any complete or partial waiver of any coinsurance obligation, the insurer is informed in writing of the reduction so that the insurer is aware of the arrangement; and (vi) the professional courtesy arrangement does not violate the anti-kickback statute or any billing or claims submission laws or regulations.⁵⁰ In the Stark III regulations, CMS revised the professional courtesy exception slightly, as follows:

This Phase III final rule makes one substantive change to §411.357(s), deleting the requirement that an entity notify an insurer when the professional courtesy involves the whole or partial reduction of any coinsurance obligation. We have also modified the exception to make clear our intent that §411.357(s) applies only to hospitals and other providers with formal medical staffs.⁵¹

II. <u>2008 Medicare Physician Fee Schedule</u>

CMS issued its proposed revisions to the Medicare Physician Fee Schedule for 2008 ("MPFS") on July 12, 2007. The MPFS not only proposes changes to the Medicare payment for physician services, but it also discusses concerns with the Stark law, proposing numerous changes and soliciting comments on additional changes to close various loopholes in the current law. Overall, the Stark concerns outlined in the MPFS show an increased tendency of the government to examine prohibiting certain arrangements viewed as abusive use of certain Stark Act exceptions. Unlike the Stark III Regulations, the suggested revisions in the MPFS are just proposals, and thus may not ultimately become final rules.

1. Summary

The changes to the Stark law proposed in the MPFS address areas that CMS perceives as subject to significant abuse. The proposed revisions seek to,



^{48 72} Fed. Reg. 51095

⁴⁹ Id. at 51061

^{50 42} C.F.R. § 411.357(s)

^{51 72} Fed. Reg. 51064

among other things, 1) prohibit physicians from marking up the certain services when billing Medicare, 2) tighten the requirement of the in-office ancillary services exception, 3) restrict the use of "under arrangements" structures, and 4) limit percentage-based compensation relationships. In addition, the MPFS proposes to drastically limit per-click leasing arrangements, and seeks input on whether such type of arrangement should be banned completely.

2. Proposed Changes

a. Anti-Markup Rules

Currently, several types of imaging and laboratory 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 or lab 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:

- 1. 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.
- 2. 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."
- 3. 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.
- 4. 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 inoffice ancillary services exception to the Stark Act. However, this restriction is not included among the proposed revisions.

b. 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 selfreferral of DHS.52

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

- 1. require a minimum size centralized building;
- 2. 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
- 3. require that a group have a full time employee or substantially full time presence at the centralized building.⁵³

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

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

^{52 72} Fed. Reg. 38181 (July 12, 2007)

^{53 71} Fed. Reg. 49057 (August 22, 2006).

- 2. whether CMS should adopt changes to the definition of "centralized building," such as those changes suggested above; and
- 3. 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.⁵⁴

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

c. 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. 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.

d. 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.55

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

- 1. may only be used for paying for personally performed physician services, and
- 2. 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).⁵⁶

e. 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.

f. Per-Click Leases

The proposed rules also provide certain limitations on per use or "perclick" 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

⁵⁵ Id. at 38184.

⁵⁶ Id.

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.⁵⁷

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.

g. 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.⁶⁰

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.

h. 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.

⁵⁷ Id. at 38183.

⁵⁸ Id. at 38224.

⁵⁹ Id. at 38183.

⁶⁰ Id. at 38184.