

## CMS Issues New Stark Regulations

### **INTRODUCTION**

On July 31, 2008, CMS issued the CY 2009 Inpatient Prospective Payment System Final Rule (“IPPS Final Rule”). Buried in its 1,743 pages of text were several hundred pages of new Stark regulations. Taking a cue from Congress, which has found it convenient to attach non-budget legislation to omnibus budget reconciliation bills to help assure passage, CMS has continued its recent confusing policy of issuing substantive Stark regulations not as stand-alone regulations, but rather as part of a larger statutorily-required regulation. The new Stark rules nonetheless are binding and enforceable. This paper summarizes the following relevant Stark provisions found in the IPPS Final Rule.

- I. Stand in the Shoes Provisions
- II. Percentage based Compensation Formulas
- III. Per Click Arrangements
- IV. Under Arrangement Contracts
- V. Miscellaneous Provisions:
  - A. Period of Disallowance
  - B. Alternative Method for Compliance
  - C. Ownership in Retirement Plans
  - D. Burden of Proof
  - E. Hospital Relationships with Physicians

#### I. Stand in the Shoes Provisions

Brandy Schnautz Johnson

Providers and health lawyers for years have recognized the difficulties inherent in the concept of “indirect compensation arrangements.” The interplay of the definition and the exception caused providers to jump through unnecessary hoops, and also, according to CMS, resulted in providers claiming that they were exempt from the Stark statute’s purview.

CMS attempted to clarify the ambiguity by publishing its “stand in the shoes” provisions of the Stark regulations on September 5, 2007, with an effective date of December 4, 2007. Under those provisions, CMS deemed any physician affiliated with a “physician organization” to stand in the shoes of that organization for purposes of determining whether a compensation arrangement existed with a DHS entity and what exception might apply. Thus, a physician who does not personally have a compensation arrangement with a DHS entity but whose physician organization does have such an arrangement cannot claim to be exempt from the Stark statute, but will be deemed to have the same direct relationship with the DHS entity as does his organization.

Recognizing that the stand in the shoes provisions would adversely impact and require the renegotiation of some common business arrangements involving physicians and academic medical centers (“AMCs”) and integrated non-profit health care systems, CMS delayed the enforcement date of the provisions to such AMCs and integrated non-profit health care systems

to December 4, 2008. Specifically, AMCs were concerned that general “mission support payments” made by faculty practice plans (“FPPs”) to AMCs would violate the Stark statute after applying the stand in the shoes provisions.

In the 2009 IPPS final rules, CMS finalized various revisions to the existing physician stand in the shoes provisions codified at 42 CFR § 411.354(c). Specifically, CMS amended the prohibitions described above to only require a physician who has an ownership or investment interest in a physician organization to stand in the shoes of that physician organization. A physician who has no ownership, or only a “titular ownership or investment interest” in a physician organization, is not required to stand in the shoes of the organization. CMS considers a titular ownership or investment interest to be “an ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment.” In adopting this definition of titular interest, CMS rejected some commenters’ suggestions that “titular ownership” should be decided based on whether a physician has a “material” right to receive profits from the physician organization’s compensation arrangement with the DHS entity. CMS considered its adopted definition as providing a clearer, bright-line rule.

The final stand in the shoes provisions, however, do allow non-owner physicians or titular owners of a physician organization electively to stand in the shoes of their physician organizations for purposes of determining whether a compensation arrangement exists. Thus, non-owner employees and contractors of a physician organization may stand in the shoes of the organization if they wish to do so. If the parties choose to treat the physician as standing in the shoes of the physician organization, the parties then are required to satisfy the requirements of one of the exceptions for direct compensation arrangements under 42 CFR §§ 411.355 or 411.357.

Additionally, in response to concerns expressed by AMCs, CMS clarified that the final physician stand in the shoes provisions of § 411.354(c) do not apply to arrangements that satisfy the requirements of the exception for AMCs provided at § 411.355(e). CMS has stated, however, that if an FPP elects to compensate its physicians in such a way as to preclude compliance with the exception for AMCs, the FPP then will be treated like any other group practice under the rules.

CMS determined, however, not to finalize other proposed stand in shoes provisions. Specifically, CMS decided not to finalize its “DHS entity stand in the shoes provisions.” Under these provisions, CMS proposed to provide that a DHS entity that owns or controls an entity to which a physician refers Medicare patients for DHS would stand in the shoes of the entity that it owns or controls and would be deemed to have the same compensation arrangements with the same parties and on the same terms as the entity that it owns or controls. CMS also did not finalize its proposed rule regarding compensation arrangements between physician organizations and AMC components for the provision of services required to satisfy the AMC’s obligations under the Medicare GME rules at 42 CFR Part 413, Subpart F.

## Summary

Physicians who have an ownership interest in a physician organization must stand in the shoes of that organization with respect to compensation arrangements between that organization and a DHS entity. A direct compensation arrangement exception thus must be complied with. Physicians with no ownership, or only a “titular” non profit-generating ownership, may elect to use the stand in the shoes provisions, or may use the indirect compensation arrangement definition and exception to determine compliance with Stark. Finally, physicians affiliated with AMC’s need not stand in the shoes of the AMC but may avail themselves of the AMC exception at 42 C.F.R.§ 411.355(e). The new rules are effective October 1, 2008.

## II. Percentage Based Compensation Arrangements Jeff Drummond

In several places throughout the Stark Law and Stark Regulations, CMS requires the concept that compensation be “set in advance” or “fixed in advance” for exceptions to apply. Is compensation “set in advance” if the compensation is based on a percentage of collections, revenues, costs, or some other variable? The formula is set in advance, but the actual amount of compensation is not. While this is also true for agreements for the purchase of goods or services on a per-unit or per-hour basis, percentage-based arrangements contain a greater risk for abuse, particularly when the amount of collections or revenues can be specifically impacted by the physician making the referral.

In the calendar year 2008 Physician Fee Schedule regulations, CMS proposed regulatory provisions that compensation using a percentage-based formula could only be used for paying for personally-performed physician services, and must be based on revenues directly relating to the physician services, rather than on other factors such as savings by a hospital department. In the final rule, the ability to pay compensation according to a percentage-based formula is not restricted only to personally-performed physician services; however, it is specifically restricted in office and equipment leasing.

In retail leasing, such as malls and shopping centers, it is not uncommon for the rent to be calculated, at least in part, on the amount of business the tenant does in the store location. The ultimate value of the space is dependent on the business the tenant can do there, and a rental rate based in part on the sales receipts of the tenant’s business incentivizes the landlord to ensure that the shopping center or mall is well-run and attracts business for tenants. However, it is obvious how such a percentage arrangement, in a situation where the landlord is in a position to refer to the tenant, could result in the landlord receiving remuneration directly related to his referrals to the tenant, and encourage the landlord to overutilize the tenant’s business.

The final rule states that compensation is not “set in advance” for purposes of the leasing of office space or equipment if a percentage-based formula is used to determine the rent to be paid. This impacts the rental of office space and rental of equipment exceptions, as well as the fair market value compensation and indirect compensation arrangements exceptions (to the extent they relate to the lease of office space or equipment).

CMS specifically notes that many billing and management service arrangements use percentage-based formulae to calculate compensation, and no action is currently taken to curtail such arrangements. However, CMS specifically states that, while they are not extending the prohibition to arrangements for such services, they will “continue to monitor arrangements for non-professional services that are based on a percentage of revenue raised, earned, billed, collected, or otherwise attributable to a physician’s (or physician organization’s) professional services.” CMS’ failure to restrict percentage-based compensation in instances other than leasing of space or equipment should not be interpreted as tacit approval of such arrangements by CMS, or an indication that CMS won’t regulate such arrangements in the future.

CMS does recognize that this prohibition may require physicians and DHS entities to restructure existing office or equipment lease arrangements, and therefore the effective date of these provisions has been set for October 1, 2009.

### III. Per Click Arrangements

Barron Bogatto

In its prior Phase I final rule, CMS originally adopted an interpretation of the Stark statute’s legislative history finding that Congress specifically intended to permit certain “per-click” and “unit of service” type leases. However, since that time CMS has become increasingly concerned that such per-click lease payments are susceptible to abuse, and the agency has been working toward limiting the arrangements. In the 2008 proposed Physician Fee Schedule (“PFS”) regulations, CMS clearly stated its belief that “arrangements involving a physician lessor to an entity lessee under which the physician lessor receives unit-of-service (also known as per-click or per-use) payments are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee.” CMS proposed in the 2008 PFS regulations that such arrangements would not qualify for the Stark exceptions for space and equipment leases. CMS also solicited comments on the question of whether CMS should also prevent per-click payments in the reverse situations where the physician is the lessee and a DHS entity is the lessor.

Although the proposed per-click regulations were not adopted when CMS issued the final 2008 PFS regulations, CMS did not abandon its efforts. As recently as the July 2009 annual meeting of the American Health Lawyers Association, a CMS representative put the industry on notice that CMS still considered per-click arrangements to be problematic and clearly indicated that CMS was still analyzing the issue.

Now, in the latest Stark regulations buried in the 2009 IPPS payment regulations, CMS has finalized regulations that under certain circumstances prohibit unit-of-service and per-click payments from qualifying for the Stark exceptions for compensation arrangements involving space and equipment leases. In the 2009 IPPS regulations, CMS now includes a new provision in the Stark exceptions for rental of office space (§411.357(a)(5)(ii)(B)) and rental of equipment (§411.357(b)(4)(ii)(B)) that requires:

“The rental charges over the term of the agreement are set in advance, are consistent with fair market value, and are *not* determined-- ...(ii) Using a formula based on-- ...(B) *Per-unit of service rental charges, to the extent that*

*such charges reflect services provided to patients referred between the parties.”*  
(emphasis added)

These revisions prohibiting per-click lease payments in certain circumstances are clearly a 180 degree reversal from CMS’ original interpretation of Congress’ intent. CMS has totally backtracked and said that although it believes Congress specifically intended to permit certain per-click leases, it now does not believe Congress intended an unqualified exception for per-click leases under the Stark statute. Upon further analysis of the legislative history, CMS no longer believes the interpretation it adopted in the Phase I final rule is the only reasonable interpretation of the statute and legislative history, and CMS is relying upon its authority under certain provisions of the Stark statute to impose upon space and equipment leases additional requirements for per-click leases to protect against alleged program or patient abuse.

In promulgating this new final rule, CMS considered comments to the previously proposed “under arrangements” and “per-click” regulations, and CMS acknowledged that it considers the per-click and under arrangements “entity” definition issues to be intertwined. CMS also agreed with a commenter that its concerns with per-click payments for office space or equipment are not fully addressed if parties could structure an equipment or office lease arrangement as an indirect compensation arrangement that would qualify for the exception for such arrangements in §411.357(p). Likewise, CMS noted that it did not believe the parties should be able to circumvent the new per-click prohibition by using the fair market value exception at §411.357(l) (which is also applicable to equipment leases). As a result, CMS’ new per-click limitations in this final rule are also included as elements in the indirect compensation arrangement (§411.357(p)(1)(i)(B)) and fair market value compensation (§411.357(l)(3)(ii)) exceptions, as well as the equipment and office lease exceptions noted here.

At the end of the preamble discussion regarding these new per-click regulations, CMS stresses that this “final rule does not impose a blanket prohibition on per-click payments, but rather prohibits per-click payments to the extent that such payments reflect services provided by the lessee to patients referred to the lessee by the lessor.” In other portions of the preamble discussion to these final regulations, CMS also downplays the impact of the new rule, stating that “we are not prohibiting per-click arrangements involving non-physician-owned lessors to the extent that such lessors are not referring patients for DHS, nor are we prohibiting per-click payments to physician lessors for services rendered to patients who were not referred to the lessee by the physician lessors.”

However, one should not be misled by such statements into believing that the new per-click prohibitions are not extremely broad or limited solely to situations involving physician lessors who refer DHS to the lessee. In the two examples used by CMS above to downplay the impact of the new rules, the Stark statute does not even apply to such referrals. In fact, the new regulations are significantly broader in scope than what CMS proposed previously in the 2008 PFS regulations, because they now prohibit per-unit of service rental charges, to the extent that such charges reflect services provided to any “*patients referred between the parties.*” CMS refers to this as being “neutral” and a “symmetrical approach” in order to address not only situations where the physician is the lessor and the DHS entity is the lessee, but also where the reverse is true-- where patients are referred to physician lessees by an entity lessor. Because it is

difficult to separate Medicare and Medicaid referrals from non-Medicare/Medicaid referrals (and because the OIG frowns on parties keeping track of governmental program business anyway), the practical effect is that CMS has now created a regulation that will prohibit almost every conceivable lease arrangement involving physicians, per-click lease payments, and referrals of DHS by or to those physicians, irrespective of whether they are lessor or lessee.

Block Leases--Notably, in its preamble discussion of these new regulations, CMS said it believes that current leasing arrangements with physician lessors can be restructured on a block time or other basis. Unfortunately, CMS does not provide any further guidance on what block lease arrangements would be acceptable nor any specific guidance on what block lease elements might be problematic. However, CMS noted that there was concern on its part and the part of some commenters with regard to “on-demand” time-based arrangements. CMS believes that “on demand” lease arrangements are essentially a per-use or per-click type of arrangement, and considers them to be covered by its revisions in this final rule. CMS also stated its belief that the same concerns noted in the preamble with respect to certain per-click lease arrangements can exist with certain time-based leasing arrangements, “particularly those in which the lessee is leasing the space or equipment in small blocks of time (for example, once a week for 4 hours), or for a very extended time (which may indicate the lessee is leasing space or equipment that it does not need or cannot use in order to compensate the lessor for referrals).” CMS indicated it will continue to study the ramifications of “block time” leasing arrangements and may propose rulemaking in the future. Therefore, parties who utilize “block time” leasing arrangements to avoid the new per-click lease limitations need to structure them carefully, taking into account the anti-kickback statute and being vigilant in watching for further guidance and future regulations from CMS that will surely come regarding block time leases.

These new final regulations affecting the Stark exceptions for rental of office space and rental of equipment in §411.357(a) and §411.357(b), respectively, which do not permit per-click fees to the extent that such charges reflect services provided to patients referred between the parties, are effective for lease payments made on or after October 1, 2009, in order to provide parties sufficient time to restructure existing compensation arrangements or to unwind lease arrangements. Notably, although specifically by some commenters, CMS did not provide for grandfathering of existing per-click arrangements. Therefore, per-unit-of-service and per-click payment arrangements that do not meet the requirements of the newly revised applicable Stark exceptions, must be restructured or unwound by October 1, 2009.

#### IV. Under Arrangement Contracts

Jed Morrison

The Stark statute prohibits a physician from referring Medicare or Medicaid patients to an “entity” that furnishes designated health services if the physician (or his immediate family member) has a financial relationship with the entity, and if no exception is present. In July, 2007, in the CY 2008 Physician Fee Schedule Proposed Rule, CMS proposed changes in the definition of “entity” under the law in order to address what it perceived as abuses in the use of “under arrangement” contracts between hospitals and physicians. The proposed rule met with significant objections in the provider community, however, and CMS did not enact the rule in final form when the fee schedule final rule was published in November, 2007. However, CMS

indicated that it would continue to evaluate the proposal and intended to publish future regulations.

In the CY 2009 IPPS final rule, CMS now has proposed to finalize (with some modification) its original proposal regarding under arrangement contracts. The gist of the proposal is to redefine “entity” for Stark purposes to include both the entity that (i) bills the Medicare program for designated health services (“has presented a claim to Medicare for the DHS”) as well as the entity that actually performs the DHS (“has performed services that are billed as DHS”) 42 C.F.R. § 411.351. Although CMS does not define exactly what it means to perform the DHS, CMS’s clear intention is to capture the common under arrangement contract whereby a group of physicians provides equipment, space, personnel and other services to a hospital, and the hospital bills for those clinical services under its own provider number. CMS noted at p. 1130 of the IPPS Rule that:

“By way of example only, we consider a service to have been ‘performed’ by a physician or physician organization service if the physician or physician organization does the medical work for the service and could bill for the service, but the physician or physician organization has contracted with a hospital and the hospital bills for the service instead.”

By defining “entity” to include the organization that performs the DHS billed by another provider, CMS intends not just to make it more difficult, but to effectively prohibit referring physicians from engaging in under arrangement contracts for designated health services. Here is the “Catch 22”. In a typical arrangement, a group of physicians owns the equipment and space and directs the personnel where the under arrangement services are performed (*e.g.*, radiation therapy services). Under current law, only the compensation arrangement between the JV entity and the hospital need meet an exception. The indirect compensation arrangement exception usually applies. And even if the physician is deemed to stand in the shoes of his JV entity, the personal services or equipment lease exceptions typically would apply.

But the physicians now will be deemed to have made a referral both to the partnership entity that he owns (the joint venture radiation therapy equipment provider) as well as to the hospital that bills for the services. And under the new regulation, the physician’s ownership interest in the equipment company will not meet any known Stark exception. CMS thus has created a Stark definition for which virtually no exception applies.<sup>1</sup>

There is one bright light in the proposal. CMS has acknowledged that “performs the DHS” is not subject to easy definition or analysis. In responding to public comments expressing concern of the extremes that CMS could take the analysis of what it means to perform the DHS, CMS acknowledged that:

“We do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management,

---

<sup>1</sup> Unless the joint venture is in a rural area, or is publicly traded

billing services, or personnel to the entity performing the service, to perform DHS.”

There is thus still some leeway for physician joint ventures to provide selected services to hospitals or other DHS providers “under arrangement” without running afoul of Stark. However, the risk is on the physician organization to determine exactly when it may have crossed the line from simply being a vendor of space, equipment, etc., to actually having (in the eyes of CMS) “performed...[the]... DHS”. And that line is not as bright as Congressman Stark would have us believe.

In implementing the new definition, CMS will not grandfather existing relationships. However, because of the lead time required for parties to restructure existing relationships, CMS proposes to make the new definition effective October 1, 2009. So providers have some time to get their under arrangement house in order and restructure existing relationships to comply with the new standard.

## V. Miscellaneous Provisions

### A. Period of Disallowance Carla Cox

Section 1877 of the Social Security Act prohibits (1) a physician from making referrals for designated health services (DHS) payable by Medicare to an entity with which the physician or an immediate family member has a financial relationship (ownership or compensation) unless an exception applies; and (2) prohibits the entity from filing claims for Medicare payment for those DHS rendered as a result of a prohibited referral.

Previously, the Stark regulations did not limit or define how long a provider could not bill for prohibited referrals. 42 C.F.R. § 411.353(c) simply stated no Medicare payment may be made for a prohibited referral. After inquiries and comments from providers, however, CMS concluded it must publish a rule describing the outer limits of such period of disallowance. The rule now not only defines the length of the “period of disallowance”, but also prescribes what must be done by either the physician and/or by the entity that received the prohibited referrals to end the period of disallowance.

The proposed rule was published in April, 2008. One of the responses to the comments to this rule contains the following statement by CMS: “We believe that revised §411.353(c) ... is *clear, non-complex and useful* to physicians and entities as it sets forth bright line rules as to the outside limit of the period of disallowance for noncompliant financial relationships.” It would certainly be interesting to see CMS’ version of an obtuse and complex rule.

The first step in determining the applicable period of disallowance (POD) is to determine when the period begins. The rule provides that the period of disallowance (POD) begins at the time the financial relationship fails to satisfy the requirements of an applicable exception. While this determination might appear to be straightforward when there is a written agreement between the physician and an entity, CMS indicates the beginning date of a POD may predate the date of the agreement. For example, CMS states that “compensation that does not meet the requirements



of any exception may establish a financial relationship that began prior to, or ended later than, the period specified in a written agreement.” In the example given by CMS, a physician is paid excess compensation under a personal service agreement that (except for the excessive compensation) otherwise meets the personal service agreement criteria. CMS’ comments indicate that if the excessive compensation is a reward for referrals by the physician that occurred before the date of the personal services agreement, it may establish a financial relationship that began prior to the date of the personal services agreement. Although it is unclear how a financial relationship can exist prior to the initiation of compensation, CMS indicates that “compensation that does not meet the requirements of any exception may establish a financial relationship that began prior to, or ended later than, the period specified in a written agreement” and that the existence of a new compliant agreement does not “remove the tainted effects of the nonconforming compensation.” As a result, in determining the period of disallowance, the individual circumstances that resulted in any nonconforming compensation must be closely scrutinized to determine the applicable beginning date of the POD.

The next step involves determining the ending date for the POD. Although CMS states that the regulations are intended to place an “outside limit” on the POD, neither the regulations nor the CMS responses to comments describe circumstances that could result in an earlier termination of the POD. Where the noncompliance does not relate to compensation, for example when a personal services agreement is not for a period of six months but the compensation to the referring physician is reasonable, the latest date that the period of disallowance would end would be the date that the agreement was brought into compliance. It would appear that most noncompliant arrangements that are not related to compensation are likely to be agreements involving missing signatures. If a compensation arrangement is otherwise compliant but is missing a signature, it may fall within the grace periods provided in §411.353(g).

For compensation arrangements that result in either excess compensation or too little compensation, the latest ending date of the POD is the date that the excess compensation is returned or the date that the under compensation is supplemented in an amount sufficient to satisfy the requirements of an applicable exception. For example, if a physician is paid an excessive rate for services provided to a hospital to which the physician refers patients pursuant to a personal services agreement, the date he refunds the excess amount of payment to the hospital is the latest end date for the POD. The hospital is prohibited from receiving Medicare payments for any referrals from the physician involved in the noncompliant compensation arrangement. If the hospital has received Medicare payments for the physician’s referrals during the POD, the hospital must refund the Medicare payments pursuant to §411.353(e). Therefore, the length of the hospital’s POD is potentially dependent on when the *physician* repays any excessive payments to the hospital. Presumably, if the hospital terminates or revises a noncompliant personal services agreement to bring the agreement within an exception, the termination (or revision) date could arguably be the appropriate end date for the POD even if the physician has not repaid the excess compensation to the hospital.

As an example of a situation in which a party has underpaid compensation, if a hospital leases office space to a physician at below market value, the length of the hospital’s POD is potentially dependent on when the physician makes up the insufficient lease amount. Once

again, the termination (or revision) date of an offending lease could arguably constitute an earlier POD termination date.

These scenarios as to over and under compensation raise some interesting questions. What happens if a referring physician does not agree that his personal services agreement provides for excessive compensation or that his lease with a hospital is below market value and the physician refuses to repay the under or overpayment. Even if the hospital terminates or revises the agreement or lease, under the rules, the fact that the physician has not repaid the under or overpayment may subject the hospital to an extended POD.

Consider the following scenario, six months into a lease, a hospital's compliance officer determines that its lease with a referring physician is for less than fair market value. The hospital notifies the referring physician that his lease has been under fair market value for six months and requests the physician to make up the different between the rent paid and fair market value. The physician replies that he does not agree that his rent has been undervalued and that he will make repayment "when Hell freezes over." However, the physician agrees to raise his rent payments going forward and the physician and hospital enter into an amended lease at fair market value. The POD clearly would last at least through the date that the lease is revised to fair market value, but conceivably could extend indefinitely if the physician refuses to repay. How is the hospital to know whether the POD ended when the lease was revised? If they have received Medicare payments during the POD for patients referred by the physician, the hospital must refund the payments. Can the hospital assume that the lease revision cures the problem and begin filing Medicare claims after the date of revision or must the hospital wait until Hell freezes over before filing Medicare claims for patients referred by the physician? Neither the rules nor CMS's responses to comments provide an answer.

Who said these regulations are clear and non-complex?

B. Alternative Method of Compliance with Signature Requirements  
Jeff Drummond

CMS is also proposing a new paragraph (g) under Section 411.353 (the Stark Regulations provision containing the general prohibition on referrals when a financial relationship exists) for parties who have failed to precisely meet an exception solely because the parties did not obtain all required signatures prior to the establishment of the financial relationship. Several Stark Law exceptions include a specific requirement that all parties to a financial relationship sign the written contract evidencing the terms of the relationship; these include the rental of office space, rental of equipment, personal services arrangements, physician recruitment, fair market value compensation, indirect compensation arrangements, referral services, obstetrical malpractice insurance subsidies, retention payments in underserved areas, electronic prescribing items and services, and electronic health records items and services.

The new subsection 411.353(g) states that the failure to obtain all signatures is not fatal to the applicability of one of those exceptions, so long as the physician and the entity obtain the missing signature within either 30 days of the beginning of the relationship (if the parties knew

the signature is missing) or 90 days of the beginning of the relationship (if the failure to obtain the signature was inadvertent).

This grace period only applies to the signature requirement of those exceptions; all other requirements, including the existence of a written contract evidencing all of the terms of the relationship, must be in place. Additionally, the provision may only be relied upon by a DHS entity once every three years in connection with any particular physician. The new rule is effective October 1, 2008.

### C. Investments in Retirement Plans

Barron Bogatto

The Stark regulations provisions regarding financial relationships, compensation, and ownership or investment interests have for some time included in §411.354(b)(3)(i) an exclusion from the definition of “ownership or investment interest” of an interest in a retirement plan. In 2007, CMS proposed to revise that rule to clarify that the exclusion from the definition of “ownership or investment interest” of an interest in a retirement plan pertains only to an interest in an entity arising from a retirement plan offered by that entity to the physician (or the physician’s immediate family member) through the physician’s (or immediate family member’s) employment by that entity. After receipt and review of comments to the proposed clarification in the 2008 PFS regulations, CMS has now finalized the regulations making that clarification in the 2009 final inpatient prospective system (“IPPS”) payment regulations.

In the preamble to the new rule, CMS notes that where a physician has an interest in a retirement plan offered by “Entity A”, through the physician’s (or immediate family member’s) employment with Entity A, CMS intended to except from the definition of “ownership or investment interest” any interest the physician would have in Entity A by virtue of his or her interest in the retirement plan. Where the retirement plan invests in another DHS entity, however, CMS did not intend to exclude from the definition of “ownership or investment interest” any interest the physician may have in an “Entity B” through the Entity A retirement plan’s purchase of an interest in Entity B. CMS apparently felt this clarification was necessary due to concern from some source that some physicians may be using retirement plans to purchase or invest in entities (other than the entity sponsoring the retirement plan) to which the physicians refer patients for designated health services (“DHS”) otherwise subject to the Stark prohibitions.

In the new final Stark rule, CMS has revised §411.354(b)(3)(i) to provide that ownership and investment interests do not include, among other things –

“(i) an interest in an entity that arises from a retirement plan offered by *that* entity to the physician (or a member of his or her immediate family) through the physician’s (or immediate family member’s) employment with *that* entity;”  
(emphasis added)

Therefore, this revised rule excludes automatically *per se* a physician’s (or immediate family member’s) interest in a retirement plan offered by an entity as a result of the physician’s (or immediate family member’s) employment from being considered an ownership or investment

interest in that entity. However, where a retirement plan purchases or invests in another DHS entity, the new rule would not automatically exclude *per se* the physician's (or immediate family member's) interest in the retirement plan from being considered an ownership or investment interest in the other entity. In such case, the parties will need to determine if the ownership or investment interest is problematic, and if so, search for an applicable exception.

Parties should note that this revised rule is final and effective October 1, 2008, and there is *not* the delay until October 1, 2009 for restructuring or unwinding provisions that has been granted to some of the other new Stark regulations in the IPPS regulations. Therefore, if this retirement plan ownership or investment interest is an issue, the parties will need to act immediately to rectify that issue.

D. Burden of Proof

Virginia Alverson

As part of the CY 2009 IPPS Final Rule, CMS has published a final rule establishing a burden of proof in Stark payment denial appeals. CMS states that when payment for a designated health service is denied on the basis that the service was furnished pursuant to a prohibited referral, and such payment denial is appealed, the ultimate burden of proof at each level of the appeal to establish that the service was not furnished pursuant to a prohibited referral is on the entity submitting the claim for payment. CMS notes, however, that while the burden of proof at each level of the appeal is on the claimant, the burden of production may shift to CMS during the course of the appellate proceeding depending on the evidence presented by claimant.

CMS contends that this burden of proof requirement is consistent with its existing procedures in connection with claim denials. However, several commenters expressed concern with placing the burden of proof on the provider or entity appealing the claims. Below is a summary of some of the objections voiced by commenters:

- The burden to prove that a service was provided pursuant to a prohibited referral should be on CMS and/or its contractors because the law historically places this burden on the party that makes the rules.
- Placing the burden on the providers makes CMS “the judge and jury” and fails to adhere to the fundamental principle that people are innocent until proven guilty.
- The new rule is a “hidden tax” which requires physicians to prove that they have conducted their actions legally.
- Many exceptions to the physician self referral prohibition require compliance with the anti-kickback statute. The proposed language would require the provider to show that either they: 1) meet an anti-kickback safe harbor; 2) have received a favorable advisory opinion; or 3) otherwise do not violate the anti-kickback statute. As a result, in some cases the providers will have the unreasonable burden of “proving a negative” even though the government has the burden to prove intent under the anti-kickback statute.
- Because the physician self-referral law is a strict liability statute, it is even more important for the burden of proof to be on the government.
- The proposed rule will provide greater incentive for Medicare contactors to deny claims based on alleged violations of the physician self-referral law.

Nevertheless, CMS defended itself against each of these claims and stated that “the burden has always been on the party seeking Medicare payment to prove entitlement to payment if the claim is denied.” Further, because government funds are at issue, CMS believes it appropriate to place the burden on the providers and suppliers to show that they “are entitled to payment from the public fisc and not on the government to show that the provider or supplier is not entitled to such payment.

CMS also explains that although the burden of proof remains with the claimant throughout the appellate process, the burden of production on a particular issue (i.e., the burden of actually producing evidence on a particular point) may shift from the claimant to CMS. CMS states that it is appropriate that the burden of production be on the claimant (the appellant) initially with respect to all requirements in the self-referral regulations, but that the claimant may produce evidence in such quantity or quality as to shift the burden of production to the Medicare program requiring it to show that the requirement was not met.

In summary, pursuant to the final rule, if Medicare denies a provider’s claim because Medicare believes the service was provided pursuant to a prohibited referral, the provider appealing the claim will have the burden to prove that he or she did not violate the self-referral law.

E. Hospital Relationships with Physicians:  
Disclosure of Financial Relationships Report Dan Hayes

On July 31st, CMS published final Stark regulations on a number of controversial topics that had been previously been issued in proposed form. One of those topics concerns the collection of information regarding existing financial relationships between hospitals and referring physicians.

Section 411.361(a) of the Stark regulations states that, except for entities that furnish 20 or fewer Part A and Part B services during a calendar year, or for Medicare covered services furnished outside the United States, all entities furnishing services for which payment may be made under Medicare must submit information to CMS or to the Office of the Inspector General (OIG) concerning their reportable financial relationships (any ownership or investment interest, or compensation arrangement) in the form, manner, and within the timeframe that CMS or OIG specifies.

CMS has developed the Disclosure of Financial Relationships Report (“DFRR”) reporting tool to implement that regulation. In the FY 2009 IPPS proposed rule, CMS proposed to send the DFRR to 500 hospitals. The July 31 final rule represents CMS’ final decision regarding this matter. Because CMS’ estimate of the amount of time it will take providers to respond to the DFRR has increased to 100 hours, CMS felt compelled to publish a further notice under the Paperwork Reduction Act (“PRA”), under which the public will be given 30 days to comment. However, absent some new and compelling argument, it appears that the 2009 IPPS final rules published on July 31 will be unaffected.

The highlights of the final rule are as follows:

- CMS is not adopting a regular reporting or disclosure process at this time. Rather, the DFRR will be used as one-time collection effort. Of course, this does not foreclose CMS from proposing future rule making to use the DFRR or some other instrument as a periodic or regular collection instrument.
- CMS is revising the amount of time it will take hospitals to complete a DFRR from 31 hours to 100 hours, and the cost associated with completing the DFRR from \$1,550 to \$4,080 per hospital.
- Hospitals will be given 60 days to complete, certify, and return the DFRR to CMS. Failure to timely submit a DFRR can result in the imposition of civil monetary penalties of up to \$10,000 a day. Before doing so, however, CMS states that it will send a letter to the delinquent hospital inquiring as to why the hospital has not returned the DFRR. Additionally, a hospital may, upon a showing of good cause, receive an extension of time to submit the DFRR.
- At this time, CMS is proceeding with its proposal to send the DFRR to 500 hospitals, both general acute care hospitals and specialty hospitals. However, based on review and comments it receives in response to the PRA package that will be published separately in the Federal Register, CMS may decide to decrease, but not increase that number.
- Hospitals may, but are not required to submit DFRRs electronically.
- Hospitals will be permitted to submit one copy of a uniform rental or recruitment agreement; i.e., an executed contract between a hospital and a physician that is representative of the terms and conditions found in a number of similar contracts entered into between that hospital and other physicians. However, hospitals will be allowed to do so only if all material terms of such contracts are the same. For example, if a hospital has entered into lease agreements with different physicians for space in the same medical office building, in order to be considered “uniform” the lease agreements must: value the space equally from one office to the next; charge the same price per square foot to each physician, and contain the same rights and obligations. If this is the case, CMS will consider the agreements to be uniform for purposes of the DFRR. The hospital would need to transmit only one such agreement to CMS, although it must also inform CMS of the names of all the physicians with whom it has similar agreements.

The bottom line is that the DFRR process will be time consuming and expensive, entailing the efforts of both a hospital’s administrative staff and, in all likelihood, outside accounting and law firms. Because the consequences of not filing in a timely manner can be draconian, it is imperative that any hospital “lucky” enough to receive one begin filling out a DFRR immediately upon its receipt.